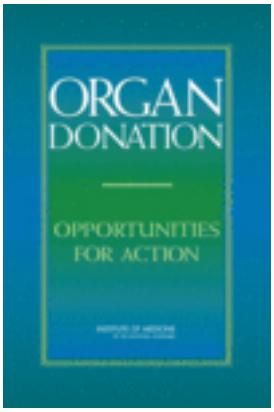

Organ Donation: Opportunities for Action

Committee on Increasing Rates of Organ Donation,
James F. Childress and Catharyn T. Liverman, Editors
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ORGAN DONATION

OPPORTUNITIES FOR ACTION

Committee on Increasing Rates of Organ Donation

Board on Health Sciences Policy

James F. Childress and Catharyn T. Liverman, *Editors*

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Willing is not enough; we must do."
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Independent Report Reviewers

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's (NRC's) Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations nor did they see the final draft of the report before its release. The review of this report was overseen by **Bernard Lo**, University of California, San Francisco, and **Judith R. Lave**, University of Pittsburgh. Appointed by the NRC and the Institute of Medicine, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

Preface

Organ transplantation offers immense benefits. It extends the lives and improves the quality of life of thousands of individuals each year. However, the field faces the challenge of reducing the ever widening gap between the demand for and the supply of transplantable organs.

In looking back over the slightly more than two decades since enactment of the National Organ Transplant Act, we can see progress in the wide range of ongoing efforts to improve organ donation rates in the United States. Furthermore, this report comes at a time of focused efforts to improve the quality, coordination, and reliability of the multiple organizations and systems involved in organ donation.

In seeking to reduce the gap between supply and demand for transplantable organs, the committee notes that several policies and practices beyond its purview offer considerable potential. These include strengthening preventive efforts to improve health and reduce the need for transplantation, ensuring equitable access to transplantation by negating current financial and insurance constraints, and providing ongoing access to immunosuppressive medications to ensure that each donated organ is fully used.

Many people have thought long and hard about possible solutions to the shortage of transplantable organs; and the committee greatly benefited from the depth and breadth of the scientific, ethical, and policy literature and from the insights provided by individuals who met with the committee in workshops, open sessions, and discussions.

It was a privilege and a pleasure to chair this Institute of Medicine committee, whose diverse and remarkable members brought their own rich personal, disciplinary, and professional perspectives and insights to bear on this important topic. Committee discussions and deliberations were always illuminating, because members were devoted to carefully and thoughtfully examining the complex issues in light of the best available evidence and arguments. It is probably safe to say that by the end no single individual held all of the same positions that he or she had held at the outset.

The committee could not have accomplished its goals without the unstinting support, valuable advice, and constant good cheer provided by Cathy Liverman and her staff. We are grateful to them.

The committee hopes that this report will open up discussions, stimulate actions at many levels, and contribute to efforts that can increase the supply of transplantable organs.

James F. Childress, Chair
Committee on Increasing Rates of Organ Donation

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ORGAN DONATION

Summary

In the 50 years since the first successful organ transplant, thousands of recipients of a transplanted kidney, heart, pancreas, liver, or other solid organ in the United States and throughout the world have had their lives extended and their health improved as a result of organ transplantation. Since 1988, more than 390,000 organs have been transplanted, with approximately 80 percent of the transplanted organs coming from deceased donors. In 2005, 7,593 deceased donors provided 23,249 transplanted organs in the United States, and there were 6,896 living donors.

The number of organ donors has increased each year since 1988, with a steady increase in the number of organs recovered (an average of approximately 1,100 more organs are recovered each year than in the previous year). However, the growth of the waiting list has been much more dramatic, increasing by approximately 5,000 transplant candidates[1] each year. The net result is a widening gap between the supply of transplantable organs and the number of patients on the waiting list (Figure S-1). The U.S.

[1]The waiting list is dynamic and changes throughout the year as new candidates and registrations are added, individuals receiving a transplant are removed, and other changes are made. The Organ Procurement and Transplantation Network (OPTN) provides data on the number of waiting list candidates and registrations. These numbers differ because one waiting list candidate may have multiple registrations. For example, a patient who is listed through more than one center or for multiple organs would have multiple registrations. Throughout this report, the statistics used are for transplant candidates, unless indicated otherwise in the text.

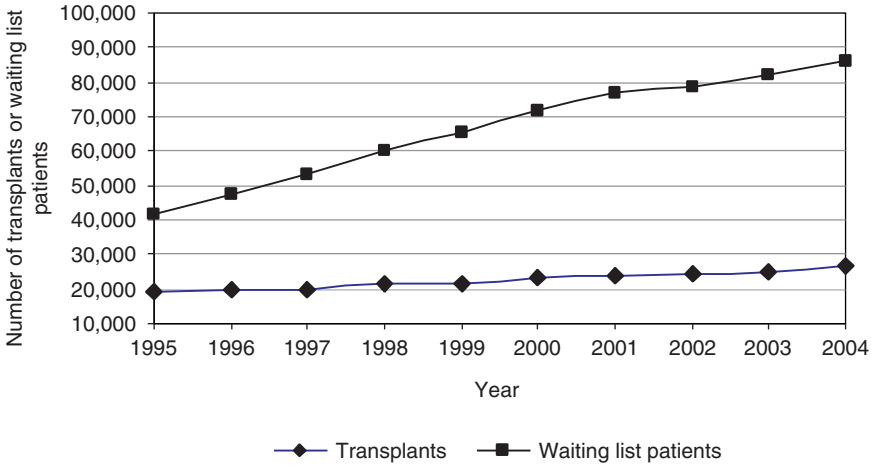


FIGURE S-1 Growth in the number of transplants and in the number of candidates on the transplant waiting list.

waiting list for organ transplants, which listed 16,026 individual candidates for transplantation in 1988, has grown more than fivefold to greater than 90,000 in January 2006. The need for kidney transplants is the major driving force in the increase in the waiting list, with individuals waiting for a kidney transplant constituting more than 70 percent of the individuals on the current transplant waiting list. In 2005, 44,619 transplant candidates were added to the waiting list.

Over the past 10 years, minority populations have donated organs at increased rates. In the past, donation by minority populations has been hindered by mistrust of the healthcare system, inequities in access to transplantation, and failure to request donation. Although donations by minority populations are steadily increasing, several of these matters remain unresolved and need further attention. The donation rates by minority populations are now in proportion to their population distribution in the U.S. census. However, there is an increased need for transplants, particularly kidney transplants, in minority populations because of the higher incidence of end-stage renal disease among the members of these populations. In addition, there is still room for improvement in the rates of consent to organ donation among all ethnic groups.

As the demand for organ donation far exceeds the current supply of available organs, various efforts are under way to determine how best to reduce the gap between supply and demand. In addition to refinements in hospital processes and protocols, several proposals are being discussed that

might further enhance the system or provide incentives for more individuals or families to consent to organ donation.

In 2004, the Health Resources and Services Administration (HRSA) and The Greenwall Foundation asked the Institute of Medicine (IOM) to study the issues involved in increasing the rates of organ donation. This report is the result of a 16-month study conducted by an IOM committee composed of experts in the fields of bioethics, law, health care, organ donation and transplantation, economics, sociology, emergency care, end-of-life care, and consumer decision making.

PERSPECTIVES AND PRINCIPLES

The committee carefully examined the ethical and societal implications of a range of proposals to increase the rates of organ donation by deceased donors in the United States and also considered several of the ethical issues regarding organ donation by living donors.

The committee's deliberations were undertaken from the perspective of the shared interest that all members of society have in access to organs for transplantation should the need arise. The perspectives and principles guiding the committee's report are as follows:

- **Common stake in a trustworthy system:** Everyone in the national community has a common stake in the creation and maintenance of an effective and trustworthy system for providing timely access to transplantable organs and, if organs are scarce, in increasing the number of organs recovered and distributing them fairly.
- **Acceptable appeals for donations:** Policies and practices designed to increase organ donation may properly appeal to a variety of motivations for donation, including altruism, community spirit, and reciprocity.
- **Respect for persons:** Policies and practices designed to increase the rates of organ donation and the recovery of organs from deceased individuals must be compatible with four limiting conditions deeply rooted in the cultural, religious, and legal traditions of the United States: (1) respect for the moral worth and dignity of each human being; (2) respect for each individual's right to govern the disposition of his or her body after death, including the voluntary choice of whether or not to donate organs; (3) respect for the remains of human beings, as represented in particular cultural and religious practices; and (4) respect for the wishes and feelings of families of deceased individuals.
- **Fairness:** Policies and practices designed to increase the supply of transplantable organs need to be fair in their distribution of both benefits and burdens, with particular attention to their impacts on disadvantaged groups.

CLARIFYING TERMINOLOGY

Because the concepts and processes of organ donation are so closely intertwined with emotional issues of death and dying, it is of utmost importance to the committee, as it is to the transplantation community, that the terminology used to describe and discuss all aspects of organ transplantation be both as sensitive and as accurate as possible. Terminology in this field has had both positive and negative connotations, which have sometimes changed over time. Terms that have seemed descriptive or useful in the past are now being reconsidered in favor of terms that are more sensitive to the donor family and that affirm the value of individual human life. Table S-1 highlights some of the terms recommended by the committee.

A SYSTEMS APPROACH

The committee considered a number of approaches that have been suggested for increasing the rate of organ donation. The remainder of this summary examines each of these approaches and presents the committee's recommendations.

Organ transplantation involves a complex, collaborative set of interactions among patients, family members, healthcare professionals, organ procurement and transplant coordinators, the hospital where the donation occurs, the organ procurement organization (OPO) that facilitates the acquisition and the distribution of organs, and the transplant center. The U.S. organ donation system has evolved over the past half century, having been shaped by a series of federal and state laws and regulations, private-sector oversight, and individual hospital policies. The system has focused primarily on deceased donors whose deaths have been determined by neurologic criteria.

This report is being written at a time when many initiatives in the organ donation system have been undertaken to increase rates of organ donation.

TABLE S-1 Recommended Terms

Instead of:	Use the Recommended Term:
Cadaver or cadaveric donor	Deceased donor
Harvest or procure	Recover or surgically remove
Life support	Mechanical support or ventilated support
Cardiac death	Circulatory determination of death
Brain death	Neurologic determination of death
Donation after cardiac death	Donation after circulatory determination of death (DCDD)
Donation after brain death	Donation after neurologic determination of death (DNDD)

A major new initiative is the series of Organ Donation Breakthrough Collaboratives. Directed by HRSA, the collaboratives attempt to increase rates of organ donation by encouraging hospitals and OPOs to use methods of continuous quality improvement to enhance the process of deceased organ donation.

The opportunity to decide whether to be an organ donor should be a part of end-of-life decision making. Patients and their families should be offered this opportunity as standard end-of-life care. For the organ donation process to be fully integrated into end-of-life care, a wide range of healthcare professionals need enhanced awareness of and training regarding the organ donation process.

Recommendations:

Sustain Continuous Quality Improvement Initiatives.
HRSA should be sufficiently funded to provide technical assistance to hospitals and OPOs for continuous quality improvement efforts, including the identification and dissemination of best practices. An infrastructure that can support the collaboration, the dissemination of findings, and evaluations of the Breakthrough Collaboratives should be funded. Furthermore,

- **Individual OPOs and hospitals should develop, implement, and evaluate continuous quality improvement processes.**
- **Accrediting and monitoring organizations, such as the Association of Organ Procurement Organizations, Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and National Committee for Quality Assurance (NCQA) should require and monitor measures of continuous quality improvement, including process measures as well as conversion rates.**
- **HRSA, the Centers for Medicare & Medicaid Services, and private insurers (where appropriate) should ensure that organizational quality improvement efforts are recognized as part of normal healthcare operations and should be reimbursed accordingly.**

Increase Research on Innovative System Changes.
HRSA, the National Institutes of Health, and the National Center on Minority Health and Health Disparities should be allocated funds sufficient to increase research efforts to identify further innovative and effective system changes for improving the organ donation process and increasing the rates of organ donation and to evaluate the impacts of such changes on the healthcare system. Research efforts should be evidence based, interdisciplinary, and culturally relevant.

Strengthen and Integrate Organ Donation and Quality End-of-Life Care Practices.

Hospitals, OPOs, and other healthcare entities should consider how best to integrate the organ donation process with quality end-of-life care practices. Interdisciplinary teams should align end-of-life protocols, practices, and guidelines with organ donation protocols.

Enhance Training for Healthcare Professionals.

HRSA, in collaboration with palliative care and other professional associations representing diverse disciplines and specialties (including, but not limited to, critical care professionals, transplantation professionals, social workers, and clergy), should strengthen training in end-of-life practices and organ donation, including processes of communication and decision making, with the goal of establishing a knowledgeable and positive environment that supports organ donation.

EXPANDING THE POPULATION OF POTENTIAL DONORS

Most transplantable organs come from deceased donors who have been declared dead by neurologic criteria. Because many more deaths in the United States are determined by circulatory criteria than by neurologic criteria, there is great potential to expand the number of potential organ donations. The committee acknowledges that donation after circulatory determination of death (DCDD) can be a more complex and less facile process than donation after neurologic determination of death. However, expanding the nation's capabilities, particularly in large urban areas with excellent emergency medical care, could provide the opportunity for donation to larger numbers of individuals and families. One set of conservative estimates suggests that at least 22,000 of out-of-hospital cardiac arrest deaths annually in the United States could be potential donors if important ethical and practical matters could be resolved. Before proceeding further, demonstration projects to assess the feasibility of undertaking such a strategy within a defined community should be considered.

Recommendations:

Implement Initiatives to Increase Rates of Donation after Circulatory Determination of Death.

HRSA, the National Institutes of Health (NIH), OPTN, OPOs, donor hospitals, transplant centers, and professional societies

should implement initiatives to increase rates of DCDD. Particular emphasis should be given to

- **funding of interdisciplinary research by NIH and HRSA to understand and remove institutional, professional, and community barriers and resistance to DCDD;**
- **enhancing public and professional education, disseminating best practices, and monitoring and evaluating DCDD efforts;**
- **clarifying required referral regulations to ensure that all potential donors are considered; and**
- **adding preparation for organ donation to the end of standard resuscitation protocols.**

Encourage and Fund DCDD Demonstration Projects.
The U.S. Department of Health and Human Services, states, and local entities should encourage and fund demonstration projects to determine the feasibility of increasing the rates of uncontrolled DCDD in cities with established and extensive trauma centers and emergency response systems. Such demonstration projects should include extensive public and professional education, including an emphasis on donor registry efforts, and participation by all relevant stakeholders in the development of protocols and processes.

Maintain Opportunities for Organ Donation.
OPOs should work with relevant stakeholders to obtain community authorization for the use of postmortem organ preservation techniques during the time needed to seek family consent for donation when the deceased person's donation intention is unknown.

Increase Research on Organ Quality and Enhanced Organ Viability.
NIH should request and allocate funds for the purpose of determining the characteristics that modify and define organ quality. NIH should fund further research on enhancing the viability of organs for transplantation, including improved methods of organ preservation and improved criteria (with appropriate point-of-care testing) for determining the viability of organs.

PROMOTING AND FACILITATING INDIVIDUAL AND FAMILY DECISIONS TO DONATE

Making an informed choice regarding organ donation, documenting that decision (by designating the decision on a driver's license or a donor

card or through a donor registry), and sharing the decision with family members are the key steps in ensuring that individuals are able to exercise their rights to make a determination about the disposition of their organs after death. This decision is a significant expression of personal autonomy, as the individual considers an action that after his or her death has the potential to save lives and improve the quality of life for others.

Many myths surrounding organ donation and transplantations—such as the fear that having a donor card will compromise the extent of health care that the patient receives—often constitute barriers to increased rates of donation. Therefore, public education that is culturally sensitive and that uses effective community education strategies is needed. Public education about organ donation should emphasize that all members of society have a common interest in an adequate supply of organs because all are potential recipients as well as potential donors. Each individual should have multiple opportunities to learn about organ donation and to express his or her desire to donate. Furthermore, mechanisms are needed to ensure that recorded decisions to donate are accessible to the relevant healthcare professionals and OPO staff on a 24-hour-a-day, 7-day-a-week basis.

The committee believes that it would be premature to move toward a policy of mandated choice (which would require an individual to make a decision about donation). To be successful, a mandated-choice model needs an informed citizenry that understands organ donation and what it means for the individual and for the recipient and that sufficiently trusts the system to go on record as an organ donor. Without giving people adequate and accessible information, merely forcing them to choose to be an organ donor or not does not capture the potential of mandated choice and weakens the argument for it. A broad-based and multidimensional educational campaign is needed that confronts issues around death and dying, debunks the myths and misperceptions surrounding organ donation, and emphasizes the benefits of organ donation. Pilot tests of mandated choice could be reconsidered in the future when there is a broader and more accurate understanding of organ donation among all sectors of U.S. society. If public education is successfully intensified, however, mandated choice may prove to be unnecessary.

Recommendations:

Increase Public Understanding of and Support for Organ Donation.

HRSA, NIH, the Centers for Disease Control and Prevention, the United Network for Organ Sharing, OPOs, voluntary health organizations, faith-based organizations, community coalitions, and other interested parties should strengthen their efforts to provide

public education about organ donation through multiple media and educational venues. They should pay particular attention to developing and disseminating culturally sensitive educational materials that can be understood by individuals with different levels of education. Entertainment and media organizations should strive to accurately portray organ donation and transplantation.

Increase Opportunities for People to Record Their Decision to Donate.
HRSA, state and local governments, nonprofit organizations, community coalitions, and other interested parties should provide multiple opportunities for individuals to receive information on organ donation and to record their donation decisions. These opportunities should be provided at the times of driver's education and licensing and advance care planning, as well as through work-, faith-, school-, and community-based initiatives.

Enhance Donor Registries.
State governments (including departments of motor vehicles), OPOs, and HRSA should work together to:

- **ensure full access to and sharing of donor registration data;**
- **ensure that a nationwide networked system of registries that identifies self-declared organ donors is readily accessible to OPOs and healthcare professionals on a 24-hour-a-day basis, and is updated daily.**

Mandated Choice Should Not Be Enacted.
At this time, states should not enact legislation requiring people to choose whether or not to be an organ donor (mandated choice).

PRESUMED CONSENT

In the United States, deceased organ donation occurs only with express consent (often in response to an inquiry or request). This consent may be given in advance by the individual while he or she is still alive, or it may be given by the next of kin after the death of the individual. The state laws that govern organ donation thus require opting in (or contracting in). The default option, in the absence of express consent, is nondonation. Proposals to increase the availability of transplantable organs often recommend a policy of presumed consent or opting out. Under such a policy, organs from deceased individuals could be removed for transplantation unless the decedents—or their families, after their deaths—had followed the prescribed

measures for opting out. The default option, in the absence of express objection, would become donation.

The committee believes that it would be premature to attempt to enact presumed-consent policies at this time. Although the committee is supportive of the principles of a presumed-consent approach (namely that under certain clear and well-defined circumstances, in the absence of an individual's expressed decision, one may presume his or her consent rather than refusal to donate), the first step is to build sufficient social support before introducing presumed consent in the United States. This can be accomplished through intensified public education regarding organ donation, building greater trust in the healthcare system, and encouraging a general shift in societal understanding of the value and moral grounding of donation. The current emphasis on the use of first-person (donor) consent to organ donation can reinforce the importance of individual decision making. Coupling this change with the move towards use of an expected donation approach with families can also strengthen the societal norm of organ donation as a social responsibility and standard practice.

Although conditions essential for a change to a presumed-consent policy do not currently exist and do not appear to be likely in the foreseeable future, it is both appropriate and important to seek to realize them over time. When the necessary conditions exist for a shift to a presumed-consent policy it will be critical to provide clear, easy, nonburdensome, and reliable ways to opt out.

Recommendation:

Presumed Consent.
At this time, states should not replace the existing legal framework, which requires explicit consent for organ donation, with a framework under which people are presumed to have consented to donate their organs after death unless they have declared otherwise. However, it would be appropriate for all interested parties to seek to create over time the social and cultural conditions that would be essential for the adoption of an effective and ethical system of presumed consent.

INCENTIVES FOR DECEASED DONATION

The committee was asked to examine the use of financial and nonfinancial incentives to increase the supply of organs from deceased donors. A financial incentive is the provision of something of material value to motivate consent for organ removal. For example, a direct payment could be

made in exchange for the organ, with the price for the organ determined by the free market or set by regulatory authorities. In either case, the exchange of money for organs would constitute a purchase and sale. Alternatively, financial incentives might be used to induce donations, just as the prospect of a tax deduction is used to induce charitable contributions. Such incentives might be a cash payment usable for any purpose; a cash payment earmarked for a specific purpose, such as funeral expenses or a charitable contribution; or a material good or service, such as bereavement counseling or health insurance. The financial incentive could go to the donor before death or to the donor's estate after death in exchange for the donor's agreement to allow his or her organs to be recovered after death. In situations in which the donor's family makes the decision to donate, the incentive could go to the family. Nonfinancial incentives to donate could take the form of community recognition or preferential access to donated organs.

Every society draws lines separating things that are treated as commodities from things that should not be treated as "for sale." The committee believes that there are powerful reasons to preserve the idea that organs are donated rather than sold, even in a regulated market.

The committee examined financial incentives within the gift model of donation to determine if they would provide additional increases in the rates of organ donation. Hard data on the impact of incentives are lacking, and it may be difficult to obtain reliable data to address these issues. A pilot study of financial incentives for organ donation may set in motion a societal process that is difficult to reverse even after the pilot study itself is abandoned. For example, if people begin to view their organs as valuable commodities that should be purchased, then altruistic donation may be difficult to reinvigorate.

Additionally, in principle, the provision of anything of material value raises some of the same justice concerns as do payments within a regulated market: although some might consider an incentive to be fair to donors or donor families, there is also the fear that incentives would disproportionately affect those who are poor or marginalized from the system.

Furthermore, there are concerns that the relationship between financial payments and a willingness to donate may not conform to the pattern that applies to ordinary consumer goods; payments may "crowd out" other motivations, and some families who would donate under an altruistic system may refuse to donate.

Much remains to be done to remove disparities in the provision of health care and to build the trust in the medical community. Although incentives might serve to increase donation rates, the committee believes that the actual need for incentives can be determined only after other alternatives have been explored. Promising options are the use of quality im-

provement methods to improve the process of organ donation under a gift model and making medical practice changes that increase the number of deceased individuals who are potential organ donors.

In examining nonfinancial incentives, the committee was concerned that a reciprocity model for receiving a transplant would—at least in the short term—accentuate existing social inequalities and disadvantage those who are uninformed about organ donation. Moreover, reciprocity introduces a criterion for organ allocation that is not related to medical need. Similarly, preferred-status programs risk penalizing uninformed individuals and introduce a nonmedical (non-need-based) criterion into the allocation equation.

Recommendations:

Financial Incentives.
The use of financial incentives to increase the supply of transplantable organs from deceased individuals should not be promoted at this time. (The term "financial incentives" refers to direct cash payments as well as contributions toward funeral expenses or to a charity of choice.)

Preferential Access.
Individuals who have recorded a willingness to donate their organs after their death should not be given preferential status as potential recipients of organs. This recommendation does not imply opposition to the assignment to living donors of additional points for the allocation of organs should they subsequently need a transplant.

ETHICAL CONSIDERATIONS IN LIVING DONATION

Organ donation by living donors clearly saves lives, improves transplantation outcomes under some circumstances, and reduces recipients' waiting times. It also increases opportunities for patients without living donors to receive organs from deceased donors. However, it raises a series of ethical questions that have not been fully addressed. The transplantation of organs from living donors seems to violate the traditional first rule of medicine—*primum non nocere* (above all do no harm)—because it involves the removal of a healthy organ from one person for implantation into another person who is already a patient.

Although the committee believes that the whole practice of organ donation by living donors now needs a careful review and assessment on its own, in the interim the committee makes a few specific recommendations, build-

ing on ethical concerns and proposals already present within the transplantation community and drawing on the ethical perspectives that inform this report. These recommendations focus on the need for better information for improved risk-benefit analyses by transplantation teams, donor advocates, and potential donors themselves and on the increased use of independent donor advocate teams committed to the rights and welfare of the donor as patient, before, during, and after the donation.

Recommendations:

Protect Living Donors.
Hospitals that perform living donor transplantations should provide each potential living donor with an independent donor advocacy team to ensure his or her voluntary and informed decision making.

Facilitate Living Donor Follow-Up.
HRSA, OPTN, and transplant centers should work to establish registries of living donors that would facilitate studies of both short-term and long-term medical and other outcomes of living donation.

OPPORTUNITIES FOR ACTION

The recommendations provided in this report set forth a number of actions that the committee believes can have a positive impact on organ donation (Table S-2). Together, these recommendations identify a set of actions that in isolation might have only limited results but that in concert should strengthen ongoing efforts and open up new opportunities to increase the supply of transplantable organs, thereby saving the lives and improving the quality of life of many individuals.

It is the committee's hope that this report will contribute to the development and implementation of new efforts to increase the rates of organ donation. In addition, the committee hopes that these efforts, along with concurrent actions focused on the prevention of health conditions that lead to the need for transplantation and research to explore alternatives to transplantation, will significantly reduce the size of the organ transplant waiting list in the near future.

TABLE S-2 Actions to Increase Organ Donation

Individuals	• Register as an organ donor through driver's license, donor card, or donor registry • Inform family members of organ donation decisions
Families	• Discuss organ donation decisions • Honor prior donation decisions made by the deceased family member • Provide consent for donation if the deceased family member did not make a decision regarding donation

Healthcare, emergency care, and transplantation systems	• Implement system changes
	  • Sustain mechanisms and support for continuous quality improvement
	  • Integrate organ donation and end-of-life care practices and services
	• Expand donation opportunities
	  • Increase opportunities for donation after circulatory determination of death
	• Expand and enhance professional education about organ donation and end-of-life care

Nonprofit organizations, academia, government, media, employers	• Provide multiple opportunities for donor registration and education
	  • Encourage registration through donor cards, driver's licenses, or donor registries
	  • Promote programs to increase donor awareness
	  • Improve media coverage to increase public awareness and reduce misperceptions
	  • Increase public education
	• Coordinate efforts through the use of
	  • Donor registries
	  • Uniform state laws
	• Fund research on innovative approaches to increasing rates of organ donation and enhancing organ viability

1
Introduction

In the 50 years since the first successful organ transplant, thousands of recipients of a transplanted kidney, heart, pancreas, liver, or other solid organ in the United States and throughout the world have had their lives extended and their health enhanced as a result of organ transplantation.

Organ transplantation is unique among surgical procedures, in that the procedure cannot take place without the donation of an organ or a partial organ from another person. Since 1988, more than 390,000 organs have been transplanted, with approximately 80 percent of the transplanted organs coming from deceased donors. In 2005, 7,593 deceased donors provided 23,249 transplanted organs in the United States, and there were 6,896 living donors (OPTN, 2006[1]).

The success of organ transplantation as a treatment option, the rising incidence of related or contributory medical conditions, improvements in immunosuppressive medications, and other factors have resulted in a rapid escalation in the waiting list for transplantation[2] in recent decades. In 1988, there were 16,026 individuals on the waiting list for an organ transplant; by 1995 the waiting list had increased almost 275 percent to 43,937; and it

[1]Data are provided from the National Data Reports on the OPTN website (www.optn.org). The data used in this chapter are current as of March/April 2006; data on the website are continuously updated.

[2]The waiting list is not strictly hierarchical, as recipients are matched to donors by the use of a number of allocation factors, including geographic proximity, blood type, and genetic characteristics.

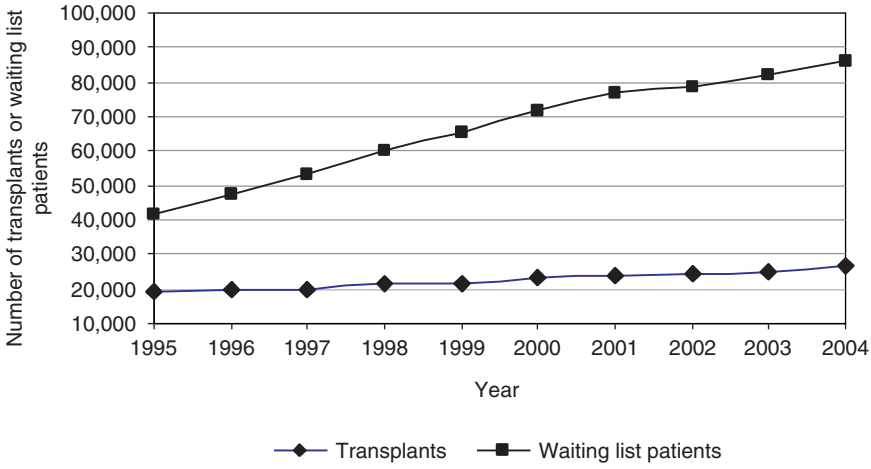


FIGURE 1-1 Growth in the number of transplants and in the number of candidates on the transplant waiting list.
SOURCE: HRSA and SRTR (2006).

has since more than doubled so that by January 2006 the waiting list topped 90,000 individuals (Figure 1-1) (IOM, 1999; OPTN, 2006). The waiting list is primarily driven by the need for kidney transplants. The statistics on the transplant waiting list are continually updated, and as of March 24, 2006, there were 91,214 transplant candidates[3] on the waiting list, of whom 65,917 individuals (approximately 70 percent of the waiting list) were candidates for kidney transplantation. In 2005, 44,619 transplant candidates were added to the waiting list (OPTN, 2006).

As the demand for organ transplants far exceeds the current supply of available organs, various efforts are under way to determine how best to reduce the gap between supply and demand. In addition to refinements in hospital processes and protocols, several proposals are being discussed that

[3]The waiting list is dynamic and changes throughout the year as new candidates and registrations are added, individuals receiving a transplant are removed, and other changes are made. OPTN provides data on the number of waiting list candidates and registrations. These numbers differ because one waiting list candidate may have multiple registrations. For example, a patient who is listed through more than one center or for multiple organs would have multiple registrations. Throughout this report, the statistics used are for transplant candidates, unless indicated otherwise in the text.

might further enhance the system or provide incentives for more individuals or families to consent to organ donation.

In 2004, the Health Resources and Services Administration (HRSA) and The Greenwall Foundation asked the Institute of Medicine (IOM) to study the issues involved in increasing the rates of organ donation. This report is the result of a 16-month study conducted by an IOM committee composed of experts in the fields of bioethics, law, health care, organ donation and transplantation, economics, sociology, emergency care, end-of-life care, and consumer decision making.

SCOPE OF THIS REPORT

The IOM committee was charged with reviewing the current efforts and proposals to increase organ donations from deceased donors, including but not limited to educational activities, media campaigns, financial incentives, and presumed-consent laws. The committee was asked to identify ethically controversial proposals and, for those proposals, to

- evaluate and address the impact that these proposals may have on existing donation efforts and public perceptions regarding organ donation;
- evaluate and address the impact that these proposals may have on specific groups, such as ethnic minorities (specifically, African Americans), socioeconomically disadvantaged individuals, those likely to be disproportionately affected by the proposal, and living donors;
- make recommendations about whether particular alterations can be made to various proposals to reduce ethical problems; and
- provide recommendations regarding the cost-effectiveness, feasibility, and practicality of implementing such proposals.

To address its charge, the committee held five meetings and gathered information by holding a scientific workshop (see Appendix B for the workshop agenda) and two public comment sessions, talking with numerous individuals in the organ transplantation field, and conducting a literature review. The committee developed a set of perspectives and principles that guided its consideration of the complex issues that it was asked to address (Chapter 3). This report benefits from the work of prior IOM committees that examined organ allocation and donation after circulatory determination of death (IOM, 1997, 1999, 2000). However, this report focuses on organ donation, not on the equally complex issues of organ allocation. Furthermore, it focuses on solid-organ donation and does not address eye and tissue donation. Finally, this report concentrates on increasing rates of deceased donation and considers living donation only briefly in Chapter 9.

To set the context for the report, this chapter provides an overview of the history and current status of the U.S. system of organ donation and

transplantation and describes in brief some of the organ donation policies and practices of other countries. The chapter also highlights the committee's thoughts on the evolving terminology in the field of organ donation, provides a discussion of the economic value of increasing the organ supply, and concludes with an emphasis on the benefit of preventive measures to reduce the demand for organ transplantation and minimize the rejection of transplanted organs.

OVERVIEW AND HISTORY OF THE CURRENT U.S. SYSTEM

The current U.S. system of organ donation, recovery, allocation, and transplantation has developed and evolved during the past 50 years. In 1954, the first successful U.S. transplantation involved the transplantation of a kidney between living twin brothers (Merrill et al., 1956). Immunosuppressive medications began to be used in the late 1950s, leading to the first successful transplantation of a kidney from a deceased donor in 1962 (Halloran and Gourishankar, 2001). This transplantation involved an unrelated donor and recipient and the use of the immunosuppressive drug azathioprine (Morrissey et al., 2001). Cyclosporine, discovered in 1978, provided significantly improved immunologic tolerance; and numerous subsequent pharmacologic, surgical, and clinical advances have continued to improve the rates of graft survival and reduce the potential for organ rejection. The growth and development of the field of organ transplantation and the nature of its organization and structure have been guided by state and federal laws and regulations (Box 1-1).

Clarifying Criteria for Determination of Death

The early transplants were generally the result of donations of kidneys from living donors or donations of organs from deceased donors who had been declared dead following the irreversible cessation of circulatory and respiratory function (DeVita et al., 1993). In the late 1960s, improvements in mechanical ventilation and other types of medical support to sustain cardiopulmonary function highlighted the need to clarify the criteria for determining death. This led to clarification of the determination of death by circulatory criteria and to examination of the concept of determining death by neurologic criteria (Report of the Ad Hoc Committee, 1968; Guidelines for the determination of death, 1981). As a result, in addition to clarification of the criteria for the diagnosis of death by irreversible cessation of circulatory function, criteria were developed for the diagnosis of death based on the irreversible loss of function of the whole brain, including the brain stem (neurologic criteria). These criteria were incorporated into the Uniform Determination of Death Act, which was codified into state law in

BOX 1-1
Relevant Legislation

1968 Uniform Anatomical Gift Act (UAGA) (National Conference of Commissioners on Uniform State Laws)
- Provided a uniform legal environment for organ donation
- Adopted in some form by all 50 states and the District of Columbia
- Gave adults the right to donate their bodies or organs for use upon their death "without subsequent veto by others"

1981 Uniform Determination of Death Act (National Conference of Commissioners on Uniform State Laws)
- Codified and extended existing common law basis for determining death
- States that "An individual who has sustained either irreversible cessation of circulatory and respiratory functions, or irreversible cessation of all functions of the entire brain, including the brain stem, is dead"

1984 National Organ Transplant Act (Public Law 98-507)
- Established the Organ Procurement and Transplantation Network to be run by a private nonprofit entity
- Provided grants to expand regional organ procurement organizations
- Prohibited commercial transactions in organs
- Established the Task Force on Organ Transplantation

1986 Omnibus Budget Reconciliation Act
- Required hospitals participating in Medicare or Medicaid to institute a "required request" policy

1987 Amended UAGA
- Enacted in 25 jurisdictions (NCCUSL, 2005)
- Provided explicit priority to the intention of donors over that of their relatives
- Prohibited the sale of body organs
- Included required request provisions

2004 Organ Donation and Recovery Improvement Act (Public Law 108-216)
- Authorized the provision of grants for the reimbursement of travel, subsistence, and other expenses incurred by living donors
- Established a public education program to increase awareness of organ donation and authorized grants for studies, demonstration projects, public education, and outreach activities to increase rates of organ donation

various forms. For each set of criteria the diagnosis of death requires both the cessation of function and irreversibility (Guidelines for the determination of death, 1981). The use of neurologic criteria for the determination of death has gained wide medical, legal, ethical, and public acceptance in the United States, although debates continue (Bernat, 2005; Laureys, 2005).

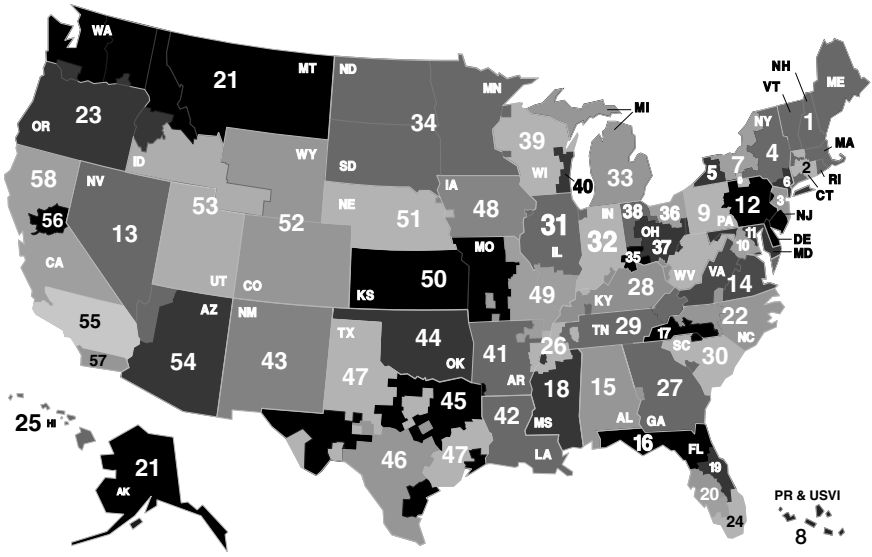
Growth and Organization of the Transplantation Field

The increased number of transplantation operations in the 1970s and 1980s and concerns about the allocation of donated organs led to an expanded role for organ procurement organizations (OPOs), some of which had emerged in the 1960s as localized efforts. In 1972, legislation authorized Medicare coverage for kidney transplantation as a treatment for end-stage renal disease. In 1978, amendments to that legislation increased the length of availability of Medicare benefits after a successful kidney transplant from 1 year to 3 years and also increased coverage of kidney acquisition costs and home dialysis costs (Eggers, 2000). The next breakthrough in transplantation came with the advent of reliable and effective immunosuppressive medications to improve graft functioning and survival for patients posttransplantation.

The growing demand for organ transplantation, controversies regarding the allocation of organs, and concerns about payment for organs prompted congressional hearings on organ transplantation in the early 1980s. The resulting federal legislation, the National Organ Transplant Act of 1984, prohibited the sale of human organs; established a task force to address organ donation and allocation issues; and established the Organ Procurement and Transplantation Network (OPTN).

OPTN is charged with developing policies for and implementing an equitable system of organ allocation, maintaining the waiting list of potential recipients, and compiling data from U.S. transplant centers (OPTN, 2004). The United Network for Organ Sharing (UNOS), a nonprofit, private voluntary organization, has been the sole administrator of OPTN since the initial contract was awarded in 1986. Oversight for the OPTN contract is provided by the Division of Transplantation in the Health Resources and Services Administration of the U.S. Department of Health and Human Services. OPOs and transplant centers are required to participate in OPTN. OPTN's oversight responsibilities focus on solid organ donation and transplantation from deceased donors. OPTN has limited responsibilities regarding living donation and does not have oversight responsibilities regarding tissue donation and distribution, although most OPOs recover tissue as well as solid organs, and a few OPOs are involved in tissue processing.

Currently, the organ donation and transplantation system in the United States is coordinated by 58 OPOs serving unique geographic areas (donor service areas) (Figure 1-2). When a donated organ becomes available, the organ allocation algorithms developed by OPTN-UNOS identify a potential recipient on the basis of multiple factors, including severity of disease; geographic proximity; and blood, tissue, and size matches with the donor. Ongoing efforts are made to ensure impartiality in the allocation process. OPOs are charged with working with individuals, families, and hospital staff to explore consent for and facilitate organ donation; evaluating the



1. New England Organ Bank
2. LifeChoice Donor Services
3. NJ Organ and Tissue Sharing Network
4. Center for Donation and Transplant
5. Upstate NY Transplant Services
6. NY Organ Donor Network
7. Finger Lakes Donor Recovery Network
8. LifeLink of Puerto Rico
9. Center for Organ Recovery and Education
10. Washington Regional Transplant Consortium
11. Transplant Resource Center of Maryland
12. Gift of Life Donor Program
13. Nevada Donor Network
14. LifeNet
15. Alabama Organ Center
16. LifeQuest Organ Recovery Services
17. LifeShare of the Carolinas
18. Mississippi Organ Recovery Agency
19. TransLife
20. LifeLink of Florida
21. LifeCenter Northwest Donor Network
22. Carolina Donor Services
23. Pacific Northwest Transplant Bank
24. Life Alliance Organ Recovery Agency
25. Organ Donor Center of Hawaii
26. Mid-South Transplant Foundation
27. LifeLink of Georgia
28. Kentucky Organ Donor Affiliates
29. Tennessee Donor Services
30. LifePoint
31. Gift of Hope Organ and Tissue Donor Network
32. Indiana Organ Procurement Organization
33. Gift of Life Michigan
34. LifeSource, Upper Midwest OPO
35. LifeCenter Organ Donor Network
36. LifeBanc
37. Lifeline of Ohio
38. Life Connection of Ohio
39. University of Wisconsin Hospital & Clinics OPO
40. Wisconsin Donor Network
41. Arkansas Regional Organ Recovery Agency
42. Louisiana Organ Procurement Agency
43. New Mexico Donor Services
44. LifeShare Transplant Donor Services of OK
45. Southwest Transplant Alliance
46. Texas Organ Sharing Alliance
47. LifeGift Organ Donation Center
48. Iowa Donor Network
49. Mid-America Transplant Services
50. Midwest Transplant Network
51. Nebraska Organ Recovery System
52. Donor Alliance
53. Intermountain Donor Services
54. Donor Network of Arizona
55. OneLegacy
56. Golden State Donor Services
57. Lifesharing Community Organ & Tissue Donation
58. California Transplant Donor Network

FIGURE 1-2 Donor service areas. Reprinted courtesy of the Association of Organ Procurement Organizations.

medical eligibility of potential donors; coordinating the recovery, preservation, and transportation of donated organs; and educating the public about organ donation (UNOS, 2006).

In addition to the OPOs, the other key organizations involved with organ donation are the donor hospital and the transplant center. Although organ donation, recovery, and transplantation may all occur in the same medical center, it is often the case that the organs are recovered in the donor hospital and are then transported to several transplant centers in the region or across the country. In 2005, 267 transplant centers were operating approximately 865 transplant programs in the United States (UNOS, 2005). This represents significant growth from the 244 transplant programs functioning in 1984 (UNOS, 2004). The number of annual organ transplants

has also significantly increased, from an estimated 7,692 in 1984 to 28,110 in 2005 (UNOS, 2004; OPTN, 2006).

Some of the challenges in further improving the organ donation system result from the heterogeneity of the OPOs, donor hospitals, and transplant centers, each of which serves populations with different demographics. Furthermore, the priorities and norms of the OPOs vary, such as in their approaches to families and their policies on donation after circulatory determination of death (Chapters 4 and 5). For example, there is variability in the rates at which consent is obtained for deceased organ donation in various transplant centers and OPOs (Chapter 4). A 2003 study examining the variability among 190 transplant centers found that 30 centers (16 percent) had consent rates of 70 percent or higher, whereas 18 centers had consent rates below 30 percent (DHHS, 2003). This is similar to the variation of donation rates reported by OPOs, which ranged from 34.3 to 77.9 percent in 2004 (SRTR, 2005). As discussed throughout this report, efforts by OPOs and participating hospitals to increase the availability of organs for transplantation are focusing on increasing the consent rate for donation as well as on increasing the population of potential donors.

Although this report focuses on solid organ donation, many of the matters it discusses are closely tied with tissue donation. However, the tissue recovery and distribution system is quite different, particularly in the extent of private-sector commercial involvement. The resulting issues and challenges impact both the solid organ and tissue donation and recovery systems (Youngner et al., 2004).

Deceased Organ Donation

In the United States, deceased organ donation is an opt-in system in which the donation decision is made by the individual or by his or her family.

Most current U.S. transplantations from deceased donors result from deaths determined by neurologic criteria. The donor-eligible deaths determined by neurologic criteria—estimated to number between 10,500 and 16,800 per year—represent only a small fraction of the more than 2 million annual deaths in the United States (Guadagnoli et al., 2003; Sheehy et al., 2003; NCHS, 2005). For deaths determined by neurologic criteria, organ viability can be maintained through ventilatory support and thereby improve opportunities for successful transplantation. Death determined by circulatory criteria is much more common in the population at large, but, because it often occurs outside of the hospital setting, maintaining the viability of the organs presents distinct challenges (Chapter 5).

The Uniform Anatomical Gift Act (UAGA) of 1968 specified that the donor's authorization to donate is legally binding, and the subsequent

amendment of UAGA in 1987 assigned explicit priority to the donor's intent even if his or her family objected to donation. In several states, the individual's decision to donate is recorded on an organ donor card, on the individual's driver's license, or in a donor registry and is as legally binding as an advance directive regarding end-of-life care (DHHS, 2000). In practice, however, organ donation and recovery involve a complex set of circumstances and decisions.

When the individual's wishes regarding donation are not known, discussions between the family of the deceased individual and the OPO and hospital staff focus on the opportunity for donation and the family is asked to make a decision about donation. Families often view organ donation as a way to redeem an otherwise tragic situation; as a way to honor their loved one's life, passions, and philosophies; and as a way to help others live. Despite such positive reasons to consider organ donation, historically only 50 percent of families asked to consent to organ donation do so (JCAHO, 2004). However, progress has been made both in identifying dying patients who would be potentially suitable donors and in obtaining family consent for donation. Gortmaker and colleagues (1998), examining 1990 data, found that 27 percent of eligible patients had not been identified as potential donors or the family had not been contacted. The study found that 48 percent of the families who were asked to donate their loved one's organs consented to the donation and that 33 percent of the deceased persons who were potential donors became actual donors. This contrasts with data collected between 1997 and 1999 by Sheehy and colleagues (2003), who found that only 16 percent of eligible patients were not identified as potential donors. Results from the latter study showed that 54 percent of the families who were asked to donate consented and that 42 percent of the potential donors became actual donors. These results suggest substantial improvements over the course of the decade, and consent rates have continued to improve in recent years. The process of organ donation is outlined in Figure 1-3.

It is difficult to determine the uppermost potential for the number of deceased organ donors. Efforts to date have focused on estimating the number of potential deceased organ donors with neurologic determination of death. However, the potential pool also includes a large number of individuals whose deaths are determined by circulatory criteria, although estimating the number of such potential donors is a complex task (see Chapter 5).

Guadagnoli and colleagues (2003) estimated the number of potential deceased organ donors (neurologic determination of death) in the United States in 1998 to be 16,796; the actual number of deceased donors in 1998 was 5,793. This analysis used hospital case-mix data, hospital bed size, medical school affiliation, and status as a trauma center to estimate the

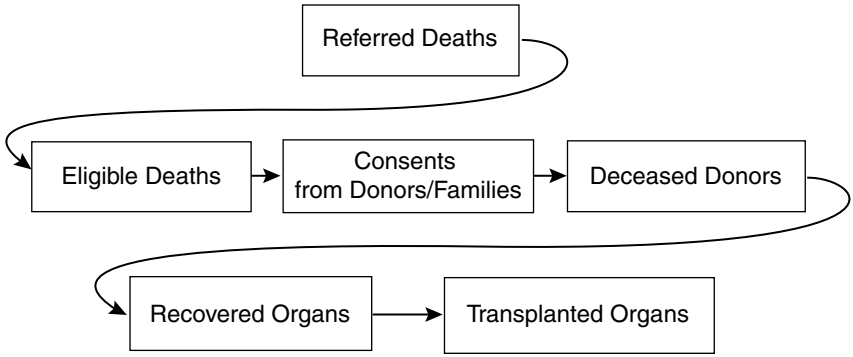


FIGURE 1-3 Process of organ donation.
SOURCE: Adapted from Delmonico et al. (2005). Reprinted with permission from Blackwell Publishing.

number of potential organ donors per hospital and then aggregated the data for each OPO. Because of variations in demographics, the number of eligible hospitals, and other factors, there is wide variation in the number of donations that a single OPO works with each year (in 2004 ranging from 13 to 387 donors) (HRSA and SRTR, 2006).

Sheehy and colleagues (2003) reviewed hospital medical records of deaths submitted by 36 OPOs from 1997 through 1999. Forms were completed for deaths occurring in hospital intensive care units for all individuals who met the neurologic criteria for death and who were 70 years of age or younger. That study estimated that each year in the United States there is a national pool of 10,500 to 13,800 potential donors for whom death is determined by neurologic criteria.

As seen in data from 2002 and 2003 (Table 1-1), the annual pool of eligible donors with neurologic determination of death has numbered approximately 12,000.

In 2003, there were approximately 2.4 million deaths in the United States; of those approximately 1 million deaths were of individuals age 15 to 74 years (NCHS, 2005). Despite a number of coexisting conditions that would preclude organ donation, a comparison of the number of potential eligible donors with the number of actual donors (Table 1-2) shows that there could well be a large number of additional donors if technologies and systems are developed in the future to keep organs viable. This would include an increased focus on donation after circulatory determination of death (Chapter 5). Furthermore, issues regarding organs that are recovered but that are not used have yet to be fully explored (Chapter 2; Delmonico et al., 2005).

TABLE 1-1 Eligible,[a] Actual, and Additional Donors, 2002 and 2003

Parameter	2002	2003
Eligible deaths[a]	12,015	12,031
Consents for donation	6,370	6,630
Actual deceased donors[b]	5,743	5,908
Donation rate (%)[c]	48.7	49.8
Additional deceased donors[d]	444	547
Total deceased donors	6,187	6,455

[a]Eligible deaths include any individuals with a heartbeat meeting or imminently meeting death by neurologic criteria and aged 70 years or younger who have not been diagnosed with exclusionary medical conditions.

[b]At least one organ recovered for transplantation from deceased donors who meet the definition of an eligible death.

[c]Excludes additional donors (Scientific Registry of Transplant Recipients analysis, May 2004).

[d]At least one organ recovered for transplantation from deceased donors that do not meet the definition of an eligible death.

SOURCE: HRSA and SRTR (2005).

TABLE 1-2 Deceased Organ Donors, Potential Versus Actual

Criteria Used to Determine Death	Annual Number of Estimated Potential Donors	Actual Number of Donors, 2003[a]
Circulatory determination of death		
Uncontrolled	22,000[b]	17[c]
Controlled	Unknown	236
Neurologic determination of death	12,000[d]	6,178

[a]Data provided by OPTN-UNOS as of September 8, 2005 (see Chapter 5, Table 5-2) include an additional 17 DCDD donors in 2003 with unknown circumstances of death.

[b]Estimate of annual out-of-hospital cardiac arrest deaths meeting criteria for uncontrolled DCDD (see Chapter 5).

[c]OPTN data indicate that most of the uncontrolled DCDDs were Maastricht Category IV deaths.

[d]Based on 2003 data on eligible donors (Table 1-1; HRSA and SRTR, 2005; see also Guadagnoli et al., 2003; Sheehy et al., 2003 for estimates ranging from 10,500 to 16,800 potential donors with neurologic determination of death).

Transplant Recipients

Transplant recipients probably know best the real value of increasing the numbers of donated organs: an extended lifetime, improved quality of life, and a chance to resume activities that would have been precluded without a transplant. A 10-year overall increase in life expectancy is reported for kidney transplant recipients compared with the life expectancy

for individuals on transplant waiting lists (Wolfe et al., 1999). Transplant recipients not only experience gains in life expectancy but also enjoy improvements in the quality of their lives. A literature review of 218 independent studies involving approximately 14,750 transplant recipients demonstrated statistically significant improvements in physical functioning, mental health, social functioning, and overall perceptions of quality of life following transplantation (Dew et al., 1997). These improvements are particularly striking when they are contrasted with the pretransplant conditions of patients requiring a transplant, such as the health complications and difficulties associated with long-term dialysis and other medical interventions. Moreover, many individuals face imminent death without a transplant. The lack or inferiority of alternative therapies should be considered when posttransplant quality-of-life data are evaluated (Whiting, 2000).

Other factors may have negative effects on a patient's quality of life posttransplantation. The financial burden of immunosuppression therapy is thought to play a significant role in patient noncompliance with treatment regimens (Chisholm et al., 2000), which may eventually lead to rejection of the transplant and the need for other therapies or retransplantation.[4] Physical side effects and the psychological and social issues that a patient encounters following a transplantation must also be considered. Improved immunosuppression protocols and the provision of patient education and support services have been recommended as ways to promote positive outcomes and enhance the quality of life for transplant recipients (Galbraith and Hathaway, 2004).

INTERNATIONAL PERSPECTIVE

Most countries around the globe also face such problems as long waiting lists for organ transplantation and challenges with the allocation of scarce organs. In the last decade, organ donation systems, transplantation programs, and organ exchange organizations have received increasing resources and attention from governmental agencies. In some countries, such as Spain and France, the government itself operates those organizations. In other countries, such as the United Kingdom, the organ donation and allocation efforts remain in control of a nongovernmental body affiliated with the nation's department of health. Most countries (e.g., Austria, Belgium, Denmark, Sweden, Germany, and The Netherlands) continue to operate a quasipublic system. Most organ exchange organizations operate on a na-

[4]Retransplantation may be needed for a number of reasons. In 2004, 14.5 percent of the 7,915 recipients of a deceased donor kidney transplant had previously received a kidney or kidney/pancreas transplant (HRSA and SRTR, 2006).

tional basis. However, the Eurotransplant International Foundation serves Austria, Belgium, Germany, Luxembourg, The Netherlands, and Slovenia; UK Transplant serves the United Kingdom and Ireland; and Scandiatransplant serves Denmark, Finland, Iceland, Norway, and Sweden.

Bolstering the infrastructure for organ donation and transplantation has been a major focus in a number of countries. In recent years Spain has been successful in significantly increasing its donor rates. Among the major changes instituted in Spain are an active donor detection program conducted by well-trained transplantation coordinators; an extensive transplant coordination network linking national, regional, and hospital efforts; hospital-level coordinators; increased economic reimbursement for hospitals; professional and public education efforts; systematic death audits conducted in hospitals; and a focus on expanded-criteria donors and on donation after circulatory determination of death (Matesanz, 1998, 2003, 2004).

Cross-country comparisons of donation rates are generally based on the number of donors per million population, a measure that has been criticized because of inconsistent definitions (Box 1-2). According to a report by the Council of Europe, Spain had the highest number of deceased donors per million population (34.6) in 2004, with the United States having 24.1 per million population (Council of Europe, 2005) (Figure 1-4). However, it is difficult to draw accurate or meaningful international comparisons, even for those countries closely aligned geographically, politically, and socioeconomically. A combination of factors influences the effective-

BOX 1-2
Comparing Rates of Organ Donation

The methods used to calculate the rates of donation remain a subject of debate. There is no international harmonized definition of "the number of donors per million population." Different organizations have different definitions of "donor." These definitions include "consented donors" and "actual donors." Rates also differ by organ type and by live versus deceased donation. The Council of Europe has made an attempt to develop a general definition for Europe, that is, a donor is a person from whom "at least one organ has been recovered for the purpose of transplantation" (Roels, 2005).

Thus, the methods used to calculate donation rates can alter international comparisons. In addition, the validity and the reliability of the data must be considered. However, even when different methods are used to calculate donation rates, several countries consistently have high rates of donation: Spain, Austria, Belgium, Norway, France, Switzerland, Portugal, Italy, and the United States. Measures of the efficiency of a given national system, that is, its adequacy in converting the potential for donation into a realized donation (Roels, 2005), can provide important insights into the potential for additional organ donations.

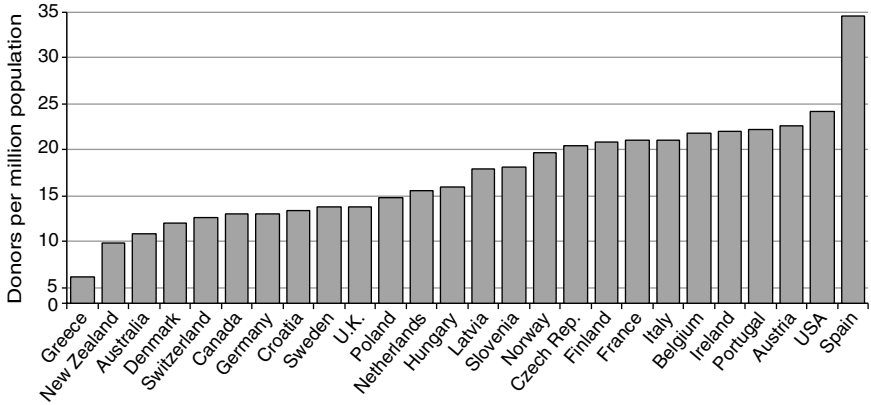


FIGURE 1-4 Numbers of deceased donors per million population for various countries, 2004.
SOURCE: Council of Europe (2005).

ness of a given country's response to organ donation and transplantation: history; political philosophy; social, legal, and cultural factors; economics; and medical professional practices.

In many countries, explicit consent is needed for organ donation. Countries with opt-in policies include the United States, Canada, United Kingdom, Germany, The Netherlands, and New Zealand (Abadie and Gay, 2004).

An alternative approach used by a number of countries is a presumed-consent or an opt-out approach, in which the default policy is that citizens are presumed to be organ donors unless they have expressly opted out of the system (Chapter 7). Opt-out or presumed-consent structures enable either verbal or computer registration of an individual's objection to organ donation. This is applied with various degrees of strictness. Some countries follow a strict or strong presumed-consent model with little to no role for the family in the organ donation decision-making process. Other countries have a presumed-consent law, but in practice the donor family is involved in the consent process. For example, this is the case in Belgium, Bulgaria, Croatia, Spain, Italy, France, and Sweden (Abadie and Gay, 2004).

Ethical, Social, and Cultural Issues

The ethical issues surrounding transplantation have come under close scrutiny in most countries, and legislation has gradually been introduced to

regulate the transplantation process and to protect donors. Trust in a country's medical establishment is crucial, however. For example, the relatively low rate of donation in Brazil has been attributed, in part, to distrust of the medical community. Brazil has a large underclass with poor access to health care, and the quality of health care varies greatly. When a new policy of presumed consent was established, Brazilians reported difficulties, even obstacles, in registering as nondonors, further fueling fears that the health-care system authorities were not to be trusted (McDaniels, 1998). The presumed-consent statute was subsequently repealed.

There are wide differences in the policies and statutes regarding living donation among various countries. For example, Iran has a government-regulated program that compensates and monitors living unrelated kidney donors (Ghods, 2004), whereas many other countries prohibit the exchange of money for transplantable organs.

Cultures vary in the extent to which people are willing to donate their own organs and the organs of their deceased relatives (Sanner et al., 1995). Repeated surveys in Sweden have shown that about 66 percent of the public supports donation, but only 40 percent would consent to removal of a relative's organs if the wishes of the deceased were not known (Sanner, 1994). A common problem across cultures, however, is that few individuals have informed their families of their wishes, and where donor cards are available, even fewer have signed them (Sanner et al., 1995).

Cultures have different views and traditions about death, and there have been significant debates about the determination of death by neurologic criteria. In Denmark in the 1980s and Germany in the 1990s, many believed that prolonged public debates over the determination of death by neurologic criteria led to declines in organ donation rates (Matesanz, 1998). In Japan, cultural and religious beliefs, particularly those associated with the wholeness of nature and of the human body, have played a role in resistance to the determination of death by neurologic criteria. Under a law adopted in 1997 in Japan, death is pronounced by neurologic criteria only in cases of organ donation and only for those who consented, while they were alive, to organ donation and to the use of brain-based criteria (Veatch, 2000). The next of kin must also give their consent to organ procurement and agree to the pronouncement of death (Fitzgibbons, 1999).

Cultural and religious traditions and beliefs about the treatment of the dead body, beliefs about life after death, and fears of mutilation can also influence decisions about organ donation. The major tenets of nearly all religious traditions, however, are compatible with the practice of organ donation (Chapter 2). Yet, religious beliefs are often invoked in expressing resistance to organ donation, perhaps in part reflecting differences between official religious policies and folk beliefs and practices.

TERMINOLOGY

Because the concepts and processes of organ donation are so closely intertwined with emotional issues of death and dying, it is of utmost importance to the committee, as it is to the transplantation community, that the terminology used to describe and discuss all aspects of organ transplantation be both as accurate and as sensitive as possible. Terminology in this field has had both positive and negative connotations. On the one hand, some terms have played a role in creating or propelling myths, have led to increased misconceptions and fears about organ and tissue donation, or have bred mistrust of the system in general. Other terms have a more positive role in the healing process of a hurting family and in motivating the public to agree to donation. The National Donor Family Council and numerous recipient and donor family organizations have been active in addressing terminology.

Some terms that have seemed descriptive or useful in the past are now being reconsidered in favor of terms that are sensitive to the donor family and that affirm the value of individual human life (see Table S-1 in the Summary). In the past, the term *donor* did not require any specificity. Today, as more people choose to become living donors, there is a need to distinguish between *living* and *deceased* donors. The term *cadaveric* has been used in the past but has an impersonal connotation (a dead body intended for dissection). The term *deceased donor* is preferred because it conveys a more positive message and also denotes that it is a donation by an individual human being.

Although the medical community has used the term *harvest*, it has agricultural and impersonal connotations for the general public. Similarly, the word *retrieval* suggests the reclamation of an object and can be quite unpalatable, especially to donor families. The preferred word, *recovery*, helps people to understand that the removal of a loved one's organs for transplantation is a respectful surgical procedure. The word *receive* might even be more appropriate because it highlights the gift relationship. Even though the term *procure* is widely used, it is also receiving close scrutiny. This term, similar to *retrieve*, has an impersonal connotation that does not fit with the intensely personal and emotional decisions regarding the end of a human life.

The term *life support* can be a confusing term for a family who has been notified that their loved one is dead. When death occurs, there is no support that can make the individual alive again. After the declaration of death by neurologic criteria, if there is consent for organ donation, the organs may be perfused with oxygen for several hours through mechanical support. *Mechanical support* and *ventilated support* are appropriate terms for the support given a deceased person's organs in the event of organ donation.

Further confusing to families in times of crisis are the terms *brain death* and *cardiac death*. To some, these terms imply that certain organs have died but do not convey that this is a final determination of death. In order to avoid such confusions, the committee recommends use of the word *death*, adding either *circulatory determination of death* or *neurologic determination of death* where it is important to have greater specificity. Instead of *donation after cardiac death* and *donation after brain death*, the committee believes it would be clearer to use the phrases *donation after circulatory determination of death* (DCDD) and *donation after neurologic determination of death* (DNDD). Even though these phrases are more cumbersome, they better convey the finality of death and provide additional information on how that death was declared.

As terms continue to evolve, the committee urges all who are involved in organ transplantation to use words and phrases that clarify rather than mystify the process of organ transplantation and that affirm the value of each individual human life.

It is also important at the outset of this report to clarify the measures of deceased donation that the committee used. The *consent rate* is defined as the number of patients for whom consent is granted for organ donation (permission may be granted by the individual donor while he or she is alive or by the donor's family after death) per the total number of patients eligible to be donors. The *donation rate* (also termed the *conversion rate*) is the number of actual donors (i.e., the organs are removed for transplantation) per the total number of individuals eligible to be donors. The consent rate can be slightly higher than the donation (or conversion) rate, since after consent is obtained it might be determined that the organs are not suitable for recovery. Both of these measures have focused on donation after neurologic determination of death. As the measures are currently defined, the denominator for each excludes patients who are eligible for donation after circulatory determination of death. The implications of this approach are further discussed in Chapter 5.

U.S. EFFORTS TO INCREASE ORGAN DONATION

Current efforts in the United States to increase rates of organ donation involve the collective work of numerous governmental and private-sector organizations. This section provides a brief overview of ongoing efforts. The chapters that follow provide further insights into the many parties that enable, facilitate, and promote organ donation.

HRSA is a major federal funder of research and initiatives to increase organ donation rates in the United States. HRSA's Division of Transplantation is responsible for administering the federal contracts for OPTN and for the Scientific Registry of Transplant Recipients, which collects and analyzes

data on solid-organ transplant recipients. In addition to this operational role, HRSA works to increase organ donation rates through three major avenues: an extramural grants program, which funds model interventions, including social and behavioral, media-based, and clinical interventions (Appendix E); the Organ Donation Breakthrough Collaboratives, an ongoing initiative that emphasizes quality improvement and that focuses on improving hospital and OPO collaborations and encouraging best practices in organ donation (Chapter 4); and additional Gift of Life initiatives, including efforts in workplaces, schools, and driver's education centers, as well as model donor card, donor registry, and similar projects (Chapter 6). In recent years, the level of funding for HRSA's Division of Transplantation has decreased, with a significant reduction encountered in fiscal year 2006 (Table 1-3). The potential impact of these budget reductions on organ donation efforts is of concern.

The National Institutes of Health (NIH) funds grants for organ transplantation research that primarily focus on biomedical studies of improvements in surgical techniques for transplantation, understanding immune-related processes, and improving graft survival. Additionally, and to a more limited extent, NIH funds have been applied to behavioral research on organ donation. In fiscal year 2005, the National Institute of Diabetes & Digestive & Kidney Diseases (NIDDK) supported research grants primarily aimed at raising awareness of organ donation in minority communities and improving the role of healthcare professionals in encouraging donation. In addition to these grants, NIDDK and the National Center on Minority Health and Health Disparities support the National Minority Organ and Tissue Transplant Education Program (Chapter 6).

The Centers for Medicare & Medicaid Services (CMS) has the regulatory authority to certify OPOs and hospitals that perform transplantations

TABLE 1-3 Funding History, HRSA Division of Transplantation

Fiscal Year	Public Law	Appropriation
1997	104-208	$2,296,000
1998	105-78	$2,778,000
1999	105-277	$10,000,000
2000	106-113	$10,000,000
2001	106-554	$14,992,000
2002	107-116	$19,983,300
2003	108-7	$24,828,000
2004	108-199	$24,632,000
2005	108-447	$24,414,000
2006	109-149	$23,049,000

for participation in Medicare. CMS administers the End-Stage Renal Disease Program and is active in ensuring quality improvements in transplantation programs.

States play an important role in promoting organ donation through legislative action (e.g., anatomical gift acts and the criteria used for the determination of death), the funding and implementation of organ donor registries (Chapter 6), drivers' license registration options for organ donation, and other programs (Gilmore et al., 2001). Some states have mandated that information on organ donation be provided as a part of high school driver's education curriculum.

One of the key responsibilities of OPOs is "educating the public about the critical need for organ donation" (UNOS, 2006). OPOs work closely with donor families, transplant recipients, and others in a range of donation efforts.

In addition, numerous voluntary health organizations focus on public education about organ donation and the provision of support for donor families, living donors, and transplant recipients. For example, the Coalition on Donation is a not-for-profit alliance of national organizations and local coalitions across the United States that have joined forces to educate the public about organ, eye, and tissue donation (Coalition on Donation, 2004). The National Kidney Foundation and similar organizations that focus on relevant diseases and organ systems also support research and efforts for public and professional education. Other organizations, such as the National Donor Family Council, support the needs of donor families, assist the healthcare professionals who work most closely with these families, and raise public awareness.

The Joint Commission on Accreditation of Healthcare Organizations has promoted organ donation efforts by incorporating policies and procedures on the identification and referral of potential donors into hospital accreditation standards.

Professional organizations, including the Association of Organ Procurement Organizations, the American Society of Transplantation, the American Society of Transplant Surgeons, and the Organization for Transplant Professionals, are active in professional education and also work to promote organ donation through advocacy and public education efforts.

THE ECONOMIC VALUE OF INCREASING THE ORGAN SUPPLY

Numerous clinical studies have documented the benefit to patients of organ transplantation in terms of life expectancy and quality of life. Increasing the rates of organ donation would provide these benefits to more patients and would reduce the waiting time for many transplant recipient candidates. Policies that increase the organ supply also entail monetary and

nonmonetary costs. In deciding whether to pursue these policies, it is helpful to know whether the benefits to patients in terms of life expectancy and quality of life outweigh the costs and whether the cost per unit of health gained is low (or, alternatively, the "value" is high) compared with the value of other policies that are implemented to improve health.

The literature on the cost-effectiveness of transplantation provides indirect evidence of the economic value of increasing the organ supply. Kidney transplantation has been estimated to be highly cost-effective compared with the cost of dialysis (Winkelmayer et al., 2002) and is probably cost saving (Matas and Schnitzler, 2003; Whiting et al., 2004). Estimates of the cost-effectiveness of nonrenal transplantation are more variable (Ramsey et al., 1995; Cope et al., 2001; Sagmeister et al., 2002; Longworth et al., 2003; Ouwens et al., 2003). Most of these studies find that the cost per life year gained is less than commonly cited estimates of the value of a life year (Richardson, 2003), although cost data are often incomplete and, for studies based on transplants occurring in European countries, may not be generalizable to the United States. Most of these studies find that the cost per year of life gained is less than $100,000, although the data required for cost-effectiveness studies of nonrenal transplantation are often incomplete.

Several studies have directly addressed the economic value of increasing organ donation. Matas and Schnitzler (2003) estimate that every additional kidney donation from a living donor reduces total spending by more than $90,000. Mendeloff and colleagues (2004) used published estimates of the costs of and quality-adjusted life years gained from kidney, liver, and heart transplants to calculate the monetary value to society of a deceased organ donor, assuming that each donation results in 1.55 kidney transplants, 0.37 heart transplants, and 0.76 liver transplants. They estimated that a deceased organ donor is associated with a gain to transplant recipients of 13 quality-adjusted life years (summed across the transplanted organs) and a $200,000 increase in healthcare spending, although that figure is based on a conservative value of the cost savings from kidney transplantation (Schnitzler et al., 2005a). If it is assumed that a life year is worth $100,000, their "central" estimate is that each donor is worth $1,086,000 to society, or $1,800,000 when their best-case estimates of cost savings and life years gained are used.

Interpretation of the findings of these studies requires one note of caution, however, in that they are based on historical outcomes data, and the patients who would gain access to transplantation as a result of an increased organ supply may differ systematically from patients who currently receive a transplant. For example, in the case of liver transplantation, in which organs are allocated according to a "sickest first" priority rule, an increased supply would allow physicians to perform transplantations for healthier patients, who, under current supply constraints, must wait until

their health declines before they reach the top of the waiting list. Because the cost-effectiveness of transplantation varies widely by age group (Jassal et al., 2003, Schnitzler et al., 2003), primary diagnosis (Longworth et al., 2003; Groen et al., 2004), and other factors, knowledge of the characteristics of the patients who will receive additional organs is important for estimation of the impact of efforts to increase the organ supply. Schnitzler and colleagues (2005b) have made progress on this front by measuring the life years gained from transplantation on the basis of the pretransplantation death rates of patients near the top of each organ-specific waiting list. They have found that an additional deceased organ donor yields a gain of 30.8 life years for these patients (summed across the transplanted organs), assuming that each donation results in 1.4 kidney transplants, 0.80 liver transplants, 0.20 lung transplants, and 0.30 heart transplants. For the case of livers, an analysis by Gibbons and colleagues (2003) suggests that urgent patients (status 1, under the old classification system) derive a greater benefit from transplantation than nonurgent patients.

An increase in the organ supply will increase the number of patients who receive transplants, but even when the number of transplantations is held fixed, an increase in the supply will reduce the waiting times for patients who would eventually receive a transplant anyway. A number of studies indicate that longer waiting times are associated with worse outcomes (Everhart et al., 1997; Howard, 2000; Meier-Kriesche and Kaplan, 2002). It may be possible, however, to provide transplants to patients too early in the course of their disease, in the sense that the benefit of the reduced waiting time is outweighed by the immediate risk of postoperative mortality (Kim and Dickson, 2000; Alagoz et al., 2004).

A number of secondary effects of increasing the organ supply should be considered when the value of increasing donation rates is assessed, although these have not been well documented. If the organ supply increases, providers may place more patients on the waiting list, particularly those who are less likely to benefit from transplantation. Physicians may also become reluctant to use low-quality organs (Howard, 2002).

In evaluating the payoffs from increasing the organ supply, it is important to remember that cost-effectiveness studies are approximations and that some nonmonetary costs and benefits are not easily quantified. Moreover, policies that are implemented to increase the supply of organs must be compared with other opportunities to improve the length and quality of life through public policy. In a country in which so many people have limited access to effective health care, many unexploited opportunities to obtain quality-adjusted life years at a low cost probably exist. Nevertheless, with these caveats in mind, the committee concludes that the available data suggest that well-designed policies to increase deceased and living organ donation are potentially cost-effective and even cost saving.

EMPHASIS ON PREVENTION

In considering the total picture of organ transplantation, it is helpful to step back and examine each of the points at which interventions and initiatives could make a difference in equalizing the supply and the demand for organs for transplantation. The focus of the committee's task—and thus, the focus of this report—is on increasing the supply of donated organs. However, reducing the demand for organ transplantation would be even more effective, because it would mean that greater numbers of healthier individuals have not reached the point of needing an organ transplant. In general, transplantation should be seen as a rescue technology; it is an invaluable resource and option when it is needed, but prevention measures leading to improved health status are the first line of defense to avoid, where possible, the need for transplantation. The committee recognizes that not all causes of organ deterioration and failure can be prevented; however, for those cases in which prevention could make a difference, it is important to begin to implement preventive interventions at the earliest time possible and to minimize the rejection of the transplanted organ(s).

Transplantation occurs at the end of a continuum of symptoms, diagnoses, treatments, and interventions. The prevention framework of public health, with insights from the Haddon matrix (a model originally developed to address injury prevention), provides a context for considering the numerous points at which interventions could improve health status and reduce the demand for transplantation (Table 1-4).

If transplantation is considered the event, then pre-event measures and interventions could focus on efforts to prevent the onset of disease or minimize its outcomes so that it will not reach the point of requiring transplantation. Examples of pre-event interventions include education on healthy lifestyles and screenings for stroke, diabetes, and high blood pressure. Event interventions focus on high-quality care for the patient during transplantation and the provision of support to the patient and family so that they understand the transplantation procedures and the necessity for follow-up. In the third phase—the post-event phase—the focus is on restoring lost function and former quality of life, with particular attention to access to immunosuppressive therapies and ensuring that the donated and transplanted organ is fully maintained so that retransplantation is not necessary.

The goal, of course, is to minimize the need for organ transplantation by preventing the underlying disease risk factors that lead to organ deterioration and failure. Although not all the medical conditions necessitating organ transplantation can be prevented, preventive interventions and the treatment of contributory diseases as early as possible have the potential to reduce significantly the demand for organ transplantation.

TABLE 1-4 Organ Transplantation Prevention Matrix

Timing	Actions for Individuals or Populations	Clinical Action	Environmental Actions
Pretransplantation (pre-event)	• Public education • Clinical screenings (e.g., blood pressure screening)	• Treatment of precursor conditions (e.g., hypertension or diabetes) • Treatment for the condition (e.g., dialysis for end-stage renal disease)	• Environmental changes relevant to addressing precursor conditions (e.g., access to physical activity, healthful foods, insurance coverage for medications, and health care)
Transplantation (event)	• Support for patients and families	• Transplantation	• Equitable access to transplantation
Posttransplantation (post-event)	• Increase knowledge of posttransplantation care	• Immunosuppressive therapies, other posttransplantation care	• Coverage for immunosuppressive drugs and posttransplantation-related health care
Desired end result	• Limit the number of transplantations • Improve the care of those receiving transplants • Mitigate adverse consequences	• Increased access to follow-up care • Provision of care for a rapid recovery • Rehabilitation	• Minimization of disruption in daily routines

ON THE HORIZON

A variety of technological advances in development might improve organ viability or diminish the need for living or deceased organ donation. Ongoing research on organ preservation and organ culture is examining methods to improve organ function and viability. Nanotechnology offers the potential for the insertion of implantable devices that would restore organ function or serve as an organ replacement. For example, mechanical devices such as the left ventricular assist device currently serve as a bridge for those waiting for a heart transplant, but refinements or reengineering

may permit them to be used as a long-term alternative to or replacement for transplantation. Xenotransplantation (transplantation of an organ between two different species) has been an ongoing area of research and has some current clinical applications (e.g., heart valve transplants from pigs). However, the use of organs or tissues from other species continues to encounter biological barriers regarding immunosuppression, organ rejection, and disease transmission as well as the psychosocial concerns of some individuals regarding the use of organs from animals. Stem cell research offers the promise of repairing or restoring organ function in the near future.

Other technologic developments are raising new ethical questions. Organs such as the face and the ovary have been transplanted with some success and raise ethical concerns about identity and reproductive lineage. It is too early to determine if and how public attitudes regarding these developments will impact rates of organ donation.

Until the time that preventive measures diminish the need for transplantation or alternative approaches offer an effective option, numerous families, healthcare and transplantation professionals, and many others continue to make extraordinary efforts each day to ensure that organs are donated and are successfully transplanted with the goal of improving the quality of life and the length of life for transplant recipients.

OVERVIEW OF THIS REPORT

The large gap between the supply and the demand for solid organs has prompted the need to carefully examine a variety of policy, organizational, and institutional changes that might be made to increase rates of organ donation. As discussed in Chapter 2 and throughout the report, a variety of factors influence an individual's or a family's decision making regarding organ donation.

This report examines a range of proposals for increasing deceased organ donation (Table 1-5) and briefly discusses some ethical concerns raised by living donation. The committee's framework—perspectives and principles—for considering these proposals is provided in Chapter 3. The subsequent chapters examine changes in the organization, processes, and interactions of hospitals and OPOs (Chapter 4); expanding the pool of potential organ donors through donation after circulatory determination of death (Chapter 5); and individual decision making, public education, and research (Chapter 6). Opt-out policies, particularly presumed consent, are discussed in Chapter 7, and Chapter 8 focuses on financial and nonfinancial incentives. Living donation is discussed in Chapter 9, and the report concludes in Chapter 10 with a synopsis of the opportunities for action to increase organ donation.

TABLE 1-5 Several Approaches to Increasing Deceased Organ Donation, Issues Examined in This Report

Strengthen Public Communications
- Education—public education, professional education
- Marketing and media efforts to promote donation

Facilitate Individual Decisions to Donate
- Improve the current opt-in system
  - Promote registration on driver's licenses and donor cards
  - Implement and expand donor registries
  - Encourage family discussions
  - Promote a community of donors
  - Implement first-person consent
- Adopt presumed consent (it is up to the individual to opt out)
- Adopt mandated choice (which requires an individual's response)

Facilitate Familial Decisions to Donate
- Improve family support
- Improve donation discussion and request efforts
- Integrate organ donation into end-of-life care

Provide Incentives to Donate

Type of incentive	*Incentive received prior to death*	*Incentive received after death*
Financial:		
Direct	• Cash payment to donor • Futures market	• Cash payment to family or estate
Indirect	• Reduction in life or health insurance premium	• Income tax deduction or credit • Payment of medical expenses • Payment of funeral expenses • College education benefits for children • Life insurance • Contribution to a charity
Nonfinancial:		
Reciprocity	• Eligibility for future transplant	
Preferred status	• Priority for future transplant	• Preferred status for family members
Community recognition		

Expand Populations of Potential Donors
- Donation after circulatory determination of death
- Expanded criteria for suitability of organs

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2
Trends and Patterns

Increasing the rate of organ donation is a complex challenge, not only because of the emotional aspects of the decision that individuals and their families face but also because of the organizational and clinical demands of recovery, allocation, and transplantation. This chapter describes the context in which efforts to increase the rates of organ donation must occur. It begins with an overview of the statistics on organ transplantation, including statistics on each type of solid organ that is transplanted—kidney, liver, lung, heart, pancreas, and intestine. The chapter then examines the literature on the determinants of organ donation from the perspectives of both individuals and families. More research is needed to better understand the concerns of individuals and families who are not currently inclined to donate.

Although this report focuses on organ donation, it is important to keep in mind the recipients of transplants and those awaiting transplantation. They are the beneficiaries and potential beneficiaries of organ donation and their health and well-being are the reasons it is so important to increase the rate of organ donation. This chapter provides just a brief overview of some of the issues related to allocation and transplantation of specific organs.

ORGAN DONATION STATISTICS AND TRENDS

The number of organ donors has increased each year since 1988, from 5,902 total donors in 1988 to 14,489 donors in 2005 (OPTN, 2006[1]). The

[1]Data are provided from the National Data Reports on the OPTN website (http://www.optn.org). The data used in this chapter are current as of March/April 2006; data on the website are continuously updated. Data are based on the calendar year, unless otherwise indicated in the text.

annual increase in the number of donors over the prior year ranges from 26 additional donors (1988 to 1989) to 1,057 more donors (1999 to 2000) (OPTN, 2006). Furthermore, there has been a steady increase in the number of organs recovered (with an average of approximately 1,100 more organs recovered each year than in the previous year); 2,416 more organs were recovered in 2004 than in 2003,[2] the largest recent increase (OPTN, 2006). However, the growth of the waiting list has been much more dramatic, with approximately 5,000 more candidates for transplantation each year than in the prior year (Table 2-1). The net result is a widening gap between the supply of transplantable organs and the number of patients on the waiting list—hence, the increasing need for donated organs (see Figure 1-1 in Chapter 1).

The U.S. waiting list for organ transplants, which listed 16,026 individuals in 1988, grew more than fivefold to greater than 90,000 candidates for transplantation in early 2006 (IOM, 1999; OPTN, 2006). The need for kidney transplants is the major driving force in the increase in the waiting list, with individuals waiting for a kidney transplant constituting approximately 72 percent of the transplant waiting list in March 2006 (Table 2-2; Figure 2-1). As discussed in Chapter 1, the waiting list is dynamic and changes throughout the year as new transplant candidates and registrations are added, individuals receiving a transplant are removed, and other changes are made. In 2005, 44,619 transplant candidates were added, and there were 48,922 new registrations (an individual candidate can be registered at multiple centers or for more than one organ) (OPTN, 2006).

Organ Donors

In 2005, there were 7,593 deceased donors and 6,896 living donors (OPTN, 2006). Although the first transplantation in 1954 involved a kidney from a living donor, most organ transplantations are the result of donations from deceased donors. Deceased donors provide multiple organs (for 2005, a simple calculation based on the number of transplanted organs and the number of deceased donors results in 3.06 transplanted organs per deceased donor); most living donors provide only one partial or complete organ. Of the 30,148 organs transplanted in 2005, 23,249 organs were from deceased donors and 6,899 were from living donors[3] (OPTN, 2006). In 2001, the number of living donors exceeded that of deceased donors for the first time (Figure 2-2). Since then the increase in the numbers of dona-

[2]These statistics are totals for living and deceased donors. In 2005, 33,731 organs were recovered from living and deceased donors.

[3]As discussed below, not all recovered organs are eligible for transplantation.

TABLE 2-1 OPTN/UNOS Waiting List at the End of Year, 1995 to 2004

Year	Number of Waiting List Candidates at the End of the Year	Increase in Number from Previous Year
1995	41,575	
1996	47,423	5,848
1997	53,413	5,990
1998	59,908	6,495
1999	65,313	5,405
2000	71,694	6,381
2001	76,987	5,293
2002	78,627	1,640
2003	82,259	3,632
2004	86,378	4,119

SOURCE: HRSA and SRTR (2006).

TABLE 2-2 OPTN/UNOS Waiting List, Transplant Candidates (March 24, 2006)

Organ	Number on Waiting List
All organs	91,214
Kidney	65,917
Liver	17,249
Pancreas	1,748
Kidney and pancreas	2,505
Heart	3,008
Lung	3,092
Heart and lung	149
Intestine	191

SOURCE: OPTN (2006).

tions from living donors (living donations) has leveled off, and in 2004 and 2005 there were slightly fewer living donors than deceased donors.

Since 1988, more than 390,000 organs have been transplanted, with approximately 80 percent of the transplanted organs coming from deceased donors (Table 2-3; OPTN, 2006). One concern is the number of organs that are recovered from deceased donors but not transplanted; it is estimated that each year 10 to 14 percent of the kidneys recovered are not transplanted[4] (Delmonico et al., 2005). Adverse biopsy results account for

[4]The percentage of kidneys that are recovered but not transplanted has remained relatively constant since 1995 (Delmonico et al., 2005).

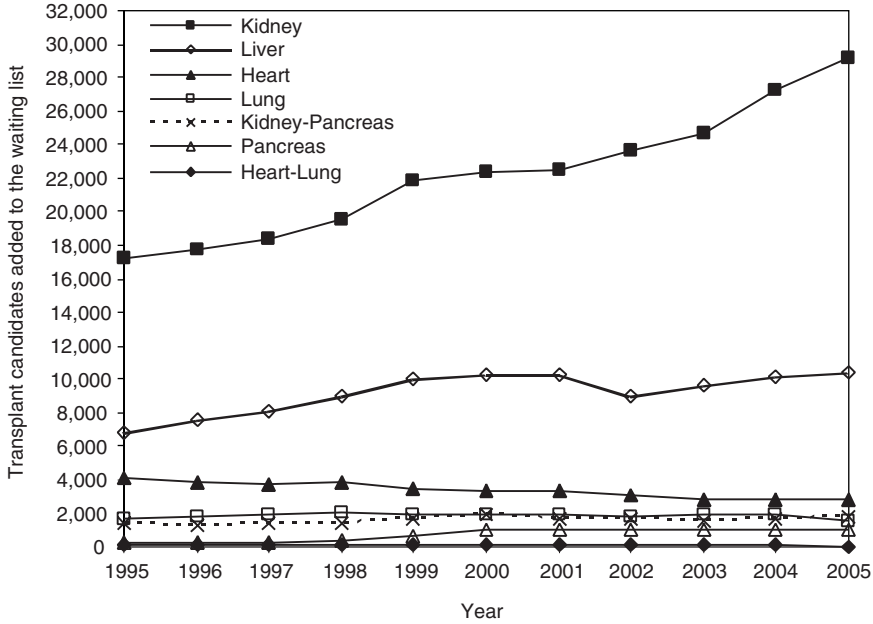

FIGURE 2-1 Waiting list additions by organ, transplant candidates, 1995–2005.
SOURCE: OPTN (2006).

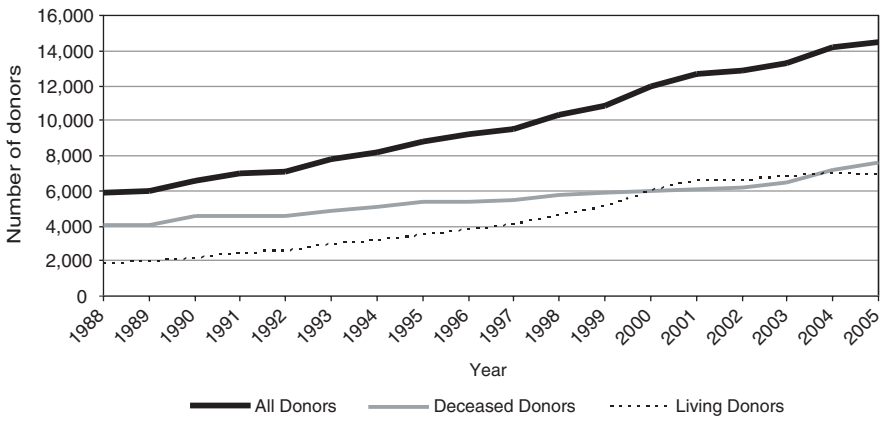

FIGURE 2-2 Organ donors by donor type, 1988–2005.
SOURCE: OPTN (2006).

TABLE 2-3 Organ Donors, Transplants, and Waiting List

Donor Characteristic or Organ	Total Number from 1988 to December 31, 2005		Number on Waiting List as of March 24, 2006[a]
	Donors	Transplants[b]	
Total	176,640	364,545	91,214
Deceased	98,926	287,047	
Living	77,714	77,498	
Sex			
Male	92,424	222,287	53,092
Female	84,216	142,258	38,178
Race-ethnicity			
White	129,940	247,882	45,008
Black	21,625	62,340	25,050
Hispanic	18,896	36,482	14,410
Unknown	336	969	8
Asian	3,465	11,353	5,092
American Indian or Alaska Native	790	2,602	876
Pacific Islander	800	1,119	534
Multiracial	788	1,798	602
Age (years)			
< 1	1,658	4,514	86
1–5	3,737	7,529	503
6–10	2,818	4,797	423
11–17	10,475	11,747	1,015
18–34	57,418	65,136	10,070
35–49	60,034	121,235	26,467
50–64	33,192	125,298	40,257
65+	7,261	24,280	12,412
Unknown	47	9	
Organ			
Kidney	165,417	217,029	65,917
Liver	81,663	74,983	17,249
Pancreas	25,277	4,776	1,748
Kidney and pancreas	13,232	2,505	
Heart	40,543	38,715	3,008
Lung	13,615	13,765	3,092
Heart and lung	900	149	
Intestine	1,363	1,145	191

[a]The total may be less than the sums of various categories due to individuals who are registered on the waiting list for more than one organ.

[b]Data are for number of organ transplantations.

SOURCE: OPTN (2006).

the inability to use approximately 40 percent of the rejected kidneys, whereas clinical judgment decisions result in the inability to use an additional 25 percent (Delmonico et al., 2005). The utilization of other organs varies; hearts are the most highly utilized with only 1 percent not transplanted after recovery. About 4 percent of recovered livers were not transplanted, primarily because of biopsy results (Delmonico et al., 2005). In some situations, organs are recovered before the intended recipients are located. This occurs more often with kidneys and pancreata (because of the organ's potential to withstand a longer time between recovery and transplantation); heart and lung transplantations generally occur at the time of recovery (Ojo et al., 2004). Further research is needed on the early identification of organs that are not eligible for transplantation. Improvements in the coordination of the recovery and transplant efforts are also needed.

Over the past 10 years, minority populations have donated organs at increased rates. In the past, donation by minority populations has been hindered by mistrust of the healthcare system, inequities in access to transplantation, and failure to request donation. Although donations by minority populations are steadily increasing, several of these matters remain unresolved and need further attention. The donation rates by minority populations are now in proportion to their population distribution in the U.S. census (Table 2-4). However, there is an increased need for trans-

TABLE 2-4 Organ Donation, Transplantation, and Waiting List by Ethnicity

Ethnicity	Population Distribution (%)[a]	Percentage of Total Donations, 2005[b]	Percentage of Transplant Recipients, 2005[c]	Waiting List Distribution (%) as of March 24, 2006
White	75.1	68.9	63	49.3
African American	12.3	14	18.5	27.4
Hispanic	12.5	13.2	12	15.8
Asian	3.6	2.6	4.0	5.5
American Indian/ Native Alaskan	0.9	0.5	0.7	0.9
Pacific Islander	0.1	0.1	0.4	0.5
Multiracial	2.4	0.7	0.7	0.6

[a]U.S. Census Bureau data, 2001. The population distribution adds up to more than 100 percent because of the option in the 2000 census to select multiple categories to accurately describe one's ethnicity.

[b]Includes deceased and living donors.

[c]0.7 percent of transplant recipients are of unknown ethnicity.

SOURCE: OPTN (2006); U.S. Census Bureau (2001).

plants, particularly kidney transplants, in minority populations because of the higher incidence rates of end-stage renal disease among the members of these populations (USRDS, 2005). In addition, there is still room for improvement in the rates of consent to organ donation among all ethnic groups.

Deceased Donors

The number of deceased donors increased over the 16 years from 1989 to 2005—from 4,010 in 1989 to 7,593 in 2005 (Figure 2-2). This reflects more successful efforts to obtain familial consent as well as efforts to focus on donation after circulatory determination of death and on extended-criteria donors (Howard, 2002).

In 2005, 18 percent of deceased donors were men between the ages of 18 and 34 years, and 14 percent were men between the ages of 35 and 49 years (OPTN, 2006). For 19.8 percent of the deceased donors in 2005, the circumstance of death was motor vehicle crashes; death from natural causes was the circumstance of death for approximately 30 percent of deceased donors and homicides accounted for 6 percent. In the past decade there have been slight decreases in the number of deceased donors for whom the circumstance of death was motor vehicle crashes—from a high of 26.3 percent in 1995 to a low of 19.8 percent in 2005 (OPTN, 2006). The primary mechanism of death among all donors was intracranial hemorrhage or stroke, accounting for 44.2 percent of deceased-donor deaths in 2005 (OPTN, 2006). The median age of deceased donors has increased in recent years, from 34 years in 1995 to 42 years in 2004 (SRTR, 2005).

Living Donors

In 2005, there were 6,895 organ transplants from living donors: 6,562 kidney transplants, 323 liver transplants, 7 intestine transplants, 1 pancreas transplant, 1 kidney/pancreas transplant, and 1 lung transplant (OPTN, 2006). The majority of living donors in 2005 were ages 35 to 49 years (n = 3,238) (Table 2-5; OPTN, 2006). As discussed in Chapter 9, there are a wide range of emotional and genetic relationships between living donors and the transplant recipients. In 2004, 781 of the living donors were parents of the recipient, 1,257 were offspring, 9 were identical twins, 1,849 were full siblings, 70 were half siblings, 550 were other relatives, 790 were spouses, 1,474 were unrelated, and 222 were of unknown relationship (HRSA and SRTR, 2006). Advances in immunosuppressive therapies have resulted in fewer barriers to the use of organs from living unrelated donors, who have become one of the fastest-growing categories of living donors, increasing from 4.7 percent of living donors in 1995 to 21.1 percent in

TABLE 2-5 Donor Characteristics, 2005

Characteristic	Deceased Donors (%)	Living Donors (%)
Total[a]	52.4	47.6
Sex		
Male	58.3	40.9
Female	41.7	59.1
Age (years)		
< 1	1.3	0
1–5	2.5	0
6–10	1.3	0
11–17	6.7	0
18–34	25.8	32.1
35–49	26.0	47.0
50–64	25.9	20.0
65+	10.3	0.9
Unknown	0	0

[a]A total of 7,593 deceased donors and 6,896 living donors.

SOURCE: OPTN (2006).

2004 (HRSA and SRTR, 2006). Additional details on living donation are provided in Chapter 9.

Type of Organ

Unique issues and challenges accompany the transplantation of each of the six types (or combinations) of solid organs that are currently transplanted—kidney, liver, heart, lung, pancreas, and intestine. This section highlights a few of the statistics and features associated with the transplantation of each type of organ.

Kidneys

Kidneys are the primary organs transplanted in the United States (Table 2-6), with the 17,667 kidneys transplanted in 2005 comprising 58.6 percent of all organs transplanted that year (OPTN, 2006). The kidney was the first organ transplanted in the United States, and because it is a paired organ, it is the organ most often transplanted in living donations. In 2005, approximately 95 percent of the organs transplanted from living donations were kidneys, as were almost 50 percent of the organs transplanted from deceased donors (OPTN, 2006).

TABLE 2-6 U.S. Kidney Transplantation, July 1, 2004, to June 30, 2005

Donors	
Number of deceased-donor transplants	9,739
Number of living-donor transplants	6,673
Posttransplant[a]	
Adult graft survival (%) at 1 year posttransplantation	91.69
Waiting List	
Number of individuals on the waiting list at the start	58,195
Number of individuals on the waiting list at the end	64,349
Number of new patient registrations[b]	28,985
Mortality rate while on the waiting list	0.08

[a]July 1, 2002–December 31, 2004.
[b]An individual transplant candidate can have multiple registrations (either at more than one center or for multiple organs).

SOURCE: SRTR (2006).

End-stage renal disease (ESRD)—which is often a result of insulin-dependent diabetes mellitus, hypertension, glomerulonephritis, or cystic kidney—is treated by hemodialysis or a kidney transplant. Diabetes mellitus accounted for 44 percent of new cases of treated ESRD in 2002 (CDC, 2005). In 2003, more than 93,000 new ESRD patients started hemodialysis and nearly 300,000 patients continued on hemodialysis in the United States (USRDS, 2005). Kidney transplantation is generally the preferred treatment for patients with ESRD, as patients experience improved quality of life and longer long-term survival rates (Wolfe, 2005). Data from the U.S. Renal Data System indicate that Medicare expenditures on ESRD in 2003 totaled $14.8 billion for the provision of dialysis, and $0.08 billion for transplantation (USRDS, 2005). Recent trends reflect increased expenditures associated with dialysis and graft failure and decreased expenditures for patients who have recently received transplants and for patients with functioning grafts (USRDS, 2005).

Potential kidney transplant candidates constitute approximately 70 percent of the individuals on the entire Organ Procurement and Transplantation Network (OPTN)-United Network for Organ Sharing (UNOS) waiting list. In 2005, 29,177 candidates for a kidney transplant were added to the waiting list (OPTN, 2006). The net increase in the kidney transplant waiting list is approximately 3,000 to 4,000 individuals each year (Danovitch et al., 2005). It has been estimated that growth at this rate will result in 76,000 to 95,000 kidney transplant candidates by 2010 (Xue et al., 2001; Danovitch et al., 2005).

The average waiting time for a kidney transplant is becoming longer. In 2003, 43 percent of patients had been waiting for more than 2 years, whereas only 29 percent of patients had been waiting for more than 2 years in 1994 (Danovitch et al., 2005). In 2003, almost 11 percent had been waiting more than 5 years. Longer waiting times are particularly a problem for minority patients awaiting kidney transplantation (Table 2-7). For example, for African Americans added to the waiting list in 1999, the waiting time has been twice as long as that for white individuals (Danovitch et al., 2005). It is hoped that the changes in human leukocyte antigen (HLA) matching criteria made by UNOS (described below) will contribute to reduced waiting times.

Another concern is the number of retransplantations needed. In 2004, 7,969 individuals on the waiting list for a kidney transplant (17.4 percent of the waiting list) had received a previous kidney or kidney/pancreas transplant (HRSA and SRTR, 2006). There are a number of reasons for graft failure and the need for retransplantation, some of which cannot be prevented, while others such as noncompliance with immunosuppressive medications can be partially addressed through increased insurance coverage for these medications and improved patient education (IOM, 2000).

There is evidence of the benefit of preemptive kidney transplantation (before the patient begins dialysis) for some patients (Becker et al., 2006); however, only 13 percent of kidney recipients in 2003 received preemptive kidney transplants, and these were primarily through living-donor transplants (Danovitch et al., 2005).

The number of kidney transplants has increased since 1994, to a great extent because of increases in the numbers of living donations. In 2005, 39.8 percent of kidney transplants resulted from living donations, and

TABLE 2-7 Kidney Transplant Waiting List Registrations, 2001 to 2002

Ethnicity	Number of Registrations Added to Waiting List	Percentage Receiving Transplants After 1 Year on Waiting List	Percentage Receiving Transplants After 2 Years on Waiting List
White	24,336	18.1	32.2
African American	13,340	10.6	20.5
Hispanic	6,546	11.1	22.6
Asian	2,396	9.2	18.6
American Indian-Native Alaskan	485	11.3	22.1
Pacific Islander	340	7.2	18.9

SOURCE: OPTN (2006).

60.2 percent resulted from deceased donations (OPTN, 2006). Of the 6,562 living-donor kidney transplants in 2005, 62.1 percent were from biologically related donors, 11.8 percent were from a spouse, 22.7 percent were from unrelated donors or donors whose relationship to the recipient is unknown, and 3.4 percent were not reported (OPTN, 2006). In 2005, 59.2 percent of living kidney donors were women (OPTN, 2006).

Kidney transplant allocation has largely focused on HLA matching, which has been critical for ensuring transplant compatibility. A close match by HLA typing and time spent on the transplantation waiting list are the primary criteria used to allocate kidneys from deceased donors, with transplant candidates with no HLA mismatches given top priority (Roberts et al., 2004). Beginning in May 2003, allocation points were no longer assigned for HLA-B similarity (UNOS Policy 3.5.11.2), in the hope that this change would reduce disparities in the allocation of kidneys to African-American patients while having little adverse impact on graft survival (Roberts et al., 2004; Ting and Edwards, 2004; Danovitch et al., 2005). Another recent OPTN-UNOS policy change (Policy 3.5.12) specifies an allocation system for the donation of kidneys by the use of expanded criteria (Chapter 5). The expanded criteria include older age and greater latitude in the clinical test results used to allow the kidney to be transplanted.

In 2005, 314 children under 10 years of age received kidney transplants as did 576 adolescents 11 to 17 years of age (OPTN, 2006). Kidney transplantation is especially advantageous for children. Dialysis is often inadequate as a treatment for children with impaired renal function, as it can result in a deceleration of growth (McDonald and Craig, 2004; Milliner, 2004). Furthermore, for children dialysis is associated with a risk of death four times greater than that for renal transplantation (McDonald and Craig, 2004).

An area of concern for children undergoing renal transplantation is the use of corticosteroids following transplantation. The use of corticosteroids is associated with cardiovascular, endocrine, and bone disorders, as well as body disfiguration and growth retardation (Vidhun and Sarwal, 2005). Children who use corticosteroids have heights that are, on average, two standard deviations below the appropriate height for their age and sex (Vidhun and Sarwal, 2005). Immunosuppression protocols that do not use corticosteroids are under investigation at a number of treatment centers. It is hoped that improved immunosuppression protocols will eliminate many of the side-effects associated with corticosteroids and improve patient compliance. Young children have the best long-term graft survival of any age group of transplant recipients (Harmon et al., 2005). In contrast, adolescents have poorer long-term graft survival; noncompliance with treatment regimens among adolescents may contribute to this problem (Harmon et al., 2005).

Liver

The first successful liver transplant was performed in 1967 with a liver from a deceased donor. Living-donor liver transplantation, which involves the removal of a lobe or partial lobe of the liver, was developed for pediatric recipients and was first performed in 1989 (Curran, 2005).

There were 6,444 liver transplants in the United States in 2005, with the livers primarily coming from deceased donors (Table 2-8). During the past decade there has been an increase in the number of liver transplants from deceased donors (from 3,591 in 1994 to 6,121 in 2005), whereas the number of living-donor liver transplants has declined from a high of 519 in 2001 to 323 in 2005, in part as a result of a highly publicized death of a donor in New York City (OPTN, 2006). The initial impetus for many living donors between 1998 and 2003 may have been the desire to donate to patients with hepatocellular carcinoma with preserved hepatic function; these patients did not receive additional priority on the waiting list for deceased-liver transplantation and would have been excluded from receiving a transplant if they developed advanced or metastatic hepatocellular carcinoma (Hanto et al., 2005). Studies of the potential health risks of living donation of the partial lobe of the liver are ongoing (Curran, 2005).

Liver transplantation is indicated in cases of acute and chronic liver failure from multiple etiologies. Patients with acute liver failure or immediate posttransplantation graft failure have the highest priority for donor organs (Status 1). Chronic conditions contributing to the need for liver transplantation include hepatitis B, C, and D; alcoholic liver disease; cholestatic disease; metabolic liver disease; and hepatocellular carcinoma. There is concern that the increasing number of individuals with hepatitis C infec-

TABLE 2-8 U.S. Liver Transplantation, July 1, 2004, to June 30, 2005

Donors	
Number of deceased-donor transplants	6,082
Number of living-donor transplants	307
Posttransplant[a]	
Adult graft survival (%) at 1 year posttransplantation	82.16
Waiting List	
Number of individuals on the waiting list at start	17,239
Number of individuals on the waiting list at end	17,661
Number of new patient registrations	11,034
Died while on the waiting list without transplant within 1 year after listing (%)	10.1

[a]July 1, 2002–December 31, 2004.

SOURCE: SRTR (2006).

tions will have a significant impact on the demand for liver transplantation in the next 20 years (Armstrong et al., 2000). As of March 24, 2006, 17,249 individuals were on the waiting list for liver transplantation (OPTN, 2006). The numbers of deaths among individuals on the liver transplantation waiting list decreased significantly in the past decade, from 225 deaths per 1,000 patient years in 1994 to 124 deaths in 2003 (Port et al., 2005).

The Model for End-Stage Liver Disease (MELD) system is used to determine priority for liver transplantation. This system uses the patient's serum bilirubin concentration, serum creatinine concentration, and international normalized ratio to determine a MELD score (Freeman et al., 2004). Similarly, the Pediatric End-Stage Liver Disease (PELD) model is used for pediatric patients and additionally takes into account the child's age at the time that he or she is placed on the waiting list, failure to grow (on the basis of the child's sex, height, and weight), and serum albumin. The PELD model does not include serum creatinine. Recently, the waiting time has been deemphasized to ensure that the sicker patients receive transplants first (Hanto et al., 2005). Determining the optimal time for transplantation is an area of ongoing discussion, particularly in light of concerns that patients are often listed when the disease is too far along to permit optimal outcomes (Merion et al., 2005).

For recipients of livers from deceased donors, Hanto and colleagues (2005) found adjusted patient survival rates of 93 percent at 3 months, 88 percent at 1 year, 80 percent at 3 years, and 74 percent at 5 years. Similar survival rates were seen for recipients of livers from living donors.

Pediatric concerns about liver transplantation focus on growth. Before the transplantation, children with chronic liver disease may have malnutrition because of absorption problems and vitamin deficiencies (McDiarmid, 2001). After the transplantation, steroid use may inhibit growth. Furthermore, many children may require concerted clinical efforts to overcome poor nutritional status. After accounting for growth after the transplantation, the heights of children with a liver transplant have still been found to remain below the 5th percentile (McDiarmid, 2001).

Heart

Human heart transplantation was successfully accomplished for the first time in Cape Town, South Africa, in 1967. The conditions that contribute to the need for heart transplantation include cardiomyopathy, coronary artery disease, congenital heart disease, and valvular heart disease. In the majority of cases, cardiomyopathy or coronary artery disease is the primary diagnosis necessitating transplantation. For heart-lung transplantation, the diagnoses contributing to transplantation include congenital disease, emphysema-chronic obstructive pulmonary disease, cystic fibrosis,

idiopathic pulmonary fibrosis, and primary pulmonary hypertension (OPTN, 2006).

OPTN reports that as of March 24, 2006, the numbers of candidates for heart and heart-lung transplantations were 3,008 and 149, respectively (OPTN, 2006). Of those individuals, 772 heart transplant candidates and 58 heart-lung transplant candidates have been on the waiting list for 5 years or more (OPTN, 2006). Because heart transplants—unlike several other organ transplants—cannot benefit from living donation or split-organ donation, the supply of hearts for donation is more restricted.

General trends over the last decade reflect an increase in the amount of time that an individual requiring a transplant is on the heart waiting list but a decrease in the number of deaths while individuals await transplantation (Barr et al., 2005) (Table 2-9). A decline from 274 deaths per 1,000 patient years to 162 deaths per 1,000 patient years occurred between 1994 and 2003. This decline may be attributable to recent improvements in therapies for advanced heart failure (Barr et al., 2005).

The OPTN-SRTR 2005 Annual Report provides statistics for 1-year adjusted patient survival between 1994 and 2003 (Table 2-10).

These data demonstrate a trend toward improved 1-year survival for heart transplant recipients and grafts over the course of the decade. Unfortunately, heart-lung transplant recipients have not experienced similar improvements. Survival rates appear to be more favorable for heart-lung transplant recipients over the age of 35 years, perhaps because of the higher risk for younger recipients with congenital heart disease (Barr et al., 2005).

TABLE 2-9 U.S. Heart and Heart-Lung Transplantation, July 1, 2004, to June 30, 2005

	Heart	Heart-Lung
Donors		
Number of deceased-donor transplants	2,054	38
Posttransplant[a]		
Adult graft survival (%) at 1 year posttransplant	86.74	57.63
Waiting List		
Number of individuals on the waiting list at start	3,390	188
Number of individuals on the waiting list at end	3,120	166
Number of new patient registrations	2,837	63
Mortality	13.0[b]	0.13[c]

[a]January 1, 2002–June 30, 2004.
[b]Died while on the waiting list without transplant within 1 year after listing (%).
[c]Mortality rate while on the waiting list.

SOURCE: SRTR (2006).

TABLE 2-10 One-Year Adjusted Patient Survival Rate (percent), 1994 to 2003

Organs	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
Heart	84.3	84.6	85.1	85.1	85.7	83.9	85.8	85.5	87.2	88.2
Heart-Lung	66.3	79.3	62.7	58.8	56.4	55.5	62.6	74.0	60.5	58.3

SOURCE: HRSA and SRTR (2006).

Policy 3.7 of OPTN describes the criteria for the allocation of thoracic organs (including hearts, heart-lung combinations, and single and double lungs). Heart allocation is determined by patient status and the geographic proximity of the donor hospital to the transplant center. Patients awaiting heart transplantation are classified according to medical urgency. If no suitable recipients are found within the local area, consideration is extended to others on the basis of their clinical status and a geographic sequence based on an established zone system.

In 2005, 313 heart transplants and 5 heart-lung transplants were performed for children under the age of 18 years (OPTN, 2006). A significant problem for children awaiting heart transplantation is allosensitization to HLA, which contributes to the mortality and morbidity of children on waiting lists and negatively affects the outcomes of the transplantation (Shaddy and Fuller, 2005). OPTN provides 5-year patient survival rates for children receiving heart transplants between 1995 and 2002. For adolescents aged 11 to 17 years, the 5-year survival rate is reported to be 69.4 percent. The rates are 75.5 percent for children aged 6 to 10 years, 72.6 for children aged 1 to 5 years, and 71.0 percent for children younger than 1 year of age (OPTN, 2006). Heart-lung transplants for children under the age of 10 years have much lower rates of success, with the 1-year patient survival rate reported to be less than 20 percent (Barr et al., 2005).

Lung

Approximately 1,000 lung transplants are performed each year, with only a few lung transplants being partial lobe transplants from living donors (Table 2-11). The first successful lung transplant was performed in 1963. In 2005, there were 1,408 lung transplants, with 1,407 deceased lung donors and 1 living lung donor (OPTN, 2006).

In 2003, emphysema, idiopathic pulmonary fibrosis, cystic fibrosis, alpha-1-antitrypsin deficiency, and primary pulmonary hypertension were the most common diagnoses contributing to the need for transplantation (Barr et al., 2005). Most lung transplant recipients are older, primarily 50

to 64 years of age. Recently, the OPTN established a new lung allocation process (UNOS Policy 3.7.6) with the goal of maximizing the survival benefit of lung transplantation by considering patients' probable benefits from transplantation rather than their time on the waiting list.

Pancreas

Pancreas transplantation (Table 2-12) is performed to reestablish insulin secretion. This operation is most commonly performed in conjunction

TABLE 2-11 U.S. Lung Transplantation, July 1, 2004, to June 30, 2005

Donors	
Number of deceased-donor transplants	1,272
Number of living-donor transplants	7
Posttransplant[a]	
Adult/teen graft survival (%) at 1 year posttransplantation	82.18
Waiting List	
Number of individuals on the waiting list at start	3,864
Number of individuals on the waiting list at end	3,538
Number of new patient registrations	1,811
Mortality rate while on the waiting list	0.13

[a]January 1, 2002–June 30, 2004.

SOURCE: SRTR (2006).

TABLE 2-12 U.S. Pancreas Transplantation, July 1, 2004, to June 30, 2005

	Pancreas	Kidney-Pancreas
Donors		
Number of deceased-donor transplants	590	876
Posttransplant[a]		
Adult graft survival (%) at 1 year posttransplantation	78.15	90.95
Waiting List		
Number of individuals on the waiting list at start	1,451	2,426
Number of individuals on the waiting list at end	1,541	2,496
Number of new patient registrations	960	1,727
Mortality rate while on the waiting list	0.04	0.10

[a]July 1, 2002–December 31, 2004.

SOURCE: SRTR (2006).

with kidney transplantation, although it can be performed in patients who have already had a kidney transplant or as a stand-alone procedure for those with glucose levels that are difficult to control. The first successful pancreas transplant occurred in 1966 with a pancreas from a deceased donor. Type I diabetes mellitus is the most common disease leading to pancreas transplantation. Research on the transplantation of the pancreatic islet cells that produce insulin is ongoing (Hering et al., 2005).

In 2005, there were 540 pancreas transplants and 903 joint pancreas and kidney transplants, the majority from deceased donors; only one pancreas transplant and one kidney-pancreas transplant from living donors were performed (OPTN, 2006).

Intestine

Transplantation of the intestine, which is usually performed as part of a multi-organ transplant, is a relatively rare procedure (Table 2-13). It is also a more recent procedure, with the first successful intestine transplant performed in 1987 and the first small intestine transplant performed in 1991 (UNOS, 2004). In 2005, there were 178 intestine transplantations. Most recipients are children; in 2005, 40 percent (71 transplants) of the recipients were 5 years of age or younger and 54 percent (96 transplants) were under the age of 17 years (OPTN, 2006). Short gut syndrome is the most common cause of intestine failure that results in the need for transplantation (Hanto et al., 2005). Few intestine transplantations are done with living donors; in 2005 there were 7 living-donor intestine transplants (OPTN, 2006). Since 2000 there has been an increase in liver-intestine-

TABLE 2-13 U.S. Intestine Transplantation, July 1, 2004, to June 30, 2005

Donors	
Number of deceased-donor transplants	162
Transplants	
Adult graft survival (%) 1 year posttransplantation[a]	78.50
Waiting List	
Number of individuals on the waiting list at start	191
Number of individuals on the waiting list at end	190
Number of new patient registrations	256
Mortality rate while on the waiting list	0.35

[a]July 1, 2002–December 31, 2004.

SOURCE: SRTR (2006).

pancreas transplants. In 2005, 109 of the transplants of the intestine occurred in conjunction with the transplantation of at least one other organ.

WHO DONATES? INDIVIDUAL AND FAMILY DECISIONS

Organ transplantation in the United States depends on voluntary donations. However, few large-scale studies have examined the correlates of individual and family decision making about organ donation. Researchers have primarily used cross-sectional methodologies, often with limited numbers of subjects. This section provides an overview of some of the patterns and factors found to be related to willingness of individuals to register as an organ donor or for families to consent to organ donation for a deceased relative. Much remains to be understood about factors influencing donation decisions.

Demographics

In 2005, approximately 60 percent of deceased organ donors were men and 40 percent were women; the reverse is true for living donors (OPTN, 2006). Over half of the deceased organ donors in 2005 (51.8 percent) were between 18 and 49 years of age, and 25.9 percent were between 50 and 64 years of age (Table 2-5; OPTN, 2006). Several cross-sectional studies have examined donation patterns by age, educational level, and gender.

Individual Decision Making

Individuals who register as an organ donor are generally younger and have higher levels of education than their counterparts, although this is only a broad pattern. A telephone survey of 385 households in the Baltimore, Maryland, metropolitan area found that individuals over 51 years of age were less willing to be considered a potential organ donor than younger individuals (Boulware et al., 2002a).

Education level has been found to be a strong predictor of attitudes toward both donation and a stated willingness to donate and sign a donor card. Preliminary results from a 2005 national survey[5] indicate higher education levels and increased income levels among individuals who said that they had already decided to be an organ donor (by signing their driver's

[5]There will soon be the opportunity to compare national public opinion changes over the past 12 years using the results of surveys conducted by the Gallup Organization in 1993 and 2005. Preliminary data from the 2005 survey were presented at the committee's June 2005 workshop (Wells, 2005). The final analysis is being completed.

license or a donor card, or by registering with a donor registry). In the Baltimore survey study by Boulware and colleagues (2002a), individuals with lower education levels (high school education or less) were significantly less likely to state a willingness to donate their organs at death than those respondents with two or more years of college education. Other studies have had similar findings (Prottas and Batten, 1991; Lam and McCullough, 2000).

Preliminary data from the 2005 national survey indicate that 58 percent of women and 54.8 percent of men had designated a willingness to donate their organs and tissues through their driver's license, a donor card, or a donor registry (Wells, 2005). Guadagnoli and colleagues (1999a) conducted telephone interviews about attitudes regarding organ donation and transplantation in 6,820 U.S. households and found that men were 50 percent more likely than women to be in a more committed stage to discuss organ donation with family members. However, other studies have not found sex to be a determinant of a willingness to donate (Boulware et al., 2002b; Haustein and Sellers, 2004).

Family Decision Making

Mixed results have also been found in studies of family decisions regarding organ donation. Interviews with 420 families of eligible donors conducted 2 to 3 months after the patient's death found that the families of younger patients and male patients were more likely to consent to donation (Siminoff et al., 2001b). In that study, consent was also associated with deaths due to trauma (consent was given in 65.1 percent of the cases when the cause of death was trauma related but was given in only 30.4 percent of the cases when the death was from other causes). DeJong and colleagues (1998) conducted structured telephone interviews with 164 family members of eligible donors (102 who had consented to donation and 62 who refused) and found that consent for organ donation did not differ by the sex of the deceased family member but that the families of younger patients were more likely to provide consent.

The education level of the family members has not been a strong predictor of the responses of families asked to donate a patient's organs. Some studies indicate that families with more years of formal education are more likely to agree to donation than families with less education (Burroughs et al., 1998; DeJong et al., 1998); however, that correlation has not been consistently found (Siminoff et al., 2001b). Because consent is generally affected by educational achievement only at the lowest levels, a lack of consent might reflect communication problems, particularly the communication of medical information in a manner that allows the donor or the donor's family to have a clear understanding.

Ethnicity

The complex factors regarding organ donation decisions—including trust and distrust in the healthcare system—seem particularly salient for minority populations and populations that experience disparities in the amount or quality of health care that they receive. Although minority populations have a pressing need for transplantable organs, especially kidneys, there is some evidence that minority families have not been asked to donate as frequently when the patient is eligible (see below). Other factors associated with low rates of donation include concerns about the equity of the organ distribution system and a lack of information about the need for donor organs. The current statistics regarding deceased donation show marked increases in minority consent, particularly among African-American and Hispanic populations. As indicated earlier in this chapter, recent data show that most minority populations are donating organs and tissues at rates that are in proportion to their percentage of the U.S. population. It is difficult to make generalizations about any particular minority group because of the broad differences in the cultural norms, belief systems, and traditions within each group.

Individual Decision Making

Past studies have found that minority populations signed donor cards at lower rates, expressed less willingness to donate, and had lower consent rates overall; but recent statistics indicate a trend toward increased rates of consent to deceased organ donation. A random-digit-dialing telephone survey of 453 individuals in three cities in the early 1990s found that African Americans were more likely than white Americans to believe that healthcare professionals will not do as much to save their lives if they are designated organ donors and to characterize the organ distribution system as unfair (Siminoff and Saunders Sturm, 2000). Similarly, a study by Boulware and colleagues (2002a) found that African-American men and women trusted the healthcare system less than a comparable white population. In that study, spirituality and religion were key factors in the individual's decision regarding donation. An earlier study also found that beliefs about institutional racism were a factor in donation decisions (Ohnuki-Tierney et al., 1994). Creecy and Wright (1990) found that knowing someone of similar ethnicity who had received a transplant was associated with a willingness to donate.

Although Hispanics and Latinos now comprise a significant portion of the U.S. population, far less research has examined their attitudes toward organ donation and their donor behavior. In a study by Alvaro and colleagues (2005), in which 1,203 Hispanic American individuals participated

in a random-digit-dialing telephone survey, the researchers found that those who indicated that they would be an organ donor were more likely to be female, to know someone else willing to be an organ donor, and to be less likely to agree that discussions of organ donation remind them of their own mortality.

Cheung and colleagues (1998) examined the cultural attitudes of Asian Americans regarding organ donation in a mail survey with 421 responses and compared them with those of their Caucasian counterparts. The Asian Americans in that study emphasized the importance of maintaining body integrity after death and displayed a lower level of trust of doctors in matters concerning organ donation. In another survey of 683 undergraduates, Asian-American students had higher rates of communication with family members about organ donation and were more likely to have communicated with their parents about funeral arrangements (Rubens, 1996).

Family Decision Making

Studies of familial decision making in hospitals have found that the process for requesting organ donation has not been consistent across different ethnicities. Several studies in the 1980s and 1990s found that white patients were more often identified as potential donors than African-American patients (Hartwig et al., 1993; Guadagnoli et al., 1999b); similar results have been noted for Hispanic patients (Pietz et al., 2004). However, these studies do not likely reflect the changes that occurred as a result of "required request" regulations (see Chapter 4).

Siminoff and colleagues (2003) conducted in-person interviews with 415 families of eligible donors and found that the reasons for consenting to donation were similar between white and African-American families. These reasons included altruism, knowledge that the patient had a donor card or would have wanted to donate, and gaining of meaning for the family from the death of a loved one. The reasons for decisions not to donate included the fact that the family was too exhausted, knowledge that the patient did not want to donate, religion, the family's desire to avoid disfiguring the patient, poor communication, and poor timing of the request. Another reason, as mentioned above and discussed below, is a lack of trust in the healthcare system.

Spirituality

The role of religion, religiosity, and spirituality in decisions about organ donation is complex and is not yet fully understood. Most major religions actively support organ donation (Box 2-1); however individuals may have their own particular sets of values and beliefs. For example, some

BOX 2-1
Religion and Deceased Organ Donation

Religion and culture both play fundamental roles in the decision of an individual or family to donate or withhold organs and tissues. Most major world religions support and encourage organ donation as an act of selflessness. Veatch (2000) provides a more in-depth discussion of the complex relationships between religious faith and organ donation. The following generalities are offered, with the acknowledgment that significant variations in views sometimes occur within religions.

Christianity

Protestant, Catholic, and Orthodox churches support organ donation and view it as expressing Christian values of selfless service to neighbors or strangers. Some denominations have active policies promoting donation while others see it as a matter of individual choice.

Islam

There is a strong belief in the principle of saving human lives and in seeking medical help for illness. Under these principles both the Shia and Sunni branches of Islam view organ donation as permissible provided the gift is freely given. Organ donation is generally supported in Arab countries; however, some Muslim scholars, particularly on the Indian subcontinent, have not been supportive of deceased organ donation.

Judaism

All major branches of Judaism (Orthodox, Conservative, and Reform) support organ donation not only as a *mitzvah* (or blessing) but as an obligation under the

individuals express a belief that the body needs to be "whole" for life after death (Sanner, 1994; Rene et al., 1995); others are not aware that organ donation is supported by their religion (Nolan and Spanos, 1989). A multistep study by Peters and colleagues (1996) included a telephone survey of people in Richmond, Virginia, followed by focus groups in five cities (Boston, Atlanta, Kansas City, Phoenix, and Seattle) to discuss organ donation. Nondonor focus group participants believed that it was important to go to the grave "whole," with one's organs intact. A survey of 158 individuals in Puerto Rico found that 12 percent believed that their body needed to be whole for resurrection after death (Rene et al., 1995).

Studies have yielded inconsistent results when examining correlations between spirituality and willingness to consent to donation. For example, a Baltimore-area survey by Boulware and colleagues (2002a) found that individuals who considered religion or spirituality to be important were less

Jewish duty to save life (*P'kuach nefesh*). There is controversy in the Orthodox branch about the criteria for death.

Hinduism

There are no religious prohibitions against donation, and the belief in continual rebirth or reincarnation does not appear to conflict with donation. Hindu mythology includes examples of using body parts for the benefit of other humans and society.

Buddhism

Although some analogues within Buddhist writings could support organ donation, there is some ambivalence about transplantation. In particular, the concepts regarding neurologic determination of death may seem to contradict the Buddhist view of the interconnectedness of life and death.

Confucianism and Taoism

Official declarations regarding organ donation have not been made in Confucianism and Taoism. Traditional Confucian views accept the inevitability of death, while Taoism supports more aggressive measures to prolong life. These traditions are also closely intertwined with traditional Chinese medicine, which emphasizes preserving the integrity of the body.

SOURCES: Gillman (1999); Veatch (2000).

inclined to be organ donors. In contrast, a focus group study in Atlanta found that many participants believed that their religious values were the basis of their attitudes of altruism and wanting to make a difference in someone else's life (Jacob Arriola et al., 2005). Siminoff and colleagues (2001b) also found that families who believed their religion encourages donation were likely (82.5 percent) to consent to donation.

In a survey of African-American adults, the perception of religious and social norms supportive of organ donation was found to be predictive of a willingness for families to discuss organ donation (Morgan, 2004). On the other hand, in a survey of outpatients visiting a community physician's office, religious affiliation or regular church attendance did not have an influence on willingness to donate (Haustein and Sellers, 2004).

In a survey of 120 Chinese Americans, Lam and McCullough (2000) found that many respondents were influenced by Confucian values and also

by Buddhist and Taoist beliefs that "associate an intact body with respect for ancestors or nature" (p. 449) but that they were still willing to consider deceased organ donation.

Rumsey and colleagues (2003) studied the individual organ donation-related decision making of 190 undergraduate students and found that religiosity predicted attitudes toward organ donation, regardless of the individual's religious denomination or the frequency with which he or she attended religious services. As the different results of these various studies suggest, much remains to be learned about the role that religion and spirituality, in official and folk manifestations, play in organ donation decision making.

Family Discussions Regarding Organ Donation

Studies indicate that individuals who are willing to discuss donation with family members are more likely to have signed organ donor cards (Morgan and Miller, 2002; Morgan, 2004). The family's knowledge of the wishes of the deceased regarding organ donation is one of the most important factors in the family's decision of whether to donate (Sque and Payne, 1996; McNamara et al., 1999; Siminoff et al., 2001b; Siminoff and Lawrence, 2002; Sque et al., 2005). Major reasons for not consenting to donation are knowledge of the deceased's wish not to donate and uncertainty about the deceased's wishes (Jasper et al., 1991; Chapman et al., 1995; Rosel et al., 1999; Siminoff et al., 2001a; Frutos et al., 2002). Conversely, knowing that the patient had a donor card, having had an explicit discussion about donation with the patient, and believing that the patient would have wanted to donate, even apart from an explicit discussion, are strongly associated with familial consent to organ donation (Jasper et al., 1991; Tymstra et al., 1992; DeJong et al., 1998; Siminoff et al., 2001b).

In one study families who were knowledgeable about organ donation were found to be more likely to consent to donation, whereas families surprised by being asked about organ donation were less likely (Siminoff et al., 2001b). Similarly, individuals who feel informed about organ donation are more likely to be committed to organ donation (Nolan and Spanos, 1989).

There is little information on the extent to which families override the donation wishes of the deceased family member. Harris and colleagues (1991) conducted an experimental study using vignettes to examine how individuals weighed the wishes of the deceased and the wishes of the next of kin. The study found that in all cases in which the donor's wishes were known, they were respected, even if the next of kin had different preferences than those of family members. Siminoff and colleagues (2001b) found in interviews with families of patients who were eligible to be donors

that 89.3 percent of families that knew that the patient had a donor card consented to donation. Some organ procurement organizations (OPOs) collect data on the number of times that families override the deceased family member's wish to donate. For example, Intermountain Donor Services reported that of those eligible donors (deaths determined by neurologic criteria) who were on the donor registry for the years 2003 to 2005, only 3.5 percent were not donors because the family either provided new information that the deceased person did not want to donate or overrode the deceased person's decision (personal communication, T. Schmidt, Intermountain Donor Services, March 2006). Other OPOs such as LifeNet (Virginia) report similar findings for 2003 to 2005 with between a 2 percent to 4 percent override experience (personal communication, K. Myer, LifeNet, March 2006); Gift of Life Donor Program (Pennsylvania) estimates an average of less than 1 percent of families have overridden a donor's expressed consent in the past 10 years (personal communication, H. Nathan, Gift of Life Donor Program, March 2006).

In cases in which the wishes of the patient are not known, families generally attempt to use what they know about the values and attributes of the deceased, seeking to honor what they believe the patient would have wanted (Sque and Payne, 1996).

Quality of Health Care and Trust in the Healthcare System

For individual decision making, trust in the medical system is a concern. In a survey of 163 patients, Yuen and colleagues (1998) found that although the majority of respondents (>70 percent) trusted the healthcare system regarding organ donation, 32 percent of African Americans, 15 percent of Hispanics, and 7 percent of whites agreed with the statement "Doctors would not try as hard to save me if they knew I was an organ donor." Other surveys have also found that potential donors are concerned about not receiving the necessary medical attention if they have agreed to be an organ donor (Nolan and Spanos, 1989; Minniefield et al., 2001; Minniefield and Muti, 2002). In 6,080 telephone interviews with white, African-American, and Hispanic respondents, a willingness to donate was correlated with agreeing with the statement that "Doctors do all they can to save a life before pursuing donation" (McNamara et al., 1999). Similarly, a distrust of the medical community was noted as a major concern about organ donation in focus group discussions (Peters et al., 1996).

For family decision making, studies have found that support by the healthcare staff, particularly by intensive care nurses, and the quality of health care were associated with consent decisions (DeJong et al., 1998; Sque et al., 2005). Siminoff and colleagues (2001b) found no association between consent rates and hospital characteristics or healthcare provider

characteristics (including age, sex, ethnicity, religion, or professional role); however, the healthcare provider's ease in answering questions at the time of donation was positively associated with the decision to donate. In interviews with 350 parents about their potential willingness to donate their child's organs, Walker and colleagues (1990) found that parents' confidence in neurologic determination of death was a key factor in being willing to consent to donation.

Other factors have been found to potentially play some role in family decisions about donation. In one study, the presence of large numbers of family members at the donation discussion led to greater numbers of nonconsents (Frutos et al., 2002). Families who felt pressured to donate were less likely to donate (Siminoff et al., 2001b); concerns about disfigurement of the body are also of concern to some families (Nolan and Spanos, 1989; McNamara et al., 1999).

Altruism, Cultural Norms, and Models of Willingness to Donate

Altruistic beliefs and values are one of the mainstays of the voluntary organ donation system. Altruism is the unselfish concern for the welfare of others, and in deceased organ donation this particularly applies to the goal of improving the life of (usually unknown) patients who are the potential recipients of the donated organs. Individuals and families often want to see something positive come out of tragedy, and the "gift of life" and "donate life" themes of organ donation efforts highlight the values of altruism. In most cultures there is a strong affirmation of organ donation as an expression of altruism. Interviews with families who have confronted a donation decision find that giving meaning to the death is a key factor in providing consent for organ donation (Sque et al., 2005). Similarly, discussions with individuals have noted altruistic motivations as central to a positive attitude toward deceased organ donation (Jacob Arriola et al., 2005). Little attention has been given to the consideration of reciprocity or moral obligation as a motivation for organ donation.

In considering the many factors in organ donation decisions, Radecki and Jaccard (1997) developed a theoretical framework for willingness-to-donate decisions that incorporates a set of five belief structures into the individual's attitude toward becoming a donor: religious beliefs, cultural beliefs, knowledge beliefs, altruistic beliefs, and normative beliefs. The interactions of these beliefs, the roles played by each of the factors, and the extent to which they can be modified to encourage donation have been and continue to be areas of study (Horton and Horton, 1991; Sanner, 1994; Radecki and Jaccard, 1997; Farsides, 2000; Morgan and Miller, 2002; Morgan, 2004).

Cultural norms can result in different donation patterns. For example, in Japan, there have been few organ donations following neurologic determination of death; living donation and donation after circulatory determination of death occur more frequently (Nakata et al., 2001). Determination of death by neurologic criteria is not compatible with Japanese cultural values that include the wholeness of nature and of the human body. Furthermore, receiving a donation from strangers denotes for many Japanese people the need to repay the favor (Nakata et al., 2001).

Research to date on the determinants of organ donation has been hampered by small sample sizes, limited variations in sample findings by geographic area, and failures to disentangle socioeconomic status variables from cultural variables, such as ethnicity and religion. Efforts to improve the organ donation process and encourage individuals and family members to consent to donation will need to take into account the many variables involved in the decision making.

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3
Perspectives and Principles

In this chapter, the committee summarizes its charge and sets forth several perspectives and principles that will guide its analyses and assessments of various proposals for increasing the rate of deceased organ donation.

THE COMMITTEE'S CHARGE

The committee was directed to analyze and evaluate proposals to increase the rates of deceased organ donation in light of the "ethical, religious, and moral standards commonly found in the United States." The term "standards" includes what is often referred to as ethical or moral principles, norms, and values. Standards may be substantive (i.e., indicating what should or should not be done) or procedural (e.g., indicating how a decision should be made and by whom it should be made or how a policy should be carried out). Even though the term "standards" is often used, other terms such as "principles," "norms," and "values" are also relevant. (The terms "ethical" and "moral" are used interchangeably in this report.)

To identify standards "commonly found in the United States," the committee has examined current practices, policies, laws, opinion surveys, and cultural and religious traditions as interpreted by the spokespeople for relevant organizations and other experts (e.g., philosophers, theologians, anthropologists, and sociologists). Notwithstanding the diversity of U.S. society and the complexities of the problem that is being addressed, the committee finds a surprising degree of consensus around several fundamen-

tal propositions. One can find strong disagreements, to be sure, but most of these disputes center on what a particular standard or principle may entail rather than on the existence or validity of the standard itself.

Some of the principles identified below have been articulated or codified in an explicit way by legislators; public bodies, such as commissions; ethicists; theologians; and others. In other cases, however, the committee has identified a latent understanding that provides a commonly accepted foundation for existing policy and practice or a constraint on the range of acceptable solutions for improving the present system. In this sense, the task of identifying "ethical, religious, and moral standards commonly found in the United States" is inescapably interpretive. However, in the committee's judgment, the principles identified below represent a genuine consensus and provide a solid framework for evaluating the proposals that have been laid before the committee.

The committee uses these principles to distinguish, as its charge requires, "ethically acceptable" proposals from "ethically controversial" ones —and, indeed, from ethically unacceptable ones (i.e., those that would represent a clear and radical departure from the "ethical, religious, and moral standards commonly found in the United States"). The committee was also charged with further evaluating "ethically controversial" proposals by considering their possible impact on existing donation efforts (for instance, what impact would nonmonetary or monetary incentives have on altruistic donations?), on public perceptions of organ donation, on "disadvantaged or disproportionately affected groups" (including both ethnic minorities and socioeconomically disadvantaged groups), and on living donation. The committee was directed to consider and recommend any "particular alterations" that could reduce the "ethical problems" in controversial proposals. Finally, the committee is expected to evaluate different proposals in terms of their cost-effectiveness, feasibility, and practicality.

PERSPECTIVES AND PRINCIPLES

This section provides a brief sketch of the guiding perspectives and principles that the committee used in discharging its task. The report's subsequent discussion of different proposals to increase the number of transplantable organs will further amplify the substantive and procedural principles summarized below (Box 3-1). Overall, the committee believes that any policies crafted to increase the rate of organ donation must be compatible with these perspectives and principles. What these principles imply and how much weight and strength they have will be clarified in the evaluation of specific proposals. For instance, it may be unclear at the outset, before the detailed analysis and assessment, what these propositions imply for a specific proposal about the use of incentives to motivate families

BOX 3-1
Guiding Perspectives and Principles

Common Stake in a Trustworthy System: Everyone in the national community has a common stake in the creation and maintenance of an effective and trustworthy system for providing timely access to transplantable organs and, if organs are scarce, in increasing the number of organs recovered and distributing them fairly.

Acceptable Appeals for Organ Donation: Policies and practices designed to increase organ donation may properly appeal to a variety of motivations for donation, including altruism, community spirit, and reciprocity.

Respect for Persons: Policies and practices designed to increase the rates of organ donation and the recovery of organs from deceased individuals must be compatible with four limiting conditions deeply rooted in the cultural, religious, and legal traditions of the United States: (1) respect for the moral worth and dignity of each human being; (2) respect for each individual's right to govern the disposition of his or her body after death, including the voluntary choice of whether or not to donate organs; (3) respect for the remains of human beings, as represented in particular cultural and religious practices; and (4) respect for the wishes and feelings of the families of deceased individuals.

Fairness: Policies and practices designed to increase the supply of transplantable organs need to be fair in their distribution of both benefits and burdens, with particular attention to their impact on disadvantaged groups.

to donate the organs of their loved ones. In the event that these principles conflict in the evaluation of a specific proposal, a further judgment regarding which of the conflicting principles should have priority will be required.

Common Stake in a Trustworthy System

Everyone in the national community has a common stake in the creation and maintenance of an effective and trustworthy system for providing timely access to transplantable organs and, if organs are scarce, in increasing the number of organs recovered and distributing them fairly.

The committee's charge focuses on increasing the number of individuals and families who donate organs. It must be recognized from the outset, however, that everyone has a stake in a robust system for recovering and transplanting organs to those in need. Just as everyone has a personal stake or interest in the availability of enough doctors, nurses, and other healthcare providers, as well as drugs and medical devices, to cure or ameliorate

disease, so, too, does everyone have a common interest in ensuring the availability of enough organs to save, extend, and improve their own lives and the lives of their loved ones. The committee estimates that among the U.S. population as a whole, each person has a 1-in-7,500 chance of needing a transplantable organ in a given year and a 1-in-100 chance of needing one in a lifetime (Appendix D). If it is assumed that any given individual has meaningful emotional attachments to 20 other people, the annual probability that a person or someone whom he or she cares about will need a transplantable organ in a given year is 1 in 358 and the lifetime probability is 1 in 5 (Appendix D).

The Link Between Organ Recovery and Distribution

Although this statement of common interest would probably be widely affirmed, it is not easy to reach a consensus about what both effectiveness and fairness require in the context of a healthcare system marked by gross inequalities. This report largely focuses on proposals that will increase the number of donated and recovered organs, but the committee also emphasizes that those proposals will not be effective or fair—or perceived to be such—without attention to fair distribution. There is thus a close connection between efforts to increase the rates of organ donation, on the one hand, and the allocation and distribution of organs, on the other (Childress, 1987).

Obviously, major increases in the rate of organ donation and in the number of available organs would reduce some of the ethical challenges and dilemmas of allocation and distribution and might bolster public confidence in the system. Less obviously, but also significantly, perceptions of unfairness in the system of allocation and distribution may have a negative impact on the rates of organ donation. In particular, people may be less willing to sign donor cards or to donate deceased family members' organs if they believe, for instance, that celebrities have an unfair advantage in obtaining organ transplants or believe that they themselves would have little chance to obtain needed transplants because of bias or a lack of health insurance.

Reciprocity

Some ethicists argue that reciprocity provides the most compelling moral basis for an effective and fair system of organ donation (Ravelingien and Krom, 2006; Siegal and Bonnie, 2006). In its strong form, reciprocity implies that everyone who expects to be eligible to be a recipient if the need were to arise has a prima facie moral obligation to register to be a donor. Whether eligibility for organs, or waiting list priority, should turn on donor

registration is a highly controversial question that is addressed in Chapter 8. For the present purposes, however, the pertinent point is that everyone who is asked to be a donor should at least be eligible to be a recipient, medical circumstances permitting. Twenty years ago, the federal Task Force on Organ Transplantation (1986) concluded that it is unfair and even exploitative for society to ask everyone, rich and poor alike, to donate organs if poor people in need would not have an equal opportunity to receive a transplant. All potential donors and their families should have an equal opportunity to be recipients. Unfortunately, the Task Force's recommendation has not been heeded. Lack of insurance coverage and inability to pay for a transplantation out of pocket effectively preclude many uninsured potential recipients from receiving extrarenal transplants. Although patients in the United States with end-stage heart failure must have health insurance or other financing to receive a heart transplant, a recent study found that 23 percent of organ donors are uninsured (King et al., 2005).

Only universal access to health insurance coverage for transplantation (Task Force on Organ Transplantation, 1986) can ensure a fully reciprocal system of procuring and distributing organs. The committee is tempted to say that resolving this long-standing flaw in the current system is a necessary condition for an ethically satisfactory strategy for increasing the rate of organ donation. It recognizes, however, that the underlying inequity is likely to be resolved only as part of a comprehensive reconfiguration of healthcare financing in the United States, a process of reform that, once begun, will require many years. In the meantime, it must be understood that the lack of reciprocity in the procurement and distribution of organs provides a serious and continuing impediment to increasing the rates of organ donation among poor and uninsured Americans. Implementation of any proposals to increase the rate of donation must take this deficiency into account.

Trustworthiness

The system for obtaining and distributing organs needs to be worthy of trust. In a system perceived as trustworthy, citizens may be more likely to donate their (or their family members') organs. If citizens believe that the system of organ recovery and allocation is ineffective or unfair or that it fails to respect other important ethical standards, they would have little reason to support the system by donating organs. After all, when it is viewed as a component of the larger healthcare system, organ transplantation is uniquely reliant on public participation: the medical procedure (transplantation) simply cannot occur without donations of transplantable organs. Hence, public trust is utterly indispensable. Focus groups and opinion surveys regularly identify distrust or mistrust as common reasons for non-

donation, particularly among populations who view themselves as socially marginal (Nolan and Spanos, 1989; Peters et al., 1996; Siminoff and Saunders Sturm, 2000; Minniefield et al., 2001; Minniefield and Muti, 2002). In addressing various proposals to increase the rates of organ donation throughout this report (as well as in this chapter), the committee identifies several policies and practices that are important conditions for the system's trustworthiness and, hence, a reasonable basis for the public's trust.

One of the most profound threats to the moral integrity and practical viability of the system of recovering transplantable organs and to its public support is the possibility that life-sustaining treatment might be forgone or terminated prematurely for the purpose of taking patients' organs. Media accounts of such episodes in other countries—indeed, reports that people have been killed—have occasionally appeared. From its inception, the U.S. organ recovery system has been designed to provide strong safeguards against such an occurrence. One such safeguard is faithful adherence to the dead donor rule (i.e., the rule that organs may not be recovered from a dying person until the person has died) by requiring a declaration of death before initiating the process of organ recovery and by separating organizational responsibility for caring for the dying patient from the responsibility for organ recovery.

Confusion about the implications of the dead donor rule has several sources. It is difficult for many people to grasp that there is a single definition of death but that there are two ways to determine that death has occurred, that is, by the use of neurologic criteria and by the use of circulatory criteria (Chapter 5). For example, DuBois and Schmidt (2003) conducted a telephone survey of 1,000 U.S. heads of household on attitudes toward the definition of death and organ donation. Eighty-four percent agreed that a person could be dead while breathing was mechanically maintained, but only 60 percent agreed that a person could be dead with a beating heart (as is the case with most donors declared to be dead according to neurologic criteria). Answers to the question "What do you think is meant by the term 'brain death'?" tended to be consistent with the medical characteristics of "whole-brain" criteria (e.g., few or no signals are sent to and from the brain or the person cannot move or communicate), but only 8 percent actually stated that "the person is dead." Forty-seven percent agreed with the false statement that "a person who is declared 'brain dead' by a physician is still alive according to the law."

In a telephone survey of 1,351 Ohio residents, Siminoff and colleagues (2004) found that even fewer respondents than the number in DuBois and Schmidt's (2003) study knew that someone who is "brain dead" is legally dead (34 percent), and 28 percent believed that "brain-dead" patients can

hear. This survey distinguished between respondents who viewed patients declared dead using neurologic criteria as "dead" (40 percent) versus "as good as dead" (43 percent). A remaining 16 percent believed that these patients are alive. Many physicians and other healthcare professionals appear to embrace concepts of death that are incompatible with the use of neurologic criteria to determine death (Ettner et al., 1988; Youngner et al., 1989), but the numbers may be falling (DuBois, 1999). Confusion or uncertainty about whether patients declared dead using neurologic criteria are really dead can affect the willingness of a family to donate the organs of a loved one (Pearson et al., 1995; Siminoff et al., 2003; DuBois and Anderson, 2006).

The protocols now being used to recover organs from people declared dead by the use of circulatory criteria (Chapter 5) have raised new risks of public misunderstanding or mistrust. In this context, public concern is associated less with the meaning of being dead than with the danger that life-sustaining treatment will be prematurely withdrawn. According to DuBois and Anderson (2006), the most commonly cited reasons for doubts about procuring organs from patients meeting the circulatory criteria of death were that, because of the withdrawal of life support, "a chance for recovery might be lost" (21 percent) and "it sounds like murder or suicide" (20 percent). The fear that organs will be taken from patients who might have benefited from additional treatment can lead to decreased donation rates (DuBois and Schmidt, 2003).

Some experts have suggested that public and professional confusion might be alleviated by decoupling organ donation from the definition of death (Youngner and Arnold, 1993; Truog, 1997) and allowing organs to be recovered once the patient or a legally authorized family member has decided to withdraw life-prolonging treatment, even if the patient has not yet died. The rationale for decoupling transplantation from the definition of death is straightforward: why go through the formality of waiting for the patient to meet the medical criteria of death and taking the risk that the organs will be wasted when the decisions to allow the patient to die and to permit organ recovery have already been made? Although the committee understands the moral logic of such proposals, it does not favor this approach. Abandoning the dead donor rule would constitute such a radical departure from the existing legal and ethical framework of organ transplantation that it would exacerbate public cynicism and distrust, no matter how carefully the clinical practices were monitored (DuBois, 1999; DuBois and Schmidt, 2003). The dead donor rule is one clear line that should not be crossed in efforts to increase the supply of organs. Educating the public about its meaning and significance—and that there is one definition of death accompanied by two ways of determining death—is a major ongoing task.

Transparency

The complex arrangements needed to stimulate and maintain a growing supply of transplantable organs amount to a delicate social system. Any perturbation in the system (arising, for example, from removing organs over the family's objection, a premature declaration of death, or an apparently discriminatory allocation practice) can have a marked and immediate impact on the willingness to donate and therefore on the supply of organs. It follows that a successful system of organ recovery, whether from deceased donors or live donors, requires continuous and unstinting efforts to promote and nurture public understanding, which is a necessary condition for trustworthiness and, therefore, for public trust.

Acceptable Appeals for Organ Donation

Policies and practices designed to increase organ donation may properly appeal to a variety of motivations for donation, including altruism, community spirit, and reciprocity.

People donate organs for a variety of reasons. Individual and familial decisions about organ donation are often grounded in altruism, a spirit of community or solidarity, reciprocity (the recognition that everyone is a potential recipient as well as a potential donor), a desire to gain some meaning out of a tragedy (e.g., a parental decision to donate a deceased child's organs), or some combination of these and other motivations. Cultural and religious traditions differ in the predominance of one of these values or another. The committee believes that these motivations are all morally acceptable and compatible and that a system of organ recovery and distribution may properly appeal to all of them.[1]

Confusion has marred much of the discussion of altruism in relation to donation of organs from deceased donors (deceased organ donation), perhaps because of an assumption that a donation or gift system (under state versions of the Uniform Anatomical Gift Act) is necessarily grounded in altruism. However, the ordinary experience of gift-giving among families or friends should be sufficient to dispel that notion—the motives of gift givers are often quite complex and may reflect a combination of generosity, perceived obligation, and a desire to be regarded with favor. Nevertheless, altruism—a motivation for action that is concerned only about others' welfare—is sometimes viewed as the predominant and only acceptable motivation for donation in the current system.

It is important to dispel this confusion between "donation" and "altruism" because it inhibits successful resolution of ethical disputes regarding

[1]The only motivation that is not currently acceptable is the prospect of financial benefit. Principles bearing on financial motivation are discussed in Chapter 8.

the permissibility of various approaches for increasing the donation rate. For example, one commentator has stated that "[t]he voluntary decision to donate must be based on altruistic motives; otherwise, it is not permitted" (Prottas, 1994, p. 50). This line of thinking is based on the assumption that altruism and financial gain are the only possible motivations for authorizing recovery of an organ and that, because our system has ruled out financial motivation, a gift of an organ must be based on altruism. This proposition, if it were true, would preclude the use of any sort of incentive, or appeal to self-interest, such as giving people who have recorded their intention to donate preferred status as recipients. It also implies that organ procurement organizations should be ascertaining families' motivations for donation, a task that they do not currently undertake as long as financial compensation does not appear to be involved.

Another analyst insists that "[o]rgan procurement activities in the United States are based on altruism. Out of their compassion for others, people agree to donate the organs of a deceased relative" (Evans, 1993, p. 3113). In fact, however, it is not really known, and it may not be possible to determine, what actually motivates people to donate organs. It seems likely, though, that people may have all sorts of reasons for donating organs. Altruism, including feelings of compassion for people in need, is clearly an important motivation for many donors. Other motives, however, as noted, may include a strong sense of communal solidarity; a sense of obligation, perhaps based on reciprocity (e.g., the Golden Rule); a desire to find redemptive meaning in a tragic set of circumstances; or a desire for praise, honor, and the like. Policies and practices aimed at increasing the rates of donation may properly appeal to all of these motivations. By overemphasizing altruism, however, the system of organ recovery has often neglected other powerful motivating reasons that could connect and align the individual's and family's interests more closely with the interests of potential recipients of donated organs. Instead, it has tended to view these interests as totally separate. As a result, organ donation has been praised as a highly disinterested, sacrificial, and heroic act that may appear to be out of the ordinary person's reach because it is so demanding. The act of donation is voluntary, in the sense that others cannot claim it as a right. This does not mean, however, that altruism is the only possible or acceptable motivation or that donation policies should appeal only to altruism.

Respect for Persons

Policies and practices designed to increase the rates of organ donation and the recovery of organs from deceased individuals must be compatible with four limiting conditions deeply rooted in the cultural, religious, and legal traditions of the United States: (1) respect for the moral worth and

dignity of each human being; (2) respect for each individual's right to govern the disposition of his or her body after death, including the voluntary choice of whether or not to donate organs; (3) respect for the remains of human beings, as represented in particular cultural and religious practices; and (4) respect for the wishes and feelings of the families of deceased individuals.

Respect for Human Dignity

The policies and practices related to organ donation and recovery must respect the dignity of each human being whose body is being used as a source of organs. The major concern here is that the deceased person not be regarded simply as a "thing" being used instrumentally for the benefit of others. Instead, the person's body represents a unique person who, while alive, chose to donate his or her organs so that others might live or in whose name and memory the family has chosen to make such a donation. This overarching concept of respecting human dignity encompasses several more specific principles: it entails respect for the wishes of living individuals, including their interest in having their wishes respected after they have died, and respect for their bodily remains. Each of these principles is elaborated on further below.

It is likely that the often expressed objections to the commodification of human body parts, characterized by the objectification of the organs and their pricing for sale, are rooted in concerns that the dignity of individual people would be violated by the routine commercial disposition of organs from dead bodies. Although they are difficult to articulate, concerns about the degradation of human dignity may explain the revulsion and repugnance that some experience at the prospect of the buying and selling of transplantable organs (Kass, 1992).

The proponents of a market for transplantable solid organs emphasize that other human biological products, particularly sperm and eggs, are being directly sold and that there is an extensive industry involved in processing, marketing, and selling human tissue and bone products. In response, those who are troubled by the commodification of dead bodies (or of the solid organs of living persons) insist that the sale of these organs would cross an important moral boundary and could erode the moral fabric of the community. The committee addresses the issues surrounding payment for organs and other types of financial incentives for donation in Chapter 8. For the moment, it is sufficient to note that whatever policies are adopted must be designed in a way that avoids the degradation of human dignity.

Respect for Decedents' Wishes

Although practices regarding the disposition of bodies after death differ from society to society, the well-established tradition in the United States and most other Western societies is to respect the living individual's wishes regarding the disposition of his or her remains. This tradition is evident in the practice of specifying, often in one's will or last testament, the conditions and mode of burial, cremation, or other method of disposing of one's remains. Although a family's failure to honor the decedent's wishes may not give rise to legal liability, families virtually always feel a moral obligation to do so. Such exercises of "precedent autonomy" have a strong moral force, even after death. The decedent's authority to govern the disposition of his or her body is not absolute, however, because the state has the authority to take control over the body to prevent the spread of disease or to conduct an autopsy, notwithstanding any directions of the deceased to the contrary.

In light of these well-established principles and traditions, it is not surprising that a living person may also direct or forbid the postmortem donation of his or her organs for transplantation. As will be further explained in Chapter 6, state legislatures have codified the legal prerogative of a living person to make binding decisions regarding organ donation. This deep respect for autonomy precludes the taking of organs when the living person forbade it and authorizes the taking of organs when the living person consented to donation, even if the family objects. Healthcare organizations or others in actual possession of the body are directed to follow the decedent's wishes and are punishable by legal sanctions in many states if they do not do so. The prospect of legal sanctions brings precedent autonomy in organ donation into alignment with the law and practice governing the disposition of property after death in accordance with the deceased person's will.

Legal recognition of the living person's prerogatives in making binding decisions regarding organ donation after death is also well aligned with the widespread recognition of the binding force of advance directives in health care, under which a legally competent adult may prescribe end-of-life healthcare decisions in the event that he or she has permanently lost decisional capacity. As discussed in Chapter 4, the committee regards deceased organ donation to be an integral part of end-of-life care. In this respect, the moral reach of the living person's prerogative to govern the disposition of his or her body after death extends not only to the possibility of making a donation decision but also to the possibility of designating a surrogate decision maker, even though this particular implication has been overlooked so far by most legislatures.

Respect for Human Remains

Another condition that must be satisfied by policies or practices designed to increase organ donation is respect for human remains. People in most cultures have deep feelings about the proper treatment of a dead body, and these feelings are often linked to beliefs about the continued spiritual existence of the person who has just died. Failure to show proper respect for the body can be offensive and disturbing to anyone who might observe it and can be profoundly painful to the deceased person's family whether they observe it or not. Concerns about the desecration of a human corpse are reflected in criminal prohibitions against such behavior and in the possible liability of the perpetrators for inflicting emotional distress on living family members (Dobbs et al., 1984). Organ recovery practices must be scrupulously sensitive to these concerns, because the failure to do so could undermine public support.

Respect for Families

The families of deceased individuals play an important role in the system of organ recovery in the United States, and their wishes and feelings deserve respect. They have a legal obligation to bury or otherwise dispose of the body, and they have a legal right to possess the body for this purpose (see, e.g., *Newman v. Sathyavaglswaran*[2]). The right to take possession of the body and determine its disposition has been characterized as a "quasi-property interest." However, as already noted, the interests of families in governing the disposition of a loved one's remains and in making a decision about organ donation are subordinate to the "surviving interest" of a deceased donor who has expressed a desire regarding donation. Nonetheless, because many potential donors fail to express their wishes regarding donation, families are often the default decision makers about donation. Because families are often the best source of information regarding the values and wishes of a dying or a deceased person, their expressions of the deceased person's preferences should be respected when those preferences are otherwise unknown. In addition, the deceased person may have designated a family member to make the decision. As mentioned above, families also often have strong emotional attachments to the body of the deceased, sometimes grounded in spiritual or religious beliefs. These deep attachments ought to be respected whenever it is possible to do so without sacrificing weightier considerations. For these reasons, policies and practices designed

[2]287 F.3d 786 (9th Cir, 2002).

to increase the rates of organ donation must be careful to involve the family in appropriate ways, even when the deceased person has directed donation.

Fairness

Policies and practices designed to increase the supply of transplantable organs need to be fair in their distribution of both benefits and burdens, with particular attention to their impacts on disadvantaged groups.

The principle of fairness—a subset of justice—has already been invoked in this chapter in the formulation of "a common stake in a trustworthy system." One aspect of that common stake focuses on the fair distribution of organs when the supply is not sufficient to meet everyone's needs. In addition, a version appeared in the discussion of reciprocity, which under ideal circumstances would involve a willingness to donate along with a willingness to receive organs. Furthermore, as already noted, the committee was charged to consider the effects of various proposals to increase the supply of transplantable organs on "disadvantaged or disproportionately affected groups" (including both ethnic minorities and socioeconomically disadvantaged groups).

All these considerations presuppose some conception of fairness, a norm that is widespread, even if it is subject to widely different interpretations, in U.S. society. At a minimum, fairness requires that similarly situated people be treated according to the same standards. Judgments of fairness and unfairness include, as the examples presented above suggest, attention to the distribution of burdens, inconveniences, costs, and harms, as well as to the distribution of benefits, such as organs for transplantation.

In evaluating different proposals to increase the numbers of available organs, the committee attends to debates about their fairness. For instance, some critics of opt-out policies contend that they would unfairly burden conscientious objectors or socially disadvantaged individuals by requiring them to take the initiative not to become organ donors. By contrast, some proponents of these policies argue that it is only fair for the majority to effectuate its will through such a policy. The committee examines the merits of these arguments, as well as possible ways to tweak such policies to eliminate unfair burdens, in Chapter 7.

Similar debates about fairness arise in discussions of proposals to institute a free or regulated market or to use financial incentives within a donation framework (Chapter 8). They also arise in consideration of nonfinancial incentives in the form of preferential access to organ transplants, if they become needed. In controversies about both financial and nonfinancial incentives, a central, even if sometimes submerged, question is who will benefit and who will be burdened by such policies and whether the rules and resultant distributional patterns are fair.

As these examples suggest, there is often no clear and easy way to resolve these debates about fairness. Nevertheless, any examination of the different proposals requires attention to the way that they provide benefits and impose burdens, particularly who gains and who loses in the process.

CRITERIA FOR EVALUATING PROPOSED CHANGES

The difference between a strictly technical and an ethical examination of ways to increase rates of organ donation is that an ethical approach must set the problem within the larger context of individual and social well-being. The committee considered the impact of various proposed policies not only on donation rates but also on many other policy-relevant variables, such as public and professional attitudes about the meaning of the body, the scope of individual freedom, and a sense of community. One act of organ donation by a deceased donor can significantly increase the length and improve the quality of life of several individuals. In addition, within both secular and religious frameworks, saving a life is deemed one of the greatest positive duties in the moral life. Nevertheless, it is important to ask what constraints should be recognized in the pursuit of the goal of increasing rates of organ donation.

Some proposals under consideration may be unacceptable—even though they might increase the supply of recovered organs—because they are fundamentally incompatible with one or more of the necessary conditions specified above, such as trustworthiness (e.g., abandoning the dead donor rule) and respect for donor autonomy (e.g., the routine removal of organs from deceased individuals without consent). These proposals can be ruled out right away.

For other proposals, the first question to be asked is whether they would probably increase the number of transplantable organs over the long run as well as the short run. Estimating the effects of a new policy or program on the organ supply is a difficult challenge, because the outcome depends heavily on the ways in which the proposed change would affect the attitudes and perceptions of potential donors and their families. A mistaken prediction could be disastrous because it could actually reduce the rate of donation rather than increase it as anticipated. Furthermore, certain alterations in policy and undesirable changes in attitudes and perceptions may be very difficult, if not impossible, to reverse. Accordingly, a cautious perspective is imperative both in predicting the effects of proposed changes and in implementing any new policies and programs. Even though the current system is far from perfect, policy makers need to be sure that changes will not make matters worse. Finally, all proposals need to be cost-effective, as well as feasible and practical.

In any case, assuming that a particular change can be reasonably expected to increase the rate of donation, it must be asked whether the proposal is problematic or controversial in light of the other important principles and values at stake, such as fairness, respect for the autonomy of individuals in governing the disposition of their bodies, and respect for legitimate interests of families. If conflicts arise, it must then be asked whether the proposed policies and practices can be reframed to minimize or eliminate the conflicts and associated concerns. This is the approach that the committee has taken in this report. Several questions may guide the justification of policy decisions when values and principles conflict (Childress et al., 2002):

- Will the proposed policy be effective in achieving the intended good?
- If it is effective in achieving the intended good, is the good significant enough to justify infringing upon other values?
- Is it necessary to infringe upon other values?
- If it is necessary to infringe upon other values, has the infringement been minimized as far as possible?

Clearly, none of these questions can be answered with a simple yes or no. Each requires the exercise of judgment. Some require controversial value judgments; others require predictions, even when the data may be scant. In the following chapters, the committee wrestles with these questions as they pertain to a series of specific proposals to increase the rates of organ donation.

Some proposed changes pose irreconcilable conflicts between weighty contending values. These are the "ethically controversial" proposals to which the charge to the committee refers. In these cases, the committee has struggled to evaluate and balance the competing concerns. Not everyone will agree with the committee's collective judgment, but the fact that the committee was able to reach a consensus is a promising indication of the prospects for achieving a wider public consensus on the plan outlined in the report.

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4

Systems to Support Organ Donation

Organ transplantation involves a complex, collaborative set of interactions among patients, family members, healthcare professionals, organ procurement and transplant coordinators, the hospital where the donation occurs, the organ procurement organization (OPO) that facilitates the acquisition and distribution of organs, and the transplant center. Although any hospital may have a patient who is a potential organ donor, specialized hospitals that treat many patients with traumatic injuries and other serious conditions (particularly those that can result in neurologic determination of death) are the ones that, to date, have been most likely to have potential organ donors in their patient populations.

Current debate and discussions about changing the organ donation process to increase the supply of transplantable organs occur within the context of ongoing efforts to improve the healthcare system as a whole. One major challenge facing the United States is improving the overall quality of health care. The increasing complexity of new technologies, the inadequate organization of the healthcare delivery system, the increased proportion of health care devoted to chronic conditions, and current constraints on taking full advantage of changes in information technology have all contributed to a healthcare system that is overburdened, inefficient, and often inequitable. In view of these problems, the Institute of Medicine (IOM) reports on healthcare quality have identified six improvement aims for the healthcare system (IOM, 2001, 2004a):

- Safe—avoiding injuries to patients from the care that is intended to help them

- Effective—providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and avoiding overuse, respectively)
- Patient centered—providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions
- Timely—reducing waits and sometimes harmful delays for both those who receive and those who give care
- Efficient—avoiding waste, including waste of equipment, supplies, ideas, and energy
- Equitable—providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status

These goals are highly relevant to the challenges facing the organ donation and transplantation system. These challenges include ensuring a patient- and family-centered system, providing equitable access to transplantation through the elimination of economic and ethnic or cultural barriers, increasing trust and confidence in the system, and providing the care needed to optimize the value of the transplant to the recipient.

As previous IOM studies on improving the quality and safety of U.S. health care have concluded, improving care requires a focus on systems, not on the individuals within those systems (IOM, 2000a). "[E]very system is perfectly designed to achieve the results it achieves" (Berwick, 1996, p. 619). Hence, if the results are unacceptable, the system's design must be changed.

This chapter focuses on the clinical systems issues that are specific to the organ donation process. It is important to note, however, that an equitable allocation system and ongoing attention to the recipient are vital to maintaining the value of the donated organ and sustaining the integrity of the entire organ transplantation system (Box 4-1). Although these allocation issues are beyond the scope of this report, addressing them is indispensable to achieving a trustworthy organ donation system and thereby increasing the rates of donation. Additionally, several aspects of tissue donation and the market for tissue-related products need attention in order to ensure the credibility of the entire donation system.

The chapter begins with a brief overview of the issues facing the U.S. organ donation system, provides a snapshot of ongoing efforts, and concludes with recommendations for next steps to improve the system. As discussed throughout this chapter, there are many opportunities to build on existing practices and to leverage ongoing quality improvement efforts to expand knowledge and implement best practices. Clinical care at the end of life receives the main attention in this chapter, while emergency care and resuscitative care are examined in Chapter 5.

BOX 4-1
Issues in Allocation and Distribution of Organs

Equitable Access to Transplantation: Medical, technical, ethical, and other issues arise in the referral for transplantation, admission to the waiting list, and selection to receive a donated organ. The criteria for each of these actions continue to need close attention by both professionals and the public to ensure equity. Particularly important is the role of the so-called green screen (which screens for insurance coverage and the ability to pay for the transplant) for nonrenal transplants and, often relatedly, the problems of access faced by minority populations.

Access to Immunosuppressive Medications Following Transplantation: Immunosuppressive medications, estimated to cost more than $10,000 per patient annually, are needed for the rest of the patient's life after transplantation; their discontinuation can result in organ rejection and the need for retransplantation (Chisholm and Garrett, 2001). It has been estimated that medication noncompliance results in the loss of 13 to 35 percent of transplanted kidneys (Yen et al., 2004), but it is difficult to determine the extent to which noncompliance is tied to the high cost of medication. Medicare currently provides initial coverage for immunosuppressive medications after most solid-organ transplants that occur in Medicare-approved facilities. However, for many patients this coverage is limited to 3 years posttransplantation. An analysis of the effects of extending immunosuppression coverage from one to three years found improved graft survival (Woodward et al., 2001) suggesting the importance of uninterrupted access to immunosuppressive medications for optimal outcomes from donation. Research models that explored extending to lifetime coverage found improved transplant and economic outcomes (Yen et al., 2004).

For individuals who are eligible for Medicare because of age or disability, the Benefits Improvement and Protection Act (incorporated into Public Law 106-554) extended the benefits to lifetime coverage of immunosuppressive medications; however, this full coverage applies to only a fraction of total transplant recipients. Private insurers offer some patient assistance programs to provide medications to patients who lack Medicare coverage or the ability to pay, but these programs are highly individualized to specific insurance companies. Immunosuppressive medications offer the dual protection of maintaining the health of the recipient and protecting a scarce resource, a transplanted organ. A 2000 Institute of Medicine analysis of the effectiveness and cost savings of extending the Medicare coverage benefit found strong evidence for eliminating the time limits for coverage of immunosuppressive drugs for all solid-organ transplant recipients (IOM, 2000b).

CONTEXT OF THE CURRENT U.S. ORGAN DONATION SYSTEM

The U.S. organ donation system has evolved over the past half century, having been shaped by a series of federal and state laws and regulations, private-sector oversight, and individual hospital policies. The system has focused primarily on deceased donors with neurologic determination of death. More recently, living donation, which is rapidly increasing, has

largely been regulated through hospital policies (Chapter 9). Internationally, some countries have developed extensive systems for organ donation and recovery, particularly in countries with national systems of health care. In addition, individuals whose deaths are determined by circulatory criteria represent a largely untapped group of potential organ donors (Chapter 5).

In the United States, people become organ donors either after the determination of death by established criteria (together with their prior consent or the consent of their family) or after an autonomous decision by a living person to donate all or part of an organ. Each circumstance presents distinct clinical, ethical, legal, emotional, spiritual, and cultural issues. This chapter focuses on the donation of organs by deceased donors (deceased organ donation). Organ donation by living donors is discussed in Chapter 9.

Under the existing legal and ethical framework of deceased organ donation in the United States, organ donation must not cause or hasten death (the dead donor rule) and the individual's wishes regarding donation must be honored. Some donors have indicated their preferences to donate before their death (e.g., on their driver's license, in an advance directive, or by signing a donor registry); others have not and the decision to donate organs is left to the family or surrogate at the time of the individual's death. Regardless of the cause of death or the decision-making pathway, one person's death creates the opportunity for others to benefit from the donation of one or more organs.

With some exceptions (for instance, where there is valid evidence of the deceased person's wish to donate, perhaps backed by state law and OPO policy), the current practice of obtaining consent for deceased organ donation generally involves hospital or OPO staff talking with the patient's family or surrogate about what is known about the potential donor's wishes and providing information on the opportunity for organ donation. This practice is consistent with other decisions made by surrogates at the end of life and the requirements for informed consent (Beauchamp and Childress, 2001; National Consensus Project Steering Committee, 2004). The family's knowledge of the wishes of the deceased individual is often a key factor in the decision about donation (Sque and Payne, 1996; Siminoff and Lawrence, 2002; Jacob Arriola et al., 2005; Sque et al., 2005; Rodrigue et al., 2006). There is wide variation from case to case and among hospitals and OPOs in who talks with the family and when and how those discussions occur (HRSA, 2003).

Systems of Care: An Organizational Perspective

Organ transplantation generally involves interactions among three organizations: the donor hospital, the OPO, and the transplant center(s).

Each organization has unique features but must meet conditions of participation established and regulated by the Centers for Medicare & Medicaid Services (CMS). To be accredited each organization must meet the accreditation criteria of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and those of other organizations (Box 4-2). The challenges to the system—as well as the opportunities for improvement—are found in the variations among organizations.

Of the 58 OPOs (recently designated collectively as "donate life organizations") in the United States, 50 are independent and 8 are hospital or university based. Each OPO serves a unique geographic area (a donation service area [DSA])[1] with specific donor hospitals and transplant centers; in 2003, the populations served by individual OPOs ranged from 1 million to 17 million people and the OPO coverage areas ranged from approximately 3,600 to more than 850,000 square miles (AOPO, 2004). Similarly, the range in the number of acute-care hospitals in a DSA is also wide, with from 12 to 220 hospitals in a single DSA. Some OPOs recover organs from many different hospitals, whereas others work with only a few hospitals. In 2003, from 6 to 78 hospitals within a single DSA reported one or more organ donors (AOPO, 2004). Also in 2003, the number of organ donor referrals to an OPO varied from a low of 52 to a high of 2,627 and the number of organs locally recovered by OPOs ranged from 86 to 1,181 (AOPO, 2004).

As a result of the demographics of a region, the demand for services in a particular region, and the administration and management of OPOs, the structures, staffing, and financing of OPOs vary widely. Most OPOs (72 percent in the 2003 Association of Organ Procurement Organizations [AOPO] survey) recover tissue as well as solid organs, and a few OPOs are involved in tissue processing; additionally, several OPOs operate an eye bank or a histocompatibility testing laboratory. The OPOs in St. Louis and Philadelphia have built, or are in the process of building, facilities for organ recovery.

The financing of organ transplantation largely occurs through the health insurance costs paid by Medicare or private insurers. In 2004, private insurance was the primary payment source for 47.9 percent of transplant recipients, with 39.3 percent having Medicare as the primary source, and 9.0 percent using Medicaid (HRSA and SRTR, 2006).

OPOs develop standardized fees (standard acquisition charges) representing the average cost for each type of organ. The fees include direct costs, organ acquisition overhead, and general and administrative costs.

[1]The DSA is the geographic area that is served by one OPO, one or more transplant centers, and one or more donor hospitals.

Direct costs consist of donor-related medical costs after declaration of death (including operating room costs, surgeon fees, tissue typing, transportation of the organ and surgical teams). Organ acquisition overhead includes donor approach and public awareness costs. General and administrative costs include finance, human resources, information technology, and occupancy costs. The standard acquisition charge is billed to the transplant center receiving the organ. The center develops its own organ acquisition fees in addition to the transplantation fees and bills them to the recipient's insurance company or other payer. The OPO does not conduct any financial transaction with the recipient or the recipient's insurance company (third party payer). In 2003, the median local standard acquisition charge for kidneys was $20,500 (AOPO, 2004).

Medicare Part A, specifically the End-Stage Renal Disease program, is authorized to pay acquisition fees for organ acquisition and organ transplantation. OPOs are subject to annual federal audits after each fiscal year to reconcile their costs and the acquisition fees billed to transplant centers. In 2003, total Medicare expenditures totaled $14.8 billion for dialysis and $0.8 billion for organ acquisition and transplantation (USRDS, 2005). CMS provides oversight to the transplantation system through the Medicare/Medicaid conditions of participation. Only transplant centers that meet the conditions of participation are eligible for Medicare or Medicaid reimbursement. OPOs must meet separate certification criteria. CMS is currently revising the conditions of participation including the process and outcome measures and the certification cycles (Box 4-2).

OPOs also vary in their approaches to staffing and hospital interaction. In 2003, 28 OPOs responding to a survey reported that they had 31 or more employees, with only one OPO reporting fewer than 10 employees (AOPO, 2004). OPO staff members include organ and tissue procurement staff (e.g., laboratory managers and technicians, coordinators), executive staff, donation request and family care staff, public education personnel, and call center staff.

Some OPOs have established in-house coordinator programs in which full-time OPO staff work at Level I trauma centers and are fully integrated into hospital operations (HRSA, 2003). Other OPOs have staff who are based in multiple hospitals, whereas others, particularly those in rural settings, have staff based at the OPO office who travel to various hospitals in the region as needed.

The heterogeneity of OPOs is evident in the range of donation rates. The Scientific Registry of Transplant Recipients calculates observed donation rates (calculated as the number of actual donors per the number of individuals eligible for donation) and expected donation rates (the expected donation rate accounts for the variations in age, sex, race, and cause of death among notifiable deaths). Among OPOs the observed donation rates

BOX 4-2
Regulation and Accreditation

Centers for Medicare & Medicaid Services (CMS): CMS is responsible for certifying OPOs and transplant center hospitals for Medicare coverage. The conditions of participation for OPOs and transplant centers are in the process of being revised to address requirements of the Organ Procurement Organization Certification Act of 2000. The proposed rules increase the recertification cycle from 2 to 4 years and establish multiple outcome and process performance measures, including changes in measurements of donor potential by replacing the current use of population data with data based on hospital referral calls to OPOs. Data submission and outcome requirements for transplant centers are also proposed to be modified to consider the care being provided rather than relying on underlying policies and procedures. The proposed rule expands outcome measures to include graft survival rates (CMS, 2005).

Organ Procurement and Transplantation Network (OPTN): OPTN develops policies and procedures for organ recovery, allocation, and transplantation and conducts reviews and evaluations of each member OPO and transplant center for compliance with OPTN policies.

Joint Commission on Accreditation of Healthcare Organizations (JCAHO): Since January 1988, JCAHO has required its member hospitals, as a prerequisite for accreditation, to develop policies and procedures on the identification and referral of potential donors. JCAHO requires hospitals that recover organs to have an agreement with an appropriate OPO and at least one tissue bank and one eye bank. JCAHO describes procedures for notifying the family of the option to donate and for maintaining the records of potential donors. A standard which became effective in July 2005 requires hospitals to measure the effectiveness of their organ procurement efforts. According to this standard, the conversion rate data must be collected and analyzed, and steps must be taken to improve the rate whenever possible (JCAHO, 2005).

Association of Organ Procurement Organizations (AOPO): AOPO sets organizational and ethical standards for OPOs and offers a voluntary accreditation program to its members. The peer review accreditation process helps ensure compliance with federal regulations as well as AOPO standards. The period of accreditation is 3 years, after which the OPO must apply for reaccreditation to maintain its status. Recent standards include an emphasis on continuous quality improvement practices.

American Board for Transplant Certification (ABTC): ABTC develops certification standards and programs for certification testing for transplantation clinicians. Specifically, clinicians may receive certification as a certified procurement transplant coordinator, a certified clinical transplant coordinator, or a certified clinical transplant nurse.

in 2004 varied from 34.3 percent (with an expected rate of 54.9 percent) to 77.9 percent (with an expected rate of 51.3 percent) (SRTR, 2005) (Table 4-1). These statistics refer only to deaths determined by neurologic criteria. Wide variations in the number of cases of donation after circulatory determination of death (DCDD) also occur (Chapter 5). In 2004, 21 of the 58 OPOs had completed five or more DCDD cases, whereas 18 OPOs had not had a DCDD case in that year. Variations among OPOs and among transplant centers are being addressed through quality improvement processes and practices through the Organ Donation and Transplantation Breakthrough Collaboratives, which are described below.

According to the best estimates, approximately 200 of the nation's hospitals host half of the nation's eligible donors (HRSA, 2005a). A 2003 report by the Office of the Inspector General of the U.S. Department of Health and Human Services found that the 190 transplant centers obtained consent from a mean of 51 percent of potential donors, with 30 centers (16 percent) having consent rates of 70 percent or higher and 18 centers having consent rates of less than 30 percent (DHHS, 2003). Hospitals with the largest potential for donation may also be the most stressed because their intensive care units (ICUs) typically run at peak capacity, despite shortages of nurses and other key personnel (JCAHO, 2004). Because of ongoing concerns about the serious shortages of nurses (IOM, 2004b) and other personnel, the extent to which the current system will be able to accommodate large increases in the numbers of donors and transplant recipients is unclear. Currently, specialized operating room and critical care professionals must be available for donation surgery and the

TABLE 4-1 OPO Donation Rates, 2004

Number of OPOs[a]	Donation Rate[b] (%) Range
7	34–45
8	45–50
14	50–55
7	55–60
8	60–65
9	65–69
6	70–78

[a]In 2004, there were 59 OPOs; a merger occurred in 2005, and currently there are 58 OPOs.

[b]The donation (or conversion) rate is calculated as the number of actual donors per the number of eligible donors expressed as a percentage. Eligible donors are defined as heart-beating individuals who meet or who will imminently meet criteria for neurologic determination of death, who are aged 70 years or under, and who have not been diagnosed with exclusionary medical conditions.

SOURCE: SRTR (2005).

subsequent transplantation procedures. In an already stressed system, shortages of nurses or anesthesiologists, for example, could limit the options for timely donation and the quality of care of either the donor or the recipient. Given these system challenges, strategic planning for such increases would need to be undertaken to ensure that these scarce resources will be able to be used the most effectively and that the necessary human resources are available.

Required Request and Required Referral

Several systemwide initiatives have focused on increasing the donation rate by ensuring that all potential donor families are asked about donation (required request) and that OPOs are notified of all imminent deaths (required referral). Beginning in 1986, the Health Care Financing Administration (HCFA; now CMS) stipulated that Medicare reimbursement to hospitals was contingent on the hospital having a required request policy to ensure that the families of patients who are eligible to be donors are given the opportunity to donate (Nathan et al., 2003). In 1998, HCFA published the stipulations, known as the Final Rule, that imposed several additional requirements, including the requirement for hospitals to have an agreement with an OPO and to put in place mechanisms to contact the OPO in a timely manner about individuals who die or whose death is imminent (required referral) (DHHS, 1998). The regulations also require hospitals working with the local OPO to inform the family of every potential donor of the option to donate organs or tissues. JCAHO has incorporated required request and referral policies into requirements for hospital accreditation (JCAHO, 2005).

Increases in the numbers of referrals to OPOs have occurred; from 2002 to 2003 the number of referrals increased by nearly 10 percent (from 1,022,280 to 1,121,392) (Delmonico et al., 2005). However, the extent to which increases in donation rates can be attributed to required referral practices alone is unclear. One potential gap in the current system is that the referrals most often involve patients whose deaths are imminent as determined by neurologic criteria and do not often include deaths determined by circulatory criteria (Bernat et al., 2006) (Chapter 5).

ORGAN DONATION AND TRANSPLANTATION BREAKTHROUGH COLLABORATIVES

In recent years, many initiatives to increase the rates of organ donation have been undertaken. Several of these efforts are early in their implementation phases and have not yet been fully evaluated. Although organ donation rates have risen in the past 5 years, it is difficult, if not impossible, to

determine exactly how much each initiative or regulatory change has contributed to that rise. Taken together, the data suggest that a multipronged approach is necessary to realize the potential of organ donation in the United States.

A major new initiative is the series of Organ Donation Breakthrough Collaboratives. Directed by the Health Resources and Services Administration (HRSA), the collaboratives attempt to increase rates of organ donation by encouraging hospitals and OPOs to use methods of continuous quality improvement to enhance the process of deceased organ donation.

The process of identifying and referring potential donors, requesting donation, recovering the organs, and ensuring that they are successfully transplanted is complex. It takes place under difficult circumstances, with time pressure and emotional stress, and in environments that vary widely across the country. In these circumstances, mobilization of the personnel involved in the local settings to identify ways to improve the process, use quality improvement methods to explore the process, and share the results

BOX 4-3
Quality Improvement in Health Care

Quality improvement can be defined as systematic activities that are guided by empirical evidence and that are designed to bring about immediate positive change. A wide variety of methods are used to achieve quality improvement, all of which involve deliberate actions to improve processes involving the provision of health care in local settings. These actions are guided by data on the effects of the methods that have been introduced. For example, introducing quality improvement methods often means encouraging people in the local setting to use their daily experience to identify promising ways to improve the quality of the care that they provide, implement changes on a small scale, collect data, and assess the results. The goal is to find interventions that work well, implement those interventions more broadly, and thereby improve local practice.

Alternatively, a quality improvement activity might begin with a review of aggregate data at the patient, provider, clinical unit, or organizational level to identify a clinical care or management change that can be expected to be an improvement over the existing procedures. The change is made, the effects are monitored, and conclusions are drawn about whether the change should be made permanent. Quality improvement can also be brought about by collecting data from multiple organizations, analyzing those data to understand what drives positive change, and using the results to design and implement a strategy to achieve a specific improvement across organizations (Berwick, 1989; Kilo, 1998; McLaughlin and Kaluzny, 1999).

with others has significant potential to increase the supply of organs available for donation (Box 4-3).

The collaboratives began with HRSA partnering with the Institute for Healthcare Improvement (IHI), a nonprofit organization that is a leader in promoting the application of quality improvement methods to healthcare systems. IHI developed the Breakthrough Collaborative model, which brings healthcare organizations together to identify, learn, adapt, replicate, and celebrate breakthrough practices that can help them achieve specific improvement goals (IHI, 2003).

The collaborative's initial analysis of data on organ donation found wide variations in donation rates (also termed conversion rates) among hospitals and OPOs. (It is important to note that conversion rates are based on data from donation after neurologic determination of death and do not reflect the larger potential population of donors after circulatory determination of death [Chapter 5].) The data also showed that large urban hospitals with busy trauma centers hold the greatest potential for increasing donor conversion rates because approximately half of the eligible donors are concentrated in slightly more than 200 of the largest hospitals nationwide (HRSA, 2005a).

On the basis of site visits, extensive interviews, and a review of the best practices at six OPOs and 16 OPO-affiliated hospitals with high donor conversion rates (HRSA, 2003), the collaborative leaders developed a change package that comprised a set of shared strategies to boost organ donation rates. Broadly, those strategies

- advocate organ donation as the mission,
- involve senior leadership to achieve results,
- deploy a self-organizing OPO/hospital team,
- practice early referral and rapid response,
- learn effective requesting, and
- implement DCDD.

The first two collaboratives focused on organ donation. In 2003 and 2004, the first collaborative began with 95 hospitals and 43 OPOs as participants (personal communication, D. Wagner, HRSA). To share best practices among participating OPOs and hospitals, the collaboratives conduct regular learning sessions, in which participants describe their experiences, discuss problem-solving techniques, and celebrate their successes. Through these interactions, a community with a shared vision and a commitment to improving the donation process has developed. Data on several process and outcome measures are voluntarily submitted: the organ transplant conversion rate, the referral rate, the number of medical examiner denials, the use of timely notification, the use of the appropriate requester, and donor before nondonor statistics. These measures serve as benchmarks

for individual hospitals and collective members of the collaborative to measure the impacts of their specific initiatives.

Although Collaborative 1, the first phase, ended in September 2004, member hospitals continued reporting data at regular intervals through October 2005. The second collaborative, launched in September 2004, included 131 hospitals of the nation's 500 largest hospitals, 50 OPOs, and a large number of satellite teams. Again, members regularly reported process and outcome measures on a shared website, offering a venue for comparison and learning.

An analysis of the impact of the first collaborative compared trends in donation rates between the 95 hospitals that participated in the first Breakthrough Collaborative and 99 control hospitals that had at least five eligible donors[2] in the year before the first Breakthrough Collaborative and affiliated with OPOs that did not participate in the first collaborative (Howard et al., under review). Collaborative and control hospitals were similar in size (535 versus 505 beds), but collaborative hospitals are more likely to be members of the Council of Teaching Hospitals (64 percent versus 20 percent). OPOs report the number of eligible donors by hospital and by month to the United Network for Organ Sharing. Because not all eligible donors are identified as such and the reliability of the classification of potential donors as "eligible" and "ineligible" is unknown, the level of the conversion rates should be interpreted cautiously. However, differential trends in conversion rates across collaborative and control hospitals provide evidence of the impact of the Breakthrough Collaboratives on donation rates (Figure 4-1).

In the year prior to the first of the Breakthrough Collaboratives, conversion rates were the same among Collaborative 1 hospitals and control hospitals (both 52 percent). By the final 6 months of the first collaborative, conversion rates among Collaborative 1 and control hospitals differed substantially (60.3 and 52.2 percent, respectively), suggesting that the Breakthrough Collaborative was successful in increasing organ donation rates. During the second of the Breakthrough Collaboratives, when best practices were disseminated more widely, conversion rates increased among control hospitals and continued to increase among Collaborative 1 hospitals as well.

The impact of the Breakthrough Collaboratives also shows up in aggregate nationwide donation trends. Figure 4-2 displays the annual increase in the number of organ donors nationwide from the prior year for the period

[2]An "eligible" donor is defined as a donor who is less than 70 years of age, who does not have a history of cancer or human immunodeficiency virus infection, and whose death was determined by neurologic criteria.

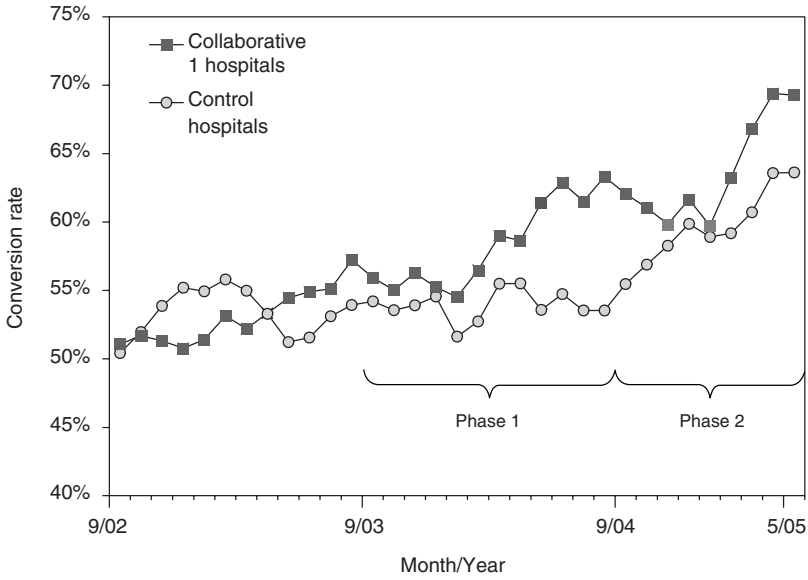

FIGURE 4-1 Conversion rates among member hospitals of the first breakthrough collaborative and non-collaborative-member hospitals.
NOTE: Phase 1 refers to the time period of the first collaborative and Phase 2 refers to the time period of the second collaborative.
SOURCE: Howard et al. (under review).

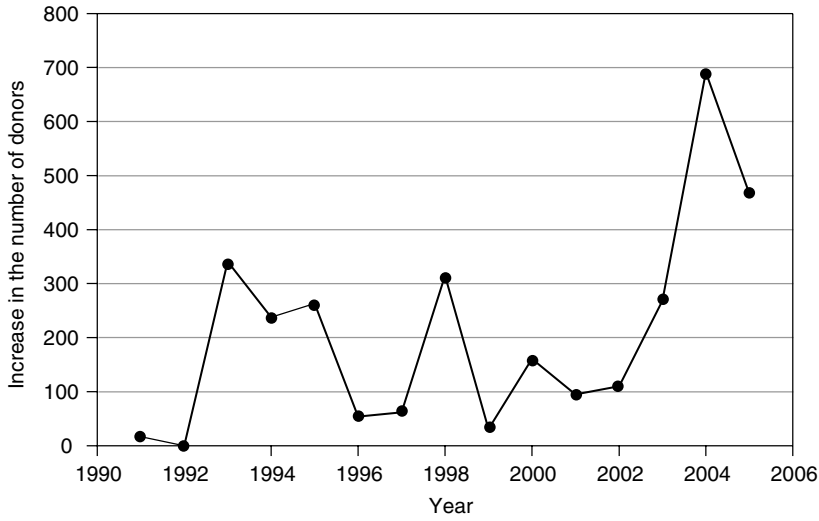

FIGURE 4-2 Annual increase in the number of deceased organ donors.
SOURCE: Howard et al. (under review).

from 1991 to 2005. The average increase from 1991 to 2003 was 150 donors, but reached 691 donors in 2004 and 445 donors in 2005 (projected on the basis of data through September 2005) (Howard et al., under review). The increase in the number of deceased donors nationwide in 2004 over the prior year was 11 percent (HRSA and SRTR, 2006).

The Organ Transplantation Breakthrough Collaborative (the third, and current, phase) is focused on increasing organ utilization. In particular, this initiative targets transplant centers, surgeons, and OPO and hospital administrators to evaluate how their institutions can increase the number of organs recovered and transplanted, with a goal of 3.75 organs per donor.

Sustaining the quality improvement efforts is critically important. The Breakthrough Collaboratives have been instrumental in enhancing the coordination, processes, and practices within hospitals and OPOs as well as among all of the relevant organizations and individuals. To maintain this level of coordination and communication between organizations and to continue to improve conversion rates will require efforts focused on instilling quality improvement into the evaluation, accreditation, and reimbursement processes and infrastructure. As recommended at the end of the chapter, resources should be invested in sustaining these quality improvement initiatives.

ONGOING EVOLUTION OF THE REQUEST PROCESS

The process of talking with a family about the opportunity for organ donation[3] has evolved considerably over the past 30 years. Various approaches regarding who does the requesting, what is discussed, how the topic is broached, and when the discussion occurs have been explored (Bires, 1999; Nathan et al., 2003); however, only a limited amount of research has been done to ascertain the most effective models.

A growing body of research shows that families' perceptions of their experience during the patient's critical illness are a major factor in their decision to donate organs. One study found that nondonor families were often less satisfied with the quality of care received in the hospital and less likely to believe that they had sufficient time and privacy to consider organ donation (DeJong et al., 1998). By contrast, donor families report greater satisfaction with the request for organ donation (Burroughs et al., 1998). In one study, 94 percent of donor families indicated that they were satisfied

[3]Requests for tissue and solid organ donation often occur simultaneously. More individuals are eligible for tissue donation than for solid-organ donation because organ viabilty is more limited, organ recovery is more complex, and tissue may be more readily recovered than organs after circulatory determination of death.

with their decision (DeJong et al., 1998). These studies suggest that communication and the relational aspects of the donation process are instrumental in creating a positive environment for considering and consenting to donation.

Formulation of the Request

The basic approach to the request process has evolved and is still changing. Although the process has been known as a process of requesting organ donation and asking for familial consent, the approach is changing in the direction of providing an opportunity for donation. As a result of these shifts, specialized skills, processes, and behaviors are needed.

One new model for the request process takes a more positive approach, which uses open-ended questions to guide the discussion with the family, presents organ donation as the expected path for families (Zink, 2004), and focuses the family's attention on the benefit to the potential recipients. This approach has been described as the "presumptive approach" (Zink, 2004). To avoid confusion with presumed-consent terminology, the committee prefers the phrase "expected donation," as suggested by Siegal and Bonnie (2006).

While this approach frames the opportunity for donation in the affirmative, clear boundaries must be maintained between offering an opportunity to consider donation, on the one hand, and using undue pressure and coercion on the other hand. This is particularly true when families are reapproached after they initially declined the opportunity to donate. In addition, further research is needed on family responses to this approach, its impact on donation rates, and its consistency with key ethical principles, such as the ones presented in this report.

Timing of Requests

The decoupled model of care that arose in response to concerns about conflicts of interest among physicians has received mixed reviews since its inception (Garrison et al., 1991; Cutler et al., 1993). This approach requires requests for organ donation to occur in a separate interaction (by separate staff, often OPO staff) after the family has been informed that the patient has died. This approach was developed largely in response to patient and familial mistrust of the healthcare system and the family's concerns that dying individuals who were identified as potential donors would not receive the full extent of life-saving measures. One early retrospective review of 155 consecutive donor referrals reported that decoupling resulted in higher consent rates (Garrison et al., 1991). Another retrospective review demonstrated a nonsignificant trend toward more probable consent if the

donation request was made subsequent to the notification of death (Cutler et al., 1993); a similar study indicated that the timing of the request made no difference in the consent rate (Morris et al., 1989). Niles and Mattice (1996) found that asking families to donate at the time of death was associated with a lower consent rate, with no difference in consent rates when requests were made before and after death. Finally, a large prospective study failed to find support for decoupling. Instead, that study found that asking families to donate before they were notified of the patient's death was associated with higher consent rates compared with the consent rates achieved when the family was asked to donate after the pronouncement of death (63.0 percent versus 56.6 percent) (Siminoff et al., 2002). This result suggests that the content of the communication and the relationships with healthcare professionals and OPO staff may be more important than the timing of the request.

Requesters

The early and consistent involvement of staff members with the family increases organ donation rates when it is coupled with effective communication. In a small study of a single hospital in Texas, the use of early notification and an in-house coordinator was associated with an increase in donation rates from 45 to 74 percent (Shafer et al., 1997). Other studies of in-house coordinators by the same group have replicated these results (Shafer et al., 2004). A recent descriptive study of the donor request process by Siminoff and colleagues (2001b) reported that the most important extrinsic factor to obtaining consent to organ donation was the time that the family decision makers spent with the requesters and the amount of time that they spent discussing specific donation-related issues.

The benefit of early and consistent involvement by OPO staff may be explained in part by the focused attention that is given to the donor family and the resultant benefit of a relationship with a knowledgeable, caring person. In an era of shortages of key healthcare personnel and hospital units stretched beyond capacity, the addition of personnel who can focus on this essential aspect of the donation process is clearly essential. Other members of the healthcare team could also be effective providers of these services, with the necessary training and the time to devote to talking with the family.

Best practices identified through the Breakthrough Collaboratives emphasize flexibility in determining who is the appropriate person to talk with the family, when to have the discussion, and how to approach the topic. This point is evident in the trend in requesting that has gone from designated requester to effective requester to effective requesting. A recent break-

through collaborative learning session (HRSA, 2005b) identified several characteristics of effective requesting. These include:

- Focus on the family and provide compassionate care. Acknowledge the uniqueness of each family situation, and do not rely on a set of scripted statements.
- Determine the most appropriate requester and the timing on a case-by-case basis. Families of patients who have been in the ICU for extended lengths of time may have developed a bond with a specific nurse or physician or may be more accepting of an impending death and willing to discuss organ donation at an earlier point than families in a more acute crisis.
- Question assumptions regarding ethnic and cultural variations among those who are likely to donate or not donate.
- Discuss donation as an opportunity, and consider the use of language that emphasizes the benefits to the transplant recipient and the healing that this can bring to the donor family.
- Continue to provide excellent-quality care to the family, regardless of the donation decision.

These requesting practices are consistent with other end-of-life practices surrounding other decisions during the dying process, such as discussions on the withdrawal of life-sustaining therapies or the use of cardiopulmonary resuscitation. The integration of these requesting and inquiring practices increases the likelihood that the healthcare professionals caring for critically ill and dying persons will see organ donation not as a totally separate activity but as one integral to the end-of-life care that they are already providing.

Hospitals and OPOs use a variety of structures to optimize the staffing that will work for their geographic area and population. For example, Life Gift in Houston, Texas, has OPO staff working as in-house coordinators in the core hospitals with maximum donor potential. An OPO covering a wide geographic area works closely with the hospital staff who often talk with the families about organ donation. Given the time-intensive efforts required to meet the needs of the family during end-of-life care (Truog et al., 2001), many OPOs have hired family advocates who work on staff in addition to transplantation coordinators. The California Transplant Donor Network uses family resource teams who provide quality care to the family, irrespective of the family's decision to donate.

South Carolina's OPO, Life Point, restructured the procurement coordinator position into five separate positions (clinical services liaison, family support counselor, donor clinician, recovery coordinator, and aftercare coordinator), each of which has specific functions and goals (Sade et al., 2002). Such a structure allows the formation of an interdisciplinary team in which each member can use his or her expertise to support the family (for

example, family support counselors provide bereavement counseling and social work expertise). Such models are consistent with interdisciplinary palliative care models. In institutions with palliative care programs, natural collaborations may develop among palliative care providers, critical care professionals, and OPO staff that provide the families of potential organ donors with the needed services.

Some data suggest that the rates of donation by members of minority groups can be increased through the use of ethnically sensitive in-house coordinators or like-to-like requesters (Kappel et al., 1993; Gentry et al., 1997; Shafer et al., 1997). Although these results appear to be convincing, not all studies support the use of race- or ethnicity-specific requesters. With improved training in cultural competence, it is possible that ethnically sensitive requesters could be just as effective as requesters of the same ethnicity as the family.

As seen in the progress made in a short time by the Organ Donation Breakthrough Collaboratives, the methods used to request organ donation will continue to evolve. Research to explore the optimal models for organ donation requests, identify the key components of those models, and provide validation of the models being disseminated through training and other educational initiatives would be beneficial.

Several curricula and methods are used throughout the country to train healthcare professionals (including nurses, physicians, OPO staff, bereavement staff, and family advocates) on effective requesting. Although a standard curriculum is not necessary, the committee concludes that research is needed to explore the key components of training modules and to validate the effectiveness of those models.

A FRAMEWORK OF TRUST

One of the key elements in the success of organ donation and transplantation is the level of trust in healthcare professionals and the healthcare system. A recent IOM report (2000c) recommended aligning organ donation with quality care at the end of life. It asserted that "trust depends on the knowledge that the best care will be provided to all patients regardless of decisions about organ and tissue donation" (IOM, 2000c, p. 17). Indeed, opinion polls often indicate that distrust or mistrust of the healthcare system is a reason for the reluctance of individuals to become donors or of families to donate a deceased relative's organs (Chapter 2).

The provision of health care is a human activity based on trust between patients and healthcare professionals. Everyone wants, needs, and deserves trust in healthcare relationships. Yet, trust is a complex concept with a variety of meanings (Reina and Reina, 2006). At a minimum, trust is confidence in and reliance upon others, whether individuals, healthcare profes-

sionals, or organizations, to act in accord with accepted social, ethical, and legal norms. In organ donation, a key donation-related factor for individuals and families is whether it is reasonable for them to place their trust in the healthcare professionals and the organizations seeking to obtain organs from their deceased loved ones. For healthcare professionals and organizations, a key task is to ensure the reasonableness of the trust placed in them. Unless healthcare professionals and organizations can count on widespread trust, many of the proposals examined in this report will not be effective.

Consider, for instance, using an "expected donation" approach with the family of a deceased person whose donation wishes are not known but who, if alive, the family believes would have wanted to donate his or her organs. Approaching such a family in this way will be ineffective and even counterproductive if the family lacks trust in the professionals and organizations involved. At best, trust is fragile; but it is particularly fragile when the families, whose trust is needed to consent to organ donation, are confronting a major tragedy in their lives: a loved one's death.

If trust is confidence in and reliance upon others to act in accord with social, ethical, and legal norms, the basis of that confidence then becomes the question. The most immediate basis is the trustworthiness of the requester, whether an individual healthcare professional or an organization. Yet, trustworthiness has at least two dimensions. One is demonstrated competence, that is, the capacity or ability to perform certain tasks; the other is a demonstrated commitment to the social, ethical, and legal norms. The first dimension is especially but not only technical; the second dimension is especially but not only a matter of dispositional character (or, in organizational terms, the makeup and direction of the system). The former has been termed competence trustworthiness (Reina and Reina, 2006), and the latter has been termed normative trustworthiness (i.e., the enacted commitment to social, ethical, and legal norms). Both are essential in a system that seeks to improve the rates of deceased organ donation.

Several tasks are central to *competence trustworthiness* in the context of seeking higher rates of organ donation: quality end-of-life care, accurate determination of death, and effective organ recovery. These competencies, which have been established by professional societies and regulatory agencies, create clear expectations about professional responsibilities, and involve a mechanism for monitoring and accountability. Moreover, these competencies align with ethical and legal standards of care. Embedded in these competencies are technical skills (i.e., determination of death); interpersonal, relational, and communication skills; and decision-making and organizational skills. Although the provision of quality end-of-life care is improving across the country, concurrent improvements in organ donation processes and end-of-life practices and processes are needed to create the trustworthiness necessary to improve donation rates.

The development of valid and reliable programs for certification of the professionals with various roles in the process of organ recovery can further enhance competence trustworthiness. The certification process aims to define and validate the knowledge base and competencies that are necessary to perform a particular role. Certification offers a method for establishing benchmarks for professional competence. To discharge well their responsibilities to the whole range of stakeholders—patients, families, and the public—healthcare professionals and OPO staff members must have access to effective ways to gain competence in end-of-life care, determination of death, and organ recovery. Evidence-based, validated curricula are necessary to support the achievement of certification and reliability in donation processes. This will be particularly important as innovative practices develop, for example, in DCDD.

Healthcare organizations demonstrate competence trustworthiness by putting into place integrated systems with clinical, educational, and administrative infrastructures that enable healthcare professionals to practice in accord with these competencies and achieve the outcomes that the process was designed to reach. Interdisciplinary teams of healthcare professionals and OPO staff who work collaboratively must be able to design systems to promote organ recovery that are flexible; that are aligned with the systems, structures, and cultures of their institutions; and that are effective. The methods used in the Breakthrough Collaboratives to engage interdisciplinary teams within a variety of healthcare organizations illustrate the flexibility needed to both respect and work effectively with the diverse organizational structures and climates where organ donation occurs. Through self-organizing teams, members of the Breakthrough Collaboratives designed unique approaches that have produced significant increases in the rates of organ donation.

Normative trustworthiness is also indispensable. One essential condition for normative trustworthiness is transparency. Patients and families need to be able to understand and appreciate the professionals' and organizations' commitments to social, ethical, and legal norms. As outlined in Chapter 3, these norms include the dead donor rule; acceptance of the decedent's previously stated preferences about donation as prima facie binding; honest disclosure of information relevant to end-of-life care and other decisions, including organ donation; respect for the family's preferences when the decedent's preferences are unknown; avoidance of coercion, exploitation, and unfairness; and protection of confidentiality. Several of these are broad norms applicable to most areas of health care, not just to end-of-life care and organ recovery.

Within the context of efforts to obtain transplantable organs, it is important that the processes used be perceived to be impartial. Hence, consistency and reliability are essential. For example, the consistent and

reliable application of the criteria used to determine death, the use of reliable processes for determining donation preferences and acting upon them, and the use of consistent criteria for organ allocation are necessary to assure the public that the organ donation system is indeed trustworthy. Another crucial factor for trust appears in collaborative arrangements: a division of roles and responsibilities is essential to avoid the reality and the perception that a conflict of interest exists. Of particular importance is the clear separation of processes and personnel who are simultaneously caring for both donors and organ recipients.

Several of these norms identify what should be done or what should not be done, but other important questions arise about how the tasks should be discharged. For instance, the honest disclosure of information about end-of-life care decisions, including organ donation, should be sensitive, particularly in addressing cultural or religious issues. Intentional recognition of the ways that trust can be built and inadvertently broken during the donation and organ recovery process is essential in designing a system that can fulfill its mission.

NEXT STEPS

In building on the existing system and the many changes that are under way, it is important to sustain the momentum in part by ensuring that healthcare and transplantation professionals have the training and support that they need to carry out their tasks. It is the committee's belief that the next steps to improving the organ donation system are to sustain continuous quality improvement, integrate organ donation requests with end-of-life care, enhance training in end-of-life communication and decision making, improve training on the criteria used in both neurologic and circulatory determinations of death, and continue to refine the process for donation requests.

Sustain Continuous Quality Improvement

As described above, the Breakthrough Collaboratives focus specifically on improving the current system for obtaining and transplanting organs. However, the goal of a collaborative is not merely to achieve the specific breakthrough improvement around which it is organized. Its long-term goal is to lay the foundation for ongoing quality improvement through the use of quality improvement methods, in the particular area of the original collaborative, and in the organization as a whole. Ideally, a breakthrough collaborative teaches quality improvement methods, enables participants to experience success in achieving a significant improvement, and begins a transformation of the organization's culture that will enable it to continue

to improve. In fact, quality improvement is also referred to as continuous quality improvement, which reflects the fact that quality improvement is properly understood as an ongoing part of the organization's normal healthcare operations and mindset rather than a set of discrete projects. To the extent that this happens as a result of the collaboratives, organizations will sustain the improvements achieved and may, in fact, find new ways to improve outcomes in the future.

To facilitate continuous quality improvement, HRSA, CMS, and private insurers (where relevant) should ensure that quality improvement efforts are recognized as part of normal organizational healthcare operations and should reimburse accordingly. It would also be desirable to provide some ongoing funding for technical assistance and the ongoing interaction of organizations around the use of quality improvement methods to improve the organ donation process. An emphasis should be placed on rigorous data reporting and analysis to ensure that the data collected are complete and of the highest quality.

Quality improvement methods are well suited for exploring the implications of the integration of organ donation and end-of-life care, as described below.

Integrate Organ Donation and End-of-Life Care

One of the overarching principles set forth by the Organ Donation Breakthrough Collaboratives is to "integrate organ donation fully into routine roles and responsibilities" while recognizing the diverse characteristics of hospitals involved in organ donation and transplantation (HRSA, 2003, p. v). Given this call for integration, the committee believes that the process of organ donation rightly belongs within the context of end-of-life care. To date, efforts to increase donation have not explicitly acknowledged this potential (Williams et al., 2003), even though policies and clinical practices in some hospitals and OPOs may include them (DHHS, 2000; HRSA, 2003).

The framework of end-of-life care, a component of palliative care,[4] is grounded in respect for individuals and families, respectful communication and decision making, and compassionate care, all of which are essential to the organ donation process. Over the past 10 years, palliative and end-of-life care have been recognized as an integral part of the care provided to critically ill and injured patients and their families (Lo et al., 1999;

[4]Palliative care provides the overarching framework for enhancing quality of life, diminishing pain and suffering, promoting advance care planning, supporting communication and values-based decision making, and providing bereavement support to families after a loved one's death (IOM, 1997).

Shannon, 2001; Truog et al., 2001; IOM, 2003; Curtis, 2004; Tulsky, 2005). Building on the recommendations of previous IOM committees (1997, 2003) and others (Hastings Center, 1987; AACN, 1998), clinical practice guidelines are now available for quality palliative and end-of-life care (National Consensus Project Steering Committee, 2004). Furthermore, progress has been made in integrating end-of-life care into the guidelines, protocols, and standards for critical care professionals (Lo et al., 1999; Shannon, 2001; Truog et al., 2001; Gilmer, 2002; Rushton et al., 2002; IOM, 2003; Curtis, 2004; Tulsky, 2005). Although a gap remains between the guidelines and the systematic integration of those guidelines into clinical practice across the country, progress in integration is being made.

An integrated model would emphasize patient- and family-centered care, interdisciplinary teams, and institutional alignment. Although unintended, one result of the current supply-demand approach is the perception that the goal of the donation request process is to get *consent* rather than to offer dying patients or their families the *opportunity* to consider donation as a natural part of dying and death (Australian and New Zealand Intensive Care Society, 1998; Streat and Silvester, 2001; Rocker, 2002; Streat, 2003, 2004; Williams et al., 2003; JCAHO, 2004).

Use of an integrated approach would expand the measures of success of the organ donation process to include whether appropriate donors were identified, whether the family was offered the option of donation (if the deceased person's wishes were unknown), and whether quality end-of-life care was provided. Other measures would include the quality of the communication about the patient's dying process and death, the availability of resources for emotional and spiritual support, the management of pain and other symptoms, the offering of end-of-life closure and rituals, and the provision of bereavement services and resources. The assumption, which has not yet been established empirically, is that the provision of excellent end-of-life care would translate into higher rates of organ donation (Williams et al., 2001).

Quality end-of-life care is still a goal rather than a reality for many institutions and organizations. Quality improvement processes and practices need to be implemented in tandem with efforts to enhance organ donation rates. Further, there is still much to be learned about how to develop and follow through on advance care directives. Nationwide efforts have focused more on the designation of healthcare agents who are able to effectively advocate for incapacitated persons. It will be incumbent on OPOs and the transplant community, as they work with hospitals and other healthcare facilities, to improve support for individuals and their families regarding end-of-life care decisions particularly through communications with healthcare professionals, patient and family education about end-of-life decisions and decision-making, and provision of opportunities for or-

gan donation. The confidence and trust in quality health care needed to promote and encourage organ donation are the same goals as those needed to ensure optimal end-of-life care. To isolate organ donation from the broader context of end-of-life care has the potential to ultimately undermine the effectiveness of efforts to increase donation rates.

Emphasis on Patient and Family Relationships

An end-of-life care framework acknowledges that care is for the patient and his or her family and continues through the patient's death and the family's bereavement. Respect for individual choices is central to a framework of end-of-life care. Likewise, respect for a person's competent choice about organ donation will guide decisions at the end of life.

Ideally, patients will have formally designated a proxy decision maker by executing a durable power of attorney for health care. In some cases, however, patients may not know or may not have discussed their preferences with family members or healthcare professionals. In a study focusing on surrogate decision making in end-of-life care, researchers found that the surrogate decision makers experienced less stress when they knew their loved one's preferences and when those preferences were documented in an advance directive (Tilden et al., 2001). By themselves, however, advance directives cannot eliminate the burdens of decision making at the end of life, in part because they are rarely clear enough or specific enough to dissolve all uncertainty and ambiguity (Tulsky, 2005).

In situations in which the deceased person's wishes have not been documented, an end-of-life care framework suggests that conversations with families be framed in terms of what most people would want if they were alive to state their desires and what most aggrieved families would want if they were able to step outside their grief. Attitude surveys consistently show that most people would want to donate and that most families are touched by the message that organ donation is an opportunity to bring some good out of their tragedy.

Because families are the most common surrogate decision makers at the end of life, it is essential that a framework for end-of-life care and organ donation be family centered. Shannon (2001) asserts that the families of critically ill patients play three important roles: they contextualize the patient's life, they serve as proxy decision makers, and they are themselves the recipients of care. Families are often the people who know the critically ill patient best and are able to help healthcare professionals understand the patient's values; preferences; and interpretations of the meaning of treatment, dying, and death. They also commonly serve as proxy decision makers when patients are no longer able to speak for themselves, for instance, because of a severe brain injury or some other catastrophic disease process.

Although concerns are frequently raised about families overriding patient's preferences, there is little or no empirical evidence that this practice is widespread (Chapter 2). In an end-of-life care framework, the presumption would be that decisions about organ donation would be consistent with the patient's recorded wishes in the absence of current and compelling evidence that the patient changed his or her mind. This presumption is consistent with clinical, ethical, and legal practices in decisions about other forms of end-of-life care. In view of the importance of the potential donor's prior wishes, it is appropriate to elicit and document the individual's views about organ donation at different times in the context of discussing a range of preferences about end-of-life care.

Use of Interdisciplinary Healthcare Teams

Increasingly, hospitals are developing interdisciplinary palliative care teams, inpatient hospice units, and bereavement programs (Manfredi et al., 2000). Consistent with an end-of-life care model, interdisciplinary teamwork is essential (National Consensus Project Steering Committee, 2004). Recently, models of training in the organ donation process have highlighted the importance of an interdisciplinary team that includes OPO staff and that closely collaborates with OPO staff. Although various roles within the process can be handled by individuals from different disciplines, there is a consensus that an interdisciplinary team approach is the most effective for achieving positive donation outcomes (DHHS, 2000).

An expansion of this approach would include the integration of organ donation and recovery practices into end-of-life protocols. The Nebraska Health System, for example, created the Acute Bereavement Service to ensure a consistent and caring approach to potential donor families (DHHS, 2000). Its interdisciplinary team provides comprehensive services to potential donor families and reports a nearly 100 percent rate of referral of hospital deaths to the OPO. New partnerships among critical care professionals, palliative care and bereavement specialists, and OPO staff would help to achieve full integration.

Enhance Training in End-of-Life Communication and Decision Making

The healthcare professional's level of comfort in discussing organ donation is associated with an increased likelihood that families will donate their loved one's organs (Siminoff et al., 1996, 2002). Increasingly, critical care professionals have access to education and resources aimed at enhancing their competencies in palliative and end-of-life care, particularly communication skills (Tulsky, 2005). These skills, which are transferable to the process of caring for a dying person who is also a donor candidate, include

the provision of humane and compassionate care, whatever the decision about donation; the relief of suffering; maintenance of respect and dignity; and nonabandonment of the patient or the patient's family (Heyland et al, 2002, 2003). Also important is the responsibility of all members of the team to foster an environment with an adequate infrastructure and sufficient resources in which patients and their families are given the opportunity to consider the option of organ and tissue donation (HRSA, 2003). Building on the successes of the Organ Donation Breakthrough Collaboratives and HRSA's demonstration projects, national initiatives for interdisciplinary training and models of collaboration should continue to be supported and expanded.

Effective communication about organ donation and end-of-life care is difficult in a culture of critical care that focuses on rescuing patients from death rather than integrating the goals of critical care with palliative and end-of-life care (Danis et al., 1999; Lo et al., 1999; Rushton et al., 2002; Curtis and Rubenfeld, 2005). Families of ICU patients often express concerns about the adequacy, reliability, and timeliness of communication about healthcare issues (SUPPORT Principal Investigators, 1995; Pierce, 1999; Azoulay et al., 2000; Heyland et al., 2002, 2003); and research on communication at the end of life continues to document deficiencies (Pierce, 1999; Azoulay et al., 2000; Kirchhoff et al., 2000; Heyland et al., 2002). Dissatisfaction with care at the end of life focuses on communication and decision making (SUPPORT Principal Investigators, 1995) and often arises from the perception of a lack of complete and consistent information and of inadequate respect and compassion for the patient and family (Heyland et al., 2002, 2003). These problems likely affect the process of organ donation in critical care settings.

Although there are curricula for end-of-life care, there are "few, if any, validated training models in EOL [end of life] care developed specifically for organ donation" (Williams et al., 2003, p. 1571). Few physicians and nurses have been trained in the skills of communication and problem resolution that may be important when clinicians broach end-of-life issues and options with patients and their families (Murphy et al., 2001). Clinicians often have misconceptions about basic ethical principles and beliefs that are widely shared in the bioethics literature and promoted by national professional organizations (May et al., 2000). Such misconceptions can make end-of-life decision making more difficult by erecting unwarranted barriers. Added to this mix are the comfort levels of healthcare team members discussing organ donation, along with misconceptions and misperceptions about neurologic determination of death, organ donation, and procurement (Siminoff et al., 2001a,b). Recent preliminary work with an experiential learning model suggests that interdisciplinary training can significantly increase consent rates (Tartaglia and Linyear, 2000; Williams et al., 2001).

A comprehensive meta-analysis of the effectiveness of such models is warranted, and the best ones should be replicated for interdisciplinary training.

SUMMARY AND RECOMMENDATIONS

This report is being written at a time when significant efforts are under way to improve the organ donation system, particularly those focused on improving the consent rates for donation after neurologic determination of death. The Organ Donation Breakthrough Collaboratives are working to galvanize the efforts of hospitals and OPOs to develop and implement continuous quality improvement methods and thereby create changes in policies, practices, and structures. Future support for continuous quality improvement efforts is critical to the progress of organ donation efforts.

The opportunity to decide whether to be an organ donor is an important dimension of end-of-life decision making. Patients and their families should be offered this opportunity as standard end-of-life care, and information on organ donation processes should be an integral part of the many other decisions that are faced at this time. For the organ donation process to be fully integrated into end-of-life care, a wide range of healthcare professionals need enhanced awareness of and training regarding the donation process. Moreover, it will be necessary for healthcare institutions to develop or improve their end-of-life care processes and competencies.

Recommendation 4.1 ***Sustain Continuous Quality Improvement Initiatives.***
HRSA should be sufficiently funded to provide technical assistance to hospitals and OPOs for continuous quality improvement efforts, including the identification and dissemination of best practices. An infrastructure that can support the collaboration, the dissemination of findings, and evaluations of the Breakthrough Collaboratives should be funded. Furthermore,

- **Individual OPOs and hospitals should develop, implement, and evaluate continuous quality improvement processes.**
- **Accrediting and monitoring organizations, such as the Association of Organ Procurement Organizations, Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and National Committee for Quality Assurance (NCQA) should require and monitor measures of continuous quality improvement, including process measures as well as conversion rates.**
- **HRSA, the Centers for Medicare & Medicaid Services, and private insurers (where appropriate) should ensure that organizational quality improvement efforts are recognized as part of normal healthcare operations and should be reimbursed accordingly.**

Recommendation 4.2 ***Increase Research on Innovative System Changes.***
HRSA, the National Institutes of Health, and the National Center on Minority Health and Health Disparities should be allocated funds sufficient to increase research efforts to identify further innovative and effective system changes for improving the organ donation process and increasing the rates of organ donation and to evaluate the impacts of such changes on the healthcare system. Research efforts should be evidence based, interdisciplinary, and culturally relevant.

Recommendation 4.3 ***Strengthen and Integrate Organ Donation and Quality End-of-Life Care Practices.***
Hospitals, OPOs, and other healthcare entities should consider how best to integrate the organ donation process with quality end-of-life care practices. Interdisciplinary teams should align end-of-life protocols, practices, and guidelines with organ donation protocols.

Recommendation 4.4 ***Enhance Training for Healthcare Professionals.***
HRSA, in collaboration with palliative care and other professional associations representing diverse disciplines and specialties (including, but not limited to, critical care professionals, transplantation professionals, social workers, and clergy), should strengthen training in end-of-life practices and organ donation, including processes of communication and decision making, with the goal of establishing a knowledgeable and positive environment that supports organ donation.

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5

Expanding the Population of Potential Donors

Much of this report has focused on increasing the rates of donation by the small and relatively static population of deceased donors for whom there has been neurologic determination of death. Of the more than 2 million deaths that occur each year in the United States, it is estimated that there are only 10,500 to 16,800 eligible donors with neurologic determination of death (Guadagnoli et al., 2003; Sheehy et al., 2003). This chapter focuses on expanding the opportunities for donation to the much larger segment of U.S. deaths, those with circulatory determination of death. Because most Americans support organ donation and many have designated their consent for donation by signing their driver's license or a donor card or by joining a donor registry, it is important to identify ways in which these individuals can have the opportunity to be organ donors after they die.

This chapter builds on the work of two previous Institute of Medicine (IOM) reports (IOM, 1997, 2000) that emphasized the importance of developing the nation's capabilities for donation after circulatory determination of death (DCDD). It is not possible for this chapter to provide in-depth coverage of the many issues that must be addressed on this topic; however, the committee urges that its recommendations be actively pursued, as there is an opportunity to significantly expand the number of organ donors and thereby provide improved health and lifelong benefits for transplant recipients.

The chapter begins with an overview of some of the key terminology that is involved and presents a brief synopsis of the clinical issues that present both challenges and opportunities for DCDD. Since DCDD has been a topic of considerable discussion, the chapter presents the highlights

of recent conferences and major reports. It then examines general ethical considerations, before focusing on the ethical issues specific to controlled and to uncontrolled DCDD. Because uncontrolled DCDD has not been fully explored, the chapter provides an estimate of the potential number of donors as well as outlining major challenges in moving forward in this area. An additional group of potential donors are those with age or medical characteristics outside of the standard criteria for organ donation. Issues relevant to expanded criteria donors are discussed. The chapter concludes with the committee's recommendations on DCDD and expanded criteria donation.

BACKGROUND AND ISSUES

Determination of Death

The fundamental tenet of organ donation is the dead donor rule, that is, that organ donation should not cause or hasten death (Robertson, 1999). As discussed in Chapter 1, the advent of external ventilation technologies and other technological advances led to the development of criteria for neurologic determination of death (based on the irreversible loss of function of the whole brain, including the brain stem) and to clarification of criteria for circulatory determination of death (irreversible cessation of circulatory function) (Report of the Ad Hoc Committee, 1968; President's Commission, 1981).

However, the terminology that has arisen, specifically, the terms *brain death* and *cardiac death*, has often been misunderstood and thought to imply only the death of an organ—either the brain or the heart—and not the death of the human being. The committee believes that it is particularly important to clarify the terms that are used so that it is fully understood that death can be declared or determined by a physician either by the use of neurologic criteria or by the use of circulatory criteria.

When it is necessary to distinguish between the ways in which death is determined, the committee suggests using the terms *neurologic determination of death* (NDD) or *circulatory determination of death* (CDD). In either case, organ donation occurs only after death. Because different kinds of protocols and procedures are used to recover organs from individuals who have died according to these two criteria, it is useful to distinguish between donation in these different contexts. The committee recommends a change in terminology to *donation after neurologic determination of death* (DNDD) and *donation after circulatory determination of death* (DCDD).[1] The com-

[1]Donation after circulatory determination of death was previously termed "non-heart-beating donation" or "donation after cardiac death."

mittee believes that current misperceptions justify the shift to a more detailed terminology to clarify important concepts that are particularly relevant to organ donation and transplantation. The change in terminology emphasizes that the starting point for organ donation is death—death that is determined by using one of two sets of criteria. For the most part, it is not necessary to qualify the way in which the determination of death is made, but when the distinction is made, it must be clearly stated.

Defining Controlled and Uncontrolled Death

The circumstances of death because of cardiac arrest or other causes leading to circulatory determination of death vary widely. Many cardiac arrests occur in the home and at other sites outside of the hospital setting. As a result, a number of factors (such as the duration of time before emergency care is provided and the availability of healthcare professionals and medical equipment) can affect the viability of the organs and the potential that they can be transplanted. In some other circumstances of death, the patient is on ventilatory support and the discussion of donation occurs only after an independent decision to withdraw supportive technologies.

In 1995, a categorization schema was developed to address the various circumstances of circulatory determination of death. The Maastricht categories (Box 5-1) outline the circumstances of controlled (or expected) death (Maastricht Category III), in which death is anticipated and occurs after medical supportive therapy is withdrawn, usually in an operating room or hospital intensive care unit, and within a closely monitored time frame. Unexpected or uncontrolled death (Maastricht Categories I, II, and IV) occurs in circumstances in which cardiopulmonary function ceases spontaneously, often with death occurring in an unanticipated fashion, frequently outside the hospital setting or in a situation in which less is known about the viability of the organs; these deaths often involve the loss of circulatory function before the neurologic determination of death (Kootstra et al., 2002;

BOX 5-1
Maastricht Categories
(as described in Kootstra et al., 1995, p. 2893)

I. Dead on arrival
II. Unsuccessful resuscitation
III. Awaiting cardiac arrest
IV. Cardiac arrest while brain dead

Doig and Rocker, 2003). For Maastricht Categories I, II, and IV, there is a greater likelihood of a long interval between the cessation of circulatory function and the opportunity for the initiation of organ preservation or removal.

The terms *controlled* and *uncontrolled* are subject to misinterpretation. Donation after either controlled or uncontrolled circumstances of death occurs only after a series of carefully delineated procedures and medical protocols have been followed. Controlled (or expected) circumstances of death typically occur after the family or surrogate has made the decision to withdraw support measures. In uncontrolled (unexpected) circumstances, death occurs after emergency medical procedures and resuscitation measures have been exhausted and are no longer productive. The committee is concerned that the term *uncontrolled* has been misunderstood on some occasions to imply a lack of procedure or protocols. Other terms, such as *unexpected*, *unanticipated*, or *unplanned,* may be better descriptors of the circumstances of death.

Organ donation in cases of expected or controlled death can differ from donation in cases of unanticipated or uncontrolled death in several ways: in the time to initiation of the preservation of the organs to be transplanted, in the psychological preparation of the family, and in the ascertainment by the healthcare team of the potential for organ donation. In controlled-death situations, the family can decide when and where life-sustaining measures will be discontinued (Edwards et al., 1999). In situations involving unanticipated or uncontrolled deaths, there may be many more unknowns; healthcare professionals may arrive after the patient has collapsed and the length of time with hypotension, cardiovascular shock, or cardiac dysrhythmia may be unknown. In general, the kidneys, lungs, liver, and pancreas can be recovered after circumstances of controlled death because the organs can continue to receive oxygenated blood until nearly the time of recovery. Kidneys and lungs are the primary organs recovered after death in uncontrolled situations, since their viability is maintained for longer periods of time (Egan, 2004). Because individuals needing kidney transplants comprise more than 70 percent of the individuals on the transplant waiting list as of March 2006 (OPTN, 2006), it is important to explore the potential of DCDD in both controlled and uncontrolled circumstances as a means to achieve increased donation rates.

Controlled DCDD[2] is the area that has been the most developed by U.S. programs; uncontrolled DCDD has been utilized primarily in Europe and in

[2]As noted above, the terms *controlled* and *uncontrolled* describe the circumstances of the death. The phrases *controlled DCDD* and *uncontrolled DCDD* are used in this report to describe donation after each of these circumstances of death.

a few pilot programs in the United States (see below). It is important to note that in the early days of transplantation, DCDD protocols were frequently used, and in some organ procurement organizations (OPOs), it remained a common practice into the 1980s. In recent years, organ recovery from DCDD has again become more commonplace.

General Considerations

As with many aspects of organ transplantation (Chapter 6), there have been misperceptions about DCDD. In particular, there have been concerns that death is hastened or that the patient's best chance for survival is compromised in some other way by measures that are used to preserve the viability of the organs for transplantation. Therefore, it is important to clarify the practical aspects of this process. Although it is uncomfortable to discuss the issues around death and, particularly, those that deal with the body after death, openness and clarity about the events that occur in the process of DCDD are very important. Furthermore, healthcare and transplantation professionals must ensure that all aspects of the planning and development of DCDD protocols are transparent and open to a wide range of patient and stakeholder inputs.

Successful transplantation of an organ from a deceased donor requires that the organ be viable, a goal that can be met by minimizing the ischemic injury caused by a lack of bloodflow carrying oxygen and other nutrients to the organ(s). The length of time in which the organ can be deprived of oxygen (ischemic) and still be successfully transplanted varies among types of organs. Thus, measures to ensure organ viability for transplantation (and decrease ischemia) must be initiated as rapidly as possible after the patient's death.

In cases of neurologic determination of death, after death is declared—and when there is consent for organ donation—continuous cardiopulmonary function is achieved with artificial assistance until the organs are removed, permitting high-quality circulation of oxygenated blood to maintain organ viability. For individuals who have had cardiac arrest, advanced cardiac life support protocols are followed (Box 5-2) and may be continued as the patient is transported to the hospital. In some cases, all resuscitation measures are administered in the home or other field setting; and if they are found to be nonproductive in regaining heart function, death can be declared in the field by emergency medical personnel, in consultation with a physician. In cases of circulatory determination of death, individuals are generally not on ventilatory support at the time of death, so there is an immediate need to proceed with organ-preserving measures to limit the damage from warm ischemia and improve the viability of the organs for transplantation (Bos, 2005).

BOX 5-2
Common Criteria for Termination of Advanced Cardiac Life-Support Efforts

Termination of advanced cardiac life-support efforts occurs if there is no response after the following interventions have been performed:

- Acceptable basic cardiopulmonary resuscitation has been provided.
- Ventricular fibrillation has been eliminated.
- An advanced airway device has successfully been placed.
- The operation of the airway device has been confirmed and the device has been secured.
- Oxygen and end-tidal carbon dioxide levels have been monitored to ensure that proper oxygenation and ventilation have been achieved.
- The intervention has been maintained for 10 minutes or longer.
- All rhythm-appropriate drugs have been administered.

SOURCE: Kern et al. (2001).

For cases of controlled DCDD, measures for preservation and recovery may include the administration of medications to improve organ viability, including heparin, or the use of intravenous cannulation or cardiopulmonary assist devices (bypass procedures). After organ removal, pulsatile perfusion may be used for the kidneys to help determine if the patient's organs will be eligible for transplantation. For cases of cardiac arrest in uncontrolled circumstances, there is not time to plan in advance to maintain organ viability, but certain organ preservation measures can be implemented after death is declared.

The outcomes of controlled DCDD transplantation have been found to be similar to those for DNDD transplantation for most organs. The University of Wisconsin has performed DCDD transplantations since 1974, with DCDD donors making up 10 to 15 percent of the total donations annually (Lewis et al., 2003). Researchers at that university reported on 568 organs transplanted from DCDD donors between 1984 and 2003 and found that the patient and graft survival rates for patients receiving kidney, pancreas, and lung transplants were similar for organs from DCDD and DNDD donors (D'Alessandro et al., 2004). Delayed graft function has been found to be higher in kidneys transplanted from DCDD donors, but long-term graft survival is similar to DNDD organs (Weber et al., 2002; Droupy et al., 2003; Cooper et al., 2004; D'Alessandro et al., 2004). Researchers have found that the liver is more susceptible to warm ischemic injury (Abt et al., 2004; Foley et al., 2005).

Much remains to be learned about methods to improve organ viability and to preserve organs recovered through both DCDD and DNDD. Re-

search efforts in these areas continue (see, for example, Magliocca et al., 2005) and need to be bolstered.

Prior Reports and Recommendations

IOM has released two previous reports on DCDD, formerly known as *non-heart-beating organ donation* (NHBD) and *donation after cardiac death*. The first report, *Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement*, undertaken at the request of the U.S. Department of Health and Human Services and published in 1997, noted that organ donations from living donors and DNDD donors would not bridge the widening gap between organ supply and demand in the United States (IOM, 1997). Despite the clear need to increase the rates of organ donation, the report found that the majority of transplantation programs in the United States did not have a mechanism or protocol for organ recovery after DCDD. The small number of programs with active involvement in DCDD concentrated virtually all of their efforts on controlled DCDD (Cooper et al., 2004).

Although implementation of uncontrolled DCDD protocols and programs is recognized as an opportunity to greatly increase the number of potential organ donors (especially kidney donors), the need to limit the warm ischemia time by means of early postmortem cannulation and cooling has raised the fundamental ethical issue of initiating organ preservation before informed consent is obtained from family members. At the time that the IOM report was published, enabling legislation existed in several other Western democratic countries and in three jurisdictions in the United States (Washington, D.C., Virginia, and Florida) that allowed this practice while the next of kin were being sought for permission for organ recovery (IOM, 2000).

Strong opposition to this position was taken by the American Society of Transplant Physicians (ASTP), who articulated the following reservation: "Uncontrolled NHBDs do not meet the principles of the ASTP, particularly in the area of consent, and therefore, the ASTP does not support the widespread use of this organ source" (IOM, 1997, p. 80). Perhaps in consideration of this testimony, which was concordant with several surveys of public sentiment conducted at the time, the IOM committee concluded: "Cannulation and cooling without consent may be a situation in which a decision based on deference to what the public is prepared to accept may be the wisest policy at the moment" (IOM, 1997, p. 55).

Despite this constraint placed on uncontrolled DCDD, the IOM committee concluded that "the recovery of organs from NHBDs is an important, medically effective, and ethically acceptable approach to reducing the gap that exists now and will exist in the future between the demand for and

the available supply of organs for transplantation" (IOM, 1997, p. 1). That report's recommendations focused on controlled DCDD and suggested that attention be given to greater consistency in DCDD policies and better support for patients and their families, sustaining the integrity of organ procurement efforts, and maintaining public confidence in the organ transplantation system (Box 5-3) (IOM, 1997).

Following publication of the 1997 IOM report, the U.S. Department of Health and Human Services again sought IOM's assistance in facilitating the adoption of protocols for DCDD, consistent with prior IOM recommendations, by all OPOs in the United States. This resulted in the publication in 2000 of *Non-Heart-Beating Organ Transplantation: Practice and Protocols* (IOM, 2000) (Box 5-4). The report's recommendations were congruent with the transplant community's long-standing orientation toward obtaining organs from DNDD donors in a planned, orderly, and controlled fashion. Subsequently, the addition of DCDD donors to the potential donor pool naturally evolved in a parallel direction that favored an emphasis on controlled DCDD. Many of the same challenges discussed in these two reports still confront the widespread adoption and implementation of DCDD. The present report further expands on those recommendations and emphasizes the need for ongoing efforts to ensure that DCDD is a priority for hospitals and OPOs.

A national conference in 2005 examined the essential actions needed to expand the practice of DCDD in the continuum of quality end-of-life care

BOX 5-3
Recommendations of *Non-Heart-Beating Organ Transplantation: Medical and Ethical Issues in Procurement*

1. Written, locally approved non-heart-beating donor protocols;
2. Public openness of non-heart-beating donor protocols;
3. Case-by-case decisions on anticoagulants and vasodilators;
4. Family consent for premortem cannulation;
5. Conflict-of-interest safeguards—separate times and personnel for important decisions;
6. Determination of death (in controlled non-heart-beating donations) by cessation of cardiopulmonary function for at least 5 minutes by electrocardiographic and arterial pressure monitoring; and
7. Family options (e.g., attendance at life-support withdrawal) and financial protection.

SOURCE: IOM (1997).

BOX 5-4
Recommendations of *Non-Heart-Beating Organ Transplantation: Practice and Protocols*

Recommendation 1: All OPOs should explore the option of non-heart-beating organ transplantation, in cooperation with local hospitals, healthcare professionals, and communities. A protocol must be in place in order for non-heart-beating organ and tissue donation to proceed.

Recommendation 2: The decision to withdraw life-sustaining treatment should be made independently of and prior to any staff-initiated discussion of organ and tissue donation.

Recommendation 3: As recommended in the 1997 IOM report, statistically valid observational studies of patients after the cessation of cardiopulmonary function need to be undertaken by appropriate experts.

Recommendation 4: Like all care at the end of life, non-heart-beating organ and tissue donation should focus on the patient and the family.

Recommendation 5: Efforts to develop voluntary consensus on non-heart-beating donation practices and protocols should be continued.

Recommendation 6: Adequate resources must be provided to sustain non-heart-beating organ and tissue donation. Adequate resources are required to cover (1) the costs of outreach, education and support for OPOs, providers, and the public, and (2) any increased costs associated with non-heart-beating organ and tissue recovery.

Recommendation 7: Data collection and research should be undertaken to evaluate the impact of non-heart-beating donation on families, care providers, and the public.

SOURCE: IOM (2000).

and identified a number of ways to increase opportunities for increasing the opportunities for DCDD (Bernat et al., 2006). As discussed at that conference, there is an ongoing need to ensure that all OPOs and hospitals have policies, organizational structures, and institutional support for DCDD and that there is adequate professional education on organ donation under these circumstances.

Furthermore, all DCDD-related efforts must have a strong component of public education, and include measures to strengthen and sustain trust in the medical system. Clear messages and transparent actions are essential for promoting DCDD as an organ donation option. Any episode of inadequate or inappropriate information being conveyed to the public can negatively

BOX 5-5
National Conference on Donation After Cardiac Death (DCD): Specific Actions Proposed for Agencies and Organizations

Association of Organ Procurement Organizations (AOPO)

- Establish a DCD mentorship in its technical assistance program.
- Add a DCD component to OPO accreditation standards.

U.S. DHHS Advisory Committee on Organ Transplantation

- Support studies assessing the frequency of autoresuscitation of patients eligible for DCD and other patients who have died after the withdrawal of life-sustaining therapy.
- Recommend that the Organ Procurement and Transplantation Network (OPTN) modify data submission standards to capture data from Phase I and Phase II clinical trials with the minute-by-minute collection of data to measure systolic and diastolic blood pressure, the level of oxygen saturation, and urine output.
- Provide guidance on issues of informed consent.

OPTN-United Network for Organ Sharing (UNOS)

- Revise transplant center and OPO membership criteria to require DCD protocols.
- Establish organ-specific subcommittees on DCD to address organ-specific suitability criteria and allocation policies.

affect public perception and damage the understanding and trust of the healthcare system regarding organ donation (Chapter 7).

The committee concurs with the actions recommended in earlier IOM reports (Boxes 5-3 and 5-4) and at the National Conference on Donation after Cardiac Death (Box 5-5) and encourages further efforts to overcome the general inertia regarding the full implementation of the policies and practices that will facilitate and expand DCDD. It will be important to focus on the systems changes at the hospital and the OPO levels and will also require that the public and healthcare professionals be engaged in discussions about the complexities of DCDD.

Learning from Past Experience and International Models

Several European countries have developed and have used the infrastructures of both the emergency medical services and the transplantation services to provide optimal emergency care and to be available as needed to

- Conduct financial analysis of the long-term impact of DCD organ use on transplant centers.
- Use regional meetings as a venue for discussion of and education about DCD.

NATCO (The Organization for Transplant Professionals)

- Expand DCD in all NATCO education programs.

American Society of Transplant Surgeons and American Society of Transplantation

- Establish a joint committee to increase DCD recovery and utilization.

Joint Commission on Accreditation of Healthcare Organizations

- Revise accreditation standards to require hospitals to implement DCD protocols.
- Provide an annual DCD report that includes regional profiles, new developments, and trends and outcomes.

Centers for Medicare & Medicaid Services

- Revise regulations governing donation, utilization, and reimbursement to reflect the unique characteristics of DCD procurement and transplantation.

SOURCE: Bernat et al. (2006).

respond to demands for DCDD (Alvarez et al., 2002; Sanchez-Fructuoso et al., 2003; del Rio Gallegos et al., 2004). Furthermore, in the early 1990s efforts were made in Washington, D.C., to develop a program for uncontrolled DCDD.

Washington, D.C.

In the early 1990s, the Washington Hospital Center in Washington, D.C., developed a rapid organ recovery program that focused on DCDD, particularly organ donation from victims of fatal trauma (Kowalski et al., 1996; Light et al., 1996). The emphasis on DCDD donors (termed "non-heart-beating donors" at the time) included a strong component of community education and input (WHC, 1993). A Community Oversight Committee was formed to provide input into the development of the DCDD protocol (Appendix F) and its implementation. Furthermore, the Office of Decedent

Affairs was established and provided continuous, 24-hour-a-day support to donor families and provided the link between the District of Columbia government (particularly, the medical examiner's office), the hospital medical staff, and the families. The office was staffed by family advocates with experience in counseling and crisis management and trained in organ and tissue donation.

The medical criteria established for donors for this program were as follows: the donor had to be 18 to 55 years of age, the time of asystole had to be known, asystole had to be for less than 30 minutes, the donor could have no infection or cancer, the donor had to have negative test results for human immunodeficiency virus and hepatitis B virus, and the donor had to have a low-risk medical history (Kowalski et al., 1996). The program used two procedures to preserve the organs: cannulation of the femoral arterial-venous system to perfuse the kidneys with preservative solution combined with iced peritoneal lavage for cooling (Kowalski et al., 1996). Forty-five minutes was the maximum length of time allowed between cardiac arrest and the beginning of in situ organ preservation. The number of solid-organ donors in the hospital increased from 9 in 1993–1994 to 15 in 1994–1995, with 60 percent of the donors in 1995 coming from the rapid recovery program. Ninety-one deaths met the criteria for the program but the family could not be reached within the 45-minute window needed to begin solid organ preservation. Families of 29 of the 91 decedents were located within 4 hours and 10 of those families consented to tissue donation.

The District of Columbia government amended its Anatomical Gift Act to permit the initiation of organ preservation methods after death and pending consent for donation. If the family could not be reached, the preservation methods were discontinued.

The Washington Hospital Center's program was successful in increasing organ donation rates and in galvanizing community support through public education and extensive opportunities for public input. The program illustrates the potential for communities to come together to support organ donation efforts; the challenges in financing this program, however, led to its discontinuation and point out the necessity of sustained funding sources for such efforts to be fully developed and implemented. Furthermore, there needs to be a broader appreciation of the impact that DCDD could have in terms of the numbers of lives that could be saved as well as the healthcare cost savings that could be achieved by reducing the numbers of people receiving dialysis.

Europe

Several European countries have explored and implemented DCDD programs focusing on patients with unanticipated cardiac arrests. The Hos-

pital Clinico San Carlos in Madrid, Spain, has developed extensive policies and criteria regarding uncontrolled DCDD (Box 5-6). Cardiac arrest is considered irreversible after a minimum 30-minute resuscitation period without a return of the circulation (Sanchez-Fructuoso et al., 2003). The criteria used to identify potential organ donors include no evidence of drug dependency or death by physical violence, and the onset of external cardiac massage and mechanical ventilation within 15 minutes of cardiac arrest. This onset of care within 15 minutes means that acceptable potential do-

BOX 5-6
Modified Madrid Criteria

Criteria used to assess eligibility for kidney and other organ preservation among individuals suffering out-of-hospital sudden cardiac-related death:

1. Age <50 years.
2. Time of cardiac arrest is known; i.e., it is a witnessed event.
3. <15 minutes has elapsed from collapse until cardiopulmonary resuscitation (CPR) is begun, either by a witness (bystander CPR) or trained emergency medical services (EMS) personnel.
4. Appearance (to be reviewed again later in the emergency department [ED]):
   a. No evidence of violence or foul play.
   b. No evidence of chronic disease, such as cancer or AIDS.
   c. No evidence of serious injury to chest or abdomen (head trauma is not an exclusion criterion if there is no evidence of violence or foul play).
5. Continuous CPR with mechanical ventilation is performed during EMS resuscitation, including transport to ED.
6. Pronounced dead after at least 30 minutes unsuccessful CPR by physician not associated in any way with the transplant team.
7. The heartbeat is absent for at least 10 minutes after CPR is stopped.
8. Transplantation team begins cannulation and cooling, obtains requisite blood samples, and, in the absence of a donor card, takes over care under previously agreed conditions of
   a. Presumed consent,
   b. Prior community agreement, or
   c. Enabling legislation.
9. The total warm ischemia time, i.e., the time from the moment of collapse until the establishment of organ preservation, is <120 minutes.
10. The family is contacted and notified of the death according to the institutional protocol.
11. The medical examiner is contacted (depending on local customs and legal requirements).
12. Donation is requested from family within 4 hours by a trained individual from the transplantation team.

SOURCES: Gomez et al. (1993); Alvarez et al. (1997, 2000, 2002).

nors include almost all individuals with in-hospital uncontrolled cardiac-related deaths and most individuals with out-of-hospital uncontrolled cardiac-related deaths.

Deceased potential donors are transported by the emergency medical services personnel to the hospital. The transplantation laws in Spain allow perfusion of the organs through cardiopulmonary bypass while the family is being located and a determination regarding donation is being made (Alvarez et al., 2002). Unique features that facilitate uncontrolled DCDD in Madrid include the use of intensive care ambulances that are staffed by a prehospital physician and nurse who deliver patient care in the field (Alvarez et al., 2002).

Examination of the 1996–1999 data from the Hospital Clinico San Carlos reveals that among 111 potential uncontrolled DCDD donors, 62 patients met the criteria for donation and 53 became actual donors (9 were lost because of an inability to obtain either family or judicial consent for donation after cold perfusion had been instituted) (Alvarez et al., 2000). From these 53 consenting donors, 72 kidneys were transplanted, 80 percent of which had the expected delayed function characteristic of DCDD grafts but had long-term graft survival rates comparable to those of kidneys from DNDD donors (Alvarez et al., 2000). It is important to note that about 40 percent of the 53 donors died of trauma. When the 36-month cumulative probability of graft survival was evaluated as a subset analysis of the same patients in a separate paper, not only were the DCDDs comparable to the DNDDs, but also both within and across these two donor groups, long-term graft functioning was similar whether death was a primary cardiac event or secondary to trauma (Sanchez-Fructuoso et al., 2000).

DCDD efforts in multiple countries (Table 5-1) show the potential for increasing the number of organ transplants, particularly kidney transplants.

TABLE 5-1 Kidneys Obtained as a Result of DCDD

Country	Year	Number of DCDD Donors	Number of DCDD Kidneys Transplanted	Percentage of All Kidneys Transplanted
The Netherlands	2003	87	158	39
Spain	2003	56	80	4
United Kingdom	2003	66	112	9
United States	2003	264	501	4
Japan	1995–2003	867	1,279	25

SOURCE: Adapted from Bos (2005).

ASSESSMENT OF DCDD STRATEGIES IN THE UNITED STATES

Data from more than a decade of assessments are now available to evaluate the effectiveness of augmenting the donor pool by increasing the number of controlled DCDD donors. Between 1994 and 2004 there was a marked proportionate increase in DCDD donors (Table 5-2). However, when viewed in absolute terms, which are the numbers that matter to patients awaiting organs, there were just fewer than 400 DCDD donors in 2004, up from about 60 in 1994. Only 5 percent of all deceased donors in 2004 were DCDD donors (Table 5-2). As might be anticipated, among this relatively small number of DCDD donors, only about 6 percent were the result of uncontrolled DCDD, and most of these were Maastricht Category IV donors (Table 5-2). Data from 2004 show that 1,038 organs were recovered from DCDD donors (Table 5-3), a small fraction of the 26,539 organ transplants in 2004 (HRSA and SRTR, 2006).

In 2004, only 21 of the 59 OPOs in the United States completed five or more DCDD cases. Eighteen OPOs did not have a DCDD case that year (Table 5-4). The potential for DCDD can be seen in the fact that in 2004 only seven donation service areas accounted for 58 percent of all cases of DCDD (HRSA and SRTR, 2006).

Efforts to increase the number of OPOs and transplant centers that are actively engaged in DCDD are ongoing. The Organ Donation Breakthrough Collaboratives (Chapter 4) are working with transplant hospitals and OPOs to increase the number of hospitals with DCDD policies and capabilities.

Because of the large and growing gap between the number of organs available for transplantation and the number of individuals on the transplant waiting list in the United States (Chapter 2), it is important to explore any scientifically credible and ethically acceptable proposal that might increase the organ supply. This may, of necessity, require a reexamination of the sources of organs and strategies for their acquisition that were rejected in the past at a time when the crisis was less acute.

To assess progress in DCDD, it is important for the conversion rate measures to include both DCDD and DNDD cases in the denominator of eligible donors. Currently, the donation rate (also termed the *conversion rate*) is calculated as the number of actual donors (i.e., the organs are removed for transplantation) per the total number of donor-eligible individuals, with donor eligibility defined as "any heartbeating individuals meeting, or imminently meeting, the criteria for neurological death (brain death), age 70 years or under, who have not been diagnosed with exclusionary medical conditions published by the Health Resources and Services Administration" (HRSA and SRTR, 2005, p. X-2). This focus on DNDD hinders the assessment of DCDD efforts and does not place a priority on DCDD.

TABLE 5-2 Deceased Donors, 1994 to 2004

	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
	Number of Donors										
Controlled DCDD	11	46	49	60	48	64	100	151	154	236	366
Uncontrolled DCDD	3	13	18	13	23	4	10	11	22	17	22
Unknown	43	5	4	5	4	19	8	7	13	17	3
Total DCDD	57	64	71	78	75	87	118	169	189	270	391
DNDD	4,017	5,282	5,282	5,354	5,666	5,700	5,848	5,905	5,994	6,178	6,751
Unknown	1,025	16	63	46	52	37	19	6	7	9	8
Total deceased donors	5,099	5,362	5,416	5,478	5,793	5,824	5,985	6,080	6,190	6,457	7,150
DCDD as percentage of total[a]	1.1	1.2	1.3	1.4	1.3	1.5	2.0	2.8	3.1	4.2	5.5

NOTE: OPTN data indicate that most of the uncontrolled DCDDs were Maastricht Category IV deaths.

[a]DCDD donors as a percentage of total deceased donors.

SOURCE: Based on OPTN data as of September 8, 2005.

TABLE 5-3 Organs Recovered from DCDD Donors in the United States, 2004

	Number of Organs Recovered			
Cause of Death	Kidney	Liver	Lung	Pancreas
Controlled DCDD	689	233	10	47
Uncontrolled DCDD	42	8	0	1
Unknown	6	1	0	1
Total DCDD	737	242	10	49

SOURCE: Based on OPTN data as of September 8, 2005.

TABLE 5-4 DCDD Cases Reported by OPOs, 1994 to 2004

	Number of OPOs Reporting										
Number of DCDD Cases	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
0	45	44	45	45	47	42	31	26	29	24	18
1 to 4	17	17	16	13	11	14	22	23	16	18	20
5 to 10	5	5	4	5	4	5	5	4	7	9	10
>10	0	0	1	1	1	1	3	6	7	8	11
Number of OPOs	67	66	66	64	63	62	61	59	59	59	59

SOURCE: Based on OPTN data as of September 8, 2005.

GENERAL ETHICAL CONSIDERATIONS

When the IOM committees examined DCDD in both 1997 and 2000, they acknowledged that DCDD raises numerous potential ethical issues, and they presented both general ethical principles and specific rules to guide DCDD. The present IOM committee concurs with the general ethical principles established in the 1997 IOM report, and these have subsequently been embraced by both U.S. and Canadian multistakeholder consensus conferences on DCDD (Canadian Council, 2005; Bernat et al., 2006):

- Organ donors must be dead at the time of organ removal.
- Active euthanasia is absolutely prohibited.

- There is complete openness about policies and protocols.
- There is a commitment to informed consent.
- The donor's and the family's wishes are respected.
- Enhancing rates of organ donation is of value to society.

The present IOM committee also endorses many of the specific ethical recommendations that these bodies have made:

- DCDD protocols must be written, locally approved, and publicly accessible.
- Informed consent for all premortem interventions (such as cannulation or heparinization) must be undertaken for the purposes of organ donation.
- Safeguards against conflicts of interest must be taken, including the use of separate times and separate personnel for important decisions.
- Determination of death may be made only after circulation has permanently been lost.[3]
- Family wishes to be present at the time mechanical supports are withdrawn should be honored, and families should not incur expenses related to donation.

Nevertheless, despite the identification of general ethical principles and some specific ethical rules to guide the practice, DCDD has remained controversial in many circles and has not achieved its full potential, in part because of the controversy surrounding the subject (Bernat et al., 2006). Although the present IOM committee acknowledges that society will never enjoy complete consensus on ethical matters and that some individuals and families will choose not to donate, it is also convinced that some obstacles to DCDD are primarily due to the inadequate education of families, communities, and healthcare professionals. Therefore, although a complete analysis of the ethical issues surrounding DCDD is beyond the scope of this report, this committee believes that it is worth examining why three IOM committees and at least two international consensus conferences have all concluded that both controlled and uncontrolled DCDD can proceed in an ethical manner yet so little has changed in clinical practice.

[3]Although U.S. state laws typically follow the Uniform Determination of Death Act in referring to the "irreversible cessation of circulatory and respiratory function," policy-making bodies that have addressed DCDD have typically understood this to mean the "permanent" loss of such functions for whatever reason, including not only necrosis but also the inability for the spontaneous resumption of function in the presence of a do not attempt resuscitation order. The 2005 U.S. consensus conference viewed this as a return to the original intention of the 1981 President's Commission.

Controlled DCDD in the United States: From Ethical Controversy to an Emerging Consensus

In the United States, transplant centers have almost exclusively focused on developing protocols for controlled DCDD. This section seeks to develop two main theses regarding controlled DCDD:

1. Although DCDD has been controversial in some circles, a consensus is emerging that controlled DCDD can proceed in accordance with widely shared ethical commitments.
2. Controlled DCDD has been successful and should be pursued by all OPOs to the fullest extent possible. To the extent that a fear of controversy presents an obstacle to DCDD, OPOs should engage in hospital and community education.

Anecdotally, DCDD is frequently more controversial among healthcare workers than it is among the general public, a situation quite the reverse of that for the recovery of organs from DNDD donors. This section explores points of controversy surrounding DCDD and presents the standards of practice and ethical resolutions that are emerging in the United States.

Controversy over Irreversibility

The Uniform Determination of Death Act (UDDA) states that "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 in accordance with accepted medical standards" (President's Commission, 1981, p. 73).

Whether death is pronounced by the use of circulatory or neurologic criteria, irreversibility is part of the legal definition of death. At the same time, under normal circumstances, organs quickly deteriorate when circulatory or neurologic functions are lost. Therefore, to enable the transplantation of organs, it is necessary to declare death as soon as possible.

In 1997, an IOM committee recommended that death be pronounced at least 5 minutes after the cessation of cardiopulmonary function. Some considered this waiting time inadequate because they believe that circulatory functions are not yet irreversibly lost and that with aggressive resuscitative efforts, some level of functioning might be restored (Cole, 1993; Menikoff, 1998).

Both in 1997 and in 2000, IOM committees presented a response to this concern that has subsequently been embraced by multistakeholder consensus conferences and several ethicists (DeVita, 2001; DuBois, 2002; Canadian Council, 2005; Bernat et al., 2006). This response comprises two key points. First, the best available data and expert judgment indicate that

individuals do not spontaneously resume circulation once it has been lost for 2 minutes (IOM, 2000; DeVita, 2001; Wijdicks and Diringer, 2004). Second, all controlled DCDD donors have "do not resuscitate" orders in place; organ recovery occurs only when an independent decision is made to discontinue all life-sustaining treatments. For these reasons, the National Conference and the Society of Critical Care Medicine have recommended that "at least 2 minutes of observation is required, and more than 5 minutes is not recommended" (SCCM, 2001; Bernat et al., 2006, p. 282).

Although this reliance on "permanent" loss of function may seem like a shift from a strict notion of "irreversibility," it is a reasonable interpretation of the concept of "irreversibility" and is compatible with the probable intentions of the Commission that formulated the UDDA definition (President's Commission, 1981, p. 76; Cole, 1993; DeVita, 2001) and with the UDDA's reference to "accepted medical standards," which may evolve, particularly in the light of expert consensus. The committee urges that further observational studies be conducted on spontaneous resumption of circulation.

Controversy over Brain Function

Although the concept of neurologic determination of death is foreign to many laypeople, medical and nursing students are taught that the brain supports consciousness, the respiratory effort, and the integrated functioning of the organism and that when the brain ceases to function the organism is dead. Therefore, it is not surprising that some medical personnel have objected to the use of circulatory criteria to pronounce death when the permanent loss of neurologic function is in question (Lynn, 1993; Menikoff, 1998).

However, here, too, a consensus on what is legally and ethically permissible is emerging. First, UDDA clearly allows the use of circulatory-respiratory criteria to determine death. Second, by requiring a 2- to 5-minute waiting period, DCDD actually exceeds requirements of ordinary medical practice, in which there is no fixed observation period from the time that circulation arrests (DeVita, 2001). Third, once circulation is permanently lost, so, too, is neurologic function permanently lost. Consciousness is lost and brain function ceases approximately 15 seconds after circulation to the brain ceases. If the circulation does not resume, neither will neurologic functions resume.

Controversy over Premortem Interventions

As noted above, heparin is an anticoagulant that is frequently administered to potential donors shortly before mechanical support is removed. The purpose is to prevent blood from clotting in the organs that will be transplanted; the omission of heparin could negatively affect organ recov-

ery and hinder the distribution of the recovered organs (Bernat et al., 2006). The use of heparin has been controversial on the basis of theoretical concerns that it could contribute to active cerebral bleeding and thereby hasten death. However, there is no evidence that heparin in fact has such an effect. Although it can successfully prevent clots from occurring, it is unlikely to dissolve clots or exacerbate active bleeding, particularly in a patient expected to die within minutes of the withdrawal of mechanical supports. Moreover, the effects of heparin can be reversed in the rare patient who might recover cardiac function within the permitted window of time allowed by DCDD protocols.

Some have further objected that medications that are not meant to benefit the donors themselves should not be administered. However, it is important to note that consent is obtained for the use of premortem medications to facilitate donation and that the entire procedure of organ donation is meant to benefit someone other than the donor.

End-of-Life Care

Careful attention to ensuring quality end-of-life care is paramount (see Chapter 4). The option to donate organs by using DCDD is a specialized form of end-of-life care. Although some previously used DCDD protocols prohibited the administration of medications that might be viewed as suppressing the respiratory effort and thereby hastening death, current practice places a priority on ensuring that standard methods for ensuring the patient's comfort (such as the administration of morphine or other comfort measures prior to the withdrawal of ventilation) are used in the context of DCDD; patients should not receive substandard comfort care because of their decision to become donors (DeVita, 1996; IOM, 2000). These practices are consistent with national standards for end-of-life care and offer reassurance that care is not oriented toward hastening death but, rather, is oriented toward honoring the patient's choices and providing comfort (SCCM, 2001; National Consensus Project, 2004). Professional education of nurses, physicians, and other healthcare providers should emphasize the central role of providing quality end-of-life care, regardless of a decision to donate organs.

Withdrawal of Treatment

The medical and ethical literature on controlled DCDD rarely discusses the fact that donation follows the withdrawal of mechanical ventilatory support. Yet, surveys indicate that among the general public the acceptability of DCDD is directly tied to the acceptability of withdrawing artificial ventilation (Keenan et al., 2002; DuBois and Schmidt, 2003).

The law clearly permits the withdrawal of life-sustaining treatments.

The U.S. Supreme Court has embraced widely accepted distinctions between foreseeing and intending death and between causing and permitting death (*Vacco v. Quill*). It is common practice to withhold or withdraw treatments that are considered unwanted, medically ineffective, or overly burdensome.

Confusion over the boundaries of ethically permissible withdrawal of life-supporting treatment in conjunction with DCDD is evident in the literature about DCDD. For example, articles on DCDD have mentioned "causing death in a controlled environment" (Spike, 2000) or have referred to the fact that "more [DCDD] donors could be survivors" if aggressive support measures were continued (Burke, 2003). Such statements indicate confusion about the cause of death (the patient's irreversible disease process) and the reasons why mechanical ventilation is discontinued (not for the sake of donation but because it is deemed unwanted, medically ineffective, or overly burdensome by those involved in the care of the patient).

Moreover, anecdotal data indicate that the connection between DCDD and the withdrawal of ventilatory support causes psychological distress for some healthcare workers involved in the transplantation process (Spike, 2000). This suggests that such confusion can have a detrimental effect on the implementation of DCDD protocols and on the healthcare professionals themselves.

Clearly, to the extent that controlled DCDD depends upon a decision to withdraw life-sustaining treatments, it is important that the legal and ethical justifications for withdrawing treatments are made explicit through education, practice, protocols, and professional standards. All individuals involved in the process must understand that the decision to withdraw life-sustaining treatment is independent of the decision to donate and that the withdrawal of life-sustaining treatment will proceed even if the patient is ineligible to donate.

Finally, whenever life-sustaining treatments are discontinued, it is important to distinguish withdrawing unwanted or ineffective medical interventions from withdrawing care for the patient or family. Standard end-of-life care for the patient continues until death is declared even though efforts to sustain the patient's life have ceased, and all families should receive proper bereavement care during and after the process of making these difficult decisions (see Chapter 4).

Conflicts of Interest

Of all the ethical issues that DCDD presents, the topic of conflicts of interest has generated the least controversy. Although potential conflicts exist between the best interests of donors and recipients, an IOM committee observed in 1997 that the matter of conflicts of interests "has generated

the most consistent approaches in protocols reviewed by the IOM. All procurement organizations and transplant programs appear to understand the need for strong safeguards to ensure that conflicts of interest do not lead to violations of prevailing medical and ethical standards" (IOM, 1997, p. 55). Chief among the specific recommendations regarding conflicts of interest is the separation of "major decisions and discussions in patient care (withdrawal of life support, discontinuing cardiopulmonary resuscitation [CPR], and declaration of death) from major decisions and discussions in organ donation and transplantation (obtaining consent for donation and other transplant-related procedures and involvement in the actual process of organ retrieval)" (IOM, 1997, p. 55). These decisions and discussions frequently require separate staff (which is always the case in the determination of death) and separation in time. Although the present IOM committee has recommended against offering financial incentives for organ donation (Chapter 8), it bears stating that under no circumstances should financial incentives for organ donation be offered to families who need to make decisions regarding the continuation or discontinuation of life-sustaining treatments.

Family Interests and Consent

As the 2000 IOM report emphasized in its fourth recommendation, DCDD "should focus on the patient and the family." Specifically, DCDD should

- follow patient and family wishes as closely as possible;
- meet family needs for information, support, and follow-up;
- recognize and respect the patient's and the family's social, economic, and racial or ethnic diversity; and
- follow clear mechanisms for identifying and covering all organ procurement costs.

Families of dying patients often want to be present when death is determined. Increasingly, protocols permit families to be present in the operating room until death is pronounced; some protocols even permit death to be declared outside of the operating room when it is feasible to subsequently quickly transport the donor to the operating room. These practices are consistent with professional standards (SCCM, 2001; Emergency Nurses Association, 2005). The committee encourages the use of such practices and the allocation of sufficient institutional and human resources and support systems to implement them.

This committee has supported the trend within the transplantation community to honor documented donor wishes. However, when donation is coupled with a decision to withdraw life-sustaining treatments—a deci-

sion typically made by family members unless there is a definitive advance directive or designated surrogate—it seems appropriate to solicit family permission for donation even in the face of first-person (donor) consent. This is primarily because DCDD directly affects the timing and environment for the withdrawal of treatment. Moreover, when families oppose donation, DCDD could introduce a conflict of interest for families as they decide whether or when to withdraw mechanical ventilation. Nevertheless, families should always be informed about the patient's wishes for donation and encouraged to honor those wishes.

Although the committee acknowledges that controlled DCDD has been controversial (Box 5-7), it also supports the direction in which standards of care for controlled DCDD are developing and encourages OPOs to pursue controlled DCDD with greater intensity.

Ethical Issues Pertinent to Uncontrolled DCDD

When IOM committees considered DCDD in 1997 and 2000, they clearly addressed both controlled and uncontrolled (unanticipated) DCDD. Nevertheless, most of their recommendations addressed only controlled DCDD, and the 2000 report included only one uncontrolled DCDD protocol, the Washington Hospital Center's Protocol for the Rapid Organ Recovery Program (Appendix F). The 2005 National Conference focused exclusively on controlled situations (Bernat et al., 2006).

It is beyond the scope of work of the present IOM committee to investigate thoroughly the obstacles to uncontrolled DCDD in the United States. This is also a complex and often misunderstood area (Box 5-8). However, given the significant potential of uncontrolled DCDD to increase the number of organs available for transplantation, this committee believes that it is imperative to further explore the essential issues and opportunities. This section briefly examines some of the ethical issues that surround uncontrolled DCDD. The discussion explores the potential impact that uncontrolled DCDD could have on the number of organs recovered and offers specific recommendations.

Because DCDD has primarily occurred in controlled settings in the United States, the unique ethical issues that arise regarding uncontrolled DCDD have not been as thoroughly examined by ethicists and policy makers. These ethical issues fall into two broad categories: concerns about resuscitation efforts and concerns about informed consent.

Resuscitation

As in all forms of DCDD, death is declared after an individual's circulatory functions are permanently lost. Likewise, as in all forms of DCDD,

BOX 5-7
Correcting Myths and Misperceptions About Controlled DCDD

Controlled DCDD protocols enable individuals who are currently on mechanical ventilation to become organ donors following a decision by the family to remove mechanical ventilation because it no longer benefits the individual.

Myth: Patients would continue to live on the ventilator if they did not decide to become organ donors.
Fact: The family's or the patient's decision to remove a ventilator is completely independent from the decision to donate organs.

Myth: Taking patients off a ventilator is euthanasia. It kills them.
Fact: Removing artificial ventilation is not homicide or euthanasia and is legal in all states. It allows the patient to die of a medical illness when further treatment is considered medically ineffective or overly burdensome or is not desired by the patient.

Myth: Patients are not really dead when their organs are removed.
Fact: Organs are not removed until an independent physician pronounces the patient dead. Patients are not pronounced dead until their heart, lungs, and brain have permanently stopped functioning.

Myth: Medications are given to organ donors that will cause their death.
Fact: No medications are given to cause a patient's death. Patients may be given medications while they are on the ventilator to keep them comfortable. They may also be given medications to improve the quality of their organs for transplantation. However, experts consider these medications safe for patients, and families are told about the use of these medicines as part of the consent process.

Myth: Families cannot be with their loved one when he or she dies.
Fact: Families can request to be with their loved one until death is pronounced. Most hospitals have mechanisms to respond to these requests.

Myth: Organs removed by using DCDD protocols do not work well for transplantation.
Fact: Most organs removed by using a DCDD protocol work as well or nearly as well as other donated organs. DCDD has the potential to vastly increase the number of donated organs in the United States.

medical caregivers may make decisions that affect the time of death and its determination. In controlled settings, decisions are made about the discontinuation of mechanical ventilatory support. In uncontrolled settings, decisions are made about the discontinuation of CPR.

At what point should resuscitative efforts be discontinued, and who should be allowed to make such decisions? The 1997 IOM committee observed the following: "The circumstantial events and medical status of

BOX 5-8
Correcting Myths and Misperceptions About Uncontrolled DCDD

Uncontrolled DCDD protocols enable individuals to become donors after they die after full efforts to resuscitate them from cardiopulmonary arrest have been made.

Myth: Only patients on ventilators can become organ donors.
Fact: Many people who die unexpectedly can become organ donors if DCDD protocols are used.

Myth: If you register as an organ donor, doctors will not do as much to save your life.
Fact: The doctors who try to resuscitate patients work independently of the doctors involved with organ removal. Uncontrolled DCDD protocols require that resuscitation efforts meet or exceed current standards of practice.

Myth: Uncontrolled DCDD will not work well in the United States because getting consent is difficult in an emergency situation.
Fact: Individuals who have signed a donor card or joined a donor registry have given permission for organ donation and can become donors by the use of uncontrolled DCDD protocols. When individuals have not given prior permission, the use of organ preservation techniques while families are contacted for permission to donate is ethically permissible and explicitly allowed by law in some states.

Myth: Organs removed by using an uncontrolled DCDD protocol are not really good for transplantation.
Fact: In Europe, uncontrolled DCDD is more common, and very good outcomes are obtained when best practices are followed.

Myth: Opportunities for uncontrolled DCDD are rare.
Fact: Uncontrolled DCDD protocols can be used for a significantly broader population of potential donors than any other protocols.

those who suffer unexpected cardiopulmonary arrest are enormously varied. It is difficult, therefore, to design a uniform approach to the determination of death in uncontrolled NHBDs" (IOM, 1997, p. 60). Although this is true when one reaches the level of specific rules, the committee nevertheless acknowledges that some valuable guidelines are commonly found in active protocols in Europe:

- Those making the decision to discontinue CPR should not be affiliated with the organ recovery team.
- To ensure a separation between the resuscitation and the transplant teams, a "hands-off" period is often observed. This period is currently between 5 and 10 minutes in European countries (Koffman and Gambaro, 2003; Bos, 2005). The committee believes that although a separation be-

tween teams is essential, the hands-off period could be very brief and may even be unnecessary.

- Solid knowledge of resuscitative evidence and the best interests of the patient who has had a cardiac arrest must guide decisions to terminate resuscitative efforts. Decisions to discontinue resuscitative efforts must be based on medical futility in restoring circulation or breathing (Box 5-2). For example, in Spain, resuscitation is attempted for 30 minutes, in accord with the standards of the European Resuscitation Council and the American Heart Association (del Rio Gallegos et al., 2004). The present IOM committee recommends that protocols be regularly updated to reflect current best practices in resuscitative medicine.
- Transplant centers that proceed with uncontrolled DCDD should do so only after a publicly created protocol that specifies resuscitative guidelines with concrete protections is developed. Appendix F provides the protocol developed by the Washington Hospital Center for uncontrolled DCDD.

Informed Consent

As this report has already observed, the National Organ Transplant Act and, more recently, specific state laws direct OPOs to honor an individual's documented wishes regarding organ donation. In the view of the present IOM committee, when an individual has signed a donor card or joined a donor registry, OPOs have adequate permission to proceed with the recovery of organs from patients after death is declared. Permission to remove organs presupposes that the donor has been declared dead by the use of accepted medical standards; it does not presuppose a specific circumstance of death or a determination of death by the use of neurologic criteria.

However, the issue of consent to donate becomes more complex when an individual has not documented his or her wishes. When neurologic criteria are used to declare death, potential donors are typically maintained on artificial ventilation. This provides OPOs with the opportunity to contact families and to devote considerable time to the process of informing families and obtaining permission. However, when death occurs unexpectedly, potential donors are not maintained on artificial ventilation and families are frequently not available (Bos, 2005).

The use of cold preservation techniques can preserve organ viability and the option for donation while the families are contacted. However, cold preservation techniques themselves are invasive procedures, and consent must either be given or presumed. In nations that rely on an opt-out system of permission, consent for cannulation and cold perfusion may be presumed. The United States uses an opt-in system of consent for donation, and the committee recommends that this approach be retained (Chapter 7).

However, the committee regards the use of preservation techniques while families are contacted—for the purpose of preserving the family's opportunity to make their own informed decision regarding donation—to be ethically acceptable in principle. In cases in which the family will be making the decision regarding donation, organ preservation interventions are a component of proper medical practice.

Surveys and community meetings conducted by the Washington Hospital Center preceding the implementation of its rapid recovery program indicate that the public believes—and the committee concurs—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 (Light et al., 1996).

Some nations that rely on an opt-in system, like The Netherlands, have enacted specific legislation permitting the use of preservation techniques until families can be contacted for consent (Bos, 2005). Similarly, the District of Columbia, Virginia, and Florida have passed legislation permitting perfusion and cooling without consent to enable a decision regarding donation (IOM, 1997, p. 26), although no transplantation programs in these jurisdictions are currently making use of the authority conferred by such legislation. The committee is not convinced that such legislation is necessary; courts might very well regard postmortem cannulation to be permissible as a potentially life-saving medical practice, in the absence of legislation explicitly prohibiting it. On the other hand, although specific legislation may not be legally necessary, some OPOs may want such legislation to remove all doubt regarding the legal permissibility of the procedure. (Either way, it is incumbent upon hospitals and physicians to develop the necessary protocols in accord with ethical principles bearing on respect for the remains of the deceased, to be transparent, and to consult relevant communities.)

REEXAMINATION OF UNCONTROLLED DCDD

Uncontrolled DCDD typically involves individuals who have collapsed suddenly out of hospital and arrive in the emergency department without spontaneous vital signs after having received CPR from emergency medical services (EMS) personnel. The American Heart Association estimates that each year in the United States about 335,000 deaths are due to sudden cardiac arrest (AHA, 2005). Although reports of the rates of survival vary among EMS systems (Eisenberg et al., 1991), about 95 percent of sudden cardiac arrest victims die before they reach the hospital (AHA, 2005). At present, virtually all of these individuals and their families are denied the opportunity to be organ donors.

Estimation of Potential Donors

Application of the Modified Madrid Criteria displayed in Box 5-6 to the estimated cohort of 335,000 cardiac arrest deaths in the United States may be the best means available of estimating the number of potential uncontrolled DCDD donors in the United States (this approximation considers potential donors to be Maastricht Category I and II decedents who had a sudden cardiac arrest outside of the hospital). Because criteria drawn from a relatively small data set are being applied to a much larger one, there will be a substantial margin of error in these estimates. In the interest of arriving at an estimate and driving this error in the direction of underestimation rather than overestimation of organ yield, the Modified Madrid Criteria can be applied to the 335,000 individuals who die of cardiac arrest in the United States each year as if all of these deaths occurred in New York City.

One advantage of this approach is that an analysis using the New York City Pre-Hospital Arrest Survival Evaluation (PHASE) data set (Lombardi et al., 1994) should provide a conservative estimate of the number of potential uncontrolled DCDD donors who meet the Modified Madrid Criteria. This assertion is based on several features of this data set that tend to make most cardiac arrest patients ineligible to meet the Modified Madrid Criteria, thus minimizing the estimated number of potential qualifying donors: (1) the median age of the PHASE cohort was 70 years (interquartile range, 60 to 79 years), which exceeds the upper age limit of the criteria by 20 years; (2) about one-third of the patients had an unwitnessed cardiac arrest, which disqualifies them from further consideration as donors because their warm ischemia time is unknown; and (3) about two-thirds of the patients did not receive bystander CPR, which, combined with lengthy EMS response times, placed many individuals outside the 15-minute time window postcollapse during which CPR must be initiated to meet the donation criteria.

Two additional advantages to the use of the PHASE data are that they constitute the largest consecutive series of data on out-of-hospital cardiac arrests in the United States with complete follow-up, and raw data from the study are available to perform the requisite analyses.

Of 2,329 consecutive patients with out-of-hospital cardiac arrests occurring in New York City over a 6-month period on whom resuscitation was attempted, 14 percent, or 326 patients, were under 50 years of age. Of these 326 patients with cardiac arrest, 44 percent, or 143 patients, received bystander CPR, plus an additional 31 percent, or 101 patients, received CPR from EMS within 15 minutes of collapse. Thus, 143 + 101 = 244 patients who experienced cardiac arrest, who were under age 50 years, and who received CPR within 15 minutes of collapse. CPR was continued for a median of 31 minutes.

The median time that elapsed from the time of collapse to the time of the pronouncement of death was 53 minutes for these 244 patients with cardiac arrest, 73 percent of whom were pronounced dead within 60 minutes. Thus, 73 percent (178/244) of the patients with cardiac arrest were pronounced dead within an hour of collapse. If one allows a 10-minute hands-off period with an absent heartbeat after the pronouncement of death and the cessation of CPR, the transplantation team would be left with 50 minutes, on average, to perform cannulation and cooling of the kidneys (which is well within the requisite window of total warm ischemia time).

Thus, 178 of 2,329, or about 7.6 percent (95 percent confidence interval, 6.6 to 8.7 percent), of all patients with out-of-hospital cardiac arrests could theoretically meet the criteria for donor eligibility. If one then applies the lower limit of the confidence interval to the American Heart Association figure of 335,000 cardiac arrest deaths in the United States each year, the result is a conservative estimate of about 22,000 decedents who meet the Modified Madrid Criteria for uncontrolled DCDD kidney donation each year. This is significantly higher than the current pool of 10,500 to 16,800 eligible donors for whom death is determined by neurologic criteria (Guadagnoli et al., 2003; Sheehy et al., 2003) and does not include potential controlled DCDD donors.

NEXT STEPS FOR DCDD

Because the vast majority of Americans die as a result of the loss of circulatory function, many individuals who during their lifetimes expressed a desire to be an organ donor are not currently able to have that wish carried out upon their death for merely technical reasons and not medical reasons of exclusion. A well-established DCDD program would meet their end-of-life wishes. DCDD is not widely practiced in the United States, and at present the circumstances for its use are largely limited to controlled situations in which artificial ventilation is withdrawn. The committee believes that a concerted effort is needed to implement DCDD in uncontrolled situations and thereby provide the opportunity for organ donation to a greater number of people. In addition to the current focus on increasing the number of controlled DCDD donors, the committee believes that the possibility of uncontrolled DCDD should be fully explored to see if this might be realistic, particularly in urban areas with extensive trauma and emergency care systems.

It is important to acknowledge the challenges and the level of effort that will be needed to ensure that DCDD is a feasible option. 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 a loss of life after every appropriate measure has been attempted.

Furthermore, it is incumbent on the healthcare system to commit the resources needed for implementation of DCDD protocols. It is acknowledged that deaths due to cardiac arrest occur at all hours and that there is often a more time-sensitive urgency with DCDD cases as compared with DNDD. Healthcare systems that are already heavily stressed and thinly stretched may be resistant to changes that will impose additional demands, albeit for lifesaving reasons (Chapter 4).

The committee has identified several actions that are needed to increase the rates of DCDD and offers a proposal to fully evaluate the potential for uncontrolled DCDD. These are outlined below.

- **Provide excellent emergency and resuscitative care.** The first and foremost action in implementing a DCDD program is the use of excellent emergency and resuscitative care. State-of-the-art guidelines must be followed, and all efforts should be made to ensure that the patient has every opportunity for survival. The priority is to focus all possible medical care on the individual's survival.
- **Provide public education.** An informed public can make the assessments that are needed to provide input into the planning and development of DCDD protocols. As with the development of the Washington Hospital Center's uncontrolled DCDD program (described earlier), 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 DCDD program. Because deaths due to cardiac arrest occur more frequently than the types of deaths that are determined by neurologic criteria, the general public is probably familiar with what it means to ascertain whether cardiac and pulmonary functions have permanently ceased and is likely to understand, and to be receptive to, public education messages regarding the conditions necessary to facilitate organ donation in that event. Uncontrolled DCDD is admittedly a complex issue, but given the potential for a dramatic increase in the number of available organs for transplantation the committee believes that high priority should be given to these public education efforts as an essential component of an aggressive effort to implement uncontrolled DCDD protocols.
- **Provide professional education.** For healthcare professionals, it is particularly important to sponsor educational efforts clarifying the elements of high-quality end-of-life care and explaining the steps and protocols needed to implement DCDD in all settings. Support for DCDD is particularly needed from professional associations. Additionally, the urgent need to implement DCDD protocols should be thoroughly discussed in continuing education and other professional education settings in order to

demystify the process and to address legitimate concerns. The overall message is that implementing DCDD protocols will offer many more individuals the opportunity to donate organs at the end of their lives. This conceptual integration of end-of-life care and organ recovery in DCDD cases will help create a more rational comprehensive clinical approach to patient and family care in these difficult circumstances (Chapter 4).

- **Ensure the opportunity for donation.** Steps can to be taken to increase opportunities for DCDD. Professional societies, such as the American Heart Association, should add steps for preparation for such donations to the end of their standard resuscitation protocols. This would prompt emergency services personnel to take various actions, such as administer organ preservation medications or search for documentation of the individual wishes (e.g., a driver's license). Furthermore, it will be important to develop standards by which organ preservation measures (such as cannulation) for DCDD can be taken. Registration with an organ donor registry or other forms of donor consent (an organ donor card or a driver's license) 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.
- **Mentor and evaluate.** Current variations among hospitals and OPOs in the number of DCDD cases need to be addressed through mentoring programs and other efforts by the Organ Donation Breakthrough Collaboratives and professional organizations, which should encourage the development of DCDD programs. As programs are being evaluated, it is important that potential DCDD donors be considered part of the denominator in all measures used to evaluate actual conversion rates.
- **Clarify regulatory and statutory requirements.** Because preservation efforts to maintain the viability of the organs must be initiated soon after circulatory determination of death to preserve the opportunity for organ donation, statutory criteria for the determination of death by either neurologic or circulatory criteria should be clearly specified. Furthermore, the regulation requiring Medicare-funded hospitals to refer all deaths and imminent deaths to an OPO (ACOT, 2005) must be strengthened and expanded to encompass imminent circulatory-related deaths. Despite this requirement, many referrals are being made after the patient has been declared dead by neurologic criteria, cardiopulmonary resuscitation has been stopped, mechanical support has been withdrawn, or the decision has been made to withdraw support. These late referrals are much less likely to result in successful organ donation. In fact, premature removal of mechanical support can be a major barrier to organ donation.

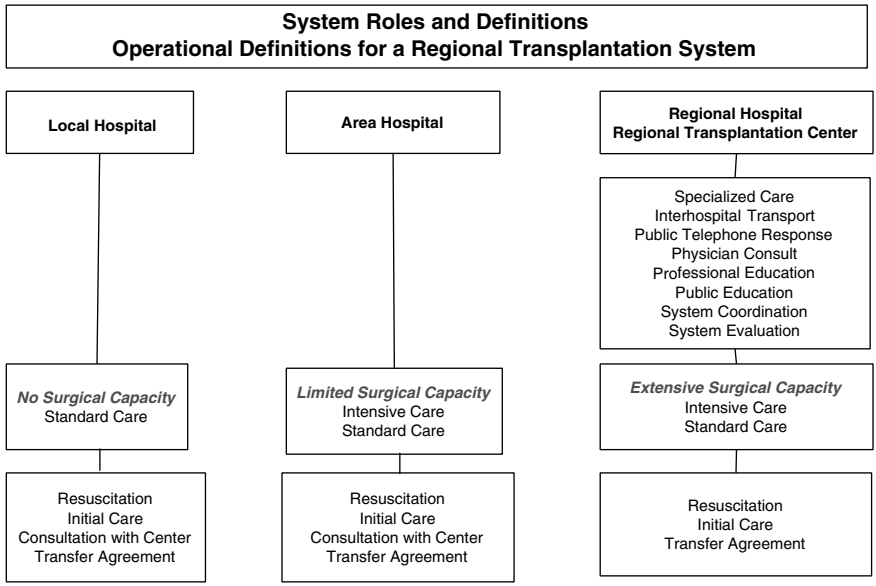

FIGURE 5-1 Regional transplantation system.

- **Develop a regionalized infrastructure.** In urban areas, particularly those with extensive EMS and trauma centers, a regionalized system of organ donation and transplantation care could be developed that would focus organ retrieval and transplantation efforts in regional transplant centers (Figure 5-1). These regional centers would centralize the expertise and would provide the capacity needed to be prepared for DCDD cases 24 hours a day. This approach is consistent with the current categorization and regionalization of EMS systems currently used in the United States for cardiac care, trauma, neurosurgery, etc. Such a regionalized system would allow EMS workers to reduce the time of transport directly to a regional transplant center or regional hospital that can perform the essential steps needed.

Economic Considerations

Careful consideration must be given to the economic impact of emphasizing uncontrolled DCDD. There are potential savings in the value of the organs procured. However, because there are multiple healthcare payers, the savings will be seen by multiple entities and would not have a direct impact on any one system. Economic questions to be considered include the

impacts on emergency department staffing and space, the impacts on operating room capacity, costs required to implement educational programs and develop community consensus, as well as costs of in situ preservation equipment and personnel.

Demonstration Projects

The committee recommends that HRSA, other federal agencies, states, and local entities fund demonstration projects to examine the feasibility of implementing donation programs focused on uncontrolled DCDD. These projects would best be developed within defined geographic areas with well-established EMS systems, particularly those served by a Level I trauma and transplant center, which is the principal receiving hospital for a single EMS system. The demonstration projects would involve the development of processes, in conjunction with hospital and prehospital personnel, to transport all patients with cardiac arrest, whether it is due to primary heart disease or secondary to trauma, to the emergency department of the hospital.

The hospital, OPO, and the EMS system must be well respected and trustworthy entities in the surrounding community that they serve. The single most important feature of the agreement reached about a DCDD protocol is that it meets with public approval and satisfies the community. Community input would be needed during all phases of the project; and public education, as well as professional education, would be important. Extensive stakeholder collaboration involving community members and hospital, OPO, and EMS staff would be needed to develop the protocols for postmortem cannulation and cooling, pending consent for donation from the next of kin. Whether or not such an agreement will also require legal sanction can be determined only by input from the various stakeholders. All organs would be considered appropriate for retrieval as circumstances permit, but the principal target would be kidney donation.

Demonstration projects would allow and enable exploration of the challenges and opportunities for uncontrolled DCDD and should be evaluated carefully. If deemed successful, donation programs focused on uncontrolled DCDD should be scaled up and disseminated to other cities and regions.

EXPANDED CRITERIA FOR ORGAN DONATION

Organ quality is a primary determinant of the likelihood of successful organ transplantation. For this reason, potential organ donors are carefully assessed. In general, the suitability of organs for transplantation has traditionally been based on donor age, the circumstances of death, the absence

of infection and malignancy, the health of the prospective donor immediately before death, and the function of the organ at the time of death (Modlin et al., 2001). Historically, the typical organ donor has been a person less than 55 years of age who has suffered a head trauma.

Over the past 5 to 10 years the methods used to evaluate organ quality and to decide organ allocation have been changing. Changes in organ donation criteria have occurred, at least in part, because of the growing number of patients awaiting organ transplantation. These changes in practice have been associated with at least a fivefold increase in the use of organs that would not have met traditional standard criteria but that have proven to be not only transplantable but also safe and associated with enhanced rates of survival and, likely, an improved quality of life (Whiting et al., 2000; Weill, 2002; Kawut et al., 2005).

Increasingly, organs from older donors and from donors with some medical comorbidities (e.g., hypertension, positive viral serology for patients infected with the same virus, and evidence of some prior organ dysfunction) are being used. Various investigators have assessed the efficacies of organs from pediatric deceased donors; organs from donors with abnormal renal function, prolonged ischemia times, diabetes, and hypertension; organs with vascular or other anatomic abnormalities; or organs retrieved from living unrelated donors and DCDD donors (IOM, 1997; Rudich et al., 2002; Tan et al., 2004).

It is apparent that there is great variation in the extent to which transplant surgeons, transplant centers, and OPOs have been interested in using expanded-criteria organs. Expanded criteria have been most thoroughly investigated and delineated for potential kidney donors (Metzger et al., 2003). Earlier investigations commented on the lack of a uniform definition of what constituted an ideal kidney for transplantation, although there was some understanding of some of the factors that were associated with poorer outcomes, e.g., age, diabetes mellitus, hypertension, and prolonged cold ischemia time (Ojo et al., 2001). These efforts resulted in a more uniform definition accepted by UNOS (Table 5-5). Factors subsequently identified through national registry data that independently predicted a significantly higher risk of graft loss by the use of expanded-criteria kidneys compared with the use of standard kidneys were ultimately included in the UNOS policy (Port et al., 2002).

The current OPTN-UNOS policy change includes the allocation of expanded-criteria donor organs solely by recipient waiting time. Candidates on the standard waiting list may also choose to be added to the expanded-criteria waiting list (HRSA and SRTR, 2006). Since expanded-criteria candidates are preidentified, preprocurement tissue typing can be performed. Human leukocyte antigen matching (for determination of the level of match between the donor and the recipient) is not an allocation

TABLE 5-5 UNOS Definition of Expanded-Criteria Kidney Donors

	Donor Age Categories (years)				
Donor Condition	<10	10–39	40–49	50–59	≥60
CVA + HTN + Creat > 1.5				X	X
CVA + HTN				X	X
CVA + Creat > 1.5				X	X
HTN + Creat > 1.5				X	X
CVA					X
HTN					X
Creat > 1.5					X
None of the above					X

NOTE: X = expanded-criteria donor; CVA = cerebral vascular accident was the cause of death; HTN = history of hypertension at any time; Creat > 1.5 = creatinine level of >1.5 milligrams per deciliter.

SOURCE: UNOS (2005).

issue for expanded-criteria donor kidneys, as long as the mismatch is not zero.

Use of these expanded-criteria kidneys is associated with a significant increase in the number of kidneys recovered and transplanted (Sung et al., 2005). Early reports suggested that the donation of expanded-criteria kidneys would be associated with survival benefits compared with those obtained by the use of maintenance hemodialysis (Ojo et al., 2001), although it was understood that the magnitude of this effect could vary according to the referent group of patients (Merion et al., 2005). As noted by Whiting and colleagues (2000), a key question was not whether transplantation with an expanded-criteria donor kidney was preferable to a lifetime of dialysis but, rather, when and under what circumstances would a policy of transplantation with expanded-criteria donor kidneys be preferable to a policy of using only "ideal" kidneys in the context of the longer waiting times for transplantation that would result.

Some centers have reported that the use of expanded-criteria organs yields results that are comparable to those obtained by using standard-criteria organs (Stratta et al., 2004). Further investigations of the potential impact of the change in OPTN-UNOS policy on expanded-criteria donation suggested that the new policy might be significantly advantageous only for specific subsets of patients, e.g., elderly individuals, awaiting transplantation of a kidney from a deceased donor unless the use of expanded-criteria kidneys dramatically reduced the waiting time for transplantation (Schnitzler et al., 2003). Recent studies also provide some evidence that

expanded-criteria organs could be expected to function less effectively and that recipients might have more postoperative complications (Sellers et al., 2004).

Merion and colleagues (2005) found that the long-term relative risk of mortality was 17 percent lower for expanded-criteria recipients (compared to standard therapy, including dialysis) and for specific patient subgroups (including patients older than 40 years of age or those with diabetes and hypertension) the benefit of receiving an expanded-criteria kidney transplant was significantly higher. The analysis suggests that expanded-criteria kidney transplants should be offered to patients who are older than 40 years of age and who face long waiting times. For OPOs with shorter waiting times, in which non-expanded-criteria kidneys for transplantation are more readily available, a survival benefit from expanded-criteria kidney transplantation was observed only in patients with diabetes. It should be noted that complication rates and the likelihood of a survival benefit are likely diminished in patients who require kidney retransplantation (Sellers et al., 2004).

Comparatively fewer studies exist on expanded-criteria considerations for other solid organs, especially the pancreas and the heart. Therefore, the recommendations for the use of expanded-criteria organs for these patients are less clearly established. Much remains to be learned about the defining characteristics of ideal potential donors, donated organs, and potential recipients so that expanded-criteria allocation and utilization policies can become more evidence based. Outcomes data from multiple centers that include quality-of-life assessments, extended follow-up data, and more rigorous examinations of recipient status and its effect on outcomes are needed.

Weill and colleagues (2002) observed that the donor criteria used for lung transplantation were developed on the basis of the experience of a few institutions in the early 1980s and 1990s. More recent investigations have suggested that the standard selection criteria currently in use[4] lead to the exclusion of some otherwise acceptable donor lungs (Fisher et al., 2004). It

[4]The standard criteria for lung donation include donor age less than 55 years; ABO blood group compatibility; partial pressure of oxygen greater than or equal to 300 millimeters of mercury on a fractional inspired oxygen content of 1.0 and positive end-expiratory pressure greater than 5 cm of water; a smoking history of less than or equal to 20 pack years; the absence of chest trauma; no pulmonary aspiration or sepsis; and a sputum Gram stain free of bacteria, fungi, and a large number of white blood cells. It was suggested that only two of the current criteria (a clear chest film and no bronchoscopic evidence of aspiration) were considered evidenced based. It is probable that not enough data have been collected from a sufficient number of centers to determine the accuracy of the current donor lung oxygenation parameter.

is especially important to address donor suitability, because only a minority of multiorgan donors are ultimately believed to be suitable lung donors. Recent studies have questioned the relationship between sputum Gram stain results and patient outcomes, now that broad-spectrum prophylactic antibiotic coverage is routinely available. In those studies, no predictive value was found in the numbers or the types of bacteria seen or the presence or absence of white blood cells in donor sputum (Ciulli et al., 1993; Gabbay et al., 1999; Weill et al., 2002). Kawut and colleagues (2005) found that patients receiving expanded-criteria lungs with specific characteristics including age of 55 years or greater, extensive smoking history, or evidence of chest trauma had acceptable rates of survival but tended to spend more time in the intensive care unit, had longer hospitalizations, and had decreased pulmonary function after one year. The use of extended-criteria donor lungs might be acceptable to improve survival because donors are in such short supply and because of the high risk of death for some patients who do not receive lung transplants (Pierre et al., 2002; Kawut et al., 2005).

A universally accepted definition of expanded criteria for liver donation has also not yet been established (Busuttil and Tanaka, 2003). Nevertheless, surgeons are beginning to transplant livers that would previously have been considered unacceptable (Fukumori et al., 2003). For example, therapeutic use of inotropic drugs, donor age, and the presence of moderate to severe hepatic steatosis independently influence the severity of liver preservation injury and the duration of stay in the intensive care unit for liver transplant recipients (Briceno et al., 2002). OPTN-UNOS's organ-sharing liver transplant registry database has been used to identify predictors of death or retransplantation in liver transplant recipients. In a multivariate regression model, donor age, recipient age, recipient creatinine concentration greater than 2 milligrams per deciliter, and ventilator dependency for the recipient were associated with graft failure at 1 year, especially in liver transplant recipients infected with hepatitis C virus (Condron et al., 2005). Various investigators have confirmed that biological factors can be used to predict liver preservation injury, because, as with other organs, ischemia time is an important determinant of organ function and transplant efficacy (He et al., 2004; Cuende et al., 2005). Renz and colleagues (2005) recently evaluated the effect of the use of extended donor liver allografts by comparing extended-criteria donor livers allocated by transplant center instead of by regional waiting list priority. Expanded-criteria liver allografts can be transferred out of the region only if they are declined by all of the transplant centers within reasonable geographic proximity.

The expanded criteria used included donor age greater than 65 years, DCDD, positive viral serology, split liver grafts, hypernatremia, or a history of cancer, steatosis, or high-risk behavior in donors. The rate of patient access to liver transplantation increased by 77 percent and the

pretransplantation mortality rate was reduced by 50 percent compared with the rates obtained by the traditional allograft allocation system. The waiting times, complications, and lengths of hospitalization were similar; and there were no significant differences in patient or graft survival, although the causes of death were different. This study confirms the need to establish and update guidelines to include all current and prospective variables that might influence donor selection, graft function, and patient and graft survival.

Ethical Considerations for Expanded-Criteria Organ Donation

The use of expanded-criteria organs raises a number of ethical issues. On the one hand, their use has the potential to save or significantly improve lives. As noted already, many expanded-criteria organs have been used and the outcomes achieved have been good; they have shortened waiting times, enabled patients to move off of dialysis, and have enabled some people who might have died waiting for an organ to live. On the other hand, because the use of some expanded-criteria organs is associated with greater risks of morbidity and mortality, there is a risk that some patients will be harmed. Moreover, given these risks, many patients will view expanded-criteria organs as less desirable, thus generating questions of the fair allocation of standard-criteria versus expanded-criteria organs. Without attempting a complete ethical analysis of the use of expanded-criteria organs, the committee offers the following guidance:

- Because expanded-criteria organ donation has the potential of increasing the number of donated organs and thereby saving and improving lives, the use of expanded-criteria organs should be further explored.
- Consent for the use of expanded-criteria organs should be obtained from transplant candidates. The consent information should distinguish between expanded-criteria organs with known heightened associated risks and expanded-criteria organs with unknown heightened associated risks. So-called expanded-criteria organs that are known to function as well as standard organs (as is the case with some categories of DCDD organs) should not be labeled or treated as expanded-criteria organs.
- Practices associated with the use of expanded-criteria organs must be evidence based. Accordingly, ongoing collaborative research is needed.
- Expanded-criteria organs should be allocated in ways that minimize potential harms, for example, by matching organs infected with a particular agent with patients infected with the same agent.
- Cost-effectiveness should be considered in the development of practice guidelines.

Next Steps for Expanded Criteria

The potential exists to expand the pool of potential donors while also maximizing the quality of the transplanted organ and protecting the safety of the recipient. The development of nomenclature that denotes different categories of organ quality is important to clinical practice. Terminology that can provide separate designations for organ quality and organ screening for disease status is needed. Less precise terms such as "expanded criteria" or "marginal" should be replaced with terms or categories of terms that convey information about the organ's quality or laboratory screening results. These categories of organ quality and designations for organ screening will evolve with new knowledge about graft survival.

Organ Quality

Much remains to be learned about the spectrum of organ variability, particularly for organs other than kidneys, and there is a need to develop the quantitative measures that can inform patients and clinicians. Although there have been age restrictions in the past, it is apparent that there is wide variability in the suitability of organs obtained from donors of all ages.

It is important to develop an evidence-based approach to the characterization of the quality of organs. Ensuring the accuracy and integrity of registry data is fundamental in this process; and a uniformly accepted, scientific method-quality, multicenter database should be supported. Such an effort would likely accelerate the development of guidelines that define acceptable outcomes after expanded-criteria organ donation and may help refine competency standards and qualifications for transplant surgeons. In addition, such an effort, in which OPOs, donor service areas, and transplant centers are more closely linked around data collection and reporting standards, will provide a unique opportunity for OPOs and transplant centers to interface with other national programs investigating the relationships between clinical effectiveness, quality, and safety. Evaluations of cost-effectiveness should be included as new practice guidelines are developed; and such evaluations are likely to be more rigorous as all data elements (e.g., age, disease state, resuscitation status, and waiting time) that could potentially influence outcome are considered.

Targeted Research Needs

The cellular changes that correlate with or predict graft function and survival are not well described. Efforts to further the understanding of warm and cold ischemia and reperfusion injury at the cellular level are needed. Such research will likely identify important molecular determinants

of viability before the organs are collected and transplanted and may identify better methods of storing and maintaining recovered organs.

Organ Screening

It is important that, in addition to and separately from organ quality, organs should be denoted as positive or negative for diseases, disorders, and infectious disease agents for which they are screened, such as hepatitis viruses and human immunodeficiency virus. This designation should affect clinical practice, including consent procedures and allocation criteria. Organs should be allocated to minimize harm, e.g., by matching infected organs with similarly infected patients, and detailed, specific informed consent should be obtained when organs are expected to perform below "gold standard" quality.

SUMMARY AND RECOMMENDATIONS

In 2004, approximately 95 percent of deceased donors were individuals declared dead by neurologic criteria (Table 5-2). However, because deaths determined by neurologic criteria constitute only a small percentage of total deaths in the United States, there is the potential to significantly increase organ donation rates by carefully reexamining and expanding the nation's ability and infrastructure to transplant organs from deceased individuals with circulatory determination of death, deaths that occur in both anticipated and unanticipated (controlled and uncontrolled) conditions. Research is needed to more fully explore the graft survival rates of other organs and to develop optimum methods for organ preservation and for categorizing the viability of organs.

It is acknowledged that DCDD can be a more complex and less facile process than DNDD. Expansion of the nation's capabilities, particularly in large urban areas with excellent emergency medical care, could provide the opportunity for donation to larger numbers of individuals and families. One set of conservative estimates suggests that at least 22,000 of out-of-hospital cardiac arrest deaths annually in the United States would meet Modified Madrid Criteria for unanticipated DCDD if important ethical and practical matters could be resolved. Before proceeding further, demonstration projects to assess the feasibility of undertaking such a strategy within a defined community should be considered. This activity should complement current ongoing efforts to expand the number of controlled DCDD and DNDD donors and should be accompanied by thorough research on the nature and extent of impediments to the implementation of DCDD protocols and on the effects of efforts to remove them.

Recommendation 5.1 ***Implement Initiatives to Increase Rates of Donation after Circulatory Determination of Death.***
HRSA, the National Institutes of Health (NIH), OPTN, OPOs, donor hospitals, transplant centers, and professional societies should implement initiatives to increase rates of DCDD. Particular emphasis should be given to

- **funding of interdisciplinary research by NIH and HRSA to understand and remove institutional, professional, and community barriers and resistance to DCDD;**
- **enhancing public and professional education, disseminating best practices, and monitoring and evaluating DCDD efforts;**
- **clarifying required referral regulations to ensure that all potential donors are considered; and**
- **adding preparation for organ donation to the end of standard resuscitation protocols.**

Recommendation 5.2 ***Encourage and Fund DCDD Demonstration Projects.***
The U.S. Department of Health and Human Services, states, and local entities should encourage and fund demonstration projects to determine the feasibility of increasing the rates of uncontrolled DCDD in cities with established and extensive trauma centers and emergency response systems. Such demonstration projects should include extensive public and professional education, including an emphasis on donor registry efforts, and participation by all relevant stakeholders in the development of protocols and processes.

Recommendation 5.3 ***Maintain Opportunities for Organ Donation.***
OPOs should work with relevant stakeholders to obtain community authorization for the use of postmortem organ preservation techniques during the time needed to seek family consent for donation when the deceased person's donation intention is unknown.

Recommendation 5.4 ***Increase Research on Organ Quality and Enhanced Organ Viability.***
NIH should request and allocate funds for the purpose of determining the characteristics that modify and define organ quality. NIH should fund further research on enhancing the viability of organs for transplantation, including improved methods of organ preservation and improved criteria (with appropriate point-of-care testing) for determining the viability of organs.

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6

Promoting and Facilitating Individual and Family Decisions to Donate

End-of-life decisions are difficult, particularly when one is confronting one's own death. One of these personal decisions is whether to be an organ donor. This decision is a significant expression and exercise of personal autonomy, as the individual considers an action that after his or her death has the potential to save lives and improve the quality of life for others. When an individual decides that he or she wishes to be an organ donor, the decision is typically called "first-person consent"; but the committee prefers the term "donor consent," thereby making it clear that the decision is being made by the "donor" not the family.

Increasingly, states are recognizing the right of an individual to make end-of-life decisions and to have such decisions honored. In addition, many states have followed the model legislation of the Uniform Anatomical Gift Act (UAGA) and have thus codified into law the primacy of the decisions of individual donors. As stated in the 1987 UAGA, "An anatomical gift that is not revoked by the donor before death is irrevocable and does not require the consent or concurrence of any person after the donor's death" (National Conference of Commissioners on Uniform State Laws, 1987, Section 2[h]). Thus, when the individual's decision regarding organ donation is known in those states (through a donor registry or some other documentation), no further family consent is needed, although families are informed and remain an integral part of the process. Nevertheless, the extent to which documents such as a driver's license are considered official documentation of an advance directive still varies among the states (DHHS, 2000). These findings suggest that the United States may be in the midst of a

paradigm shift from relying on the next of kin to make donation decisions for deceased individuals to using donor consent documentation, whenever available, as the official mechanism of consent for organ donation (Ojo et al., 2004). This transition will not be easy, as organ procurement organizations (OPOs) and hospitals must consider how to address the family's changing role in the organ donation process.

This chapter discusses the issues involved in respecting, enhancing, and encouraging organ donation decisions by individuals and their families. It begins with a discussion of the strategies used to facilitate and document the decisions made by individuals to be donors (i.e., donor consent) and considers the broader educational efforts that are used to encourage individuals and their families to make the decision to donate their organs upon death. Much of the research on organ donation decision making is conducted through the extramural grants program of the Health Resources and Services Administration (HRSA). The committee was asked to provide input on that program and the information in this chapter is augmented by a discussion of the HRSA research program in Appendix E.

A FRAMEWORK FOR INFORMED CHOICE

Questions have been raised about the extent to which full informed consent is necessary for organ donation compared with the extent to which full informed consent is required for participation in a clinical trial of a medication or a medical device. That is, concerns arise about the extent to which a person signing a donor card or designating his or her preference on a driver's license application understands the implications of the decision. The findings of research on other types of advance directives indicate that future thinking (in which the decision is made in a context devoid of actual circumstances) may be difficult for some people, and an individual's preferences may also change over time (Beauchamp and Childress, 2001). Therefore, the use of clear decision-making pathways and the availability of easily accessible opportunities to change the decision are important.

The committee believes that informed choice rather than informed consent should be the standard for public education and other related efforts on organ donation. This is because the decision concerns the disposition of the body after death rather than the survival or the quality of life of a living person. Informed choice, as envisioned by the committee, is grounded in the same principles as informed consent: respect for the autonomous choices of an individual who has the knowledge necessary to be able to make choices that are in accordance with his or her values, beliefs, and preferences (Thompson et al., 1995; Sheehy et al., 2003). The requirements for an individual to be able to make an informed choice are a decision-making capacity (the ability to understand information relevant to the decision and

the capacity to reason and deliberate about various options), understanding of the options (which requires that the relevant information be disclosed to the individual), voluntariness (so that the individual may make the decision free of coercion), and the ability to communicate a choice (Beauchamp and Childress, 2001). The development of tools that can provide the information needed in culturally sensitive ways, that inform the decision maker, and that are not coercive is imperative. Several different possible options for the solicitation of donor decisions are discussed below.

MANDATED CHOICE

Mandated choice, or required response, is an approach to donor identification in which all adults are required to state their organ donation preferences. Many states currently offer the option of voluntarily recording donation choices. The mandated-choice model would require each adult to make an explicit choice and would offer a routine, uniform, and systematic means of collection of and access to data on donation preferences (Dennis et al., 1993). By requiring all people to consider whether they would agree to organ donation, mandated choice could help ensure that their preferences would be known and respected. Mandated choice can thus be described as the most direct approach to decision making regarding organ donation because each individual states his or her decision at a time of noncrisis, in advance of illness and death (Davis, 1999). For proponents of this model, the extended reach of the government in this area is more than offset by the lifesaving potential offered by organ donation (Veatch, 1991).

As described above, UAGA and subsequent state laws have set forth the legal mandates upholding the primacy of the individual's determination to donate his or her organs. Currently, in many situations, the individual's wishes regarding organ donation are not known at the time of his or her death and it is up to the family to make the decision. Additionally, although family members agree to follow the individual's wishes (if they are known) in the majority of cases, in a small number of cases the family overrules these wishes (see Chapter 2). Under a fully implemented mandated-choice model that is within the framework of UAGA, individual decisions would be known and honored.

Proposals for models of mandated choice have focused on the incorporation of a set of questions about organ donation into official government documents, such as driver's license applications, tax returns, or state identification cards (Veatch, 1991; Spital, 1995, 1996; Herz, 1999; Farsides, 2000; Starr, 2000; Chouhan and Draper, 2003). Opportunities to indicate an organ donation preference would be as inclusive as possible to record the decisions of a wide range of adults, some of whom may not file tax returns or obtain a driver's license (Chouhan and Draper, 2003). Under

most proposals, the document would not be accepted until the individual submitting the document responded to the donation questions. One of the options for the organ donation decision could include delegation of the decision to a designated surrogate. Decisions would be binding, although opportunities to change the decision would be readily available. As part of a donor registry system, the choice would be confidential but would also be readily accessible to the appropriate medical personnel.

Modifications that have emerged under this rubric generally offer variations in the complexity of choices and in the opportunities for public education. The options could be quite broad—"yes," "no," or "let someone else decide"—or highly detailed, with multiple options to indicate specific organs for donation (Dennis et al., 1993; Herz, 1999). The option not to donate would be available, as would the option to give another person the authority to make that decision.

Public education and informed choice are areas of emphasis in most proposals. In addition, it has been argued that the mandated-choice approach should be accompanied by educational materials on organ donation that emphasize the benefits to the recipients and the importance of community solidarity (Chouhan and Draper, 2003).

There has been limited experience with approaches that have some characteristics of mandated choice. A Texas law enacted in 1991 required a "yes" or "no" choice regarding donation at the time of driver's license renewal but was repealed in 1997 because of concerns regarding a lack of public education (Herz, 1999), as drivers often confronted the organ donation decision for the first time at the time of their driver's license renewal. Furthermore, the system defaulted to "no" when drivers preferred to register an undecided decision.

In July 2000, the Commonwealth of Virginia enacted legislation requiring mechanisms to be put in place so that an individual applying for a driver's license or identification card could designate his or her willingness to be an organ donor. While all individuals were asked to respond, the choice was not mandatory and nonresponse options were available. However, because a binary computer system was initially being used by the department of motor vehicles, all responses other than "yes," defaulted to "no" (including nonresponses and undecided). The resulting high percentage that were recorded as "no" responses caused a reexamination of the system. Subsequent changes and the implementation of a web-based registry have alleviated the initial problems and provided for opt-in responses only (personal communication, K. Myer, LifeNet, March 2006).

Little empirical evidence is available on the potential impact or the effectiveness of a mandated-choice approach. A national telephone survey with random-digit dialing conducted by the Gallup Organization in 1993

found that 63 percent of respondents said that they would agree to organ donation in a mandated-choice system (Spital, 1995).

Individual Autonomy

The underlying ethical principle in discussions of mandated choice is that of individual autonomy. Proponents emphasize the choice that this approach offers. That is, this approach is centered on individual decision making and ensuring that the individual's wishes about the disposition of his or her body are followed at the time of death (Veatch, 1991; Dennis et al., 1993; Spital, 1995, 1996; Herz, 1999).

However, mandated choice has also been criticized for impinging on personal autonomy by requiring that individuals make a decision, whether they want to or not. Citizens of the United States rarely face compulsory reporting requirements. Individuals receive a direct benefit from some mandated requirements (e.g., permission to drive from a driver's license), whereas other requirements allow the individual to contribute to the common good (e.g., by registering with the Selective Service System and filing federal, state, and local taxes). The challenge is in determining whether the common good that might result from increased rates of organ donation would outweigh the government interference in mandating a decision.

Furthermore, evidence in the decision-making literature suggests that forcing a decision on an admittedly personal matter such as organ donation will have a detrimental effect and that the forced choices may be negative choices. This is particularly relevant in a country like the United States, whose citizens place a high value on individual freedoms. For example, when a person's preferences about a topic are not fully clear, being forced to choose can produce conflict and psychological discomfort, which in turn can lead to the selection of options that reduce the need to make hard choices (Lewin, 1951; Festinger, 1964; Janis and Mann, 1977) and that are associated with a lower likelihood of error and conflict (Luce, 1998). Dhar and Simonson (2003) show that the options selected in a forced-choice task tend to be those that seem safer; that are easier to justify; and that help alleviate decision conflict, discomfort, and potential regret associated with being forced to make a choice despite the lack of a clear preference. In other words, such options are not selected primarily because of their intrinsic value but, rather, because they help resolve a difficult choice. In the organ donation context, the easier choice may well be to decline to donate or to decide not to choose (if a no-choice option is available). Counteracting that tendency would require extensive public education about the common interest that all Americans have in organ donation.

It has been argued that the current system has an implied decision-

making structure, because in not choosing to join a donor registry or to make the decision on the driver's license application, the default is to let the family decide (Herz, 1999). Opponents of mandated choice are concerned that among the people currently not choosing to donate, the number of people who will say "yes" under a mandated-choice regime will be offset by the number of people saying no without conviction, a definitive act that precludes a subsequent family decision to donate the individual's organs after his or her death.

Timing and Family Involvement

One of the greatest challenges to the current system of donation is that families are confronting organ donation decisions at a time of traumatic grief and emotional stress. Mandated choice thus allows consent to be expressed before an illness or death (Davis, 1999). As stated by Carl Cohen, under the current system, "We ask the wrong persons, at the worst possible times, questions they should never have been asked" (Cohen, 1992, p. 2169). Mandated choice moves the decision-making process out of a time of crisis, and with the decision already made, families know that their loved one's wishes are being honored. In the 1993 Gallup survey mentioned above, 93 percent of respondents said that they would honor the previously expressed wishes of their deceased family member (cited in AMA, 1994). Other studies have confirmed that knowing that the family member would have wanted to donate his or her organs is strongly associated with following those wishes and with familial consent for donation (Chapter 2) (DeJong et al., 1998; Siminoff et al., 2001).

It would be important to consider the role of the family if mandated choice were implemented in the future, particularly in light of laws regarding first-person consent. A policy of mandated choice might be met with resistance because family consent would no longer be an important element of organ donation (Klassen and Klassen, 1996). For a variety of reasons, including distrust in the healthcare system and the threat of legal repercussions, members of the public, healthcare teams and hospitals, and OPOs may be reluctant to support a system that limits or discounts families' preferences in such a sensitive area after the death of a loved one.

Next Steps Regarding Mandated Choice

The committee believes that a mandated-choice approach could be implemented in an ethically appropriate manner, but only after extensive public education. At best, the number of donated organs could be increased under a mandated-choice system. If that is so, then mandated choice is not an overly burdensome requirement. However, on the basis of the limited

empirical evidence available to date, in the worst case it could be possible that the number of donated organs would decrease.

To be successful, a mandated-choice model needs an informed citizenry that understands organ donation and what it means for the individual and for the recipient and that sufficiently trusts the system to go on record as an organ donor. Without giving people adequate and accessible information, merely forcing them to choose to be an organ donor or not does not capture the potential of mandated choice and weakens the argument for it. A broad-based and multidimensional educational campaign is needed that confronts issues around death and dying, debunks the myths and misperceptions surrounding organ donation, and emphasizes the benefits of organ donation. Pilot tests of mandated choice could be reconsidered in the future when there is a broader and more accurate understanding of organ donation among all sectors of U.S. society. If public education is successfully intensified, however, mandated choice may prove to be unnecessary.

VOLUNTARY CHOICE: EXPANDING OPPORTUNITIES TO DOCUMENT DONATION DECISIONS

The current organ donation system is focused on voluntary choice: the right of the individual (or the family as the surrogate) to choose to donate organs after death. Preliminary data from the 2005 National Survey of Organ Donation show that 53.5 percent of respondents indicated that they had declared an intention to be an organ donor by designating it on a driver's license, 29.3 percent had a donor card, and 14.3 percent had signed up to be on a donor registry[1] (Wells, 2005).

Many factors influence the general public's willingness to donate organs. Although new and innovative initiatives have recently begun to increase the rates of organ donation (e.g., the Organ Donation Breakthrough Collaboratives, which focus mainly on system improvements and decision making at the time of death [Chapter 4]), the current overall low rate of organ donation has been attributed by many investigators to the varied cultural norms in the community, religious beliefs, age, ethnicity, a lack of insurance, unemployment, and a general suspicion of the heathcare system (specifically, the concern that if one were identified as an organ donor, one might receive less intensive medical care) (Chapter 2). Individuals can record their donation decisions by several mechanisms. The challenge is to ensure that the decision recorded is available to OPO and healthcare professionals, should the need arise to consider donation.

[1]The extent of overlap between these groups was not specified.

Key Issues for Donor Choice

Informed Choice

For donor consent to be valid and capable of being used as an advance directive, the general public needs to be provided with accurate information about all aspects of organ transplantation; efforts should be aimed at demystifying the process and ensuring that the choice is an informed one. To date, legal or ethical standards have not been established to delineate the minimum amount of information necessary to ensure adequately informed choice. Furthermore, disclosure of information by itself does not ensure comprehension and understanding. Later, this chapter discusses ways to enhance public education and raise public awareness.

Communicating Decisions to Family

In addition to documenting an individual's decision to become an organ donor, it is also important for the individual to communicate that decision to family members. A study involving the families of 420 donors and nondonors found that prior knowledge of the individual's positive decision on donation was significantly associated with the family's willingness to provide consent for donation (Siminoff et al., 2001). Furthermore, families who had had discussions about organ donation were more likely to agree to donate. Even if an individual has not formally taken the step of documenting his or her decision, expressing thoughts and opinions about organ transplantation with family members gives the family a basis for decision making after an unexpected death. A major source of family information related to organ donation is the media; and studies show that media stories, which are often negative or at least ambiguous, frequently influence families not to donate (Morgan et al., 2005). This finding makes family discussions about organ donation even more important.

Preliminary results from the 2005 National Survey of Organ Donation found that 70.4 percent of those who wished to donate had discussed it with their families (Wells, 2005). However, organ donation may be an uncomfortable topic for some family members: for some, it raises the specter and fear of death, and such discussions may be rapidly dismissed by family members; for others, individuals may have fundamental disagreements with their family about end-of-life decisions. Many families, on the other hand, would engage willingly in such conversations. Clearly, as with other advance directives, these conversations are important.

Honoring Donor Consent

Until recently, the deceased individual's preference for organ donation, as designated on a driver's license, a signed donor card, or a state donor

registry, was used primarily as information provided to the family to assist them in making a decision regarding organ donation. Rarely was it implemented as legally binding documentation (DHHS, 2000). Recognizing this as a limiting factor, 43 states and the District of Columbia have enacted first-person consent (donor consent) laws designed to affirm the legal strength of such documentation as advance directives (UNOS, 2005a; Appendix C).

It is natural to approach the families of deceased individuals to discuss organ donation, and recent experience suggests that families rarely object when they are advised of the decedent's documented consent (Chapter 2). However, in cases in which families are resistant, it is important to be respectful of the family's beliefs and attitudes while honoring the donor's recorded wishes.

Confidentiality of Donor Registrations

It is generally agreed that the confidentiality of donor registries is important and that access should be restricted to a need-to-know basis for relevant healthcare professionals. A culture of organ donation within a community may also be created or enhanced by publicizing the organ donation registrations of individuals who have given explicit permission for this to be done. The goal would be to encourage others to donate by acknowledging organ donation as the accepted and practiced action of many individuals in the community. Careful study will be needed to determine whether this approach is feasible, helpful, and clearly distinct from registration efforts overall.

Next Steps: Facilitating and Documenting Decisions to Donate

The most ethically appropriate manner to obtain consent for organ donation is directly from the individual (since this respects autonomy in determining the fate of one's own body), before a time of crisis, so that the individual can reflect and carefully think about the decision. Such elective decision making also facilitates the provision of culturally sensitive information about organ donation so that enough information is available for an individual to make an informed choice. The decisions should be binding on others (albeit easily changeable by the individual during his or her lifetime).

It is therefore important to provide multiple venues and opportunities for individuals to learn about organ donation and document their donation decisions. Furthermore, efforts are needed to ensure that donation decisions are accessible to the relevant healthcare professionals through secure online registries.

Driver's License Registration

Designation of consent for organ donation on a driver's license is a common and effective method for documenting organ donation decisions. More than 196 million drivers are licensed in the United States (FHWA, 2004), and license registration and renewal thus offer the opportunity to disseminate information to large numbers of individuals. Most states provide information on organ donation in their driver's education materials and also provide an option to designate the donation decision on the driver's license.

A driver's license may be located by law enforcement and made available to healthcare personnel at the time of a tragedy. However, the value of designating organ donation at the time of driver's license registration or renewal is that in most states the state department of motor vehicles uploads that data directly into the state's online organ donor registry, thereby making it readily accessible to relevant OPO and healthcare personnel. Additionally, the opportunity to designate a donation decision when a person first obtains a driver's license or at license renewal may lead individuals to discuss organ donation with their family members, a discussion that can be invaluable to the family if the need to address donation occurs because of a tragedy. An added benefit might be gained if driver's license registration triggered an educational printout or the dissemination of other educational materials at the department of motor vehicles that encourage the driver to share this decision with his or her family members.

Given the convenience of documenting donor consent on a driver's license, it is interesting to note that in a random-digit-dialing study in Maryland, 66 percent of individuals stated that they would be willing to donate an organ to a sibling, but only about half of the respondents had designated themselves a donor on their driver's license (Boulware et al., 2002). Therefore, although use of the driver's license to designate the desire to be an organ donor may be effective, it is not always used even by individuals who support organ donation.

Donor Cards

Many states have enacted laws stating that a wallet-sized uniform donor card, signed by an individual at least 18 years of age in the presence of two adult witnesses, suffices as official documentation for organ donation (DHHS, 2000). In some states, the donor card is considered the necessary legal documentation for first-person consent for donation, whereas in other states the driver's license is also accepted as documentation. For example, in North Carolina a uniform donor card signed in the presence of witnesses provides the OPO with sufficient legal authority for organ recovery without

additional authority from the donor or the donor's family or estate, whereas the indication regarding donation on a driver's license is considered to represent only the intent to donate and not legal documentation (UNOS, 2005a). In other states, such as New Mexico, legislation states that the driver's license is one means of designating first-person consent, which can also be designated by a donor card, a living will, or a durable power of attorney for health care (UNOS, 2005a).

Donor Registries

Rapid and secure access to an individual's decision regarding organ donation is important for the OPO and hospital personnel involved in organ donation. Although "donor registry" has various definitions, particularly internationally (Gäbel, 2004), the committee uses this term to mean an online systematic source of accessing donor consent information 24 hours a day, 7 days a week. The patient's driver's license, donor card, or end-of-life directive may or may not be available to healthcare providers when important decisions need to be made, and therefore, the availability of donor registry information online can quickly provide the donation decision information that OPO and hospital personnel need.

As of November 2005, 35 states had organ donor registries and others are in the legislative and administrative processes of implementing a registry (UNOS, 2005a) (Appendix C). This is a significant increase from the number in 2002, when 14 state registries were identified (DHHS, 2002b). In most states the department of motor vehicles (or the agency responsible for licensing drivers) is the primary portal for the donor registry (DHHS, 2002a,b). Additionally, a number of states have easily accessible websites for individual donor registration. The incorporation into donor registries of individual donation registrations and data from the department of motor vehicles and donor card registration sources thus increases the extent of coverage of the registry and the potential for the registry to be used to the greatest benefit.

The principal factor limiting the effectiveness of registries is that only small numbers of people are currently registered. However, many of the state registries have come into existence only in the past 5 years, and the cumulative effect of ongoing registrations and the long-term benefits of increasing the rates of organ donation will be seen only when they are tracked over time.

Beasley and colleagues (1999) modeled the cost of organ donor registries and estimated that when the incremental benefit of donor registries (above and beyond current donor strategies) is considered, 83,300 registrations would be required to realize one potential new donor within a year. However, the ongoing nature of donor registries (an individual's name will

often be in the registry for life), the new emphasis on state first-person consent (donor consent) laws, and increased efforts to expand the population of potential donors will affect these estimates.

In a more recent analysis, Howard and Byrne (in press) examined the value of donor registries based on the lifetime probability of becoming an organ donor. They found that with the cost savings of transplantation, society should be willing to spend up to $1,900 to register a single organ donor (for registration beginning at 18 years of age). The committee could not locate data on the current costs of implementing and maintaining a donor registry, but because many states use existing online systems (e.g., those for drivers' license registration), the actual cost is thought to be much less.

The advantage of an online registry system is that opportunities to register to donate can be presented in multiple locations. Furthermore, registration sites can be used for public education efforts (DHHS, 2002b). A study in Arizona indicated that people were interested in the availability of organ donor registration opportunities at healthcare facilities, places of worship, and departments of motor vehicles, as well as at kiosks that could be set up at special events or shopping areas (Siegel et al., 2005).

Some possible drawbacks of the use of donor registries include the cost of maintenance, as well as their security and accuracy, because confidentiality is highly important in gaining the public's trust in organ donor registries. Access to donor registries must be available only to appropriate medical and OPO personnel, and all entries in the database must be tracked and validated. Furthermore, it is important to ensure that the information residing in the registry remains accurate. Challenges arise in updating the registries with current information on individuals who have died or who have moved out of the state (DHHS, 2002a). Missouri has developed a useful program to address this concern and uses robust software that compares the organ donor registry with registries of deaths in the state on a regular basis (personal communication, L. Darr, Missouri Department of Health and Senior Services, January 2006). It is important to acknowledge that donor registration is not the primary mission of the department of motor vehicles; accordingly, collaborative efforts and funding that support the training of department of motor vehicles staff and that provide educational materials on organ donation are important and should be strengthened.

Additionally, it is important to enhance the effectiveness of state organ donor registries by strengthening collaborations between the state's department of motor vehicles and the donor registry particularly with regard to data access issues. Providing multiple means of registration (e.g., websites) on the donor registry is also critical.

Considering the mobility of the U.S. population, online donor registry systems must be coordinated so that appropriately vetted OPO staff and

healthcare providers can query the systems nationwide on a 24-hour-a-day, 7-day-a-week basis. Ensuring a coordinated networked system would provide the optimal ability to honor an individual's wishes regarding organ donation. Action is needed at the federal and state levels to follow up on earlier efforts to examine donor registries (DHHS, 2000, 2002a,b) and determine the optimum system for coordination.

Additional Opportunities to Document Donation Decisions

Other occasions offer additional opportunities to provide information on organ donation and to document donation decisions. End-of-life healthcare planning provides individuals with the opportunity to explicitly express their decisions on a range of healthcare options. Incorporating opportunities to consider organ and tissue donation into advance care directives and other related end-of-life decision documents (such as the Physician's Orders for Life-Sustaining Treatment) will provide individuals with another avenue to express their organ donation preferences and to provide families with a clear statement of the individual's donation decisions in the event that the person is unable to speak for himself or herself. Although this goal has not yet been fully achieved, systems are currently in place to support those who choose to exercise this opportunity. Some states are considering the development of online registries of advance directives to facilitate access by OPO and healthcare personnel and to ensure that care is provided in accordance with the patient's wishes (Maryland State Advisory Council, 2005).

Routine inquiries about advance directives and preferences for organ donation upon admission to the hospital (Essebag et al., 2002; HRSA, 2003) or as a routine part of primary care office visits have also been proposed as a means to identify patient preferences and potential organ donors. For this to be a viable option, however, all patients would need to have access to primary healthcare practitioners who are skilled and knowledgeable about basic palliative care therapies and the option for organ donation. In addition, inquiry into a person's decision about organ donation as he or she is entering a hospital for diagnosis and treatment may not constitute the most auspicious time for such a discussion. Nevertheless, such an inquiry can be appropriate if made with sensitivity.

PUBLIC EDUCATION

A key factor in increasing rates of organ donation in the United States is a knowledgeable citizenry. Having the information necessary to make informed choices is essential and is the basis of individual autonomy. Public education regarding organ donation is an area of considerable activity

involving numerous venues and all types of media. A number of nonprofit organizations are active in this area, including the Coalition on Donation and its state and regional coalitions (Box 6-1); the National Kidney Foundation and its state and regional affiliates, which sponsor many public education and donor awareness programs, including the U.S. Transplant Games; the Eye Bank Association of America affiliates; the Nicholas Green Foundation, which provides videos for public education; and the numerous chapters of recipient and donor family volunteer groups, such as the Transplant Recipients International Organization and national and local Donor Family Councils.

OPOs have a mandate to promote public education, and they are actively involved in offering a wide range of educational programs. Likewise, professional associations, including the American Society of Transplantation, the American Society of Transplant Surgeons, and NATCO (The Organization for Transplant Professionals), provide speakers and programs for public education events. Many faith-based organizations are active in promoting Donor Sabbath, a day focused on celebrating organ donors and encouraging donor registration. A number of states provide information on organ donation in their driver's education curricula.

The insights provided by individuals who are transplant recipients or family members of donors are particularly valuable in depicting the personal realities of the impact of donation decisions. For example, the Kentucky Organ Donor Affiliates' "Second Chance" Volunteers organization comprises more than 200 recipients, donor family members, and healthcare professionals who give presentations, grant interviews, interact with high

BOX 6-1
Coalition on Donation

The Coalition on Donation, founded in 1992, is a nonprofit alliance of organizations and local coalitions across the United States that works to educate the public about organ, eye, and tissue donation. The Coalition's goal is to develop and promote locally powerful messages about donation through a variety of media. The Coalition is made up of 47 local coalitions that cover 95 percent of the U.S. population (Coalition on Donation, 2006). These local groups play an important role in disseminating organ donation materials. Coalition on Donation members meet regularly to share strategies, discuss best practices, and find solutions to common problems in boosting organ donation awareness and consent. The Coalition's efforts have included collaborations with the Ad Council on multimedia methods to increase public awareness and the development of educational materials, newspaper stories, and collaborations with numerous community-based organizations to promote the Donate Life message.

school students, and act as "awareness ambassadors" in many venues. They also work to develop effective relationships with local television, radio, and newspaper media in their production of human interest stories and often connect local transplant recipients or donor families with local media.

Many states now provide the option of making a voluntary gift to cover donor awareness and education programs at the time of driver's license renewal, on state tax forms, through county treasurers, or by the purchase of specialty license plates (DHHS, 2000).

The federal government also funds projects to increase public awareness and promote public education. For example, HRSA staff members are working with the Hollywood, Health & Society organization to provide accurate information to the writers of various television shows working on stories about organ donation and transplantation (personal communication, M. Ganikos, HRSA, October 2005). HRSA's Division of Transplantation administers a strong extramural grants program focused on understanding how to improve and facilitate organ donation decision-making and donor registration and consent (Appendix E). Additionally, the National Minority Organ and Tissue Transplant Education Program (MOTTEP) focuses on educational efforts that include media campaigns and grassroots public education efforts.

Donate Life is the ongoing campaign used nationally by the Coalition on Donation (www.donatelife.net) and by HRSA and the Division of Transplantation's initiatives to increase donor awareness and donation. OPOs have agreed collectively to be referred to as Donate Life Organizations.

However, myths, misinformation, and uncertainties about organ donation and transplantation continue to abound. The challenges for public education center on both the complex nature of the information that needs to be conveyed and the need to dispel misperceptions about organ transplantation (Box 6-2), some of which may be so widespread as to be dubbed "urban legends." Adding another challenge to this topic is the focus on death and dying and confronting one's own mortality, issues that are somewhat taboo and that many Americans are definitely uncomfortable discussing and addressing.

Learning from Other Public Health Efforts

Actively engaging the general public to focus attention on a public health issue is a challenge faced in connection with a broad range of public health concerns. Public education has been an important tool in such public health successes as motor vehicle safety, childhood vaccinations, and safer workplaces. A review of the 10 greatest public health achievements of the 20th century found that mass media, school-based

BOX 6-2
Correcting Myths and Misperceptions

Many myths about organ donation and transplantation have arisen. It is important to correct these myths and misperceptions in media and educational descriptions.

Myth: If emergency room doctors know you're an organ donor, they won't work as hard to save you.
Fact: If you are sick or injured and admitted to the hospital, the number one priority is to save your life. Organ donation can be considered only after death has been declared by a physician. Many states have adopted legislation allowing individuals to legally indicate their wish to be a donor should death occur, although in some states, OPOs also seek consent from the donor's family.

Myth: When you're waiting for a transplant, your financial or celebrity status is as important as your medical status.
Fact: When you are on a waiting list for a donor organ, what really counts is the severity of your illness, the time that you have spent waiting, your blood type, and other important medical information.

Myth: Having "organ donor" noted on your driver's license or carrying a donor card is all you have to do to become a donor.
Fact: Although a signed donor card and a driver's license with an "organ donor" designation are legal documents, it is also important for individuals to discuss organ and tissue donation with family members. To ensure that your family understands your wishes, it is important that you tell your family about your decision to donate life.

Myth: Only hearts, livers, and kidneys can be transplanted.
Fact: Needed organs include the heart, kidneys, pancreas, lungs, liver, and intestines. Tissue that can be donated include the eyes, skin, bone, heart valves, and tendons.

interventions, and communitywide campaigns played a substantive role in bringing about positive changes (Table 6-1). Other components of these efforts included changes in laws and regulations (e.g., laws requiring the use of child safety seats and airbags), public support and advocacy efforts, and environmental changes (e.g., fluoridation of drinking water supplies).

An analysis of the components of social change movements found that a number of similar factors contributed to changes in society on the public health issues of tobacco use, recycling, breast-feeding, and use of seatbelts and child car seats. The factors contributing to these successes were a science base for change, economic benefits, the development of strong coa-

Myth: Your history of medical illness means your organs or tissues are unfit for donation.
Fact: At the time of death, the appropriate medical professionals will review your medical and social histories to determine whether you can be a donor. With recent advances in transplantation, many more people than ever before can be donors. It is best to tell your family your wishes and sign up to be an organ and tissue donor on your driver's license or an official donor document.

Myth: You are too old to be a donor.
Fact: People of all ages and with all types of medical histories should consider themselves potential donors. Your medical condition at the time of death will determine what organs and tissue can be donated.

Myth: If you agree to donate your organs, your family will be charged for the costs.
Fact: There is no cost to the donor's family or estate for organ and tissue donation. Funeral costs remain the responsibility of the family.

Myth: Organ donation disfigures the body and changes the way it looks in a casket.
Fact: Donated organs are removed surgically, in a routine operation similar to that for gallbladder or appendix removal. Donation does not change the appearance of the body for the funeral service.

Myth: Your religion prohibits organ donation.
Fact: All major organized religions approve of organ and tissue donation and consider it to be a praiseworthy act (Chapter 2).

Myth: There is real danger of being heavily drugged and then waking to find that you have had one kidney (or both) removed for a black market transplantation.
Fact: This tale has been widely circulated over the Internet. There is absolutely no evidence that such an activity has ever occurred in the United States. Although the tale may sound credible, it has no basis in the reality of organ transplantation. Many people who hear the myth probably dismiss it, but it is possible that some believe it and decide against organ donation out of needless fear.

SOURCE: Adapted from UNOS (2005b).

litions, media and grassroots advocacy, a dynamic spokesperson (a "spark-plug"), government involvement, use of the mass media to disseminate information, and policy and environmental changes (Economos et al., 2001). No single component was solely responsible, but the combined efforts of numerous stakeholders and the allowance of time for a common culture to develop all contributed to widespread changes. A similar case can be made for raising awareness and increasing the positive societal response to organ donation. Dispelling myths, increasing the dissemination of information, encouraging advocacy, improving the environment for change, careful regulatory and policy oversight, and thorough research efforts will likely

TABLE 6-1 Public Health Intervention Strategies

Public Health Achievement	Community-wide Campaigns	School-Based Interventions	Mass Media Strategies	Laws and Regulations	Reducing Costs to Patients
Vaccination	X		X	X	X
Motor vehicle safety	X	X	X	X	
Safer workplaces	X			X	
Control of infectious diseases	X		X	X	X
Decline in deaths from coronary heart disease and stroke	X		X		
Safer and healthier foods	X	X	X	X	X
Healthier mothers and babies	X		X	X	X
Family planning	X			X	X
Fluoridation of drinking water				X	
Recognition of tobacco use as a health hazard	X	X	X	X	

SOURCES: CDC (1999); Eriksen (2005).

all work together to foster more positive societal and individual responses to donation decisions.

Media

The multiple forms and pervasive presence of media in U.S. society make the media a powerful tool to be used to convey information on organ donation and transplantation and to be observed for the actual information that it conveys to the public. However, media portrayals often perpetuate myths about organ donation and allocation (Morgan et al., 2005). Negative publicity is often more easily recalled than positive messages. In a study of 78 families, Morgan and colleagues (2005) noted that negative opinions were usually rooted in stories or other information from television or movies, whereas positive opinions were generally grounded in personal values and beliefs. The investigators noted that many respondents recollected negative television and movie plots that often allude to myths dealing with the premature declaration of death, the transfer of personality traits from do-

nor to recipient, a U.S. black market for organs, and corruption in the medical community and organ allocation system.

The impact of negative portrayals may have an effect on the overall willingness of individuals to donate for a considerable length of time. The United Kingdom saw decreases in donor referral rates for almost 15 months after a prime time television program raised concerns regarding the validity of neurologic determination of death criteria (Bradley and Brooman, 1980), and more recent controversies about the unauthorized removal of children's organs (Fox and McHale, 2000) may have had similar repercussions. It is clear that maintaining credibility and sending strong positive messages to the public are serious challenges, particularly when fictionalized stories often deepen the public's distrust of the organ donation system.

Public service announcements and community-based efforts sponsored by the federal government, state governments, and nonprofit organizations have recently focused on encouraging individuals to register as an organ donor and to discuss their organ donation decisions with their family members. Furthermore, specifically targeted public education campaigns can address issues of particular concern to a population (Kopfman and Smith, 1996). For example, the Coalition on Donation developed a campaign aimed at providing improved, updated, and accurate information on organ donation to the Hispanic population; the Coalition developed partnerships, including partnerships with Catholic organizations to reinforce the church's support for organ donation (Weiss, 2003).

Workplace Efforts

Some attempts have been made to provide public education on organ donation through employers and employee healthcare sources. Since 2001, almost 11,000 organizations have joined the ongoing Workplace Partnership for Life, a collaboration set up between the federal government and private corporations, organizations, and associations to make organ donation education available to employees (DHHS, 2005a). Through this effort, employers and employee groups develop educational campaigns about organ donation and offer opportunities to sign donor cards. As of April 2005, the Workplace Partnership for Life had reached 23.9 million employees and association members (personal communication, M. Ganikos, HRSA, 2005). An ongoing research grant involving the New Jersey Workplace Partnership for Life is exploring methods to promote organ donation in the workplace with the goal of increasing the rate of organ and tissue donor registration as well as the number of family discussions about organ donation between employees and their families in New Jersey (NJ Sharing Network, 2005).

Driver's License Registration

As discussed above, because many states use the state department of motor vehicles as a route to register donor consent, proactive education is an opportune way to incorporate and refresh the population's education on organ donation. With more than 196 million licensed drivers in the United States needing to renew their licenses on a periodic basis, continued efforts are needed to bolster the information provided in driver's manuals and disseminated at department of motor vehicles offices. The collaboration and linkages between state department of motor vehicles offices and the transplantation and healthcare communities have played important roles in increasing the numbers of registrants in donor registries and in providing an avenue for public education regarding donation. Efforts are needed to continue to increase the cultural sensitivity of organ donation educational materials, clarify the options regarding consent for organ and tissue donation on driver's license forms, and continue the promotion of decisions regarding organ donation.

Youth

Providing information to students, particularly during driver's education classes, has been another important avenue for public education on organ donation. In 2004, HRSA began distributing "Decision: Donation," a packet of educational materials—including print, video, CD-ROM, and Internet-based materials—that teachers can use to boost awareness of organ donation issues (DHHS, 2005b). In 2004, these materials were distributed to 25,000 high schools among 16,000 school districts nationwide (personal communication, M. Ganikos, HRSA, 2005); the recipients included 23,000 driver's education programs within those schools.

Eight states currently require organ donation information to be provided in driver's education courses: Arkansas, Iowa, Louisiana, Maine, Massachusetts, Minnesota, New Mexico, and Wisconsin (personal communication, M. Ganikos, HRSA, November 2005). Among other states, Ohio includes organ donation information in driver's education courses, but it is not legislatively mandated.

Knowledge about organ donation is generally associated with positive opinions about donation (Nolan and Spanos, 1989; Weaver et al., 2000). Several studies have examined educational interventions in high schools (Weaver et al., 2000; Reubsaet et al., 2005). Researchers conducting a study of 2,868 students in 39 high schools in The Netherlands in which students were randomly allocated to attend or not attend an organ donation education program found in a posttest that students who attended the two-session program had higher levels of intention to register as an organ donor

and were more knowledgeable about organ donation than the students in the control group (Reubsaet et al., 2005). A pilot educational intervention study by Weaver and colleagues (2000) of a much smaller number students (n = 72) found increased knowledge of organ donation in the intervention group and similar changes in opinion regarding the decision to donate.

Community Grassroots Efforts and Minority Populations

Community grassroots efforts focused on public education are important to increasing rates of organ donation. These efforts are particularly valuable when the community does its own strategic planning, implementation, and problem resolution because it can better address the issues, concerns, and topics of interest to the particular ethnic, cultural, or religious groups in that community. Furthermore, there are opportunities to leverage these efforts by working with community coalition partners in events and initiatives that provide health screenings (e.g., blood pressure and diabetes screening) and health promotion information.

Additionally, it is important for faith-based organizations to continue to be involved in encouraging organ donation. For many people, issues regarding death and dying are closely intertwined with their faith and spirituality. Faith leaders are encouraged to continue to reaffirm and publicize the position of the denomination or religion regarding organ donation.

One of the challenges in increasing organ donation rates has been to engage minority populations in organ donation. Recent statistics (Chapter 2) indicate that progress is being made and that minority populations are donating in proportions equal to or even greater than their proportion of the total population. This progress may in part represent the result of programs started years ago. Beginning in the 1980s, efforts were made to identify and address organ donation barriers faced by African Americans, and in the last decade these efforts have expanded to other minority populations.

One large-scale effort is National MOTTEP, a research-based effort funded by the National Institutes of Health (NIH)[2] to address the organ donation issues of minority populations. Begun as an effort focused on organ donation by African Americans, the program has expanded to include Latino-Hispanic, Native American, and Asian-Pacific Islander populations. National MOTTEP uses media campaigns and grassroots efforts to

[2]From 1993 to 2005, National MOTTEP received approximately $16 million in funding from the NIH Office of Minority Health Research, the National Institute of Diabetes & Digestive & Kidney Diseases, and the National Center on Minority Health and Health Disparities.

disseminate a two-pronged message: preventing chronic diseases (particularly hypertension, renal failure, and diabetes) and increasing awareness of organ donation (with information provided on the options for registering as an organ donor).

Before the inception of the National MOTTEP, a community focus group identified five main points of reluctance to organ donation in the African-American community that affect donation rates: the lack of community awareness of the need for transplantation, religious myths and misconceptions, general distrust of the medical community, fear of premature death, and racism (Callender et al., 2002). The focus group determined that the most effective communicators of information to potential donors would be individuals who shared a similar ethnicity and a similar set of cultural values with potential donors; individuals who conducted face-to-face dialogues with community members; and transplant recipients, potential recipients, donors, and donor families, along with healthcare professionals. This methodology was later enhanced through the use of widespread media campaigns and college outreach activities targeted to minority communities to effectively improve awareness of organ donation (Callender et al., 1995).

In 1998 and 1999, an assessment of the effectiveness of the National MOTTEP model was conducted with 914 adults with diverse ethnicities in 13 cities (Callender et al., 2001). Surveys completed before and after a MOTTEP presentation found significant increases in the levels of awareness of perceived need, trust in doctors, future plans to donate, and shifts in religious and spiritual beliefs about donation. In a further evaluation, telephone interviews were conducted 2 to 3 months following participation in a MOTTEP presentation. The interview was designed to assess whether the alterations in behavior were sustained and explicitly assessed the number of people who had signed donor cards, determined whether family discussions about donation were conducted, and determined whether the participants were willing to be donors after the intervention. A total of 253 telephone interviews were conducted. Preliminary analysis showed improvements in all three of the behaviors being measured (Callender et al., 2002). Furthermore, an analysis comparing the number of deceased donors at MOTTEP and non-MOTTEP sites found higher rates of donation for Caucasians, African Americans, Latinos, and Asians (Callender et al., 2005) (Table 6-2).

The National MOTTEP plans to continue its grassroots campaigns to educate minority communities about organ donation and strategies that can be used to prevent diseases and behaviors that lead to organ donation. Its next phase will focus on reducing institutional racism by empowering minority communities to respond to ethnic disparities, correcting false assumptions made by the medical community about their patients, and encouraging overall behavioral and attitude changes in the medical com-

TABLE 6-2 Comparison of Deceased Donors at MOTTEP and Non-MOTTEP Sites

	MOTTEP Site		Non-MOTTEP Site		Adjusted Donation Rate[a]	
Ethnicity	Number of Deceased Donors/ 1,000 Deaths[b]	Number of Donors	Number of Deceased Donors/ 1,000 Deaths[b]	Number of Donors	Ratio (MOTTEP Site to Non-MOTTEP Site)	*P* value
White, Non-Hispanic Caucasian	59.3	4,938	59.2	11,279	1.07	0.02
Hispanic or Latino	106.9	1,055	47.4	886	2.29	<0.01
African American	43.4	1,263	32.9	1,286	1.40	<0.01
Other	50.7	228	43.4	272	1.59	<0.01

[a]Adjusted for age, sex, and Organ Procurement and Transplantation Network region.
[b]Numbers of deceased donors per 1,000 evaluable deaths.

SOURCE: Callender et al. (2005).

munity. Key to the success of this effort will be involvement by the relevant professional associations, including the American Medical Association, the National Medical Association, the National Hispanic Medical Association, the American Nurses Association, the National Black Nurses Association, and the National Association of Hispanic Nurses.

Continued funding is needed for the National MOTTEP and similar grassroots efforts. The National Center on Minority Health and Health Disparities can play a key role in promoting organ donation and in reducing the healthcare disparities of concern regarding transplantation; however, to date funding for these purposes has been limited.

Increasing the organ donation rates by all population groups is the essential first step in meeting current and future needs for organs. To accomplish this goal, robust, culturally sensitive educational materials will be needed, as will novel approaches to reaching minority communities. An interesting demonstration of an approach that is sensitive to minority populations is a study that examined the attitudes of English and Spanish-speaking U.S. Hispanics on ways to initiate discussions on organ donation. The use of kiosks with information on organ donation was identified as a potentially effective strategy, outweighing appeals via computer or the U.S. mail for the population studied (Siegel et al., 2005).

Although many organizations, states, and government agencies have developed excellent educational materials and interventions, at present no centralized set of culturally sensitive materials on organ donation exists. Such materials would provide a valuable resource for many states and organ donation organizations.

Next Steps for Public Education

For public education to be effective, it is important to consider the way in which messages are conveyed. The message should be highly visible, presented in a clear and easy-to-understand format, presented so it is accessible to individuals of various educational levels, and provided by a trustworthy source that is sensitive to the ethnicity and cultural values of the target community. It has been suggested that the most effective messengers come in the form of transplant recipients and donors, donor families, and donor candidates (Callender and Maddox, 2004). There is a need to provide information that will address specific issues of concern and dispel myths regarding organ donation. For example, recent changes in allocation policies (e.g., changes made in the allocation algorithm to deemphasize the importance of human leukocyte antigen typing for kidney transplantation) should be highlighted with explanations of the potential positive impact of these changes on reductions in waiting times for African-American candidates for transplantation (Chapter 2).

Entertainment and media outlets, particularly individuals responsible for media content including writers and producers, have responsibilities to accurately portray organ donation efforts and are encouraged to continue to work with the organ transplant community to ensure that myths and misperceptions are not perpetuated.

Improving and extending public education will require the efforts of the many stakeholders and organizations involved, including nonprofit organizations, entertainment and media organizations, community coalitions, OPOs, hospitals, HRSA, NIH, and the Centers for Disease Control and Prevention (CDC).

HRSA has been the locus of much government funding in this area, and as requested in the charge to the committee, Appendix E provides an examination of the HRSA Division of Transplantation's extramural research program in which a variety of public education and other approaches are being explored. One of the many strengths of the program is that the grants are required to be developed with a strong evaluation component. Further, the team submitting the grant proposal must be constituted as a consortium that includes an academic or other research-based partner. HRSA also provides extensive technical assistance. Limited funding is of concern as it has placed constraints on the potential to explore additional innovative

approaches and to scale up those interventions that have been found to be promising. The Division has leveraged the opportunities presented by the Organ Donation Breakthrough Collaboratives to incorporate new findings into the work of the collaborative hospitals and OPOs.

SUMMARY AND RECOMMENDATIONS

Making an informed choice regarding organ donation, documenting that decision, and sharing the decision with family members are the key steps in ensuring that individuals are able to exercise their rights to make a determination about the disposition of their organs after death. This decision is a significant expression of personal autonomy, as the individual considers an action that after his or her death has the potential to save lives and improve the quality of life for others.

Many myths surround organ donation and serve as barriers to increased donation rates. Therefore, public education that is culturally sensitive and that uses effective community education strategies is needed. Public education about organ donation should emphasize that all members of society have a common interest in an adequate supply of organs because all are potential recipients as well as potential donors. Each individual should have multiple opportunities to learn about organ donation and to express his or her desire to donate. Furthermore, mechanisms are needed to ensure that recorded decisions to donate are accessible to the relevant healthcare professionals and OPO staff on a 24-hour-a-day, 7-day-a-week basis.

The committee believes that it would be premature to move toward a policy of mandated choice, even on a pilot basis, until efforts are first undertaken to implement the recommendations made elsewhere in this report to increase first-person consent and to make donation the expected act by families of deceased individuals who have not recorded their desire to donate.

Recommendation 6.1 ***Increase Public Understanding of and Support for Organ Donation.***
HRSA, NIH, CDC, the United Network for Organ Sharing, OPOs, voluntary health organizations, faith-based organizations, community coalitions, and other interested parties should strengthen their efforts to provide public education about organ donation through multiple media and educational venues. They should pay particular attention to developing and disseminating culturally sensitive educational materials that can be understood by individuals with different levels of education. Entertainment and media organizations should strive to accurately portray organ donation and transplantation.

Recommendation 6.2 ***Increase Opportunities for People to Record Their Decision to Donate.***
HRSA, state and local governments, nonprofit organizations, community coalitions, and other interested parties should provide multiple opportunities for individuals to receive information on organ donation and to record their donation decisions. These opportunities should be provided at the times of driver's education and licensing and advance care planning, as well as through work-, faith-, school-, and community-based initiatives.

Recommendation 6.3 ***Enhance Donor Registries.***
State governments (including departments of motor vehicles), OPOs, and HRSA should work together to:

- **ensure full access to and sharing of donor registration data;**
- **ensure that a nationwide networked system of registries that identifies self-declared organ donors is readily accessible to OPOs and healthcare professionals on a 24-hour-a-day basis, and is updated daily.**

Recommendation 6.4 ***Mandated Choice Should Not Be Enacted.***
At this time, states should not enact legislation requiring people to choose whether or not to be an organ donor (mandated choice).

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7
Presumed Consent

In the United States, deceased organ donation occurs only with express consent[1] (often in response to an inquiry or request). This consent may be given in advance by the individual while he or she is still alive, or it may be given by the next of kin after the death of the individual. The state laws that govern organ donation thus require opting in (or contracting in). The default option, in the absence of express consent, is nondonation. Proposals to increase the availability of transplantable organs often recommend a policy of opting out (or contracting out). Under such a policy, organs from deceased individuals could be removed for transplantation unless the decedents—or their families, after their deaths—had followed the prescribed measures for opting out. The default option, in the absence of express objection, would become donation.

Not all opt-out policies are the same, and different issues arise in the analysis and assessment of different policies, particularly presumed consent and routine removal.[2] Presumed-consent and routine-removal policies are commonly confused or deliberately conflated. Even though both involve opting out, their differences are significant, and any adequate analysis and

[1]The term "express consent" is used to indicate explicit agreement, generally documented in writing.

[2]"Presumed consent" or "presumed donation" is shorthand for "presumed consent to donation." All of these terms are used in the discussion in this chapter. "Routine removal" is also called "routine salvaging" or, even more problematically, "routine harvesting." Only the term "routine removal" is used in the discussion in this chapter.

assessment must examine those differences. This chapter briefly discusses routine organ removal and then considers presumed consent in depth.

ROUTINE REMOVAL

Routine removal presupposes that the state or society has a right of access to the organs of deceased individuals. This right may rest on the state's or the society's claimed ownership of or authority over the bodies of deceased individuals, or it may rest on an enforceable duty of individuals and families to provide postmortem organs as needed. The fundamental distinction between policies of routine removal and policies of presumed consent rests on their different interpretations of the relation of the individual and his or her dead body to the state or society. Routine removal is broadly communitarian (Nelson, 1992), whereas presumed consent—like expressed consent—is largely individualistic, even though it may include a role for the family. Policies of routine removal also fall under the broad label of opting out, because they generally allow individuals to opt out under various circumstances. Furthermore, in most countries, organ procurement teams contact the families of decedents, even when the authorizing legislation for routine removal does not mandate consultation with the family (Prottas, 1985).

It is also important to note that broad public understanding and voluntariness are not essential for an effective policy of routine organ removal. Instead, state or societal ownership of or authority over the bodies of deceased individuals (or individuals' and families' enforceable social obligations) ground the law and social practices of implementation (Childress, 1997). Hence, the removal does not require anyone's explicit or implicit consent. However, for various reasons, public understanding and voluntary (although passive) acceptance may still be sought.

In the United States, as in many countries, the state does not claim complete authority over the disposition of the bodies of deceased individuals, and the recovery of solid organs is grounded in the consent of the donors or their families. Some states in the United States do authorize medical examiners to remove the corneas from bodies that come under their authority to conduct an autopsy to determine the cause of death. These laws do not require express consent. Even though they allow opting out, they generally do not impose an obligation on the medical examiner to notify families, even if the next of kin happens to be nearby. In one case in Florida, a family was in a nearby room while a deceased relative's corneal tissue was being removed without their express consent (*Florida v. Powell*[3]).

[3]*Florida v. Powell*, Fla., 497 So.2d 1188 (1986).

In *Florida v. Powell*, the Florida Supreme Court found that state's law to be constitutional.[4] It found that the statute had a reasonable relation to the permissible legislative objective of "providing sight to many of Florida's blind citizens" through the provision of a larger and superior supply of transplantable corneas from the medical examiner's office than that available through regular donation.

> The evidence establishes that this increase in the quantity and quality of available corneal tissue was brought about by passage of the statute and is, in large part, attributable to the fact that [the law] does not place a duty upon medical examiners to seek out the next of kin to obtain consent for cornea removal (*Florida v. Powell*).

These statutes have been considered very effective. For example, substantial increases in corneal transplants occurred after such a statute was passed in Georgia: from 25 in 1978 to more than 1,000 in 1984 (National Conference of Commissioners on Uniform State Laws, 1987).

These cornea retrieval statutes do not presume consent; rather, they authorize routine removal subject to the objection of the family. There appears to be little or no effort to educate the public about these laws, and there is no evidence of widespread public understanding that these routine-removal laws exist and will be applied under certain circumstances.

Because such routine-removal statutes have passed in state legislatures and survived constitutional challenge, the following question arises: Could states adopt similar laws for obtaining solid organs? Several factors militate against the adoption of this routine-removal model for solid-organ recovery in the United States. First, the current policies of routine removal apply only to the relatively small number of deceased bodies that come under the authority of the medical examiner. Second, corneas can be viewed as more external than solid or vascularized organs embedded in the body. As a result, the removal of the corneas may not arouse some of the ambivalent or negative emotions often associated with the removal of internal organs. Third, the removal of corneas occurs in the context of deaths declared according to uncontroversial applications of traditional circulatory criteria, whereas the removal of solid organs occurs in the context of determinations of death (whatever the criteria) that evoke public confusion and, sometimes, distrust. Finally, the passage and implementation of laws authorizing medical examiners to remove corneas subject to the objection of the family have received little close public scrutiny—perhaps for the reasons given

[4]The U.S. Supreme Court has let these laws stand without ruling on their constitutionality. See *Georgia Lions Eye Bank Inc. v. Lavant*, 255 Ga. 60, 335 S.E.2d 127 (1985); cert. denied 475 U.S. 1084, 106 S.Ct. 1464, 89 L. ed 721 (1986).

above—in contrast to what could be expected for any proposal for a policy of routine postmortem organ removal and transfer.

Proposed routine-removal policies for internal organs are controversial in the United States because they depart from the established ethical, societal, and legal principle of individual and familial dispositional authority over the body of the deceased individual and from the norm of express consent for organ transfer. Even though such policies usually allow the individual and, often, the family to opt out, they still rest on claims that the state or society has dispositional authority over the body of the deceased individual or that individuals and families have enforceable obligations to provide organs postmortem. For this reason, it is misleading when the proponents of routine removal attach the label "presumed consent" to their proposals. This label obscures the degree to which routine-removal policies would depart from U.S. standards and norms, as well as from the value of individualism. Indeed, in practice, if not in rhetoric, some opt-out policies in other countries appear to be policies of routine removal (even with notification) rather than policies of presumed consent (Veatch and Pitt, 1995; Veatch, 2000).

In conclusion, there are serious doubts that a policy of routine removal with the possibility of opting out could or even should be adopted in the United States, because of its assumption of state or societal authority over the body of the deceased individual and its organs and the corollary that no individual or familial consent, whether it is express or passive, is necessary for the removal of organs. Even if such a policy were to be adopted by a state legislature, it is likely that public resistance would be strong enough to thwart its primary purpose of increasing the supply of transplantable organs. For these reasons, the committee does not regard routine removal as a viable approach in the United States. Instead, the chapter focuses on presumed consent, which, although also controversial, would be more acceptable because it affirms the principle that dispositional authority rests with individuals while they are alive or with their next of kin after they have died.

PRESUMED CONSENT

The presumed-consent policy for the recovery of organs from deceased individuals has been explained in the following manner:

> Public policy based on presumed consent would offer every adult the opportunity to express and have recorded by publicly accountable authorities his or her refusal to be a donor of solid organs and tissues. A clinically and legally indicated candidate for cadaveric organ and tissue recovery is presumed to have consented to organ and tissue recovery if he or she had not registered a refusal (Dennis et al., 1993).

Such a policy assumes that individuals have and can exercise dispositional authority over their organs postmortem. However, it shifts permission for donation from express consent to presumed consent. In the absence of an explicit and expressed decision, the default would become donation rather than, as is currently the case, nondonation.

Varieties of Consent

Presumed consent is one of a number of different varieties of consent (Beauchamp and Childress, 2001). The paradigm of consent in biomedical ethics is express consent. It appears in the Uniform Anatomical Gift Act's framework for organ donation as well as in rules of voluntary, informed consent in both therapy and research involving human participants. However, express consent is not the only kind of consent that can be valid and effective. For instance, there is implicit or implied consent, which is inferred from other actions. In addition—and most relevant for the purposes of this analysis—there is tacit consent, that is, "consent that is expressed silently or passively by omissions or by failures to indicate or signify dissent" (Childress, 1997, p. 277). Under certain conditions, nonobjection or nondissent constitutes valid tacit consent (Simmons, 1976).

> The potential consenter must be aware of what is going on and know that consent or refusal is appropriate, must have a reasonable period of time for objection, and must understand that expressions of dissent will not be allowed after this period ends. He or she must also understand the accepted means for expressing dissent, and these means must be relatively easy to perform. Finally, the effects of dissent cannot be "extremely detrimental to the potential consenter." Some of these conditions ensure the consenter's understanding; others ensure the consent's voluntariness. When these conditions are met, the potential consenter's silence may be construed as tacit consent. Such consent may be ethically valid in some circumstances (Childress [1997, p. 277] summarizing and elaborating on the work of Simmons [1976]).

Tacit consent presupposes the consenter's competence. Children, for instance, could not give tacit consent; someone who is competent to make that decision would have to give consent for them.

Some critics claim that presumed consent is a "fiction" (Erin and Harris, 1999). However, the description of presumed consent given above as tacit, silent consent indicates that it need not always be a fiction. It can sometimes be actual, valid, and effective consent, depending on the nature and structure of social practices, as well as the competence of the individuals whose silence is presumed to be consent, their understanding, and the voluntariness of their choices. Given the current absence of established social practices in the United States that would warrant such a presump-

tion, it would not be possible to presume consent for organ donation in this country at this time.

This first model of presumed consent construes it as tacit, silent consent. At least two other models appear in the bioethics literature. A second model would presume consent to donation on the basis of a general theory of human values or on the basis of what reasonable, altruistic people should and would do. This is not what the committee's discussion of presumed consent envisions—such theories or views do not warrant a presumption of consent for organ donation by particular individuals.

A third model bases the presumption of consent on what a deceased person would have decided if he or she could be asked. The paradigm case is treatment provided in emergencies when the patient is incapacitated or time does not permit the interactions that would otherwise be needed to elicit valid consent. According to Veatch and Pitt (1995, p. 1889), the presumption of consent makes an empirical claim: "The reasoning behind true presumed-consent laws is that it is legitimate to take organs without explicit consent because those from whom the organs are taken would have agreed had they been asked when they were competent to respond." This third model marks an advance over the second model, but it is still somewhat abstracted from particular social practices. It rests presumed consent on the basis of current opinion polls that show widespread public support for organ donation. However, such a presumption, if it were implemented now, would be mistaken for a certain percentage of the population (i.e., those who do not currently support donation). It is possible, perhaps even probable, that new social practices, particularly increased levels of public education regarding donation, could make it more reasonable in the future.

In principle, presumed donation, as a form of tacit or silent consent (the first model), could be an acceptable basis for organ removal. However, as already indicated, it can be ethically valid only if it satisfies some rigorous conditions. Unless those conditions are met, silence (nonresponse) may indicate only that the individual does not understand the default or the means to avoid it. To be ethically acceptable, a policy of presumed consent would require widespread and vigorous public education to ensure understanding, along with clear, easy, nonburdensome, and reliable ways for individuals to register dissent. In view of the difficulty of interpreting silence, it is not surprising that in most policies of opting out in other countries, organ recovery teams also consult the decedent's family.

Weak and Strong Presumed Consent

There are strong and weak versions of the presumed-consent model in organ donation (Table 7-1); they differ in the extent to which the family of the decedent is involved in the donation process. In the strong version,

TABLE 7-1 Organ Donation Decision-Making Policies

Type of Policy	Description	Default
Opt-in policy	Current U.S. system Individuals or family members make an express decision to donate	Nondonation
Opt-out policy		
Presumed-consent policy	• Individuals and, secondarily, family members have the right to determine access to the organs of deceased individuals • Individuals and, in some contexts, family members may make an express decision not to donate	Donation
• Weak presumed-consent policy	• Organ recovery teams must consult with the family	Donation
• Strong presumed-consent policy	• Organ recovery teams do not have to consult with the family	Donation
Routine-removal policy	• The state or society has the right of access to the organs of deceased individuals (policies may still allow opting out)	Donation

organ recovery teams do not have to check with the family, either about the family's knowledge of the decedent's preferences or about the family's own preferences. In the weak version, organ recovery teams must consult the next of kin after an individual's death. In many countries with what might be considered strong presumed-consent legislation (or even routine-removal legislation), organ recovery teams in practice still inform the families of decedents. Whether the legal framework is express donation or presumed donation (or even routine removal), practices in different countries are generally quite similar, with the family usually playing or being allowed to play some role in the donation process (Prottas, 1985).

In sum, under presumed-consent laws, while individuals are alive they have dispositional authority over their bodies after their deaths; and within an established and well-understood set of rules and practices, their silence, or their nonrefusal of organ donation, can appropriately be construed as valid consent. In this context, organ recovery teams may legitimately remove decedents' organs without their prior, express consent. They may also consult the family as a procedural safeguard—for example, the family may be aware of the decedent's objections—or in recognition of familial interests. Within a presumed-consent framework, the dispositional authority over the organs rests primarily with the individual and only secondarily, if

at all, with the family. Neither the individual, while he or she is alive, nor the family, after the individual's death, has an enforceable obligation to donate organs. These features, along with important differences in social practice, distinguish presumed consent from routine removal. Although presumed-consent policies are still very controversial, they would be more acceptable than policies of routine removal in the United States. Presumed-consent policies fit better with the ethical, societal, and legal principle of the individual's (and the family's) dispositional authority over the individual's organs postmortem. However, presumed consent is controversial because it departs from the ethical, societal, and legal norms and practices of express consent. The discussion now turns to a closer examination of proposals for presumed-consent policies.

Assessment of Presumed-Consent Policies

The main argument for policies of presumed consent stresses their potential effectiveness in increasing the supply of transplantable organs, but questions remain about their effectiveness and their cost-effectiveness. A secondary argument for presumed-consent policies stresses their potential benefits for the grieving family by reducing the burden of decision making at a difficult time in their lives. In addition, arguments for presumed consent note that autonomy can be exercised silently or passively in social practices that have donation as the default option. Some counterarguments focus on disrespect for autonomy and on practical problems. Other objections identify possible injustices and the loss of opportunities for individual generosity. In response, supporters emphasize ways to avoid or reduce possible injustices and dispute the threat to individual generosity. The following discussion analyzes the array of arguments that have been presented on both sides of the debate and offers the committee's comments on presumed-consent policies.

Effectiveness and Cost-Effectiveness

Effectiveness in Increasing the Number of Transplantable Organs The primary argument in favor of presumed consent is that it would increase the availability of transplantable organs and that such an increase could save lives and enhance the quality of the lives of transplant recipients. If a presumed-consent policy did not have a strong prospect of increasing the number of available organs, there would be no reason to adopt it.

Countries with opt-out policies appear to have higher donation rates than countries with opt-in policies (Abadie and Gay, 2004). Nevertheless, there is debate about how to determine effectiveness (for instance, whether the rate of donation per million population is an adequate measure) (Chap-

ter 1). In addition, there is debate about the relative contribution of and connections between opt-out policies and other policies, social practices, and conditions that may also help to increase rates of organ donation. For instance, in Spain, which has greatly increased the number of available organs for transplantation, the opt-out policy has been accompanied by other significant changes, especially changes in the infrastructure and the implementation of a program of donation after circulatory determination of death (Chapters 1 and 5). It is difficult, if not impossible, to identify the single most important causal factor.

The following is one list of the factors that, along with opt-out policies, appear to have had an impact in such countries as Spain and Belgium (a summary has been provided by English and Sommerville, 2003; see other lists of factors in the works of Roels et al., 1991; Kennedy et al., 1998; Cameron and Forsythe, 2001; Gimbel et al., 2003; Abadie and Gay, 2004):

- the predominant cause of death (such as the number of road accidents),
- the availability of beds and staff in intensive care units,
- the number and efficiency of transplantation coordinators,
- the number of transplantation surgeons,
- the number of specialized units in the region, and
- the number and characteristics of the patients on the waiting list (such as what organs they need).

Other factors include religious and cultural views of and attitudes toward death and the body of the deceased individual (Kennedy et al., 1998).

Although several of these factors account for much of the international variation in the rates of organ recovery, opt-out legislation "has a positive and sizeable effect on organ donation rates"; and after accounting for other determinations of donation rates, "presumed-consent countries have roughly 25 percent to 30 percent higher donation rates than informed-consent countries" (Abadie and Gay, 2004, p. 15).[5] This level of increase would greatly ease, even though it would not totally eliminate, the organ shortage in the United States (Abadie and Gay, 2004). It is also worth noting that per capita donation rates in the United States already exceed those of many countries with presumed-consent policies, so the impact of adopting presumed consent would likely be less than a 25 to 30 percent increase.

Another problem in the evaluation of the potential effectiveness of

[5]Furthermore, Abadie and Gay (2004, pp. 16ff.) show that the difference cannot be explained by a supposed strong and widespread sociocultural commitment to organ donation that has led to and sustained a presumed-consent law; their analysis uses "annual blood donations (per capita) as an indicator of societal preferences towards organ donation."

presumed-consent policies is that the laws in some countries may involve routine removal with the possibility of opting out rather than presumed consent in a strict sense. As a result, claims about and evidence for the effectiveness of presumed-consent policies may be based in part on policies of routine removal. If so, legitimate questions arise about whether a system of presumed consent would be equally effective and cost-effective. For instance, it is an open question whether some of the measures required by ethical presumed-consent policies—for instance, vigorous educational efforts to ensure public understanding—would lead to more refusals and would decrease the effectiveness of such policies. In any event, such measures would be costly.

Some recent empirical evidence about the probable effectiveness of presumed-consent strategies for organ donation comes from studies of the effects of default mechanisms in other contexts. Johnson and Goldstein (2003, 2004) view individual preferences as constructed rather than clearly known in advance. In light of this view, they explore the hypothesis that default mechanisms influence choices, including organ donation, in one or more of the following ways: (1) by marking certain (default) actions that are favored by policy makers for the society, (2) by creating options (defaults) that require no effort, and (3) by representing the status quo through defaults, the alteration of which requires trade-offs (Johnson and Goldstein, 2003). Various reports of individuals' choices regarding insurance or pension savings indicate that default policies often have a considerable impact.

In an online experiment, Johnson and Goldstein (2003) asked 161 people whether they would agree to donate organs in response to one of three questions, each with a different default. (1) With an opt-in default policy, participants were asked to assume relocation to a different state with a default of nondonation of organs and to indicate whether they would confirm or alter this default. (2) With an opt-out default policy, participants were also asked to assume relocation to a different state with a default of donation of organs and to indicate whether they would confirm or change this default. (3) With a neutral-choice policy, participants were asked to choose in the absence of a prior default. These scenarios led to very different responses. "Revealed donation rates were about twice as high when opting-out as when opting-in. The opt-out condition did not differ significantly from the neutral condition (without a default condition). Only the opt-in condition, the current practice in the United States, was significantly lower" (Johnson and Goldstein, 2003, p. 1338).

Nevertheless, there are concerns about whether a presumed-consent policy would be effective in the United States. In 2005, the Council on Ethical and Judicial Affairs of the American Medical Association (AMA) recommended that physicians not support a presumed-consent policy unless small, well-designed pilot studies established that it would be effective

(AMA, 2005). The Council believes that unless data from these pilot studies "suggest a positive effect on donation, neither presumed consent nor mandated choice for deceased donation should be widely implemented" (p. 5). At this point, the Council contends, it is unknown whether implementation of presumed consent (or of mandated choice) "would positively or negatively affect the number of organs transplanted" (AMA, 2005, p. 5).

The following is a line of argument that expresses the concern that adoption of a presumed-consent policy might be counterproductive in the United States: some individuals now fail to sign donor cards because of their distrust of the system, including their fears that they might not receive the best possible care or that their deaths might even be hastened if they were on record as organ donors, but they may not be opposed to a family decision to donate their organs after their death. Under a presumed-consent policy, some of these same individuals might opt out to avoid the perceived risks of being on record as an organ donor (through their silent or tacit consent) (Wells, 2005); this would prevent familial donation. Therefore, not surprisingly, major questions arise about whether it is wise to seek a dramatic change in a system that works fairly well, although not perfectly. These questions are particularly challenging when the changes could possibly be ineffective or even counterproductive in part because of mistrust and distrust.

Preliminary results from the 2005 National Survey of Organ Donation suggest that about 30 percent of respondents would opt out under a presumed-consent law. In response to a question about whether they would register as "nondonors" under a presumed-consent policy, 30.9 percent said "yes," 63.1 percent said "no," and 5.9 percent said "I don't know" (Wells, 2005). If, indeed, over 30 percent of the population (which could perhaps be higher if many in the undecided population settled on "no") were to opt out, it is possible that fewer transplantable organs would be available under a presumed-consent policy than under the current opt-in policy of express consent. (These data must be used with caution, because the responses do not reflect the results of a vigorous and extensive educational campaign, which would be essential for the implementation of a presumed-consent law.)

At present, under the opt-in policy in the United States, the available evidence does not indicate that a large number of people who fail to express their wishes to donate through a document or registry actually forbid their families from donating their organs after death. As a result, family members—rather than individuals while they are alive—are the ones who most often give express consent for organ donation postmortem. If, however, under a presumed-consent donation policy approximately 30 percent of the population were to register as nondonors, almost one-third of the potential donors would effectively block their families from donation.

The fact that so many respondents to the survey indicated that they would opt out under a presumed-consent policy suggests that reasons other than inertia, a lack of thought about donation, or reluctance to think about death probably account for much of the current limited registration as organ donors (Gallup Organization, 1983, 1985, 1986, 1987). As noted above, some people do not want to be on record as organ donors because of fears that they will receive inadequate care or that their death will be hastened (Gallup Organization, 1983, 1985). By itself, however, a presumed-consent policy would not alter such attitudes. Indeed, it could possibly exacerbate them. It is simply not clear how well defaults would work in the context of such attitudes and concerns. As a result, several proposals advocate vigorous and extensive educational programs to promote public understanding of the moral values of donation, including altruism, reciprocity, and solidarity. Other proposals also stress the need for a careful, cautious, and gradual transition to a policy of presumed consent, including a phase of "expected donation" within the current opt-in policy (Siegal and Bonnie, 2006). Still other proposals would combine a presumed-consent policy with other significant changes, including the use of such incentives as preferred status (see, for example, Eaton, 1998).

Cost-Effectiveness In light of the uncertainties about how effective a presumed-consent policy would be in the United States, it is impossible to conduct a rigorous cost-effectiveness analysis. A few observations, however, may be pertinent. It is possible that an ethically acceptable presumed-consent policy would be less cost-effective than enhanced and redirected educational efforts for express donation. After all, to be valid, presumed consent requires understanding; and public understanding entails vigorous and extensive public education. In addition, there must be clear, easy, nononerous, and reliable ways for individuals to register their objections to being organ donors, as well as multiple opportunities to do so.

A tension could arise between making presumed consent cost-effective—and more cost-effective than other possible ways to increase the number of transplantable organs—and satisfying the rigorous conditions necessary to make presumed consent ethically valid. To take an example, defaults are often effective because the alternative appears to require effort and thus to be somewhat burdensome (Johnson and Goldstein, 2003). Yet, ethically, opting out of postmortem organ donation should be—and should be perceived to be—nonburdensome if presumed consent is to be valid.

Reducing the Burden of Familial Decision Making

Many argue that presumed-consent policies would reduce the burden of decision making on the grieving family (Muyskens, 1978). This is usu-

ally presented as a secondary goal of such policies. In the United States, organ procurement organizations (OPOs) have generally checked with the family even when the decedent has signed a donor card; but despite a few reports to the contrary, current evidence indicates that family members rarely object or thwart organ donation in such cases (Chapter 2). In addition, many states have now passed laws that honor the signed donor card or other donation designation as legal consent for donation (Chapter 6; Appendix C).

In the absence of a signed donor card, OPOs and hospital staff turn to the next of kin as the legally authorized decision maker about organ donation. Indeed, several years ago it became mandatory for institutions to develop policies of required request or routine referral to ensure that the next of kin would be asked about donating the decedent's organs under appropriate circumstances. Hence, the family has played and continues to play a major role in deceased organ donation in the United States.

Under a weak presumed-consent policy, families may still be approached, as happens in most European countries with opt-out policies. In actuality, as noted above, countries with opt-out laws and with opt-in laws tend to have similar practices of consultation with the decedent's family.

In the United States and the United Kingdom, both of which have opt-in policies, approximately 50 percent of the requests for organ donation directed at the decedent's next of kin, in the absence of a signed donor card, are turned down. The turn-down rate is much lower in countries with opt-out policies: in Spain the rate is about 20 percent, and in France it is about 30 percent (Abadie and Gay, 2004). The next of kin can be approached quite differently when the decedent's silence is presumed to indicate a decision to donate rather than when it is presumed to indicate a decision not to donate. A system of presumed consent allows OPO and hospital staff to approach the family as the family of a "donor" rather than as the family of a "nondonor." This shift may make it easier for the family to accept organ donation. As a result, presumed donation could provide the basis for a helpful ritual in a difficult, often tragic set of circumstances (Muyskens, 1978). It appears, based on the experience in Belgium, "that relatives may be reluctant to take a personal decision about the removal of organs, but they find it easier to agree if they are simply confirming the intention of the dead person. If this is so, a contracting out system has a moral benefit of relieving grieving relatives of the burden of deciding about donation at a time of great psychological stress" (Kennedy et al., 1998). As discussed in Chapter 4, however, it is possible to frame the communication with families along these lines (that donation is "expected" because most people want to do so), even under the existing opt-in legal framework.

More than 15 years ago Judith Areen (1988) proposed a third option

for donor cards in the U.S. opt-in framework: the possibility of designating a surrogate to act as the decision maker about postmortem organ donation. That proposal would also be appropriate and potentially helpful in a presumed-consent framework. An individual would not have to decide between remaining silent, thereby allowing donation to proceed (perhaps within a social practice of consultation with the family), or refusing, thereby blocking any use of his or her organs after death. Instead, the individual could designate someone whom he or she trusts to serve as the postmortem decision maker.

Autonomy-Based Arguments

Different arguments based on autonomy and respect for autonomy can support or oppose presumed-consent policies. Some arguments for presumed-consent policies stress that the majority of respondents in public opinion surveys indicate that they would be willing to donate their organs or to have their organs donated but that less than 50 percent actually sign donor cards. As a result, "explicit consent policies impose the costs of switching on the apparent majority" (Johnson and Goldstein, 2003, p. 1339). A presumed-consent policy "could be a much better method [than opt-in policies] of realising individuals' wishes" (English and Sommerville, 2003, p. 147). In effect, so the argument goes, a presumed-consent policy would enable the majority to do what they say they want to do or would be willing to have done with regard to organ donation postmortem.

English and Sommerville (2003, p. 150) observe:

> Given that most people, when asked, express willingness to donate their organs after their death, there are reasonable grounds for presuming that they probably really do wish to donate. The current law, however, presumes they do not. Statistically, it seems that the default position is more likely to be correct if it is based on the individual wishing to donate, unless there are clues to the contrary. Arguably, therefore, unless all the opinion polls are wrong, presumption in favour of donation is more likely to realise the autonomy of the deceased person than a presumption against.

In view of the gap between the majority's expressed preferences, as represented in opinion surveys, and what they actually do, a policy of presumed consent would enable the majority to realize its general will more effectively, with less effort, and hence would increase the number of transplantable organs.

Proponents of presumed consent further claim that under the current opt-in policy in the United States, the number of false-negative responses (i.e., cases in which silence is mistakenly construed as a refusal to donate) is

much greater than the number of false-positive responses (i.e., cases in which silence is mistakenly construed as consent to donate) that would accompany an opt-out policy. It is unclear whether this claim is accurate, particularly because it rests on a prediction that people who do not want to donate under a presumed-consent system would be more likely to opt out than people who want to donate under the current system would be likely to opt in (Gill, 2004). Another question is whether "mistaken removals" and "mistaken nonremovals" are morally equivalent. Proponents of presumed consent tend to deny the ethical significance of this distinction (Gill, 2004). By contrast, critics of presumed consent worry more about the infringement of the autonomy of those who, for one reason or another, fail to opt out under such a policy. These critics contend that postmortem organ removal in such cases violates "the right of the individual not to have his or her body invaded" (Veatch and Pitt, 1995, p. 1890).

Some critics also emphasize the substantial number of individuals in the United States opposed to organ donation: the figure in opinion polls has hovered fairly consistently around 30 percent (Wells, 2005). Hence, these critics charge, any presumption of consent would necessarily include some decedents who were opposed to donation. Even if many dissenters opted out, some would fail to do so for one reason or another. Because of such concerns, supporters of presumed consent often stress the need to develop a set of social practices before presuming consent to donation (Abadie and Gay, 2004; Siegal and Bonnie, 2006). These social practices would include both improved and extended public education and mechanisms for the clear, easy, nonburdensome, and reliable registration of objection to organ donation. Supporters of presumed consent concede that it would not be ethically justifiable or effective merely to shift legislation from express consent to presumed consent without the development and effective implementation of these social practices over time. Within such social practices, individuals' previously stated preferences may not be as stable or as strong as they had thought, and the society's affirmation, through presumed-consent legislation, of the importance of organ donation may help revise those preferences.

Justice and Fairness

Another set of ethical concerns about policies of presumed consent focus on justice and fairness in the distribution of societal burdens, including the burden of decision making about the donation of organs from deceased individuals. More specifically, concerns have emerged that "some groups, such as those who do not speak English or cannot read and write, and those with limited or fluctuating mental capacity, may have difficulty in expressing a refusal or understanding the system" (Wilks, 1998, p. 151).

Hence, the argument might go, it would be unfair to expect individuals in these groups to take action to avoid becoming organ donors. This concern could be addressed, in part, by developing and undertaking special educational efforts in minority communities; by creating handy, easy, and nonburdensome mechanisms for registering dissent; and by consulting the family of the decedent.

Some critics of opt-out policies also worry about unfairly burdening religious and other conscientious objectors to organ donation by forcing them to take action to avoid having their organs removed after their deaths. Such policies could be "perceived as culturally or religiously insensitive" (AMA, 2005, p. 3). One possible answer might be that relatively nonburdensome measures of dissent could and should be established to protect autonomy and freedom of conscience. Furthermore, supporters of presumed consent would argue, "it is not necessary to remove all need for effort or initiative in exercising these rights" (Muyskens, 1978, p. 95). A partial analogy can be found in the recognition of conscientious objectors to military service in the United States: The selective service system has recognized and provided alternatives for conscientious objectors to military service, but it has also required potential conscientious objectors to take the initiative to register and defend the sincerity of their views. As this analogy suggests, when a government allows nonparticipation in a public policy that serves an important societal goal—such as defending the country or increasing the availability of transplantable organs—it may require nonparticipants to take some affirmative action without unduly and unfairly burdening their consciences.

Still another ethical concern based on justice and fairness may also have an impact on people's willingness to acquiesce, through their silence, to presumed organ donation. This concern focuses on justice in the distribution of benefits, such as funds for organ transplantation. The national Task Force on Organ Transplantation suggested that in the United States it is unfair and even exploitative to ask poor and rich people alike to donate organs because many of the poor would not have an opportunity to receive a nonrenal organ transplant, if needed, because of the heavy personal costs involved (Task Force on Organ Transplantation, 1986; Childress, 1997).[6] Such an argument would be even more powerful in a system that presumes consent to organ donation by all who do not expressly dissent. It is arguably unfair and exploitative to include in a policy of presumed organ donation individuals who would not be able to obtain a transplant if needed

[6]By contrast, renal transplants are generally covered by the End-Stage Renal Disease Program of Medicare, at least if the individual's primary health insurance does not provide coverage, although immunosuppressive medications for many transplant recipients are covered for only 3 years posttransplantation.

because of the lack of funds or the lack of healthcare insurance coverage, specifically, for costly (nonrenal) transplants. Hence, some would argue, the provision of funds for uncovered organ transplants should be part of any shift to a policy of presumed consent (see, for example, Siegal and Bonnie, 2006).

Individual Generosity, Societal Generosity, and Mutual Self-Interest

Another objection to presumed consent holds that, in contrast to express consent for donation, presumed consent for donation "would deprive individuals of the exercise of the virtue of generosity" (Ramsey, 1970, p. 210). Supporters could respond in several ways. First, this objection, even if it were relevant, should not prevent a society from developing a policy that would effectively increase the supply of transplantable organs and thereby save the lives and enhance the quality of life of many transplant recipients. Societal generosity may take priority over individual generosity.

Second, another counterargument contends that a policy of presumed consent would not in fact prevent individual acts of generosity. On the one hand, it would still be possible for individuals to give express consent. On the other hand, individual acts of nonrefusal or nonobjection themselves can reflect the virtue of generosity. It is a mistake to suppose that only express donation embodies generosity or altruism. A decision not to block presumed donation may also be generous and altruistic, even if express donation is more dramatic (Childress, 1997).

How would proposals for presumed consent fit into a model of organ donation rooted in mutual self-interest, reciprocity, and solidarity? The typical reciprocity-driven approach is framed as an opt-in plan based on individual registration (Steinberg, 2004; Nadel and Nadel, 2005). Under this approach, people who want to be eligible to receive organs or to have priority on the waiting list would be required to document their willingness to be organ donors (Chapter 8). However, another reciprocity-driven strategy (Siegal and Bonnie, 2006) is to frame the legal structure as a social contract under which the willingness to be a recipient in the event of need and to be a donor in event of death are both presumed and transplantation costs would be covered for everyone, thereby ensuring the genuine reciprocity now lacking in the U.S. system and addressing the concern about the unfair inclusion of uninsured poor people noted above. Under this approach, individuals who prefer to opt out of the system, perhaps on the basis of religious objections, could do so. It is expected, however, that most people would recognize their mutual self-interest in ensuring an adequate organ supply and would therefore choose to remain within the plan rather than opting out. The committee agrees that reciprocity, based on recognition of a common stake in increasing the organ supply, should play a more

prominent role in organ donation policy than is now the case, and the committee also acknowledges that presumed consent might be a logical element of a reciprocity-driven system. However, because implementation of this approach would still require individuals to make a genuine choice to remain in the system, most of the autonomy-based concerns raised earlier would still have to be addressed.

Could a Presumed-Consent Policy Be Adopted in the United States?

This discussion has so far considered whether a presumed-consent policy would probably be effective and cost-effective and whether major ethical concerns could be satisfactorily addressed (Box 7-1). Another basic question is whether such a policy could feasibly be adopted and implemented in the United States. The answer to this question about feasibility is, in many ways, unclear; but there are doubts that a presumed-consent policy could be adopted and effectively implemented, at least for the foreseeable future.

The views and attitudes of medical and health professionals, particularly those who would be directly or indirectly involved in organ recovery and transplantation, are important both for enacting presumed-consent laws and for implementing them. Although it is difficult to ascertain their views and attitudes in a systematic way, the evolving opinions of the Council on Ethical and Judicial Affairs of the AMA provide some clues. In 1994 the AMA Council adopted the following statement: "a system of presumed consent for organ donation, in which individuals are assumed to consent to be organ donors after death unless they indicate their refusal to consent, raises serious ethical concerns" (AMA, 1994, p. 812). The Council recommended, instead, a policy of mandated choice. When the Council returned to this topic in 2005, it expressed a less negative view of presumed consent but recommended the adoption of neither presumed consent nor mandated choice until well-designed, small-scale studies could establish their merits (AMA, 2005).[7]

Opinion surveys also do not indicate strong public support for an opt-out policy. Indeed, although the results of opinion surveys vary, in part depending on the wording of the questions—for instance, there is inconsistency in the labels used for different opt-out policies—they generally indicate substantial opposition to opt-out legislation. The strongest opposition is directed at a policy of routine removal without notification of the family. In a 1985 Gallup poll, 86.5 percent of the respondents indicated that they

[7]By contrast, the British Medical Association has recommended adoption of presumed consent (Ashraf, 1999; English and Sommerville, 2003).

BOX 7-1
Possible Benefits and Barriers of Presumed-Consent Policies

Possible benefits of presumed-consent policies include the following:

- Opt-out policies appear to have been effective, along with other measures, in increasing the supply of transplantable organs in several countries.
- Opt-out policies have been praised for reducing the grieving family's burden of decision making, but the family is still consulted in most policies (weak presumed consent) and will probably concur more readily when they are approached from this standpoint.
- Presumed-consent policies would enable the majority (as identified in opinion polls) to follow through more easily, even passively, on its expressed willingness to donate organs or to have organs donated, whereas these policies shift the burden of decision and action to the minority.
- Presumed consent would express and effectuate an organ donation policy grounded in the idea that everyone is a potential recipient and has a reciprocal interest in increasing the supply of organs.

Concerns about a presumed-consent policy—along with possible responses and ways to address those concerns—include the following:

- Unfair imposition of burden of opting out on poor and uneducated citizens. Response: This concern could be addressed by developing clear, easy, nonburdensome, and reliable means for opting out.
- Unfair imposition of burden of opting out on conscientious objectors. Response: Parallel to military service, it is justifiable to ask opponents to take affirmative action to avoid the default in a program that serves an important social good.
- Unfair incorporation of poor people with little or no insurance in a presumed-consent policy when they would not have access to expensive nonrenal transplants if they needed them. Response: This is an issue in the current opt-in policy, but it would be worse in a presumed-consent policy and is not likely to be effectively addressed in the near future.
- Denial of opportunity for expression of individual virtue of generosity and altruism. Response: The social virtue of generosity or altruism would be realized in an effective opt-out policy, and the individual virtue could be realized either in express donation (because a policy of presumed donation does not preclude express donation) or in not blocking the presumption of consent.
- Mistaken presumptions about the wishes of individuals who, for one reason or the other, failed to opt out. Response: To reduce mistakes, vigorous public education would be essential, along with various safeguards, including clear, easy, reliable, and nonburdensome ways to register dissent and perhaps also notification of the next of kin.
- Possible ineffectiveness and counterproductivity. Response: A major shift in social-cultural attitudes in the United States is a prerequisite for an effective and productive system of presumed consent.

would oppose legislation that would give doctors "the power to remove organs from people who have died recently but have not signed an organ donor card without consulting the next of kin" (Gallup Organization, 1985). In a 1991 survey of 801 individuals, 55 percent of the respondents indicated that "physicians should not be able to act on implied consent," 38 percent indicated that "physicians should be able to act on implied consent," and 7 percent indicated indecision (Dennis et al., 1993). Preliminary analysis from the 2005 National Survey of Organ Donation indicates greater support but still majority opposition for presumed consent. When asked about their support for presumed consent, 53.6 percent said "no," 43.2 percent indicated "yes," and 3.2 percent indicated "I don't know" (Wells, 2005).

A policy of presumed consent will fail without the support of the public and of the relevant healthcare professionals. However, questions arise about how policy makers should proceed if they believe that such a policy is the best way to express and balance moral responsibilities to decedents and their families, on the one hand, and to people in need of a transplant, on the other. Should policy makers try to change public opinion and professional opinion? Or should they proceed on the assumption that legislating a shift from express consent to presumed consent would itself have a major impact, at least over time, on public and professional opinion? Should policy makers develop phase-in policies?

Some proponents of presumed consent contend that altering the default would probably produce a major cultural shift over time, with donation becoming a strong and pervasive social norm (English and Sommerville, 2003). At the very least, proponents of presumed consent argue that legislation could express and symbolize society's high valuation of organ donation as well as organ transplantation, which depends on donation. As they see it, the current opt-in laws constitute "a less than energetic endorsement of transplantation" (Kennedy [1979] quoted in English and Sommerville [2003, p. 151]). By instituting a policy of presumed consent, society would put its stamp of approval on both organ transplantation and organ donation, and the societal stamp of approval is one way that default policies shape responses. Along the same line, a presumed-consent approach might be a logical way to express and implement an organ donation policy grounded in reciprocity and mutual self-interest. Nevertheless, some supporters of presumed-consent legislation sound a cautionary note. For instance, Abadie and Gay (2004, p. 18) observe that "it seems likely that in some countries the imposition of a presumed-consent law, without building first sufficient social support, could generate an adverse response towards organ procurement efforts."

CONCLUSIONS

The committee believes that it would be premature to attempt to enact presumed-consent policies at this time. Although the committee is supportive of the principles of a presumed-consent approach (namely that under certain clear and well-defined circumstances, in the absence of an individual's expressed decision, one may presume his or her consent rather than refusal to donate), the first step is to build sufficient social support before introducing presumed consent in the United States. This can be accomplished through intensified public education regarding organ donation, building greater trust in the healthcare system, and encouraging a general shift in societal understanding of the value and moral grounding of donation. The current emphasis on the use of first person (donor) consent to organ donation can reinforce the importance of individual decision making. Coupling this change with the move towards use of an expected donation approach with families (Chapter 4) can also strengthen the societal norm of organ donation as a social responsibility and standard practice.

Questions have been raised about whether it would be possible to conduct small-scale, pilot experiments of presumed consent to help determine its effectiveness and its ethical acceptability to the public and health professionals. As noted above, the AMA Council on Ethical and Judicial Affairs (AMA, 2005) has recommended such experiments. They would be designed to "measure the change in number of organ transplants, the number of donations, awareness among the public that a presumed-consent system was in place, number of documented refusals to donate, how often families claimed to know of refusals, and acceptance by the population of the undermining of individual self-determination"[8] (AMA, 2005, p. 4).

Nevertheless, it is not clear that such small-scale, pilot experiments can be successfully undertaken without effectuating a major change in policy and taking the risks associated with doing so. Each state has structured the transfer of organs for transplantation around express consent. Hence, it would not be possible to conduct an experiment of presumed consent in the transfer of transplantable organs without changes in state law, and the experiment would probably need to be at least statewide. Moreover, even if the policy were implemented only in a few states, adverse public reaction could have undesirable spillover effects on public attitudes in other jurisdictions, thereby eroding public support for donation.

It is important to note that several possibly important differences exist between prominent U.S. beliefs and values, particularly individualism, and the beliefs and values of most of the countries with opt-out policies. With-

[8]Not everyone would agree that presumed-consent policies necessarily "undermine" individual self-determination; as noted above, such policies, under some circumstances, may provide another way in which self-determination can be exercised.

out a wider consensus in the United States about a policy of presumed consent, its passage and implementation could lead to a decline in the number of transplantable organs because a considerable number of people would probably opt out and, in doing so, would block the possibility of donation by the family after death.

Thus, the committee believes that it would be wiser to leave the current law in place while undertaking educational activities and other initiatives designed to promote donation, activities that would be necessary to lay the foundation for a transition to a presumed-consent policy if it were regarded as a prudent reform at a later time. In addition, as has been discussed, fairness requires that financial coverage for transplants and immunosuppressive medications be available so that all citizens who would be presumed to consent to donation would have fair access to transplantation in case of need.

Although conditions essential for a change to a presumed-consent policy do not currently exist and do not appear to be likely in the foreseeable future, it is both appropriate and important to seek to realize them over time. When the necessary conditions exist for a shift to a presumed-consent policy it will be critical to provide clear, easy, nonburdensome, and reliable ways to opt out.

SUMMARY AND RECOMMENDATION

Policies of routine removal of organs and presumed consent for organ donation are distinct, even though both involve opting out. Policies of routine removal assume that the state or society has a right of access to decedents' organs, whereas presumed-consent policies presuppose the individual's or family's dispositional authority over the decedent's body and organs. In the committee's judgment, a routine-removal policy, even when it allows individuals or families to opt out, represents such a radical departure from the principle of individual and family control over the bodies of deceased individuals that it could not and should not be adopted in the United States. By contrast, presumed-consent policies accept that principle but allow the transfer of organs from decedents on the basis of their presumed consent rather than on the basis of their express consent. In their weak form, they also require consultation with the family, primarily about the family's knowledge of the decedent's preferences.

In the United States, a presumed-consent policy would be more attractive than a routine-removal policy because a presumed-consent policy assigns dispositional authority over organs postmortem to the individual while he or she is still alive and, secondarily, to the next of kin (at least, as a safeguard, to confirm the decedent's choice). Presumed consent as tacit, silent consent can be ethically valid in social practices that involve extensive

and effective public education in order to ensure public understanding and that make widely available clear, easy, non-onerous, and reliable ways for individuals to register their refusal.

Recommendation 7.1 ***Presumed Consent.***
At this time, states should not replace the existing legal framework, which requires explicit consent for organ donation, with a framework under which people are presumed to have consented to donate their organs after death unless they have declared otherwise. However, it would be appropriate for all interested parties to seek to create over time the social and cultural conditions that would be essential for the adoption of an effective and ethical system of presumed consent.

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8

Incentives for Deceased Donation

The committee was asked to examine the use of financial and nonfinancial incentives to increase the supply of organs from deceased donors. A financial incentive is the provision of something of material value to motivate consent for organ removal. For example, a direct payment could be made in exchange for the organ, with the price for the organ determined by the free market or set by regulatory authorities. In either case, the exchange of money for organs would constitute a purchase and sale. Alternatively, financial incentives might be used to induce donations, just as the prospect of a tax deduction is used to induce charitable contributions. Such incentives might be a cash payment usable for any purpose; a cash payment earmarked for a specific purpose, such as funeral expenses or a charitable contribution; or a material good or service, such as bereavement counseling or health insurance. The financial incentive could go to the donor before death or to the donor's estate after death in exchange for the donor's agreement to allow his or her organs to be recovered after death. In situations in which the donor's family makes the decision to donate, the incentive could go to the family.

Nonfinancial incentives to donate could take the form of community recognition or preferential access to donated organs. Community recognition might be a public appreciation ceremony or a medal of nominal material value provided to individuals who register as potential organ donors or to the families of deceased donors. Preferential access might be given by establishing a rule that those who have previously registered as organ donors receive organs ahead of those who have not, or it might be given by

adding extra points for being a registered donor to the priority score used to allocate organs to recipients.

After a short review of the history of the current prohibition against the sale of organs, the chapter addresses direct payments for organs within free-market and regulated-market models. The chapter then examines the use of financial incentives to reward and induce donation. Finally, the chapter analyzes nonfinancial incentives, particularly preferred status on organ waiting lists, for people who record their willingness to be organ donors.

HISTORY AND CONTEXT

In the United States, organs from deceased individuals become available for use for transplantation through donation by express consent. In the 1960s, as it became possible to use organs from deceased individuals, it was sometimes unclear whose consent—the decedent's, while he or she was alive, or the family's after the person's death—was necessary and sufficient for donation because of variability in state laws. Resolving this uncertainty, the Uniform Anatomical Gift Act (UAGA) of 1968 authorized express donation by individuals and, in the absence of the decedent's prior choice, by the family. Although UAGA focuses on gifts or donations, it did not rule out transfer by sale; it simply did not address sales at all.

According to the chair of the UAGA drafting committee, the drafters did not intend to encourage or discourage payment for organs but instead left the matter entirely up to the states (or, preferably, individual conscience). He noted: "It is possible, of course, that abuses may occur if payment could customarily be demanded, but every payment is not necessarily unethical. . . . Until the matter of payment becomes a problem of some dimensions, the matter should be left to the decency of intelligent human beings" (Stason, 1968, p. 927). Sales had been illegal in some states prior to the UAGA's adoption in the late 1960s and early 1970s. However, most of those statutes banning sales were repealed when UAGA was adopted, and the legal status of organ sales or purchases for transplantation "remained uncertain" in most states, although it remained legal to buy and sell blood and sperm (Hansmann, 1989, p. 59).

Little public debate about this matter occurred until the early 1980s, when organ transplantation entered a new era with the availability of much improved immunosuppressive medications and with improved outcomes after transplantation. As a result, concern about the chronic scarcity of transplantable organs increased and several congressional committees and subcommittees held a number of hearings on transplantation. These hearings addressed several topics, including a possible federal ban on organ sales. This topic became all the more urgent when a former physician in Virginia proposed to set up a brokerage firm to purchase organs, particu-

larly in developing countries, for transplantation in the United States. Expressions of outrage were widespread (Denise, 1985), and the 1984 National Organ Transplant Act (Public Law 98-507) made it illegal "for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce." Several states also enacted bans.

These legal bans did not end the discussion. The discrepancy between organ supply and need remained troubling; and even though the rates of organ donation increased, they remained disappointing, even with the adoption of measures such as required request, which assumed that there was no shortage of givers, only a shortage of askers (Caplan, 1984; Caplan and Welvang, 1989). Not surprisingly, proposals for the use of financial incentives and new nonfinancial incentives emerged with greater frequency and forcefulness. The most radical of these proposals involved legalizing the purchase and sale of organs in a free market.

In fact, allowing an unregulated free market in organs is too radical a departure from current practice to be a feasible alternative. The policies under active consideration are more likely to involve the provision of limited financial incentives defined through administrative processes and provided under highly regulated conditions. Nevertheless, consideration of the case for such a market is a useful exercise. It shows that an unregulated free market is unlikely to live up to the claims that its advocates make for it, given the actual circumstances of the human organ supply and organ demand in the United States. Consideration of the case for a free market in organs also provides insights useful in the evaluation of the more limited incentive-based proposals for increasing the supply of organs available for transplantation.

WHY A FREE MARKET IN ORGANS IS PROBLEMATIC

Many economists begin from the position that a market is almost always the best way to allocate a scarce resource. In the standard model of a competitive market economy, markets use prices to allocate scarce resources in an automatic, decentralized fashion. In each market, the price of the good adjusts until the amount that suppliers are willing to sell at the prevailing price equals the amount that consumers are willing to pay. A higher price coaxes out more supply by making it worthwhile for producers to produce more of the good or, if the total amount of the good is fixed, by encouraging the current owners to put more of the good up for sale. On the demand side, a higher price chokes off demand, as some buyers decide that the good is not worth the new price to them.

In this model, the market outcome can be considered both efficient and equitable, provided the distribution of income and assets meets a commu-

nity standard of fairness. On the demand side, price rations the good to the people who value it the most, that is, those who need it the most, where need is assessed by the people concerned rather than a regulatory body. On the supply side, the supplier is compensated for the cost of production, including a reasonable profit; and in general, resources are directed to the most productive uses. If all markets are perfectly competitive, the resulting distribution of goods is efficient; and because it is the result of voluntary trades from a fair initial distribution of income and assets, it can be argued that it is also equitable.

On the basis of this model, permitting a market in organs could be an equitable and efficient way to achieve an increase in supply that would reduce the number of people on organ transplant waiting lists. However, this conclusion is dependent on the accuracy of the strong assumptions that underlie the theoretical model. When the assumptions do not hold, the normative arguments for the desirability of markets do not hold either. A market process might still be preferable to the available alternatives as an instrument for increasing the organ supply, but the case for it must be built, brick by brick, in light of the actual circumstances. Because the application of the market model raises different issues on the supply side and the demand side, the chapter will address them separately.

The Supply Side of an Organ Market

The market model's assumptions about supply seem most plausible for living donors. In living donation, a mentally competent adult has an organ (or organ part) that can be supplied to the market at some risk and financial cost. When the person donates the organ or organ part, that is, supplies it at a zero market price, he or she suffers a loss as a result of the discomfort of the operation, the opportunity cost of the time involved, and the long-term health risks. The donor's expectation of a benefit to the recipient is some compensation for this loss, which is why some organs are supplied at a zero price. Reducing the donor's loss by making a financial payment for the organ seems fair, however, and it seems likely that more people would be willing to provide organs as a result. In an efficient market, the additional organs would come from those who require the least financial compensation for the organ and for enduring the donation process.

In evaluating a policy of allowing payment for organs from living donors, two issues that are not assumed in the standard market model become important: distributional inequity and imperfect information. Many people would agree that large, unjust disparities in income and assets exist among Americans. Poor people value extra money more highly because they need it for basic necessities, so the additional organs are likely to come from the poor, a result many find morally troubling. A common economist's

response to this concern is, "True, the distribution of income and assets is not fair. But if society cannot (or will not) do anything about it, is it fair to deprive people of an opportunity that they believe would improve their situations? Competent adults should be free to make their own decisions about the medical procedures that they will undergo and the risks that they will take."

This argument is compelling superficially, but it assumes that the organ suppliers have the information and the capacity that they need to make the decision. Information about the long-term risks of donation may not be complete, and the buyers of organs have an incentive to understate the risks. In an unregulated market, organs are likely to come from people who do not fully appreciate the risks that they are taking. Avoiding this result would require the development of complete information for potential living donors and other efforts to ensure that the decisions made by living donors are fully informed, which would require planning and substantial resources. Concerns about inadequate information arise, however, even under the gift model now in place and are discussed in Chapter 9 of this report.

The living-donor case is mentioned here mainly to contrast it with the far less straightforward case of obtaining organs from deceased donors. In the latter case, the organs become available only when the person dies. There is no risk to the donor at that point, but a financial payment would not provide any direct benefit to the donor either—the benefit to the donor arises from the interest that the donor had while alive in providing for the well-being of his or her family after death. In practice, the family of the donor often makes the donation decision, and market advocates usually assume that the payment would be made to the family. Essentially, this means that the family is selling a relative's body parts, which raises the issue of cultural norms surrounding the treatment of dead bodies.

Commodification of Dead Bodies

Most societies hold that it is degrading to human dignity to view dead bodies as property that can be bought and sold. As explained in Chapter 3, bodies are supposed to be treated with respect—with funeral rites and burial or cremation—and not simply discarded like worn out household furniture and certainly not sold by the relatives (or anyone else) to the highest bidder. These norms are very powerful. Illicit markets for bodies have existed throughout history; for example, in the 19th century, England had an illicit market in which bodies were dug up in the night by body snatchers and sold for dissection, arguably a socially useful purpose (Richardson, 2000). Buying and selling bodies for dissection was considered a despicable business, however, and even desperately poor people did not willingly sell their relatives' bodies for whatever they could get.

Organ transplantation has provided a compelling justification for using the body parts of deceased individuals, namely, the opportunity to restore life and health to someone on the brink of death. Many people see donating a person's organs for this purpose as a highly meritorious act that honors the sacredness of the body rather than degrades it. At the same time, however, many people regard the act of donating the organs for this purpose as being conceptually and morally distinct from the act of selling the organs (even when the organs are to be used for the same purpose). Currently, the sale of solid organs is prohibited, but the prohibition reflects preexisting and widely accepted cultural norms. In the context of these norms, and the attitudes underlying them, it is not at all clear that the supply of organs from deceased donors would actually increase if sales were made legal. It is possible that the reasons people have for not donating cannot be overcome by money, or that offering money induces some to provide organs while leading an equal or greater number of people who would have provided organs to decide not to. For example, family members may wish to avoid appearing to be profiting from a deceased relative's body, especially if there is any chance of appearing to have participated in a treatment decision that might have hastened death. (These concerns about how allowing the buying and selling of organs would affect the attitudes and behaviors of families are explored in greater depth later in this chapter.)

Barriers to a Futures Market

Traditionally, the relatives of deceased individuals had the final word about whether organs would be donated, but this has been changing. Because society supports the right of individuals to control what happens to their bodies when they are alive, it is a natural extension to assume that they should also decide what happens to their bodies after death. This adds more intricacy to the application of the market model. Because money is of no use to a corpse, for financial payments to influence the donor's decision, one must introduce a futures market or a bequest motive into the picture.

A futures market is a market in which the commodity bought and sold is the right to sell organs at a future time in the event that a person dies in circumstances that permit organs to be recovered and transplanted. The person receives payment for these contingent organ sale rights while he or she is still alive. Futures markets are inherently complex. In this case, the chances of dying in the appropriate circumstances are low, death may occur far into the future, and it may not be easy to execute the right to the organ at the appropriate moment; therefore, the right to a potential organ is not worth nearly as much as an actual organ at the time of death. What if sellers want to change their minds? Can they rescind their contracts and, if so, on

what terms? Also, once the rights to an individual's organs have been sold, the buyer (who would probably be an organ broker) has a financial interest in the seller's death. Some people already worry about receiving suboptimal treatment at the end of life if they are registered organ donors and adding financial interests resulting from the selling of organ rights might add to those concerns. Further, it seems unlikely that there would be enough interested investors to allow a private futures market in organ rights to develop, given the long time horizon required and the uncertainty about the size of the profits.

Alternatively, one can assume that people get satisfaction in life from the knowledge that their heirs will receive inheritances when they die. If this is so, a person could be allowed to spell out his or her wishes for the disposition of his or her body in advance (in a will or in a special organ donor registry) stating whether his or her body should be buried or cremated intact, donated all or in part to a specific organization for a specific purpose, or sold whole or in part with the proceeds forming part of the estate. To the extent that more people would agree to organ removal if they had this option, the supply of organs would increase. This is an empirical question, and as before, there is no certainty of a positive effect. Again, implementation would be complex. For example, a registry would be better than a will, because one cannot wait until the will is probated to determine whether the organs can be sold. The possibility of such an advance directive is discussed later in the chapter.

Other Complexities

It has been assumed thus far in the discussion that paying people or their families for organs would increase the supply of organs for transplantation. However, some other complexities of the organ procurement process suggest that the creation of financial incentives for organ donation may be less important for donors and their families than it is for healthcare organizations and the participating healthcare professionals. A family does not simply make the decision to donate (or to honor the decedent's wish to donate) and then it happens automatically. First, the potential donor must be in the process of dying under the right circumstances to be eligible to donate his or her organs. Second, the medical staff must make the family aware of the possibility of organ donation. Only then does the opportunity to say yes or no to donation arise. Many people have not thought much about organ donation before the issue arises, and in any case, they are in an extremely stressful situation. How and when they are told about the opportunity for organ donation and the way in which the request is made can make a significant difference to the relatives' response. Finally, the organs

must be removed, the recipients must be identified, and the organs must be transported to their final destinations. These are complex tasks that must be carried out under extreme time pressure.

Many factors—including the structure of financial incentives to the healthcare workers and organizations that carry out these organ transplant-related activities—influence the way in which the process of notification, request, removal, and conveyance to a recipient occurs. If this process is the problem, the introduction of financial payments for organs may simply raise the cost of the transplantation process without having any effect on the number of organs recovered. The efforts and successes of the Organ Donation Breakthrough Collaboratives of the Health Resources and Services Administration suggest that the process is part of the problem and, indeed, is perhaps most of it (Chapter 4). The collaboratives have demonstrated that the application of quality improvement methods to the steps in this process can significantly increase the percentage of potential organ donations that are converted into actual donations. There is also potential to increase the organ supply through medical practice changes that make more decedents medically eligible to be organ donors (see the discussion in Chapter 5 on donation after circulatory determination of death), that is, to give more people the opportunity to consent.

The Demand Side of an Organ Market

The demand side of an organ market is also complicated. The simple market model assumes that those who benefit from the use of the good pay for the good, and this is an important element in the normative theory in favor of markets. In the case of organs, advocates for payments for organs from deceased donors generally do not expect the recipients to make the payments. Most people believe that health care is a special kind of commodity that should not be allocated strictly according to an ability to pay because of the unusual importance of health care to the well-being of all people and the uneven distribution of illness among the population. The distribution of health care, especially life-saving health care, should be determined separately from the distribution of other goods and in accord with special ethical principles. This is a major departure from the standard market model and means that even if a fair distribution of income and assets could be arranged, letting health care be determined by voluntary market trades would not yield equitable outcomes, even under the highly unrealistic assumption of the existence of a perfectly competitive market.

In the United States, the result of this societal value judgment is a complex array of private and public policies that are implicitly or explicitly intended to provide people with care that they would not receive if all health care were distributed through unregulated private markets. Unfortu-

nately, there is no general, transparent consensus on the nature and extent of healthcare services that people should be able to receive without regard to the ability to pay and how the cost of that care should be distributed across the population. The unfortunate result is a financing system that distributes both care and cost arbitrarily in a manner that meets no rational standard of efficiency or equity.

The U.S. healthcare system does not guarantee access to life-saving treatments such as organ transplantations, and the ability to pay does play a role in the distribution of this important good. Few people pay directly for organ transplantation, which is expensive even without payment for the organs. People in need of organs rely on public or private insurance to pay the cost of acquiring the organs and transplanting them, and a transplant is not received unless insurance coverage or access to charity care is available (the so-called green screen).

Given this system of healthcare financing (or any system that might replace it), what would the demand side of a market for organs look like? Presumably, most of the actual buyers would be the healthcare organizations that perform transplantations. They would compete with one another for the available organs, the price would settle down at the market-clearing price, and the cost of organs would become part of the total charge to a third-party payer for an organ transplant. This market would inevitably be very complex.

So far the chapter has referred to "the price" of an organ, but an actual market would have multiple prices for organs because organs are highly differentiated products. For example, hearts differ from kidneys and kidneys differ from one another along many medically significant dimensions. Organ recipients also differ from one another, and matching an organ with the right recipient is important in achieving the benefits of transplantation. This means that the kidney market or the heart market would actually be a whole set of interconnected markets for goods that are close substitutes for each other (e.g., kidneys or hearts from people of different ages, with different blood types, or different human leukocyte antigen factors). The price of a kidney would therefore actually be a price structure for all the different kinds of kidneys. This price structure would result from the interaction of the array of kidneys available with the variety of patients in need of a kidney at any point in time and the trade-offs among kidney characteristics that are medically possible for transplantation into various patients.

Of course, the original suppliers and the end users of the organs do not have the medical knowledge to make sophisticated sales and purchase decisions, and even if they did, they are hardly in the best physical condition to apply their knowledge at the time of donation or transplantation. Like the rest of the healthcare market, this market would be characterized by complicated agency relationships (situations in which decisions are made by an

expert on someone else's behalf). The various potential agents here would include the transplant recipient's physician, the organ donor's physician, the healthcare organizations in which the organ recovery and the transplantation occur, a specialized organ "broker" such as the United Network for Organ Sharing (UNOS), the private and public third-party payers that pay for the transplantation-related care, and so on.

Real-world markets in which differentiated products are sold under circumstances of imperfect information and intricate agency relationships do exist, and such markets can be superior to other methods of allocation. In the case of organs, however, it is interesting to note that a nonmarket process for allocating organs to recipients and managing waiting lists has been in place since the beginning of the transplantation era. The Organ Procurement and Transplantation Network system grew up in response to a perceived need to manage the organ allocation process within the transplantation community, although it has come to have substantial government involvement. There is ongoing pressure to adjust the process to make it more efficient and equitable, with the usual difficulties in defining exactly what efficiency and equity mean in such a complicated context. There is also recognition that financial and other incentives should be aligned with ultimate goals, but little enthusiasm for relying completely on an unregulated market process exists.

In summary, in a hypothesized market for organs, the good to be sold is highly differentiated and must be matched to the final user in many ways. The process of making an organ available requires skilled labor and technology. The good is highly perishable, and recovery and transfer to the final user must be accomplished under extreme time pressure. The good has unique cultural significance that would powerfully influence the response of suppliers to market incentives, even in the absence of the existing legal constraints on their behavior. Imperfect information issues are significant, and the end user is not in a position to act as an informed buyer. The need for information, skilled labor and technology, and third-party payment means that the market transactions involve complex agency relationships. With all of these departures from the standard assumptions of the market model, organ transplantation occurs in a world of imperfect markets when it comes to evaluating efficiency. A perfectly functioning market and a fair distribution of income and assets would not likely produce equity in the current healthcare system. As a society, it is not clear what an equitable distribution of health care and its cost would look like, but it is generally agreed that the distribution of organ transplants should not be totally determined by the ability to pay.

Given all of these factors, the committee doubts that it would even be possible to have a well-functioning free market in organs from deceased donors. If such a market existed, there is no certainty that it would produce

a greater supply of organs. Moreover, a free market in organs would deviate substantially from prevailing norms in the United States regarding the nature of health care and the fair distribution of organs for transplantation, norms that have been developed within various communities of stakeholders and that are now well entrenched.

REGULATED COMMERCE IN ORGANS

The proposals that warrant more serious consideration involve cash payments for organs—or other financial incentives for organ donation—determined within a regulatory framework. They focus on obtaining organs while leaving organ distribution and allocation to other mechanisms, either current or newly devised.

For concreteness, the committee considered the prototypical proposal to be one in which organs are purchased from the families of deceased individuals within a regulated system. It is assumed that the proposal specifies that either (1) the family makes the decision to provide the organs or (2) the individual makes an advance decision, with the family deciding only if the decedent's wishes are unknown. In either case, if the decision is made to provide the organs, the donor's family would be paid a specified price for one or more of the deceased person's organs (assume $2,500 for a kidney). In theory, the regulatory framework could be established by the government, a private nonprofit organization, or some combination thereof. To be stable, however, the framework would have to have government sanction, and the details of its structure would therefore be perceived to be an expression of social values. The committee's evaluation of this proposal proceeds in three steps. (1) Should organs be bought and sold? Here the commodification problem is addressed. (2) If it is assumed that the selling of organs is not categorically objectionable on moral grounds, would payment for organs actually increase the supply? (3) If it is assumed that paying for organs would increase the supply, is doing so at this time the most cost-effective policy option?

Should Organs Be Bought and Sold?

The first question that arises is whether society should allow organs to be sold at all, even when the price is regulated and the organs are to be used to save lives. As indicated in the previous section, the existing approach—in which organs are gifts rather than items for sale—rests in part on a widely shared supposition that solid organs of deceased individuals should not be bought and sold. This tradition is expressed in the ban on the exchange of organs for valuable consideration in the National Organ Transplant Act. The basis for this traditional view is explored to consider the possibility

that it should be discarded. The possibility of shifting from a model of donation to one of payment for organs raises a fundamental question: to what extent should transplantable organs be treated like other commodities in the American society and healthcare system, where financial incentives play a significant role in eliciting supply?

Every society draws lines separating things treated as commodities from things that should not be treated as "for sale." Americans in the 21st century, for example, do not sanction the buying and selling of human beings. The lines between things that are commodities and things that are treated as being outside the realm of market exchanges are blurry and are always changing, however. Some years ago, for example, policy makers promoted the selling of blood to increase the availability of blood products, only to then step away from the practice in the wake of growing concerns about the fact that payment encouraged donation from people whose blood compromised the safety and the quality of the blood supply (Contreras, 1994; Eastlund, 1998). The selling of sperm appears to be uncontroversial in the United States, but the buying and selling of eggs, although widespread, is less accepted (Meyer, 2001). Commerce in eggs raises ethical concerns related to the fact that eggs are unlike sperm and blood, in that the donation process is riskier for the donor and eggs are not renewable or replenishable (although a woman has a substantial lifetime supply). Human tissue is donated and is then processed, bought, and sold in a flourishing secondary market, but this market has also generated ethical controversy (Mahoney, 2000; Youngner et al., 2004).

Despite the growing market for body parts and products, there remains a strong societal taboo not only against buying solid organs from living people but also against buying and selling dead bodies or certain parts of dead bodies, including solid organs. Many people do not wish to see body parts commodified. Why is this? What is the moral difference between solid organs and parts of dead bodies and the body parts of living individuals that are now legitimate articles of commerce? Should people view bodies (or body parts and products) as property that can be bought and sold, should such buying and selling be legally permitted, and should it actually occur?

Advantages of the Gift Model

Those who defend the social norm that a dead body is not property to be sold argue that significant social benefits are associated with preserving that norm, namely, that it preserves a set of values about gift-giving that have been at the core of the donation and transplantation system. It is argued that the gift model of organ donation reinforces the values of human dignity, solidarity, compassion, and altruism (Murray, 1987, 1996; Kass,

1992; Delmonico and Scheper-Hughes, 2002). Family members frequently find organ donation to be healing, insofar as they may draw meaning out of an otherwise tragic situation (Burroughs et al., 1998); and skeptics of payment for organs argue that these psychological benefits may be threatened if the act of donation is viewed as a sale for one's own benefit or as degrading the value of the deceased individual (Murray, 1996; Sells, 2003). In addition, as noted above, some argue that if financial payment for transplantable organs becomes socially acceptable, the overall social norm that bodies are not property is likely to erode. In this view, the radical uncertainties associated with potentially shifting the meaning of organ transfer from "gift" to "sale" should give advocates pause, for such a shift could result in negative effects that are difficult to identify in advance and that could be profound.

Is There a Liberty Right to Sell Organs?

Some advocates of payments argue that individuals own their organs and accordingly should enjoy liberty rights to sell what they own. Libertarians frequently appeal to the basic principle that people should be free to control their own bodies, as long as no harm is done to others. When organs are recovered after death, one might argue that the exercise of this liberty harms neither the donor nor society in any direct fashion and that this use of organs is thus overwhelmingly beneficial to the individuals who need organs and to society at large. The prohibition of compensation, in this view, violates the autonomy of the individual and limits his or her ability to make a significant contribution after death by improving the length and quality of life of others in society. In spite of the religious and other arguments in support of a ban, others question whether the state has the moral authority to prohibit the sale of body parts when informed consent is given (Cherry, 2005; Taylor, 2005). In response, some philosophers and theologians challenge the ownership metaphor, suggesting instead that individuals are better understood as having stewardship over their bodies (Caplan and Coelho, 1998).

Even if the libertarian argument that individuals have the presumptive right to sell one's own body parts is assumed, two limitations must be noted. First, the living person's hypothesized liberty interest is not an absolute one and is subject to being overridden by important societal interests. Thus, for example, if payments to individuals were to interfere with efforts to maintain support for organ donation and were to reduce the organ supply, as suggested above, then the state could reasonably restrict an individual's right to sell his or her organs. Second, the libertarian argument focuses on the living person who "owns" his body; it does not entail the conclusion that a family has a right to sell the deceased person's organs if

the deceased has not exercised his or her own right to do so. To make that case, one must posit that families have a property right in the body, a claim that is more problematic in both philosophical and legal terms. As discussed in Chapter 3, the most expansive legal understanding of the rights of families is that they have a legally protected interest (sometimes characterized as a "quasi-property interest") in having possession of the body and in making decisions about its disposition. However, these interests have never entailed a right to sell the body parts, nor have libertarian philosophers postulated that families own the dead bodies of their loved ones. Thus, if the case for a family's prerogative to sell the organs of a deceased family member is to be made, it will have to rest not on a rights argument but, rather, on the claim that according to the family this prerogative will produce beneficial consequences, that is, that it will increase the supply of organs.

Would Payments Actually Increase the Organ Supply?

The primary argument for paying for organs is that doing so will increase the number of organs available for transplantation. Although some advocates for payments acknowledge that the adoption of a sale model raises legitimate ethical concerns, they believe that the lives saved by increased rates of organ donation outweigh all opposing concerns (Barnett et al., 1992). However, the impact of payments on organ removal consent rates cannot be accurately predicted from the currently available data. As Kaserman and Barnett (2002, p. 101) observe, the reason why all existing data are inconclusive "is the fact that observable market transactions for cadaveric human organs have never taken place."

Advocates of a sale model argue that because payments play a major role in motivating the provision of most goods and services, they are likely to motivate the provision of organs for transplantation (Schwindt and Vining, 1986; Cohen, 1989; Peters, 1991; Harris and Alcorn, 2001; Kaserman, 2002; Tabarrok, 2004). Some advocates assume that even a trivially small payment will increase consent rates dramatically because, after all, dead bodies have no practical use to families. The committee is skeptical of this conclusion, given the emphasis and resources that members of all cultural groups in U.S. society devote to giving deceased relatives a proper burial. A more plausible claim is that incremental increases in the payment would eventually result in a reasonable but not exorbitant payment level at which the vast majority of families would grant consent. Thus, if families were to respond to the financial incentive as they do to other commercial exchanges, it is conceivable that the shortage of organs could be significantly reduced, if not eliminated.

As noted earlier, however, the relationship between financial payments

and the willingness to provide organs may not conform to the pattern that applies to ordinary consumer goods. Many people now document a desire to donate, and more than half of families now consent to donation in the absence of any compensation. In some institutions participating in the Organ Donation Breakthrough Collaboratives, conversion rates for donation after neurologic determination of death are close to or exceed 75 percent. In a situation in which nonpecuniary ideals have traditionally motivated behavior, the introduction of payments may lead to a crowding out of other motivations (Frey and Jegen, 2001). The concern is that if organ donation were to become "commercialized" because of the use of payments, some families who are willing to donate under an altruistic system may refuse to provide consent for organ donation because the payment would seem to be insufficient compensation for violating the bodily integrity of the deceased family member.

The committee is unaware of any scientific research bearing on the possibility that legitimizing financial payments will crowd out nonfinancial motivations for organ donation or on whether the problem could be reduced in a carefully regulated market. Policy makers are left to speculate about the effects of allowing financial payments on the perceptions and attitudes of a heterogeneous population of potential donors and potential vendors with varied and complex motivations. Would setting a price for organs (by the government or a nonprofit organization acting on behalf of society) be interpreted by some families as a societal judgment on the worth of the person who has died? Would some families refuse to consent to donation to avoid the appearance of profiting from a relative's body or to avoid the appearance of participating in a treatment decision that might have hastened death? One experimental organ donation survey found that when incentives for donation were introduced into a vignette that involved a decision to withdraw life support, people prolonged the use of life support (Evans, 2003).

Public Opinion

Given these conflicting a priori arguments and the absence of empirical evidence on actual behavior, some researchers have attempted to gauge the impact of payments by drawing on surveys of public attitudes. Survey results must be interpreted with caution, however. The wording of surveys is important, as seemingly minor variations in wording can cause major shifts in responses. Few surveys ask respondents directly how payments would affect their decision to allow the recovery of organs from a deceased family member. Instead, many surveys simply ask whether respondents "support" payments as a tool to increase consent rates. Because the surveys do not ask explicitly whether it would it be good public policy to pay for

organs, the answers may simply reflect a belief that organ donation is a good act rather than a belief that paying for organs is a good policy. Moreover, surveys that do ask directly about the willingness to consent require many respondents to contemplate hypothetical situations that they have not previously considered, even on a casual basis. Comparisons of surveys that ask about the willingness to donate and actual registration rates often detect a disconnect between the responses and the actual behavior. Furthermore, the public lacks an understanding about the transplantation system, suggesting that public education efforts could shift opinion.

Despite these limitations, surveys provide inferential evidence bearing on the potential impact of payments on consent rates. Unfortunately, their findings are mixed and suggest that the public is largely ambivalent. The 2005 National Survey of Organ Donation (Wells, 2005) found that 18.8 percent of respondents would be more likely to donate a family member's organs if they were offered a payment, 10.8 percent would be less likely to grant consent, and 68.2 percent would be neither more nor less likely to grant consent (2.2 percent of respondents selected "don't know"). The responses to these questions from the 1993 survey were 12, 5, and 78 percent, respectively (Wells, 2005). In a recent survey of Pennsylvania households, 17 percent of respondents stated that direct payments would make them more likely to grant consent and 8 percent responded that monetary incentives would make them less likely to grant consent. The vast majority of respondents stated that payments would have no effect on their decision to donate (Bryce et al., 2005). A survey of 561 adults who had recently been asked to grant consent for organ donation found that equal proportions (approximately 11 percent) stated that incentives would make them more likely or less likely to donate and 78 percent stated that incentives would have no effect (Rodrigue et al., in press). Among respondents who had previously declined to grant consent, 19 percent stated that incentives would make them more likely to grant consent, 13 percent stated that incentives would make them less likely to grant consent, and 68 percent said that incentives would have no effect. The survey did not ask separate questions about monetary versus nonmonetary incentives.

Siminoff and colleagues reported that many families are confused about their liability for the cost of donation and funeral expenses, and these concerns are disproportionately held by families who refuse consent (Siminoff et al., 2001a,b). The possibility that consent rates could be increased by simply clarifying the fact that the family of a deceased organ donor does not incur any additional costs as a result of consenting to donate should be explored.

Some surveys ask respondents about their support for incentives generally, without inquiring about the impact of incentives on their decision to

donate or grant consent. Nelson and colleagues (1993), reporting on surveys by UNOS and the National Kidney Foundation in the early 1990s, found that 48 percent of respondents generally supported incentives. Responses varied across demographic groups, with younger, nonwhite, and lower-income respondents reporting higher levels of support for incentives of various sorts (Nelson et al., 1993; Bryce et al., 2005).

Religious Group Opinion

In addition to data from surveys of individual attitudes, the potential impact of the views of organized religion should be considered in assessing the impact of payment for organs on donation behavior. Some religious groups are likely to be fiercely opposed to any policies that appear to allow the sale of organs, on the grounds that such sales are an affront to human dignity. Organ donation currently enjoys strong support from most major religious groups; however, a policy of paying for organs may weaken or eliminate the commitment of religious organizations in encouraging their members to donate (Caplan et al., 1993; International Congress on Transplants, 2000; Arnold et al., 2002).

Opinions of Healthcare Professionals

The opinions of healthcare professionals are also a significant factor. Some data indicate that most healthcare professionals involved in the donation process would be less comfortable requesting organ donation if financial incentives were offered (Altshuler and Evanisko, 1992). Because uncomfortable requesters are less likely to obtain consent (Malecki and Hoffman, 1987), donation rates could decrease. Moreover, in testimony before the committee, organ procurement organization (OPO) requesters were adamant that offering cash payments to donor families while simultaneously appealing to their altruism would be awkward. Some families may respond positively, but they fear that the commercial nature of the transaction may turn off others.

Even if Paying for Organs Would Increase Supply, Is It the Most Cost-Effective Policy?

In sum, the committee strongly doubts that paying for organs would substantially increase the supply of transplantable organs, notwithstanding the common assumption to the contrary, especially among economists. Assuming, however, that paying for organs would increase the supply, one must still ask whether this is the most cost-effective approach to achieving the expected increase. In considering the cost of a system of

regulated payments, the most obvious cost is the total cost of the payments themselves. The cost of each additional organ is not just the payment for that organ, however. Once a socially sanctioned payment system is in place, the payments will presumably be made to every organ donor family. For example, suppose there are 10,000 eligible organ donors, each donor can provide one transplantable organ, and initially, there is a 50 percent consent rate, producing 5,000 organs. If the consent rate increases to 52 percent in response to a $2,500 payment per organ, 200 more organs become available, to yield 5,200 organs. The total amount of the payments for all the organs would be 5,200 × $2,500 = $13,000,000, which means that the average cost of each additional organ is not $2,500 but $65,000 ($13,000,000 divided by 200). Of course it is important to consider that the real resource cost of a dollar spent on payments (which is transferred rather than consumed) may differ from the real resource cost of a dollar spent on other programs to increase donation (e.g., a print media campaign to encourage donation). Costs related to administering the payment system (establishing the payment levels for the organs, identifying the appropriate recipient, etc.) must also be incorporated into these figures.

Is an additional organ worth this amount? First, it is important to note that the question does not arise in a purely private market, or, more accurately, it does not arise as a policy question for society. The individual sellers and buyers in a market make their own individual decisions about what they are willing to accept or pay for a commodity, and the market price adjusts to equilibrate the amounts supplied and demanded. In a regulated organ market, however, the size of the administered price is a policy question. The government or a government-designated agent for society would have to establish the price, and collective resources from private and public insurance programs would be used to cover the payments. To determine whether this is the best use of these resources, their opportunity cost should be considered. What benefits to society result from this use of the resources? What societal benefits would the next best use of the resources produce?

Chapter 1 presented some estimates of the monetary value to society of increasing the supply of organs. These estimates suggest that increasing the organ supply would produce substantial benefits in exchange for the associated increase in healthcare costs; in the case of kidneys, increasing the supply may even produce a net cost savings because the recipients of successful kidney transplants no longer need dialysis, an expensive treatment that is covered under Medicare's End-Stage Renal Disease program. If the estimates in the literature are accepted as correct, a payment of $65,000 or even more might be considered reasonable to obtain an additional transplantable organ.

The value of an additional organ is not the question here, however. Rather, the question is, given that the goal is increasing the supply of organs, how does the cost of doing so through a regulated market in organs compare with the cost of increasing the supply in some other way? Reaching an answer to this question requires a series of analyses. First, as already noted, there is substantial uncertainty about whether a regulated market system would in fact increase the organ supply, and it is possible that the supply would actually decrease. Second, potential costs to society have been identified that are over and above the direct costs of the payment program as a result of the impact on the transplantation program and society in general of the commodification of body parts. These costs are difficult to predict and even more difficult (perhaps impossible) to quantify, but they could be substantial. Third, and most important, some alternative options are at least as likely to increase the organ supply but do not generate the same level of ethical controversy or present the same concerns about unanticipated societal consequences.

Two especially promising options are the use of quality improvement techniques to improve the process of organ donation under a gift model (Chapter 4) and making medical practice changes that increase the number of decedents who are potential organ donors (Chapter 5). These changes carry costs also, but these costs are modest in relation to the additional expenditures that would be required to operate a regulated market, and they do not entail the ethical and social concerns associated with commerce in organs. Moreover, these two changes are desirable in any case, and given the concerns of healthcare professionals about introducing payment into the process of requesting donation and removing organs and the concerns of the public about the appropriate treatment of patients at the end of life, the committee thinks that the changes could be more easily implemented in an environment in which organs are donated, not sold.

FINANCIAL INCENTIVES WITHIN A DONATION FRAMEWORK

The committee believes that there are powerful reasons to preserve the idea that organs are donated rather than sold. The gift model now elicits donations from more than 50 percent of families, and improvements in the organ recovery system suggest that the rate can be significantly increased to 75 percent or higher. However, the question remains whether rates of donation would increase even more if current motivations to donate were reinforced by the provision of something of material worth. Human behavior is complex, and people often have multiple motivations for engaging in an act. For example, charitable gifts continue to be perceived as donations, even though they are also accompanied by tax incentives. Under the right

circumstances, donated organs might continue to be viewed as gifts, despite the presence of financial incentives.

A number of approaches have been suggested for indirect financial incentives that would be paid to a third party and thereby reduce the concerns raised by direct compensation. Incentives could have a benefit to the individual while living (e.g., reduced life or health insurance premiums) or could benefit the family members and heirs after death (e.g., income tax deductions or credits, payment of medical expenses, payment of funeral expenses, college education benefits for children, or providing life insurance coverage) (see for example, Siminoff and Leonard, 1999; Arnold et al., 2002; Parker et al., 2002). Contributions made to a charity on behalf of the decedent could also be considered as an indirect financial incentive.

To provide a specific context for discussing the issues regarding financial incentives, the committee decided to focus on one approach; this chapter assumes that the financial incentive is a $1,000 payment to the family to defray funeral expenses (linked either to the advance directive of the deceased donor or to the decision of the family to donate after the death). The possibility of giving people a financial incentive to register as a donor is considered below.

Financial incentives for donation are meant to function within the gift model of donation. Proponents of this approach argue that the distinction between an incentive of material value and a payment for organs is sometimes lost in public discussions. Whether or not the strengths of the gift model can be preserved when donation is rewarded by a financial payment depends entirely on whether this distinction can be upheld. It would need to be upheld in the minds of families that consent, even after the decision to donate has been made. For example, would families question whether their decision to donate was motivated by the desire to save the life of others or by the funeral benefit? Would this affect the meaning that they find in donation? Again, these are empirical questions to which answers are lacking.

The Commodification Issue

Thoughts vary on whether a financial incentive for organ donation successfully avoids the commodification concern and preserves the strengths of the gift model. Offering and making a $1,000 payment earmarked for the deceased donor's funeral expenses as an incentive to consent to donation and an expression of gratitude for the decision may be conceptually and morally distinguishable from buying an organ. Such a payment in no way reflects the actual value of the organ, and it would be positioned within a gift model of organ donation, analogous to a tax incentive for charitable giving rather than a purchase. Proponents of this view believe that such a benefit can be presented to the public in a way that avoids the perception

that deceased bodies are being commodified and that allows families to preserve the healing meaning that they may find in donation.

Others have thought that a payment (or tax incentive) contingent upon the provision of an organ is not genuinely distinguishable from a payment for the organ. They believe that a financial incentive policy would immediately be interpreted by many members of the public as allowing the sale of organs, albeit under controlled conditions. For example, in 2002 an ethics panel of the American Society of Transplant Surgeons (ASTS) made a statement in which the members of the panel unanimously opposed the exchange of money for organs, whether it was in the form of direct payments or a tax incentive. However, the panel stated that as a sign of gratitude it would be acceptable to provide some level of reimbursement for funeral expenses. ASTS was surprised to find that the *Medical Post* wrote an article on the panel's actions entitled "Paying for Organs." Its first line read, "American transplant surgeons and ethicists have ventured onto a tightrope with their recent suggestion that families who donate a deceased relative's organs be given some kind of financial compensation" (Murray, 2002). The concern is that providing an "incentive" or "expression of gratitude" of material value in exchange for "donation" of an organ while claiming to oppose the sale of organs would be perceived as hypocrisy and would decrease respect for the organ transplantation enterprise.

Impact on Donation Rates

Although the point of the financial incentive is to increase the supply of organs, there are a priori reasons why it could either increase or decrease donation rates. To the extent that the incentive is not perceived as a payment, one might argue that altruistic motives would be less likely to be crowded out by pecuniary motives than they would be under a regulated market model. As noted above, however, it is by no means clear that the transplantation community can control public perceptions of incentives, particularly if they have significant material value.

Payments to Families for Funeral Expenses

Survey data consistently indicate that the public would be more receptive to an incentive program involving a funeral payment than a direct cash payment for organs. In the Pennsylvania household survey referred to above, 17 percent of respondents stated that a direct payment for organs would make them more likely to consent to donation, 8 percent stated that payments would make them less likely to do so, and the vast majority stated that payments would have no effect on their decision. In contrast, when the respondents were asked about funeral benefits, 23 percent stated that they

would be more likely to grant consent and only 3 percent stated that they would be less likely to grant consent (Bryce et al., 2005). The same study found that general support for funeral benefits was 81 percent, whereas support for cash payments was 53 percent.

Support for financial incentives among transplantation professionals and within the medical community more generally is fluid, with support for incentives increasing over time and with support for indirect incentives stronger than that for direct incentives (Joralemon, 2001). A 1992 survey found that a vast majority of professionals involved in organ procurement oppose financial incentives of any kind (Altshuler and Evanisko, 1992). More recently, several professional associations, including the American Medical Association and the Organization for Transplant Professionals, have indicated cautious support for pilot studies or demonstration of incentives (NATCO, 2002; Taub et al., 2003). Other groups, such as the National Kidney Foundation, remain opposed (NKF, 2002).

The committee acknowledges that at present it is impossible to know the impact that incentives would have on the rates of organ donation. Moreover, although the impact could be positive, it is far too easy to imagine scenarios in which a $1,000 payment toward funeral expenses would be perceived in undesirable ways: as an insultingly low payment given the real cost of a funeral and the vast amount of money invested in organ transplantation; as a payment intended to purchase organs; as a conflicting interest in the decision making of a family; or as a motivation that shifts attention from intrinsic motivators (e.g., the "gift of life" that many families find healing). Given the substantial uncertainty about the effects of offering financial incentives for donation and the genuine possibility that it could reduce the rates of organ donation, the committee is not in favor of making financial payments to benefit families, whether directly or indirectly, to increase organ donation rates.

Payments to Register

In the second prototypical proposal involving payment, individuals are paid to register their agreement to have their organs removed at death for the purpose of transplantation (with no payment to the family). Again, the supply effect is uncertain. The number of registrants might increase, but practical problems may arise later on. Because the decision to register as an organ donor may occur many years before death, some individuals may change their minds and wish to deregister. Individuals could be allowed to deregister by paying back the money that they initially received to register. What would happen, however, if a registered organ donor clearly stated before his or her death that he or she no longer wished to donate but

refused to pay the money back? OPOs might find it difficult to proceed with organ removal even if they had the legal right to do so.

Paying individuals to register makes sense only when the registration decision alone is used as the basis for organ removal. In practice, until recently most organ procurement organizations would not recover organs from a registered organ donor if his or her next of kin objected. Registries have existed mainly as a mechanism to allow individuals to communicate their preferences to family members, not as a binding contract. Under such circumstances, it is possible that paying individuals to register would actually decrease consent rates (Byrne and Thompson, 2001). Consider the situation of a family trying to divine the intent of a deceased relative. If the individual registered but was not paid to do so, then the family may correctly infer that the individual wished to donate. However, if the individual was paid to register, then it is not clear if the registration signaled the intent to donate or only the intent to obtain the payment. In Georgia, where until recently organ donation registrants obtained an $8 discount on driver's license registration fees, the OPO did not use registration as an indicator of donor intent for this reason. Paying registrants may not increase consent rates under such circumstances.

On the other hand, making registration into a firm contract that is difficult to back out of and always overrides family wishes may make some people less willing to register as donors, despite the payment. Under these circumstances, a family may assume that the decedent does not want to donate because he or she did not register, despite the financial payment. Essentially, payment interferes with the signal that families obtain from the individual's decision to sign up with an organ donation registry.

Pilot Studies

One response to the uncertainty about whether financial incentives for donation would increase the supply of organs for transplantation is to implement a pilot program that would try out a payment system on a small scale and study its effects. This proposal has several drawbacks, however. First, those who find payments to be morally unacceptable in principle are naturally opposed to a pilot study, so relying on experimentation does not avoid the underlying controversy. Second, a pilot study has a limited ability to produce the information needed for policy decisions. The pilot study may produce evidence of an increase in supply in the short term, but by its nature it cannot produce evidence on the longer-term effects on the transplantation enterprise and society that are of concern. As payment gradually changes perceptions, and comes to be viewed as a routine part of donation, consent rates may decline for families with primarily altruistic motives.

Furthermore, if a payment does not increase the organ supply in the pilot study, it could be argued that the circumstances of the pilot study were at fault, that the payment should have been a little higher, and so on. Finally, conducting the pilot study might make it difficult to retreat to the original position of prohibition of the provision of financial incentives for organ donation, even if the study did not yield positive results. In short, the committee believes that a pilot study of the effect of financial incentives should be undertaken only if other, less controversial strategies of increasing organ donation have been tried and proven unsuccessful and if, as a result, policy makers have become inclined to implement such a strategy. The pilot project would then be understood to be a carefully designed, initial step in the implementation of a new policy rather than as an experiment. Under the present circumstances, the committee sees little value in undertaking such an experiment.

PAYMENTS AS A TOKEN OF GRATITUDE

The committee's charge was to consider ways of increasing the rates of organ donation in the United States. Therefore, the provision of anything of material worth in the context of donation has been considered primarily through the lens of its potential impact on the rates of donation. However, a funeral benefit, for example, might be presented exclusively as a token of gratitude rather than an incentive to donate (which is precisely how ASTS framed a proposed funeral benefit in 2002). Alternately, a funeral benefit might be understood as a form of good stewardship or proper treatment of the deceased body that was made available to the transplantation community before the funeral services. This view suggests that, through the act of donation, the transplantation community acquires an interest in the proper burial or cremation of the deceased body; the interest may not be as strong as the immediate family's but nonetheless sufficient enough to contribute to funeral expenses.

Although the committee acknowledges that these motives for covering a funeral expense are both legitimate and morally distinguishable from the motive of increasing organ donation rates, the committee rejected the proposal to provide funeral benefits, even if it is justified and explained on these grounds. First, because such benefits are of material value, it is feared that the public would not distinguish them from payments for donation or for the organs themselves. This could then contribute to perceptions of duplicity or deception. Second, because the benefits involve material value, there is no way to prevent them from functioning, in economic terms, as financial incentives; and thus, they potentially raise the same concerns as financial incentives including the risk of diminishing the meaning of dona-

tion for families, crowding out of other motivations, or polarizing the community.

The committee hastens to emphasize that societal expressions of gratitude toward deceased organ donors (e.g., a donor medal of honor) are appropriate, but tangible gifts should not have such significant material value that they would provide a monetary incentive for donation.

NONFINANCIAL INCENTIVES: PREFERENTIAL ACCESS TO DONATED ORGANS

The two forms of nonfinancial incentives generally proposed are community recognition and preferential access to donated organs. Community recognition might take the form of a public appreciation ceremony or the awarding of a medal of nominal material value to people who register as potential organ donors or to the families of deceased donors. There is general agreement that the decision to donate deserves gratitude and community recognition, but it is also agreed that the impact of recognition programs on organ donation rates would be small (Arnold et al., 2002). The committee regards public expressions of gratitude less as incentives than as mechanisms of persuasion and as opportunities for raising the visibility of organ donation, capturing public attention, and communicating pertinent messages and information (Chapter 6). This section therefore focuses on preferential access proposals.

Proposals to give people who have registered as organ donors preferential access to available organs conform to either of two models. Pure reciprocity models restrict the pool of organ recipients to those who are willing to donate their own organs (and, in some cases, to those not only willing but also eligible to donate their organs). Preferred allocation models do not restrict the pool of eligible recipients to people who have recorded their willingness to donate but add extra points for being a registered donor to the priority score used in allocating organs to recipients (just as UNOS's current system awards priority points for medical urgency, the length of time on the waiting list for an organ, and the level of organ match). Such programs would be most effective with government sponsorship; however, because they are currently neither funded nor prohibited by U.S. law, implementation has occurred only in the private sector, for example, through the LifeSharers program, in which members use advance directives to direct donation to other members (LifeSharers, 2005).

This section presents the arguments for and against these approaches, with attention to their impact on organ donation rates and their broader implications for the transplantation system, the healthcare system, and society. The two models are addressed together because the arguments

supporting and opposing them are similar. They are referred to collectively as either reciprocity-driven approaches or preferred-access approaches.

Arguments for Preferred-Access Approaches

To evaluate these proposals, it is necessary to imagine that the U.S. Congress had embraced a national program changing the legal structure of the organ transplantation system. Under a pure reciprocity model, the only people legally eligible to receive transplanted organs would be those who have recorded a willingness to donate pursuant to whatever procedures are specified. Under a preferred-status approach, regulatory authorities would be directed to conduct the necessary rulemaking to give allocation points to people on the waiting list who have registered to be donors in a qualifying manner.

A pure reciprocity model would reduce the gap between the number of organs available and the number of people on the waiting list in two ways. It would shrink the waiting list by excluding individuals unwilling to donate organs, and it could potentially increase the supply of organs by providing a self-serving motive (potential eligibility for a transplant, if needed) to register as a donor to supplement the altruistic motive (Jarvis, 1995). What would happen to donor registration rates if such a plan were adopted? One article estimates that half of the people unwilling to donate their own organs are willing to receive an organ, so the number of people excluded might not be negligible (Kolber, 2003). However, if the policy were really in effect, it seems reasonable to assume that most people would register if they were aware of and understood the policy. In any case, these are critical assumptions that surveys have not addressed. The point is that it is simply not known whether the people who currently decline organ donation would become organ donors if a reciprocity-based legal structure was in place, accompanied by an aggressive public education program and full implementation. LifeSharers had roughly 3,300 members in 2005 and is thus far too small to provide useful data on the impact on donation rates of a public policy based solely on reciprocity. Moreover, testimonials on the LifeSharers website reveal that some of the members were already organ donors before joining LifeSharers and joined to implement a quid pro quo concept of justice, to increase their personal chances for obtaining an organ, or to reduce the size of the waiting list.

Aside from the aim of increasing the rate of organ donation, those who favor a reciprocity model often emphasize that such a model would promote justice in organ allocation. Given the shortage of organs, any allocation system must give preference to some potential recipients over others. Although medical need is a reasonable criterion to determine whether one is a potential recipient, it is not the sole criterion even under present policies.

Proponents of reciprocity-driven proposals argue that fairness justifies preferential treatment of those who are willing to donate their organs (Kolber, 2003; Sackner-Bernstein and Godin, 2004; Steinberg, 2004; Veatch, 2004; Nadel and Nadel, 2005). "Free riders," that is, those who are willing to receive an organ but who are unwilling to donate their organs even after death, would either be excluded from the system (as in a pure reciprocity model) or given reduced priority (as in a preferred-status model). The argument is that willingness to donate one's organs—in contrast to other personal characteristics, such as race or "social worth"—is a morally relevant difference and justifies preferential access to donated organs (Jarvis, 1995). In addition, advocates argue that a reciprocity-driven model would promote a strong sense of community. Creating a reciprocity-driven model of organ donation and allocation might also enhance the perception that citizens are all mutually dependent members of a community with rights that depend upon a willingness to meet the duties that people have to each other (Steinberg, 2004). Finally, some claim that reciprocity models would achieve the goal of reducing the waiting list for organ transplantation without some of the ethical drawbacks that many find in financial incentives, for example, the commodification of the body or the risk of exploiting the poor (Nadel and Nadel, 2005).

Although preferred-status models embrace the idea that a willingness to donate should carry moral weight in organ allocation, they are less radical than pure reciprocity models because they do not entirely exclude anyone from the system, treating willingness to donate as just one criterion for awarding allocation points. By the same token, however, the claim that implementing this approach would increase donation is correspondingly weaker. There is no direct evidence that giving registered donors preferred status would in fact increase the rates of organ donation. In the committee's judgment, the argument for this approach seems to rest more on its signaling effect (emphasizing the importance of reciprocity) than on its incentive effect.

Arguments Against Preferential Access

The committee does not favor either of these models, largely because of insuperable practical problems in implementing them fairly. Even if it is assumed that an organ recovery and allocation system is properly grounded in reciprocity and that the adoption of either of the proposed approaches would increase the rates of organ donation, the committee is deeply concerned that they would not be fairly and carefully implemented and, as a result, that the adoption of either model would accentuate existing social inequalities and would disadvantage those who are uninformed about organ donation: most likely, poor people, recent immigrants, and the least-

educated individuals in society. To the extent that these models require individuals to be adequately informed about the option of donation and to have the opportunity to make their wishes known, they erect another potential barrier to health care, particularly among individuals who lack adequate access to the healthcare system (Siminoff and Leonard, 1999; Wigmore and Forsythe, 2004). It is worth noting that many people who believe that reciprocal obligation is an important moral underpinning of a system of organ donation nonetheless oppose proposals to replace the existing legal structure of allocation with one that either limits eligibility for transplantation to patients who have agreed to be donors or gives them legal priority in allocation (see, for example, Siegal and Bonnie, 2006).

The Information Problem

All proponents of preferred-access models concede that many people unregistered as donors—for example, children and adults who lack a decisional capacity—would nonetheless be entitled to equal access as potential recipients. Preferential access would be denied only to legally competent adults who had an opportunity to register and failed to do so. However, fair implementation of such a model would require aggressive public education so that everyone would be on an equal footing in deciding whether to register as a donor. People would need to be informed about the nature of organ donation and how to choose donation. A nationwide donor registry would need to be established and would need to rely unambiguously upon first-person (donor) consent. Without extensive education and a nationwide donor registry that is easily accessible to all citizens, a preferred-status system runs the risk of unfairly excluding people who have not been educated about donation or who lack easy access to donor registration (e.g., because they do not or cannot hold a driver's license, which currently provides the most common opportunity to express donation wishes).

The Adverse Selection Problem

Any type of preferential access system based on a recorded willingness to donate presents what insurance experts call "adverse selection"; that is, that people who are most at risk for needing an organ will be disproportionately likely to sign up to be a donor. Should people be permitted to gain preferential access by agreeing to become donors only after they have discovered that they are likely to need an organ? If not, how should this rule be enforced? What about those who are not ill but who know that they are in a high-risk group? If people are permitted to register as potential donors after they already know that they are at higher risk of needing an organ, should they receive fewer allocation points than other people on the list

who registered before knowing that they were at higher risk? Should people with less desirable or extended-criteria organs receive a lower priority? In the committee's view, there is really no way to substantially reduce the adverse selection problem without requiring everyone who signs up to be a donor to turn over their medical records and take a medical examination at the time of registration. Any significant degree of adverse selection erodes one of the strong moral arguments for reciprocity-driven approaches: the emphasis on a mutuality of interest and the effort to prevent free riding.

The Unfair Allocation Problem

Any type of preferential access based on donor registration introduces a criterion for organ allocation that is not related to medical need. Major institutional stakeholders such as UNOS and the American Medical Association have avoided the use of non-need-based criteria (Sanchez, 2003); for example, criteria that would give lower priority to patients with alcoholic cirrhosis, patients without dependents, or older patients. Although some factors unrelated to need, such as geography, are taken into account, the preeminent considerations relate to medical need and the predicted outcome. To the extent that reciprocity-based allocation embraces the idea that some patients merit a transplant (rather than need a transplant) more than others because they are willing to contribute their organs, these models would effect a significant change in the existing criteria for organ allocation. If society is going to step onto that slippery slope (Gillon, 1995), it is not clear why a willingness to contribute organs should be paramount. Why should not other contributions to society be taken into account?

Some of the people most in need of an organ will be people who have never been medically eligible to donate, so their willingness to donate would be an empty gesture. What should be done in such cases? Is it fair to exclude people who could never have been donors, that is, those who were free riders from birth or adulthood? Not surprisingly, reciprocity-driven proposals typically grant equal access to potential recipients who are medically ineligible to be donors, recognizing that the reciprocity principle requires some qualification. What, then, about people who have a strong emotional or religious concern about donating their own organs? Should religious objection to donation preclude equal access to organs when they are needed? What if the religious objector had made other major contributions to society? The reciprocity argument also fails to take into account the lack of trust that some people from historically disadvantaged groups have in the healthcare system. A person who has inadequate access to health care and fears that organ donor status might increase his or her chances of receiving suboptimal treatment in a life-threatening health situation may be reluctant to be an organ donor, even though he or she would like to receive an organ

if he or she needed one. It is understandable why UNOS would strongly prefer to anchor allocation in medical criteria.

CONCLUSIONS AND RECOMMENDATIONS

In evaluating the various arguments for and against incentives and in arriving at recommendations, the committee has drawn on the assumptions and principles summarized in Chapter 3. The committee's reasoning, summarized below, serves both to explain and to limit the reach of its recommendations.

First, given the committee's charge, the primary goal of any new incentive policies should be to increase the rates of organ donation rather than to serve other goals (for example, to enhance autonomy, express gratitude, improve the lot of the poor, or provide fair reimbursement). Other principles and values must come into play in delineating the ethical constraints on the use of incentives for donation, but they should not be decisive factors in the adoption of an incentives policy.

Second, as noted above, hard data on the impact of incentives are lacking, although individuals on both sides of the debate have provided some a priori and some empirical data. Accordingly, recommendations might need to be revisited should better data become available.

Third, obtaining reliable data to address these issues may be difficult. Although some have proposed an experimental approach to the use of incentives, others have expressed concerns about this approach. On the one hand, if financial incentives are ethically unacceptable in principle, then pilot testing should not be encouraged to determine whether they would actually increase the organ supply. On the other hand, if the concern is primarily consequentialist, then one is also concerned that pilot studies may set in motion a societal process that is difficult to reverse even after the pilot study itself is abandoned. For example, if people begin to view their organs as valuable commodities that should be purchased, then altruistic donation may be difficult to reinvigorate. As explained in Chapter 3, the committee believes that caution is warranted under these circumstances.

Fourth, in weighing arguments for and against incentives, the committee did not require either side to carry the burden of proof. Rather, it is noted that both sides of the debate have argued that the other side should shoulder the burden of proof: proponents because they would deviate from the status quo; opponents because they oppose policies that allegedly would save lives (Radcliffe-Richards et al., 1998).

Fifth, the committee's deliberations have been influenced by the recent success of donation initiatives that do not rely upon donor incentives. The Organ Donation Breakthrough Collaboratives have demonstrated that the application of quality improvement methods to this process can signifi-

cantly increase the percentage of potential organ donations that are converted into actual donations (Chapter 4). Putting financial resources into this kind of improvement activity might well be a more cost-effective approach to increasing the organ supply than introducing financial incentives for donation and would avoid the controversial cultural issues that surround paying for human bodies. The collaboratives provide data suggesting that adopting best practices in the process of organ recovery and allocation could increase conversion rates from 50 percent to at least 60 percent; some institutions have achieved close to or greater than 75 percent conversion rates by following best practices models. Additionally, by implementing and expanding donation after circulatory determination of death protocols, it may be possible to greatly increase the number of available organs without the use of controversial incentives.

Finally, much remains to be done to remove disparities in the provision of health care and to build trust in the medical community. Although incentives might serve to increase donation rates, the committee believes that the actual need for incentives can be determined only after equal access to the transplantation system by all groups in the population is ensured and by building the trust of those groups in the medical community. Moreover, the premature provision of incentives could be viewed as a sign of disrespect and as an effort to manipulate donation in the face of perceived injustices.

Recommendation 8.1 ***Financial Incentives.***
The use of financial incentives to increase the supply of transplantable organs from deceased individuals should not be promoted at this time. (The term "financial incentives" refers to direct cash payments as well as contributions toward funeral expenses or to a charity of choice.)

Recommendation 8.2 ***Preferential Access.***
Individuals who have recorded a willingness to donate their organs after their death should not be given preferential status as potential recipients of organs. This recommendation does not imply opposition to the assignment to living donors of additional points for the allocation of organs should they subsequently need a transplant.

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9

Ethical Considerations in Living Donation

The demand for solid organs far exceeds the number of organs available from deceased donors. Not surprisingly, instead of facing years on the transplantation waiting list, some patients, often with the encouragement of transplantation teams, seek to identify relatives or others who would be willing to donate the needed organ or partial organ directly or, in some cases, through a donor exchange program. Still other donors offer a kidney or a partial organ to patients whose stories have become known to them, perhaps through the media, whereas still others make a nondirected donation of a kidney to the transplantation system for use by any patient who needs it.

Organ donation by living donors clearly saves lives, improves transplantation outcomes under some circumstances, and reduces recipients' waiting times. It also increases opportunities for patients without living donors to receive organs from deceased donors. However, it raises a series of ethical questions that have not been fully addressed.

The transplantation of organs from living donors seems to violate the traditional first rule of medicine—*primum non nocere* (above all, do no harm)—because it involves the removal of a healthy organ from one person for implantation into another person. One person becomes a patient to benefit another person who is already a patient. In a survey of 100 liver transplant surgeons, Cotler and colleagues (2003) found that 77 percent experienced a moral dilemma in placing a living donor at risk. Nevertheless, 72 percent also agreed that transplant centers had a duty to offer their patients the possibility of transplantation using living donors.

Because the committee's mandate calls for primary attention to ways to increase the rates of organ donation from deceased donors, this report will not provide a detailed discussion of the scientific, clinical, and ethical issues involved in organ donation by living donors. However, the committee believes that it is important that living donation be the subject of intense discussion and study. This chapter can do little more than flag a number of issues and concerns that warrant further attention.

The committee believes that it would be appropriate for the Health Resources and Services Administration (HRSA), perhaps in conjunction with other organizations, to establish an appropriate mechanism to conduct this full and long overdue review, a portion of which has been undertaken by the U.S. Department of Health and Human Services (DHHS) Advisory Committee on Transplantation (ACOT). Nevertheless, even before a full review is conducted, the committee finds warrant for two recommendations to increase and improve the available data and to protect donors' rights and welfare (see Summary and Recommendations below).

This chapter begins with an overview of the statistics regarding living donation followed by a discussion highlighting a number of the ethical issues. The chapter concludes by focusing on the need for further examination of this issue and on the committee's recommendations to provide independent donor advocate teams and to follow up on the health of living donors.

BACKGROUND

The first successful organ transplantations involved living donors. In 1954, surgeons at Peter Brent Brigham Hospital in Boston removed a kidney from a young man and implanted it in his identical twin brother (Merrill et al., 1956). Through the 1960s developments in transplantation technology enabled kidney transplantation to evolve into a viable alternative to hemodialysis (Surman et al., 2005). As developments in immunosuppressive medication allowed the use of organs from unrelated deceased donors—at first from individuals declared dead by the use of circulatory criteria and subsequently from individuals declared dead by the use of neurologic criteria—it also expanded the pool of potential living donors of kidneys (Abecassis et al., 2000; Surman et al., 2005). Transplant centers initially allowed only genetically related family members to donate kidneys. Over the years, however, more and more patients have received kidneys from emotionally related donors (those who do not have a genetic link to the donor but who are nevertheless close, e.g., spouses and friends), from acquaintances, and even from altruistic strangers (those who are not currently known by the recipient) (HRSA and SRTR, 2006).

Because the identification of a living donor is an ad hoc process that largely involves the actions of the potential recipient, government oversight of the living donation process is limited. Individual transplant centers have largely borne the responsibility for living organ donation (Steinbrook, 2005). Although the Organ Procurement and Transplantation Network (OPTN) has collected and analyzed data regarding deceased donors, its data on the living donation process and on its effects on living donors over time are quite limited. Perhaps one reason for this imbalance is that the National Organ Transplant Act of 1984, which established the OPTN, did not address living donation. At that time, living donation was not as significant a percentage of donation as it has since become. Hence, there are huge gaps in the available data on living donation and its effects on the donors. OPTN has, however, recently taken steps to increase and improve the data on living donors (Steinbrook, 2005).

Living donation has become more frequent in recent years (Figure 9-1), with significant increases in the number of unrelated donors in the past 10 years (Figure 9-2). From 1988 through December 2005 over 77,000

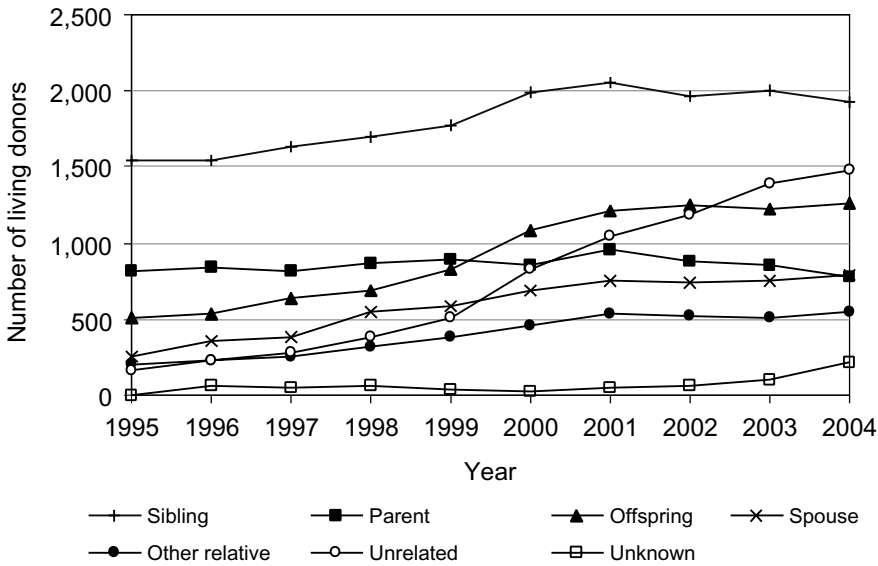

FIGURE 9-1 Relationships between living donors and recipients, 1995 to 2004. SOURCE: HRSA and SRTR (2006, Table 2.8).

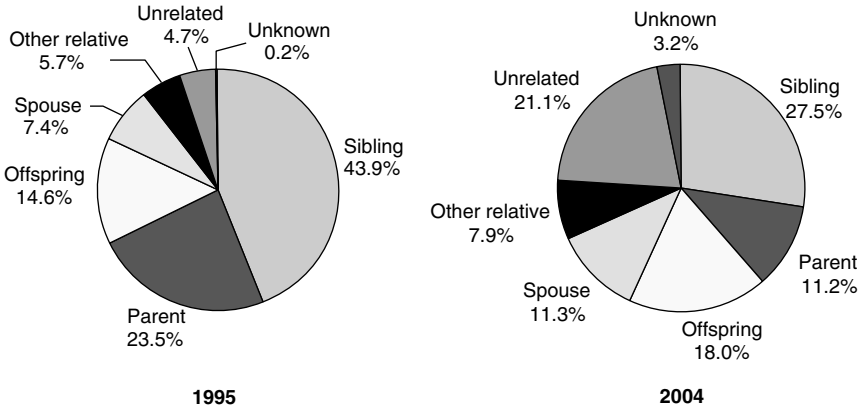

FIGURE 9-2 Relationships between living donors and recipients, 1995 and 2004. SOURCE: HRSA and SRTR (2006).

living donations occurred (OPTN, 2006[1]). Most organs donated by living donors are kidneys, which constituted 95 percent of the organs from living donors transplanted in 2005 (OPTN, 2006). In 1988, of the 8,873 kidneys transplanted, about 20 percent (1,812 kidneys) came from living donors (OPTN, 2006). A total of 16,477 kidney transplants were performed in 2005, with 9,915 (60.2 percent) of the transplants resulting from deceased donations and 6,562 (39.8 percent) resulting from living donations (OPTN, 2006).

From 2001 to 2003 the number of living donors slightly outnumbered the number of deceased donors (although the latter provided more organs). This trend reversed in 2004 and 2005 due to substantial increases in the number of deceased donors (Chapter 2). Over the last decade and a half, it has become possible for living donors to donate organs other than kidneys, including partial liver, partial lung, and, most recently, parts of the small bowel. Hence, organ donation by living donors is not a single kind of activity because of the different organs that can be involved, the different ratios of the potential benefit to the risk, the variety of possible relationships between the donor and the recipient, and other factors.

The relationship between the donor and the recipient often has a bearing on the donor's motivation for giving an organ. The living related donor is genetically related to the recipient. Duties and obligations associated with

[1]Data are provided from the National Data Reports on the OPTN website (http://www.optn.org). The data used in this chapter are current as of March/April 2006; data on the website are continuously updated.

family relationships and roles often weigh heavily on the decision to donate, as do emotional bonds within the family, because the living related donor is usually also an emotionally related one as well. Major ethical concerns about organ donation by living related donors focus on the possibility of undue influence and emotional pressure and coercion.

By contrast, the living unrelated donor lacks genetic ties to the recipient. The living unrelated donor and recipient may be emotionally related (e.g., a spouse or a friend), they may be known to each other but not emotionally close (e.g., coworkers), or they may be complete strangers. Living unrelated donors respond to a need that may come to their attention in various ways. They may become aware of a person's need for an organ through a shared personal story of a coworker, teacher, church member, or friend of the family; through a story in the media; or through a public solicitation, such as on a billboard, in an advertisement, or on the Internet. Although organ donations in such cases are usually directed donations, that is, the organ is directed to a specific patient in need, there are some cases of nondirected donation. For example, in response to the shortage of transplantable organs, a living unrelated donor may simply wish to donate an organ or part of an organ anonymously to save a life or enhance the quality of life of another person (Matas et al., 2000; Jacobs et al., 2004; Gilbert et al., 2005; Truog, 2005).

Other models have emerged to address situations in which a donor wants to provide a kidney to a particular individual but cannot do so because of incompatibility. The paired donor exchange is a quid pro quo situation in which two donors provide a kidney, each to the other's intended recipient, because their tissue or blood type is incompatible with that of the originally intended recipient. The donor's motivation here is ensuring the best outcome for his or her originally intended recipient.

Another arrangement involves a living undirected donation to the pool of transplantable kidneys with the explicit expectation that the donor's loved one will receive priority for a kidney from a deceased donor. For instance, Region 1 of the United Network for Organ Sharing has devised a live donor list exchange. In this system, a living donor who wants to provide a kidney to a patient but who cannot do so because of blood type or cross-match incompatibility provides a kidney to the system, and the originally intended recipient then receives a kidney from a deceased donor (Delmonico et al., 2004).

In some circumstances it is possible to perform "domino transplantations" in which medical circumstances allow the transplant recipient's kidney or liver to be donated to another individual on the waiting list. This can occur with specific medical conditions (e.g., familial amyloid polyneuropathy) or with some heart-lung transplantations.

The varieties of recipient-donor relationships raise a number of specific

ethical issues. For example, the solicitation of living donors has become an area of concern and discussion following some widely publicized cases of solicitation for organs through billboards, newspaper advertisements, and the Internet (e.g., through MatchingDonors.com) (Steinbrook, 2005; Truog, 2005). In such cases, as well as in some other types of donation by living unrelated donors, the ethical concerns focus on the possibility of the buying and selling of organs as well as on the impact on the equitable allocation of organs (Steinbrook, 2005).

RISK-BENEFIT RATIOS

The ethical justification for the use of organs from living donors begins with a consideration of the potential benefits, mainly to the recipient but also to the donor, balanced against the risks to the donor, understood in terms of both the probability and the magnitude of harm. Before a potential living organ donor makes the decision to donate, she or he needs to have an accurate understanding of the risks and the potential benefits associated with the donation. However, as this chapter will emphasize, the information disclosed to potential donors to increase their understanding of the risks involved is inevitably inadequate because, for instance, the long-term health outcomes of living donation are only beginning to be explored, particularly for nonrenal organs.

An acceptable risk-benefit ratio is a precondition for a living organ donation. Even though the term "risk-benefit ratio" is common, a more precise formulation is risk-probable benefit ratio. Because the term "risk" reflects both the probability and the magnitude of harm, cost, or burden, the comparable language for benefit needs to include probability as well as magnitude; hence, the ratio is between risk (probability and magnitude of harm, cost, or burden) and probable benefit. Therefore, when this chapter uses the common formulation "risk-benefit ratio," this interpretation is operative.

A complication in determining a risk-benefit ratio for living organ donation is that the donor bears almost all of the risks. The recipient, on the other hand, is the primary beneficiary because of the reduced waiting time for an organ, survival, and improved health and quality of life if the transplantation is successful. The donor may be a secondary beneficiary, perhaps gaining the psychosocial benefits that result from donating an organ to someone in need. In short, the living donor accepts the risks of major surgery for another's medical benefit and any psychosocial benefits to himself or herself (Spital, 2004). In this situation, a risk-benefit analysis is thus complicated and difficult to conduct.

Nevertheless, the transplantation team and, ideally, an independent donor advocate team must make a judgment about the acceptability of the

risk-benefit ratio for particular potential donors, who must also make their own assessment. The transplantation team and donor advocate team must be comfortable with the risk-benefit ratio before proceeding. For instance, they may view the risks as excessive to a particular potential donor because of some preexisting medical problem, such as a condition that might increase the risk that his or her remaining kidney may fail in subsequent years. The donor also needs to weigh information on the medical condition of the potential recipient and the potential for a successful transplantation. Even if these teams agree that the risk-benefit ratio is acceptable, the potential donor, whose subjective evaluation is crucial to the decision, must still make his or her own judgment. A negative judgment by either party precludes the donation. Nevertheless, the potential donor's decision often reflects, at least in part, his or her relationship to the potential recipient.

Living donors often report that they receive important psychological and social benefits from exercising their autonomy to become a living donor. The kinds of benefits, both those that are anticipated and those that are actually experienced, vary to some extent according to the type of relationship between the donor and the recipient. When the donor is biologically and emotionally related to the recipient, donors may experience increased self-esteem for making such a gift, gratitude from the recipient, praise by others, and so forth. Similarly, even when the donor is unrelated to the recipient, donors may experience the gratification of having performed an altruistic act and may receive the praise of others (Spital, 2004).

However, it is difficult for transplantation teams, independent donor advocate teams, and prospective donors themselves to perform their analyses and assessments of risks, benefits, and risk-benefit ratios because of incomplete data about the health outcomes of living donation. Even for the more than 67,000 living donors who donated a kidney through 2004, the data on short-term health outcomes are not comprehensive, and there has been little long-term follow-up to determine the physical and psychosocial effects of living donation over time (Ellison et al., 2002; Matas et al., 2003; Davis and Delmonico, 2005; Ingelfinger, 2005). An example of the need for follow-up data is the number of patients who after donating a kidney later need kidney transplant; as of 2002, an analysis of the OPTN database identified 56 living donors who had subsequently received a kidney transplant or were on the waiting list for renal transplant (Ellison et al., 2002).

For those who have donated parts of their liver, lung, or intestines, the data on the health outcomes of donation come from recent, short-term studies that are not comprehensive; little is known about the long-term effects of these donations (see, for example, Renz and Roberts, 2000; Beavers et al., 2001; Bowdish and Barr, 2004; Bowdish et al., 2004).

Nevertheless, on the basis of the currently available data, it is apparent that the risk-benefit ratio largely depends on the organ or organ part to be

donated because the risks of mortality and morbidity as a result of donation vary greatly by the organ or organ part that is donated. The risk-benefit ratio also depends on the donor's motivation, which is closely connected to the kind of relationship that exists between the donor and the recipient. A highly motivated donor may derive significant psychological benefit from his or her donation and may thus be willing to incur more risk. Regardless of the organ that is donated, however, complications may occur at the time of the donor workup, during and shortly after the surgery, or long after donation.

In addition, the act of donation may result in some negative psychosocial consequences. For example, lingering health problems could delay or prevent a return to work, and may create difficulties in obtaining life, health, and disability insurance (Russo and Brown, 2003). Furthermore, the donor may confront significant financial costs. These costs, which may be a major disincentive to prospective donors, include lost wages as well as travel, lodging, and other expenses. For these reasons, the federal government and transplantation organizations have begun to take steps to make organ donation as financially neutral as possible. In 1999, the U.S. Congress enacted the Organ Donor Leave Act (Public Law 106-56). This law allows federal employees to take 7 days of paid leave to be a bone marrow donor and 30 days of paid leave to be a solid-organ donor. A number of states and many private-sector businesses have followed suit and have created similar leave provisions for their employees (Davis and Delmonico, 2005; NCSL, 2006). Efforts are also under way to implement the provision of the Organ Donation and Recovery Improvement Act (Public Law 108-216) that provides for the implementation of programs that would grant reimbursement for travel and subsistence expenses and incidental nonmedical expenses incurred by living organ donors (Davis and Delmonico, 2005).

OTHER ETHICAL CONSIDERATIONS

In addition to the ethical considerations involved in risk-benefit analyses and assessments, living organ donation raises several other ethical concerns. Whatever the relationship between the potential donor and the recipient, it is crucial that the potential donor be adequately informed and that the decision be made in an environment that is conducive to thoughtful decision making without undue influence or coercion.

Informed Consent

Ethically justifiable living organ donation presupposes the competent donor's voluntary informed consent. Competence or capacity in this context refers to the prospective donor's ability to understand the relevant

information in relation to his or her personal values and interests and, on that basis, to make a thoughtful decision about donation. When the individual being evaluated for living donation lacks the capacity to make such a decision, he or she cannot, strictly speaking, be a "donor," that is, one who competently decides to donate. Such an individual can only be a "source" of the organs, even though sometimes such a source of organs is loosely called a "donor." Although children and some adults who are incompetent or doubtfully competent to make complex health-related decisions are sometimes involved in living donation, with the decisions made by others, such donations are difficult to justify ethically and, at a minimum, must satisfy special substantive and procedural conditions. Discussions on the issues regarding children as living organ donors continue (see, for example, Ross, 1998; Abecassis et al., 2000; Delmonico and Harmon, 2002; Holm, 2004; Jansen, 2004; Ladd, 2004; Zinner, 2004).

Nevertheless, even when individuals are competent, problems with communication may compromise the process of informed consent in living donation as well as in other settings, such as therapy and research (Beauchamp and Childress, 2001) (Chapter 3). In addition, the close affective ties in most donations involving related donors may lead the prospective donor to make a decision to donate before he or she fully receives and understands all the pertinent information, particularly about the risks involved (Simmons et al., 1987). The knowledge that a loved one needs a life-saving or life-enhancing transplant may be powerful enough by itself to lead the individual to agree to donate an organ or part of an organ without extensive deliberation.

The goal of the informed-consent process in living donation is adequately informed consent. Even if the individual immediately agrees to donate, it is appropriate to provide the range of relevant information and to ask the potential donor questions to ensure that he or she has an adequate understanding of the act of donation and its possible and probable effects. In light of the potential donor's desire to help a loved one, the transplantation team and the donor advocacy team need to indicate to the potential donor as clearly as possible the prospective recipient's need, possible medical alternatives, and the chances for a successful outcome. The patient's perceived need is important in the prospective donor's risk-benefit calculus, but so is the patient's probable outcome.

Nevertheless, adequate understanding (i.e., understanding adequate for informed consent to living donation) may be difficult and perhaps impossible for prospective donors to achieve because of the incomplete and limited data about donor outcomes. Robust informed consent thus remains an elusive ideal because the data about specific health and other risks have not been rigorously collected and analyzed. For example, little is known about the time to recovery; the nature and extent of subsequent morbidities and

complications, or even death; the financial consequences of living donation, including out-of-pocket costs; or the impact of living donation on obtaining or maintaining health and life insurance. Hence, it is important to develop registries that can track such outcomes for living donors.

A few years ago the DHHS Advisory Committee on Transplantation made several recommendations about living donation that called for the creation of a database with data on the health outcomes of all living donors (ACOT, 2005). In May 2005, ACOT noted the continuing lack of a donor registry and reiterated its concern "that provisions in living donor informed consent cannot be fulfilled without the existence of a living donor registry" (ACOT, 2005).

Voluntary Consent

General ethical concerns focus on a potential donor's competence, level of understanding, and voluntary choice, whatever the relationship between the donor and the recipient. When the prospective donor is related to the recipient, which usually involves close affective ties as well as the genetic relationship, specific concerns focus on the dangers of undue influence, pressure, and coercion, even if he or she is competent, has received adequate information, and appears to understand that information.

It is important to develop mechanisms and procedures to ensure the voluntariness of the prospective donor's decision. Because the potential donor's interests may sometimes conflict with the potential recipient's interests (and, perhaps, with the interests of the recipient's family, which is also the potential donor's family), a confidential process is needed for the evaluation and selection of donors, with particular attention to their willingness to donate. Potential donors sometimes feel trapped in a process that they do not know how to stop without jeopardizing their relationships with members of their family or other people. A donor advocate can often be helpful in such circumstances. The transplantation team or donor advocate may sometimes believe that it is justifiable to offer a medical excuse to enable the potential donor to escape the pressure of donation and still protect his or her relationships with the family and others who have an interest in the transplantation. For example, in a survey of 100 liver transplant surgeons, 87 percent indicated that "they would provide a medical or technical reason that precluded donation" if the potential donor changed his or her mind regarding donation (Cotler et al., 2003, p. 640).

Transplantation teams and donor advocates also need to recognize that, for poorly understood reasons, a striking gender imbalance exists in living renal transplantation: women donate kidneys at a significantly higher rate than men. For example, in 2005, 59.2 percent of living kidney donors were women, continuing a long-term trend in which women constitute 56

to 59 percent of the living kidney donations each year (OPTN, 2006). Examining the data for living kidney transplants between 1990 and 1999, Kayler and colleagues (2003, p. 15) observed that "The higher incidence of end-stage renal disease among males and the slight predominance of females in the general population did not explain these gender disparities. . . . Gender disparities in living donor transplantation result from a higher proportion of wife-to-husband donations and disproportionate female-to-male donations among biological relatives and unrelated pairs." This quotation describes but does not explain why women donate more often. A much earlier study, which needs to be updated, indicated that men and women donate at roughly the same rates when they are asked to do so and suggested that women were asked more often (Simmons, 1981). Transplantation and donor advocacy teams need to attend to any factors, such as power imbalances, that might lead to the singling out of particular individuals as prospective donors and to pressure on them to donate.

Donations, Not Sales

An ethical concern about living unrelated donation that frequently arises is that the organ is actually being sold or, at least, that financial incentives partially motivate the donation. For example, such concerns have arisen with regard to solicitations on the Internet (Steinbrook, 2005). Money may be a factor in living related donations, too. Whatever the context, compensation for organs is illegal under Section 301 of the National Organ Transplant Act: "It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration" (Public Law 98-507). Compensating living donors opens up the possibility of exploiting poor and underprivileged people and also increases the risk that potential donors will withhold relevant medical information.

The committee's reasons for rejecting a market in organs from deceased individuals (Chapter 8) apply with even greater force to a market involving organs from living people. These reasons hold even though a few analysts argue that it would be effective and cost-effective to pay individuals as much as $90,000 to provide a kidney for transplantation and even propose changes in the laws to permit such a payment in a regulated market (Matas and Schnitzler, 2003; Matas, 2004). These proposals have yet to gain traction in the United States because they are incompatible with the fundamental values and norms that govern transplantation (Delmonico et al., 2002) and because international markets in organs from living individuals appear to involve the exploitation of relatively impoverished people and inadequately informed and perhaps manipulated consent, as well as, in many cases, adverse consequences for both sellers and purchasers. Although the

direct sale of organs has been debated for several decades, it has been condemned by most national and international governmental organizations and professional societies because of concerns about human rights abuses; the inability to obtain adequately informed consent; and the exploitation of vulnerable people, who are often vulnerable because of poverty (Marshall and Daar, 1998). Although some contend that a regulated market would be a better solution than prohibition, critics doubt that it could avoid all of those negative consequences. Furthermore, they worry about the broader societal impact of the commodification of organs on human dignity.

These ethical concerns also apply to markets for organs that operate, often illegally, in other countries and attract an international clientele (Scheper-Hughes, 2000). Goyal and colleagues (2002) conducted a cross-sectional survey of 305 individuals in Chennai, India, who had sold one of their kidneys. Ninety-six percent of the respondents stated that paying off debt was their motivation; however, selling a kidney did not produce any long-term economic benefit among those interviewed. The results of the study demonstrated a one-third decline in family income, and the majority of participants were still in debt and living below the poverty line at the time of the survey (on average, 6 years after they had sold their kidney). Eighty-six percent of those interviewed reported deterioration in their health status following the nephrectomy.

In addition to the risks to the sellers of a kidney, so-called medical tourism often creates problems for the buyers. A 2005 study of the health outcomes of 16 individuals (mainly from Macedonia) 10 years after they had purchased organs from living unrelated donors (mainly in India) found relatively poor outcomes and several deaths as a result of severe pulmonary infections because of sepsis, hepatitis B with liver cirrhosis, and other complications. Two patients died in the first month, and two patients died at the end of the first year after transplantation (Ivanovski et al., 2005). These results suggest that surgical and medical complications arising from such transplantation practices may outweigh the benefits, all other ethical issues aside (Ivanovski et al., 2005).

NEXT STEPS

Although the committee believes that the whole practice of organ donation by living donors now needs a careful review and assessment on its own, in the interim the committee makes a few specific recommendations, building on ethical concerns and proposals already present within the transplantation community and drawing on the ethical perspectives that inform this report (Chapter 3). Ethical needs include the generation of better information (through a registry for living nonrenal donors and a registry or rigor-

ous sample studies for renal donors) for improved risk-benefit analyses by transplantation teams, donor advocates, and the potential donors themselves; a clinical commitment to the welfare of the donor as a patient before, during, and after the donation; vigorous efforts to ensure fairness and nonexploitation in the selection of donors and to ensure the prospective donor's understanding and voluntary decision; and the increased use of independent donor advocate teams. The specific recommendations that follow are particularly important for partial liver transplantation and partial lung transplantation because of their greater medical risks and inadequate data about those risks, but they would also be valuable in the context of kidney transplantation. Indeed, these recommendations are crucial to promoting and protecting the potential donor's voluntary and informed consent in a nonexploitative context.

Independent Donor Advocate Team

In determining which potential living donors will be accepted, transplantation teams serve as ethical gatekeepers, with less societal oversight than occurs in much of transplantation. Additionally, they may have an inherent conflict of interest because they seek to obtain an organ for patients on the waiting list while assuming major responsibilities to potential and actual donors.

The development and use of an independent donor advocacy team that focuses on the donor's needs is of paramount importance. Such a team can best protect the donor if it offers the multidisciplinary expertise needed to address the whole range of medical, ethical, social, and psychological questions and issues. Each team should include a clinician with experience in transplantation, a social worker or other mental health professional with experience in interpreting donor motivations and addressing intrafamilial conflict, and a nurse. Whether these healthcare professionals or another group of healthcare professionals are involved, the goal is to provide the expertise and skills necessary to ensure (1) that the potential donor adequately understands the risks that surround his or her donation and recognizes the uncertainties involved, especially in the absence of comprehensive data about outcomes, and (2) that the potential donor is making a voluntary decision regarding donation without undue pressure or coercion by family members or by anyone else. Focusing on the welfare and rights of the donor, the donor advocacy team can also act as a safety valve by providing a confidential way out for prospective donors who believe that they are being pressured or coerced to donate.

Living Donor Follow-Up

As this chapter has stressed repeatedly, more information is needed about the short-term and long-term health and other effects of living organ donation, particularly the donation of nonrenal organs. For the most part, living donation developed on an ad hoc basis in various transplant centers and has never had the central oversight and supervision that has marked practices of donation by deceased individuals. As a result there is no national infrastructure for gathering information and for ensuring accountability as there is for donation by deceased individuals.

Establishing registries of living donors would be a first step in developing the infrastructure needed for follow-up studies. Registries are particularly important for nonrenal transplants, and they could be developed without excessive cost because the numbers are small: there are just over 300 living liver donors and about 30 living lung donors (for about 15 lung transplants) each year (HRSA and SRTR, 2006). It could be argued that such a registry is not needed for living kidney donors because this procedure has been used for decades and many thousands of living donors have provided a kidney. However, it is important to start the process of registering all living donors and then to determine, through an appropriate mechanism, what data should be collected after the first year, at what intervals, and for how long, balancing the costs and probable benefits of the data collection.

Important concerns for registries and for sample studies include the long-term effects as well as the short-term effects of donation on physical and mental health and on financial resources, insurability, and other relevant issues. OPTN could be the locus for data collection and management because it is well situated for managing large data sets relating to transplantation. In addition, placing the responsibility for the collection of long-term data on living donors within OPTN would effectively bring living donation under the general scrutiny of the transplantation community and the public.

The committee further observes that many of the available studies of the decision-making process about living donation by potential donors were conducted years ago with living kidney donors (see, for example, the work of Simmons et al., 1977; Sanner, 2005). In addition to continuous quality improvement in the process of selecting, informing, and ensuring the voluntariness of the decisions of prospective donors, transplantation and donor advocacy teams need information from rigorous studies of their processes and of donor and nondonor decision making.

SUMMARY AND RECOMMENDATIONS

The realistic goal of the recommendations developed in this report is to reduce the gap between the supply and the demand for transplantable

organs by increasing the rates of organ donation by deceased persons. One important effect of the reduction of this gap would be the reduction in the need for organs from living donors because such donations are often ethically problematic in view of the risks to donors, particularly in nonrenal transplants, and the difficulty of ensuring voluntary, informed consent.

The committee urges further scrutiny of the complex ethical issues related to living donation and, in the interim, offers two specific recommendations designed to enhance the assessment of donors' risks and their voluntary, informed consent.

Recommendation 9.1 ***Protect Living Donors.***
Hospitals that perform living-donor transplantations should provide each potential living donor with an independent donor advocacy team to ensure his or her voluntary and informed decision making.

Recommendation 9.2 ***Facilitate Living Donor Follow-Up.***
HRSA, OPTN, and transplant centers should work to establish registries of living donors that would facilitate studies of both short-term and long-term medical and other outcomes of living donation.

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10
Opportunities for Action

The recommendations provided in this report set forth a number of actions that the committee believes can have a positive impact on organ donation (Table 10-1). Together, these recommendations identify a set of actions that in isolation might have only limited results but that in concert should strengthen ongoing efforts and open up new opportunities to increase the supply of transplantable organs, thereby saving the lives and improving the quality of life of many individuals.

The committee believes that it is possible to increase the opportunities for organ donation in the two populations of deceased donors: individuals whose deaths have been determined by neurologic criteria and individuals whose deaths have been determined by circulatory criteria. It has been estimated that each year organs are recoverable from approximately 10,500 to 16,800 individuals whose deaths are determined by neurologic criteria. Currently, however, approximately only half of these individuals become organ donors. Nevertheless, more and more organ procurement organizations and hospitals are increasing their donation rates and some are approaching or are achieving 75 percent conversion rates. Increased quality improvement, organ donor registration, education, and research efforts have the potential to sustain these increases and to realize similar increases in other institutions.

Additionally, the committee estimates that each year in the United States organs are potentially recoverable from 22,000 individuals whose deaths are determined by circulatory criteria. This population of potential donors is only beginning to be recognized. In 2004, there were 391 dona-

TABLE 10-1 Actions to Increase Organ Donation

Individuals	• Register as an organ donor through driver's license, donor card, or donor registry • Inform family members of organ donation decisions
Families	• Discuss organ donation decisions • Honor prior donation decisions made by the deceased family member • Provide consent for donation if the deceased family member did not make a decision regarding donation

Healthcare, emergency care, and transplantation systems	• Implement system changes
	  • Sustain mechanisms and support for continuous quality improvement
	  • Integrate organ donation and end-of-life care practices and services
	• Expand donation opportunities
	  • Increase opportunities for donation after circulatory determination of death
	• Expand and enhance professional education about organ donation and end-of-life care

Nonprofit organizations, academia, government, media, employers	• Provide multiple opportunities for donor registration and education
	  • Encourage registration through donor cards, driver's licenses, or donor registries
	  • Promote programs to increase donor awareness
	  • Improve media coverage to increase public awareness and reduce misperceptions
	  • Increase public education
	• Coordinate efforts through the use of
	  • Donor registries
	  • Uniform state laws
	• Fund research on innovative approaches to increasing rates of organ donation and enhancing organ viability

tions after circulatory determination of death (DCDD). Although the committee recognizes the challenges in developing and implementing DCDD programs, the opportunity to save lives necessitates a careful effort to fully explore the recovery of organs after the circulatory determination of death.

It is the committee's hope that this report will contribute to the development and implementation of new efforts to increase the rates of organ donation. In addition, the committee hopes that these efforts, along with concurrent actions focused on the prevention of health conditions that lead to the need for transplantation and research to explore alternatives to transplantation, will significantly reduce the size of the organ transplant waiting list in the near future.

A
Acronyms

ACOT	Advisory Committee on Transplantation
AHA	American Heart Association
AMA	American Medical Association
AOPO	Association of Organ Procurement Organizations
AST	American Society of Transplantation
ASTP	American Society of Transplant Physicians
ASTS	American Society of Transplant Surgeons
CDC	Centers for Disease Control and Prevention
CDD	circulatory determination of death
CMS	Centers for Medicare & Medicaid Services
CPR	cardiopulmonary resuscitation
DCDD	donation after circulatory determination of death
DHHS	U.S. Department of Health and Human Services
DNDD	donation after neurologic determination of death
DoT	Division of Transplantation, Health Resources and Services Administration
EMS	emergency medical services
ESRD	end-stage renal disease
FHWA	Federal Highway Administration
FY	fiscal year

HCFA	Health Care Financing Administration
HLA	human leukocyte antigen
HRSA	Health Resources and Services Administration
ICU	intensive care unit
IHI	Institute for Healthcare Improvement
IOM	Institute of Medicine
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
MELD	Model for End-Stage Liver Disease
MOTTEP	Minority Organ and Tissue Transplant Education Program
NATCO	Organization for Transplant Professionals
NCCUSL	National Conference of Commissioners on Uniform State Laws
NCHS	National Center for Health Statistics
NCQA	National Committee for Quality Assurance
NCSL	National Conference of State Legislatures
NDD	neurologic determination of death
NHBD	non-heart-beating organ donation
NIDDK	National Institute of Diabetes & Digestive & Kidney Diseases
NIH	National Institutes of Health
NKF	National Kidney Foundation
NOTA	National Organ Transplant Act
OPO	organ procurement organization
OPTN	Organ Procurement and Transplantation Network
PHASE	Pre-Hospital Arrest Survival Evaluation
SCCM	Society of Critical Care Medicine
SRTR	Scientific Registry of Transplant Recipients
UAGA	Uniform Anatomical Gift Act
UDDA	Uniform Determination of Death Act
UNOS	United Network for Organ Sharing
WHC	Washington Hospital Center

B
Workshop Meetings

Committee on Increasing Rates of Organ Donation

Second Meeting
June 20–21, 2005
Keck Center of the National Academies
500 5th Street, NW
Washington, D.C.

WORKSHOP AGENDA

8:10–9:00 **Panel 1: Determinants of Donation and Views on Incentives**
(Moderator: David Schkade)

8:10 Laura Siminoff, Case Western Reserve University
8:25 Jim Wells, The Gallup Organization
8:40 Discussion with the committee

9:00–10:15 **Panel 2: International Perspective**
(Moderator: Raul de Velasco)

9:00 Leo Roels, Donor Action Foundation, Belgium
9:20 Rafael Matesanz, Organización Nacional de Trasplantes, Spain
9:40 Discussion with the committee

10:15–12:00 **Panel 3: System Changes**
(Moderator: Clive Callender)

10:15 Jade Perdue, Organ Donation Breakthrough Collaborative
10:35 Nancy Ascher, University of California, San Francisco
10:45 Pamela Lipsett, Johns Hopkins University
10:55 Richard Hasz, Gift of Life
11:05 Janet Mart, Kentucky Organ Donor Affiliates
11:15 Discussion with the committee

12:00–1:00 p.m. Lunch

1:00–2:00 **Panel 4: Economic Considerations Regarding Incentives**
(Moderator: David Howard)

1:00 David Kaserman, Auburn University (via phone)
1:10 Lloyd Cohen, George Mason University
1:20 Emanuel Thorne, Brooklyn College, City University of New York
1:30 Discussion with the committee

2:00–3:30 **Panel 5: Ethical Issues Regarding Incentives**
(Moderator: Jim DuBois)

2:00 Frank Delmonico, New England Organ Bank
2:10 Robert Veatch, Georgetown University
2:20 Dan Brock, Harvard University
2:30 Sheldon Zink, University of Pennsylvania
2:40 Discussion with the committee

3:30–4:30 **Panel 6: Individual Decision Making**
(Moderator: Debra Schwinn)

3:30 Aaron Spital, New York Organ Donor Network
3:40 Eric Johnson, Columbia University
3:50 Kevin Myer, LifeNet
4:00 Discussion with the committee

4:30–5:30 **Panel 7: Donation After Cardiac Death**
(Moderator: Lewis Goldfrank)

4:30 Frank Delmonico, New England Organ Bank
4:40 Jimmy Light, Washington Hospital Center

4:50 Kenneth Wood, University of Wisconsin Hospital and Clinics
5:00 Discussion with the committee

5:30–6:15 Public Comments by Registered Speakers

1. Howard Koh
   Harvard School of Public Health
2. Luis Tomatis
   RDV Corporation
3. Alan Leichtman
   University of Michigan Medical School
4. Paul Schwab
   Association of Organ Procurement Organizations
5. David J. Undis
   LifeSharers
6. Mark S. Nadel
7. Trent Tipple
   National Kidney Foundation
   transAction Council
8. Stacey Wertlieb
   NATCO, Organization for Transplant Professionals
9. David Cohen
   American Society of Transplantation

Tuesday, June 21, 2005

8:30–9:45 a.m. Panel Discussion on Living Donation
Mark Fox, University of Oklahoma
Art Matas, University of Minnesota
Tim Pruett, University of Virginia

Committee Discussion with Panel Members

Committee on Increasing Rates of Organ Donation
Fourth Meeting
October 28, 2005
Keck Center of the National Academies
500 5th Street, NW
Washington, D.C.

Friday, October 28, 2005

8:30–12:00 **Presentations and Discussion with the Committee**

8:30–9:45 **Organ Donation Breakthrough Collaborative**
Dennis Wagner, HRSA
Frank Zampiello, Quality Reality Checks

9:45–11:00 **Organ Procurement Organizations**
Paul O'Flynn, Kentucky Organ Donor Affiliates
Howard Nathan, Gift of Life, Philadelphia
Paul Schwab, AOPO

11:00–12:00 **Public Forum**
Registered Speakers
Lisa Dinhofer, Transplant and Healthcare Consulting
Robert Sade, Medical University of South Carolina
Dolph Chianchiano, National Kidney Foundation
David Cohen, American Society of Transplantation

C

First-Person Consent Status and Organ Donor Registry Participation

Table C-1 provides information on each state's first-person (donor) consent laws and the status of its organ donor registry. In addition, Institute of Medicine staff contacted the appropriate officials in some states and asked them to provide the number of individuals in their donor registries.

TABLE C-1 First-Person (Donor) Consent Status and Organ Donor Registry Participation

State	First-Person Consent[a]	Registry[a]	Approximate Number of Individuals Registered (as of December 2005)[b]
Alabama	Yes	Yes; affiliated with the DMV (registry.legacyalabama.org)	
Alaska	Yes	Yes; affiliated with the DMV (www.alaskadonorregistry.org)	~216,000
Arizona	Yes	Yes; not affiliated with the DMV (www.azdonorregistry.org)	42,913
Arkansas	Yes	Yes; affiliated with the DMV	~800,000
California	Yes	Yes; affiliated with the DMV (www.donatelifecalifornia.org or www.donevidacalifornia.org)	
Colorado	Yes	Yes; affiliated with the DMV and accessed through Statline (coloradodonorregistry.org)	
Connecticut	Yes	Yes	868,215[c]
Delaware	Yes	Yes; affiliated with the DMV	
District of Columbia	Yes		
Florida	Yes	Yes; affiliated with the DMV	
Georgia	No	Yes; affiliated with the DMV	
Hawaii	Yes	Yes; affiliated with the DMV	
Idaho	Yes	Legislation recently created a registry, but the bill needs to be revisited	
Illinois	Yes	Yes (www.cyberdriveillinois.com)	
Indiana	Yes	Yes; through the Indiana Donation Alliance Foundation (www.indianadonationalliance foundation.org)	
Iowa	Yes	Work in progress with DMV (www.iowadonorregistry.org)	42,339
Kansas	Yes	Yes; affiliated with DMV and housed within the OPO (www.mwtn.org)	233,037
Kentucky	Yes	April 2006, law passed to create a registry	
Louisiana	Yes	Yes; housed within the OPO	
Maine	Yes	Law passed to create a registry; development is under way	
Maryland	Yes	No	
Massachusetts	No	Law passed to create a registry; development is under way	

continues

TABLE C-1 Continued

State	First-Person Consent[a]	Registry[a]	Approximate Number of Individuals Registered (as of December 2005)[b]
Michigan	Yes	Yes; affiliated with the DMV	861,854
Minnesota	Yes	Yes; affiliated with the DMV	1,732,434
Mississippi	No	No	
Missouri	Yes	Yes; affiliated with the DMV (www.Missouriorgandonor.com)	2,014,191
Montana	Yes	Yes; affiliated with the DMV (www.livinglegacyregistry.org)	286,950
Nebraska	Yes	Yes; affiliated with the DMV (www.nedonation.org)	
Nevada	Yes	Yes; affiliated with the DMV	~731,000
New Hampshire	No	No	
New Jersey	Yes	Yes; affiliated with the DMV (www.sharenj.org)	~45,000
New Mexico	Yes	Yes; via driver's license or valid I.D.	766,262[d]
New York	No	Yes; affiliated with the DMV and administered by the New York Department of Health (www.health.state.ny.us)	
North Carolina	Yes		~3,000,000
North Dakota	Yes	Yes; affiliated with DMV	
Ohio	Yes	Yes; affiliated with the BMV (www.ohiobmv.com)	3,870,930
Oklahoma	Yes	Yes; affiliated with the DMV; online registry officially launched in April 2004 (www.lifeshareregistry.org)	
Oregon	Yes	No	
Pennsylvania	Yes	Yes; affiliated with the DMV	
Rhode Island	Yes	Yes	
South Carolina	Yes	No	
South Dakota	Yes	Yes; affiliated with the DMV	284,859
Tennessee	Yes	Yes; passed in 2001	
Texas	No	Development is under way	
Utah	Yes	Yes; affiliated with the DMV; online registry launched in April 2002 (www.yesutah.org)	
Vermont	No	Law passed to create registry; development is under way	

continues

TABLE C-1 Continued

State	First-Person Consent[a]	Registry[a]	Approximate Number of Individuals Registered (as of December 2005)[b]
Virginia	Yes	Yes; affiliated with the DMV; online registry officially launched in August 2003 (www.save7lives.org)	
Washington	Yes	Yes; affiliated with the DMV (www.livinglegacyregistry.org)	3,017,287
West Virginia	Yes		
Wisconsin	Yes		
Wyoming	Yes	Yes; affiliated with the DMV (www.wyomingdonorregistry.org)	

NOTE: DMV = Department of Motor Vehicles; OPO = organ procurement organization; I.D. = identification; BMV = Bureau of Motor Vehicles.

[a]SOURCE: http://www.unos.org/inTheNews/factsheets.asp?fs=6. The information is current as of November 2005. Information on Kentucky legislation updated April 2006.

[b]Institute of Medicine staff contacted a number of states to inquire about the number of individuals currently registered in the state's organ donor registry. Not all states were contacted.

[c]As of September 22, 2005, approximately one-third of registered drivers.

[d]As of January 2005.

D

Quantifying Self-Interest in Organ Donation

Historically, the donation of solid organs (e.g., the heart, kidney, liver, and lung) has been discussed primarily in terms of charity, compassion, generosity, empathy, and philanthropy. It can also be argued, however, that people have a personal interest in maintaining a community that provides options such as organ donation. This motive is usually discussed in qualitative terms as a philosophic principle.

This motive can also be viewed in terms of traditional (and more narrowly focused) self-interest; that is, how does this apply to me? From this view, the natural questions are "Could this happen to me?" and, if so, "How likely is it to happen to me?" The committee has written this appendix in an attempt to quantify self-interest by roughly estimating the probability that solid-organ donation will touch the life of a given person or someone close to him or her over various periods of time. The derivation and sample computations follow below, including a chart that compares the risk that solid-organ donation will touch the life of a given person or someone close to him or her with other risks.

In the end, the likelihood that over the course of a lifetime a given person or someone that he or she cares about will need a solid-organ transplant is surprisingly high (about 1 in 5). Although this committee's focus is strictly on solid organs, each year there are many more transplants of other tissues than there are of solid organs. If tissue transplants are also considered, the average risk of the need for a transplant that each person and the individuals in his or her close social network faces over a lifetime rises substantially and certainly rises to more than one person in two.

These computations could be refined to produce more exact figures, but a clear conclusion emerges: even if charitable motives are discounted, people still have a substantial personal interest in maintaining a system in which organ transplants are available.

NOTATION

The notations used in the equations presented in this appendix are defined as follows:

- N = total relevant population,
- w = annual number of additions to the waiting list for a solid-organ transplant,
- y = number of years in which a person might be on a waiting list for an organ,
- g = number of people in a person's "close" social network, and
- $p_{g,y}$ = probability that at least one of g specified people will be placed on a waiting list in a y-year period.

ASSUMPTIONS

For the simple base model presented here, assume that all people have the same probability of being placed on a waiting list for organ transplantation in any given year and that their fates are independent of each other. Also assume that the proportion of the population that is added to the waiting list in a given year and the age distribution of the population are constant over the years. These assumptions are not crucial to the qualitative results but greatly simplify the initial analysis and exposition and can be relaxed in a more general derivation later.

The probability that the average person will be placed on a waiting list for a solid organ in a given year ($g = 1$, $y = 1$) is a simple relative frequency

$$p_{1,1} = \frac{w}{N} \tag{1}$$

The probability that at least one of a specified group of g people will be placed on a waiting list in a given year is

$$\begin{aligned} p_{g,1} &= P \text{ (one or more of } g \text{ waitlisted this year)} \\ &= 1 - \text{P (none of } g \text{ waitlisted this year)} \\ &= 1 - (1 - p_{1,1})^g \end{aligned} \tag{2}$$

The general expression for any group of g people and y years is given by

$$\begin{aligned} p_{g,y} &= 1-\left[1-p_{g,1}\right]^{y} \\ &= 1-\left[1-\left\{1-\left(1-p_{1,1}\right)^{g}\right\}\right]^{y} \\ &= 1-\left[1-1+\left(1-p_{1,1}\right)^{g}\right]^{y} \\ &= 1-\left[\left(1-p_{1,1}\right)^{g}\right]^{y} \\ &= 1-\left(1-p_{1,1}\right)^{gy} \end{aligned} \tag{3}$$

Next, apply Equation 3 to several relevant situations (i.e., different combinations of y and g). Some of these situations are described in detail below.

1. What is the probability that a randomly selected person will need an organ in a given year? For this estimate, assume the rough current values, where w is equal to 40,000 and the U.S. population (N) is equal to 300,000,000 (g = 1, y = 1).

$$\hat{p}_{1,1} = \frac{40{,}000}{300{,}000{,}000} = 0.0001\overline{3} = 0.01\overline{3}\% \approx 1 \text{ person in } 7{,}500$$

2. What is the lifetime probability that a randomly selected person will need an organ? A 75-year life span is assumed (g = 1, y = 75).

$$\hat{p}_{1,75} = 1-(1-0.0001\overline{3})^{1\cdot 75} = 0.00995 = 0.995\% \approx 1 \text{ person in } 100$$

3. What is the probability that someone whom the person cares about will need an organ? The average number of "close" people in a person's family and social networks has been variously estimated by sociologists to be anywhere from 10 to 200, depending on how "close" is defined. The calculation here is interested in the number of people that a person knows for whom, if they needed a transplant, it would be of emotional significance to the target person. For this purpose, numbers in the several dozens seem a bit high. Assume for now a more conservative value of 20. Then, together with the person's own risk, there are 21 chances in a given year that a person will need an organ transplant (g = 21, y = 1):

$$\hat{p}_{21,1} = 1 - (1 - 0.0001\overline{3})^{1 \cdot 21} = 0.002796 = 0.2796\% \approx 1 \text{ person in } 358$$

and the lifetime probability is (g = 21, y = 75):

$$\hat{p}_{21,75} = 1 - (1 - 0.0001\overline{3})^{21 \cdot 75} = 0.01894 = 18.94\% \approx 1 \text{ person in } 5$$

4. Sensitivity analysis. This base model uses several assumptions. Here, briefly consider the implications of relaxing some of them, as described below. Overall, the assumptions are conservative, in the sense that they probably produce an underestimation of the true number of people who will eventually find themselves on an organ transplant waiting list.

- All people have the same probability of being placed on an organ transplant waiting list in any given year. The chance of needing an organ differs depending on various individual characteristics. Thus, different subgroups would have different probabilities, but the overall probability is the same as that given above if these subgroups are weighted according to their relative frequency in the population. Over time, however, this could change. For example, age is a characteristic that has a large impact. Up until approximately age 65 years of age the likelihood of being placed on an organ transplant waiting list increases with age. The American population has been aging over time, and this trend is projected to continue into the foreseeable future. Thus, with respect to age, the base model presented above will underestimate the probability in future years, with all other characteristics being equal. The impact of decomposing the analysis according to other characteristics will depend on whether the categories of individuals with greater risk are increasing or decreasing over time.
- Individual fates are unconnected. This assumption is probably true most of the time for people who are not related. Although some diseases that increase the possibility of needing an organ are hereditary to some degree, if anything, this positive correlation produces an even larger number of additions to the waiting list.

5. How do these probabilities compare with those for other more familiar risks? Figure D-1 shows how these probabilities compare with those for other more familiar risks.

REFERENCE

Wilson R, Crouch EA. 2001. *Risk-Benefit Analysis,* 2nd ed. Cambridge, MA: Harvard University Press.

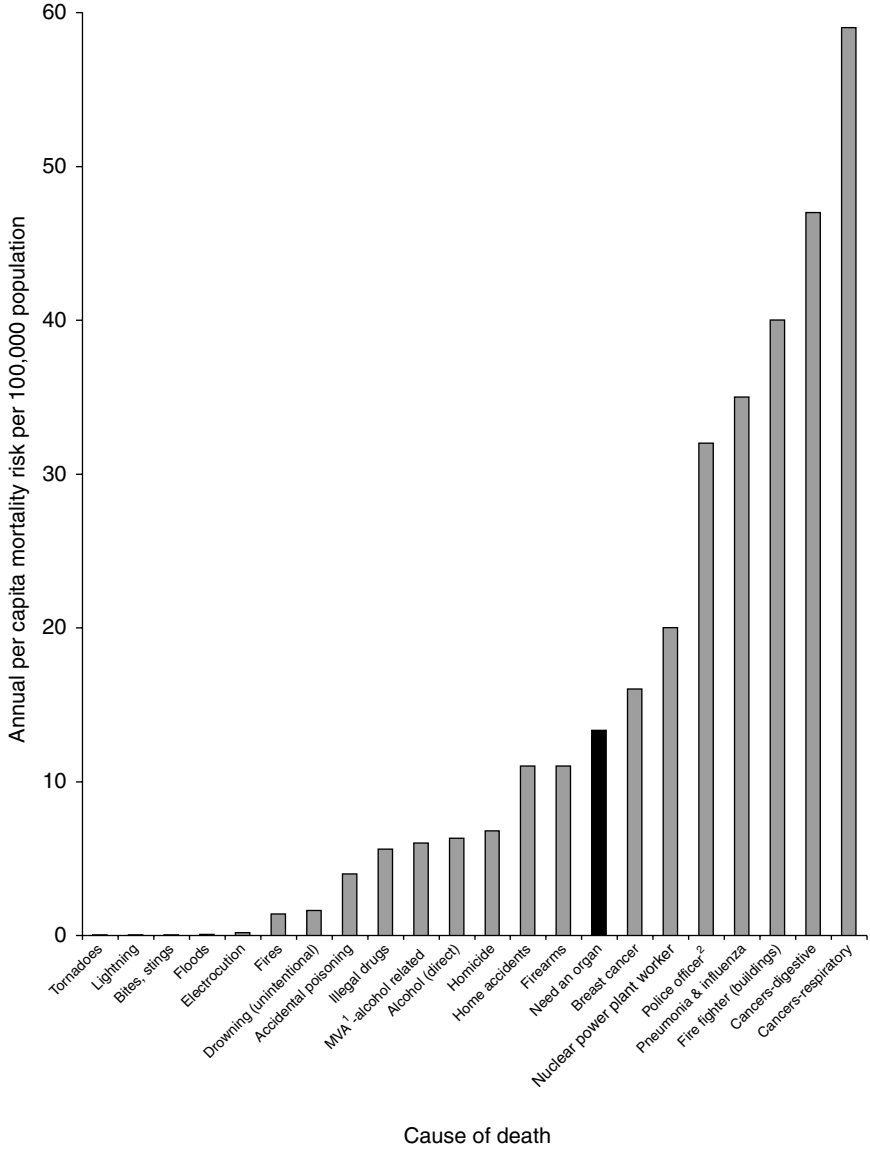

FIGURE D-1 Annual risk of being placed on a waiting list for an organ transplant versus the annual risk of various causes of death.

[1]Motor vehicle accident (blood alcohol level >0.01)

[2]Killed in line of duty

SOURCE: Wilson and Crouch (2001).

E

HRSA's Extramural Research Program

As discussed in Chapter 1, one of the primary sources for the funding of behavioral research related to increasing the rates of organ donation is through the extramural grant program funded by the Division of Transplantation (DoT) of the Health Resources and Services Administration (HRSA). The committee was asked to provide input on methods of evaluation of HRSA's research grant program, and this appendix focuses on that program. Committee members had the opportunity to have discussions with the grantees and with the Division of Transplantation staff administering the program, as well as to review the published literature resulting from the extramural grants.

OVERVIEW OF HRSA'S EXTRAMURAL RESEARCH PROGRAM

The Division of Transplantation is charged with overseeing the Organ Procurement and Transplantation Network, the Scientific Registry of Transplant Recipients, and the National Bone Marrow Donor Registry and with developing and implementing national programs to increase the rates of organ, tissue, bone marrow, and blood donation.

HRSA's extramural grants program examines a wide array of interventions to increase organ donation rates. The grants are generally funded for 3 years, with annual reviews. The grants program targets key points across the donation continuum. The primary emphasis is on the Social and Behavioral Interventions grants program, which seeks to raise public awareness of organ donation and generate public commitment. Related to this effort,

HRSA has piloted the Media-Based Interventions program to increase the rates of organ donation by members of minority populations. At the other end of the donation continuum, HRSA has previously funded the Clinical Interventions grant program (personal communication, J. Perdue, HRSA, 2005).

Between fiscal years (FY) 1999 and 2005, the Social and Behavioral Interventions program funded 61 projects, with total funding of $49.5 million (personal communication, M. Ganikos, HRSA, 2005). First-year funding levels for new grants have significantly decreased in recent years, from a high of greater than $3.3 million in FY 2003 to approximately $1 million in FY 2005 and an expected $1.25 million in FY 2006. This decrease in funding has placed severe restraints on the grant program.

Social and Behavioral Interventions

HRSA's major extramural research grant program focuses on social and behavioral interventions in schools, workplaces, and community locations. Roughly 40 percent of the projects have focused on minority populations, principally African Americans and Hispanics (personal communication, M. Ganikos, HRSA). One study, for example, is evaluating the use of community projects and individually tailored interventions on donor decision making. Another study is evaluating how effectively peer educators in workplaces increase employees' intent to donate.

Despite the diverse content among Social and Behavioral Interventions program grants, all such projects approved by HRSA must include several key components:

- a consortium of researchers and transplantation organizations to bridge the gap between academic research and the service-oriented work of transplantation professionals;
- a rigorous evaluation component; and
- precise performance measures, such as an increase in consent rates for organ donation or an increase in declarations of intent to donate.

An HRSA technical review panel that includes three reviewers—a donation and transplantation specialist, a research and evaluation specialist, and a research reader—reviews each grant application. To guide the applicants, HRSA regularly offers programs on grant application preparation, issues related to research with human subjects, and grants management. During the grant project periods, HRSA offers additional technical assistance, including yearly project presentations and work group discussions to review the lessons learned and problem-solving techniques.

HRSA research has examined the effectiveness of a number of donation strategies, many of which have been incorporated into the work of the

Organ Donation Breakthrough Collaboratives. These include the value of early referrals (timely hospital reporting of deaths to an organ procurement organization [OPO]), the use of appropriate and effective requesters, the incorporation of family support counselors into the consent process and the provision of bereavement assistance, and contacts with families with the expectation of donation (the presumptive-consent or expected donation approach).

Media-Based Interventions

In FY 2004, HRSA designated $3.6 million in grants to media-based organ donation projects (personal communication, M. Ganikos, HRSA, 2005). The seven grant recipients included donor networks, foundations, and medical centers. The grantees used the funds to raise awareness and encourage organ donation through the use of radio, television, and print advertisements; public events; and outreach efforts. This program focused on audiences comprising minority populations, in particular, by using targeted media and community events to reach African-American and Hispanic groups. For instance, HRSA supported almost 19,000 traffic advertisements in 15 African-American and Hispanic markets. HRSA is evaluating the effectiveness of media-based interventions and may continue this program in the future.

Clinical Interventions

The goal of the Clinical Interventions grants program is to find clinical strategies that speed up organ placement, such as the more efficient identification of potential donors. Specifically, HRSA provides 3-year Clinical Interventions grants for research that results in measurable increases in transplantation rates.

Between FY 2002 and 2004, HRSA provided roughly $9 million in grants for 11 projects that used clinical interventions to increase organ procurement (personal communication, J. Perdue, HRSA, 2005). The FY 2005 budget ($2.5 million) and the FY 2006 budget ($1 million) included only noncompeting funds to maintain these efforts, during which time the program was and is being evaluated.

Grant Summary

Table E-1 categorizes HRSA's grant projects from 1999 through 2004 by intervention type and target audience. Several of the projects could have been categorized under several headings, such as "public education" and "registry enrollment," as public education projects often aim to increase

TABLE E-1 HRSA-Funded Extramural Research, 1999 to 2004

	Target Population[a]		
Intervention Type	General Public	Minority Populations	Total
Public education	9 (13)	25 (37)	34 (50)
Registry enrollment	9 (13)	2 (3)	11 (16)
Hospital-based	16 (24)	1 (1)	17 (25)
Living donation or other	5 (7)	1 (1)	6 (9)
Total	39 (57)	29 (43)	68 (100)

[a]Data represent the number of projects (percentage of all projects).

registry enrollment rates, as well as improve public attitudes toward donation more broadly. Half of the funded projects can be categorized as public education, although many are focused on specific subpopulations (for example, college students and Asian Americans).

Hospital-based interventions constitute approximately one-quarter of the projects. Projects in this category attempt to increase organ donation consent rates by improving the care of dying patients and the organ donation request process. The advantage of hospital-based research is that it is relatively straightforward to translate findings into practice. Many of the interventions are inexpensive or even costless, and mechanisms that are already in place, such as HRSA's Organ Donation Breakthrough Collaboratives, can be used to disseminate the results. Hospital-based research also has some important constraints. The Breakthrough Collaboratives have led to rapid changes in donor identification and requesting practices, making it difficult for future studies to isolate the impacts of specific interventions. Also, organ donation is a relatively rare event, even at large hospitals, so it is not easy to accrue adequate sample sizes.

More than one-half of the funded projects are for studies that examine the impacts of public education and registry enrollment programs on organ donation rates. For example, the New Jersey Sharing Network, New Jersey's OPO, tested various educational and promotional interventions to encourage the workers employed by 45 large employers to sign donor cards and discuss organ donation with their family members. Many of these projects target minority groups. For example, the Arizona Kidney Foundation conducted a media campaign to increase the number of people willing to donate and to promote favorable attitudes toward donation among Hispanics. As OPOs move toward first-person (donor) consent, education programs, particularly those that promote enrollment in registries, will become more important. Public education interventions are costly, however, and

the potential for the uptake of study findings is limited in the absence of an ongoing public education campaign.

Other examples of innovative research efforts include the work of researchers at the University of Pennsylvania who are examining the impact of a presumptive-consent (expected donation) approach on organ donation consent rates (see Chapter 4). Researchers at the University of Wisconsin examined the impact of the implementation of protocols for donation after circulatory determination of death.

The committee found that some of the grants test similar strategies for increasing the rates of organ donation. Although some amount of replication is inevitable and even desirable, it is important that HRSA develop mechanisms to ensure that, over the long run, the projects build on one another by incorporating the lessons learned and adding new features to be examined.

EVALUATING HRSA'S EXTRAMURAL RESEARCH GRANTS

Evaluating the impact of a program or an initiative to improve the rates of organ donation, particularly those that are community or behavior based, is particularly challenging in the midst of the many external factors that can also influence perceptions of and decisions about organ donation. Furthermore, the actions regarding organ donation could occur long after the intervention. For an individual, his or her actions regarding organ donation might follow directly after participation in an intervention (such as by signing a donor card) or might occur years after the intervention (for example, as part of a family decision to donate the organs of a loved one after his or her death).

The challenges involved in evaluating organ donation initiatives are similar to those faced in evaluating interventions for other public health issues, including youth smoking, underage drinking, obesity prevention, and diabetes prevention (NRC, IOM, 2003; IOM, 2005). For many public health programs, evaluation is an afterthought that is not built into or budgeted into the program from the outset. One of the strengths of DoT's extramural grant program is that the grants are required to have a strong evaluation component. Furthermore, the team submitting the grant proposal must be constituted as a consortium that includes as a partner an academic institution or some other research institution. The use of the evaluation expertise from the early stages of a project and throughout the project is of great benefit in strengthening the implementation of an evaluation plan. HRSA also provides extensive technical assistance. Grantees are required to attend two technical assistance workshops during the first year of the project and one workshop during subsequent years. The workshops

are provided as an opportunity to assess progress, discuss outcome measures, and consider various evaluation methods.

It is important that HRSA better define the purpose of the grant program and expand the scope of projects considered for funding. The large number of funded public education grants raises the issue of whether the major aim of HRSA's grant program is research or whether the program serves as a vehicle for funding public education on an ad hoc basis. Currently, funded projects must have the potential to "i) increase organ donation and ii) improve understanding of how to increase organ donation." The first of these two goals severely limits the types of projects that can be funded, as projects that address only the second goal are ineligible for funding. Yet, projects of this nature may, in the long run, lead to system-wide changes that have a large impact on donation rates.

The limited resources for grant funding available to the Division of Transplantation in recent years have hindered the ability to explore additional innovative approaches and to scale up those interventions that have been found to be promising (see Chapter 1). The Division has leveraged the opportunities presented by the Organ Donation Breakthrough Collaboratives to incorporate new findings into the work of the hospitals and OPOs participating in the Breakthrough Collaboratives.

The committee believes that the Division of Transplantation should receive increased funding for its extramural program to support additional grants focused on innovative approaches to increasing organ donation rates (these projects, for example, examination of families' acceptance of first-person consent, may or may not have a direct impact on donation) as well as projects whose findings are easy to translate into practice (for example, improvements to the request process and improvements to workplace registry programs). Ideally, projects would meet both requirements, but in practice there is often a trade-off between innovativeness and replicability.

Furthermore, HRSA should critically assess the findings of the studies that have resulted from previous grants and similar studies; give priority to projects that are highly innovative, replicable, or both; and consider funding some projects that will increase the knowledge base and serve as a foundation for future interventions or policy changes.

REFERENCES

IOM (Institute of Medicine). 2005. *Preventing Childhood Obesity: Health in the Balance*. Washington, DC: The National Academies Press.

NRC (National Research Council), IOM. 2003. *Reducing Underage Drinking: A Collective Responsibility*. Washington, DC: The National Academies Press.

F

Washington Hospital Center: Protocol for the Rapid Organ Recovery Program, Transplantation Services*

OVERVIEW

The single greatest factor limiting the number of renal transplants performed today is the size of the donor pool. The number of patients awaiting renal transplantation today is greater than ever, but the size of the donor pool has failed to increase to meet this demand. We have proven that kidneys can be recovered from the non-heart-beating donor (NHBD) and through utilization of unique pulsatile preservation methods verify viability of these organs prior to transplantation. Work in Europe suggests that addition of the NHBD to the pool could increase the number of available kidneys by at least 20 percent.

In the fall of 1993, under the sponsorship of the Medlantic Research Institute (MRI), we hosted a Consensus Conference on the Asystolic Trauma Donor. Expert panels addressed medical, legal, ethical, social, and community concerns raised by our proposed protocol for recovering organs from victims of fatal trauma in the MedSTAR. The conferees concurred with protocol implementation with a variety of recommendations. Chief among which was a community oversight committee.

We have implemented those recommendations and have undertaken the recovery of kidneys from the NHBD for transplantation. However, a variety of research initiatives must continue to explore consent issues, com-

*Provided courtesy of Jimmy Light, Washington Hospital Center, Washington, D.C. Previously printed in IOM, 2000.

munity attitudes, and experimental aspects of organ recovery, training and education. Our goal is to assure that the option of organ donation is available to all potential donor families, successfully recover transplantable organs, and recover costs.

Design and Methods

Oversight

This protocol is subject to the oversight of an advisory committee, as recommended by the consensus conference participants. This committee is composed of community members who have an interest in seeing that the program is sensitive to community needs and concerns. The Community Oversight Committee is comprised of nurses, physicians, morticians, clergy, legal services representatives, D.C. government officials, educators, and local transplant groups. The advisory committee is currently chaired by the Director of the Office of Decedent Affairs (ODA) and reports directly to the Office of Community Affairs of the Medlantic Healthcare Group. This advisory committee meets at least on a quarterly basis and began in December 1993. All policies, protocols, and practices were available for review by the Committee Oversight Committee.

Regular reports are submitted to the Institutional Review Board (IRB) for continuing review. Although the Rapid Organ Recovery Program (RORP) does not constitute a research program, we are requesting the same consideration under the existing internal review mechanisms. We feel that because of the nature of the program and the community that we serve, the IRB must be kept apprised of the program's progression and offer advice or direction as the board deems appropriate.

Donor Criteria

Potential deceased organ donors will include all patients pronounced cardiac dead in MedSTAR, an ICU or the emergency department at Washington Hospital Center (WHC). The potential donors will have the following acceptability criteria:

- Patients should generally not be over 60 years of age or younger than 18 years of age (<18 with next-of-kin consent). Exceptions will be made on a case by case basis.
- Patients must have a known time of death.
- Patients *must not* have active, untreated systemic bacterial sepsis at the time of death.
- Patients *must not* have documented positive testing for HIV, HBsAg, or HTLV1.

- Patients *must not* have cancer except primary brain tumors, lip/skin cancers, in-situ carcinomas.
- Patients *must not* be among those classified high risk by the CDC, including homosexual/bisexual males, current I.V. drug abusers, or patients with hemophilia/coagulation disorders.

The identity of the patient *must* be known. In those cases where the identity of the patient is unknown, the Family Advocate will make an assessment of the circumstance of death that will include discussions with the involved law enforcement agency. Line placement pursuant to the provisions of the Anatomical Gift Amendment Act of 1996 will not occur unless a high probability of patient and next-of-kin identification and notification can be accomplished within four hours after the known time of death.

ICU Donor Protocol (controlled donors)

There are several potential ways to obtain organs from non-heart-beating donors in the intensive care units. Any patient under 60 years old from whom withdrawal of support is anticipated and who is expected to suffer a cardiac death shortly after withdrawal should be considered a potential donor. When such patients seem medically suitable according to the criteria in this document, a member of the primary or critical care term should notify the ODA. After the approval of the responsible intensivist the ODA will contact the Medical Examiners Office (if necessary) and the OPO to evaluate the patient. The OPO coordinator will discuss the potential of organ acceptability with the intensivist. The patient's attending along with the critical care team will discuss withdrawal of support with the family or person responsible for the patient's health care decisions. If organs seem acceptable a member of the primary or critical care team will introduce the family to the OPO coordinator who is generally the individual who will discuss the option of organ donation along with the ODA Family Advocate. The family member or other person responsible for the patient's healthcare decisions may then elect to have organs donated. If consent for organ donation has been obtained, the primary medical team and critical care team will notify the ODA of the impending withdrawal of support. The ODA will communicate with the ROR team and the OPO to coordinate their efforts with the primary or critical care team which will direct the withdrawal process. If the patient dies during or after the withdrawal of support the ROR line placement and preservation protocol will be instituted. A patient will remain in the ICU during this time unless it is determined that the operating room, MedSTAR, or the PACU is the preferred setting.

To accomplish preservation, abdominal cooling lines will be inserted and femoral artery and vein catheters inserted within the 60 minute time allowance. The kidneys will be flushed with a perfusion solution designed to limit the amount of further ischemic damage. Once cooled, the donor can be maintained up to four hours until an operating room is available and a standard organ recovery can be performed.

Fatal Trauma Victim Protocol (uncontrolled donors)

The second method for recovering organs from non-heart-beating donors is applicable to patients in MedSTAR or the emergency department who suffer uncontrolled cardiac arrest. In this situation it is imperative that the respective unit physicians pronounce death prior to any intervention from the Transplantation Services Department and that there be a clear delineation of the time of death versus the initiation of organ preservation protocols. Based on recommendations made by the attendees of the Consensus Conference on Trauma Victims and Organ Donation (WHC, MRI, WRTC, 1993), numerous steps have been taken to educate the community about this program.

Since appropriate steps have been taken, and with concurrence from the Community Oversight Committee, it has been determined that line placement for the purpose of preserving the option of donation for the next-of-kin is both legal (Anatomical Gift Amendment Act of 1996) and appropriate in the event that the family is not present. If the family is present, the Family Advocate must obtain consent prior to the placement of the cold preservation lines.

When a potential donor is identified, the Trauma Fellow, Trauma team leader (R4), trauma nurse, or designee in MedSTAR shall page the in-house Family Advocate through the in-house MedSTAR emergency page system. MedSTAR staff may participate in the ROR Protocol only in a support role to the line placement team. This type of support may include locating supplies and movement of the decedent to a more suitable location for line placement. They may not participate in direct hands-on donor preservation line placement.

Placement/Transfer of Potential Rapid Organ Donors

Potential ROR donors shall be cared for in MedSTAR or an ICU or the PACU until organ recovery occurs. Under no circumstance should these patients be transferred to a floor to await ROR unless specific arrangements are made between the ICU medical staff and the nursing supervisor covering the ICU.

Consent

The majority of deaths in MedSTAR or an ICU may fall under the jurisdiction of the Medical Examiner for the District of Columbia. The Family Advocate shall assist with notification and must obtain consent from the Medical Examiner's office prior to initiation of any procedure, should this death fall under their jurisdiction. Regardless of the next-of-kin's wishes, the Medical Examiner has the right to object to donation of any organs or tissues, if such removal would potentially impact the determination of cause and manner of death. *Under no circumstances will any procedure be initiated without the Medical Examiner's approval.* Once the Medical Examiner has agreed to allow intervention, the Family Advocate will immediately notify the Line Placement Team.

The Family Advocate shall respond to the MedSTAR unit immediately (they carry a code pager) and determine whether a decedent is a potential rapid organ recovery candidate. This determination will be made in consultation with the attending physician/intensivist. The Family Advocate will then immediately notify the Line Placement Team. A search for the next of kin in conjunction with local authorities will be instituted if a family member cannot be located. The Family Advocate is responsible for offering the option of organ/tissue donation to the decedent's next-of-kin. The consent will be obtained utilizing the standard Uniform Donor Form according to WHC Standard Practice #583.20 and ODA SP#C.300. Additionally, the decedent's medical/social history must be obtained from the legal next-of-kin and documented utilizing the standard OPO Medical History Form.

A Line Placement Team will be available in-house 24 hours a day to respond to a preservation call. If deemed necessary, the team member will draw 10 ccs of blood and run a STAT HIV screening. Should the potential donor test positive, organ preservation will be discontinued. Two 10cc red top tubes and one lavender top tube of blood will be drawn and labeled. One red top tube will be held for the project coordinator to be sent for virology testing and the second sent to the stat lab for ABO determination, BUN, creatinine and electrolyte levels. The lavender top will also be sent for CBC evaluation. Aerobic and anaerobic blood cultures will also be drawn and sent. The bladder will then be catheterized and a specimen sent for stat urinalysis and urine culture. An additional 3 red top tubes of blood must also be drawn for the Medical Examiners Office along with as many PVC test tubes of urine as possible. All tubes must be labeled with the donor's name, social security number (if available), medical record number, and the date and time of death. A visual image will be recorded at the medical examiner's request. The OPO will be advised as soon as possible about the potential donor and the whereabouts of the blood samples. The OPO Coordinator will notify the central donor lab so that arrangements can be made

for the transport of the samples to that lab for tissue typing serological testing.

Line Placement Technique

A cooling blanket is placed under the donor as soon as possible and set at the lowest possible setting, as an adjunct to core cooling the donor. Supplies for the cannulation and flushing procedure will be provided by the Line Placement Team. A member of the Line Placement Team places the abdominal lavage lines and cannulates the femoral artery and vein in the following manner:

1. PERITONEAL LAVAGE:

Two small incisions in the abdomen shall be made to insert the inflow and outflow peritoneal lavage trocars. A sterile disposable trocar, 1–1.5 cm, provided in the onsite donor kit is then placed through the abdomen into the peritoneum, preferably in the patients left upper quadrant, for infusion of peritoneal lavage. A second modified trocar (with holes in it) and pool suction cannula should be placed in a similar fashion into the right lower quadrant directed towards the pouch of Douglas for outflow. Cold 0.9% saline solution is infused until abdominal distention is noted (usually 4 liters). This tubing will be connected to a sterile submersion pump with heat exchanger. The lavage should be run continuously until organ recovery. Documentation must be maintained according to Standard Operating Procedures regarding the amount, type and flow rates of fluid used in the lavage on the NHBD/MedSTAR Flow Sheet.

2. PERFUSION CATHETER:

A femoral cut-down is performed through a vertical incision centered on the inguinal ligament. The femoral artery is isolated and controlled with a 0 silk ligature. An arteriotomy is performed and a Porges Multiple Organ Recovery Balloon Catheter passed to the level of the xiphoid process. The distal balloon is inflated with approximately 15cc of 50% hypaque solution and the catheter withdrawn until it lodges at the aortic bifurcation. The proximal balloon is similarly inflated and a stat abdominal x-ray obtained to confirm proper positioning. The infusion tubing should be connected to the mixed cold I.V. perfusate solution and primed to expel any air in the line. The arterial access point is then connected to the primed infusion tubing, and secured to the patient with a 0 silk suture. IN SITU FLUSH SHOULD BEGIN NOW.

The flush solution shall consist of several liters of Viaspan solution, each augmented with:

4 mg Stelazine
40 units insulin
16 mg dexamethasone
20,000 units heparin

When the effluent is clear, the infusion rate is slowed to a steady drip of about 2cc/minute.

3. EFFLUENT CANNULA:

In the same cut-down site utilized for placement of the perfusion catheter, the femoral vein is isolated and controlled with a 0 silk ligature. A venotomy is performed and a marked 22 or 26 fr. 30cc balloon Foley Catheter is inserted to the marking to allow venting for the perfusate solution. This 30cc balloon is to be inflated with approximately 20–30cc of 50% hypaque catheter must be pulled taut to set the balloon at the femoral bifurcation. The catheter should be secured with a 2-0 silk ligature. The venous catheter is connected in a sterile fashion to a 2000cc urine collection bag to collect the venous effluent by gravity only.

ALL SUPPLIES NECESSARY FOR CANNULATION AND PERFUSION ARE SUPPLIED IN THE ON-SITE RAPID ORGAN RECOVERY CART.

These solutions shall be maintained at 4°C in the refrigerator or igloo cooler until the time of infusion. Pre-mixed solutions shall be stored in the refrigerator located in MedSTAR and should be used only if there is no time to mix them in the lab under sterile conditions. To allow for optimal kidney flush and preservation, the solutions should be infused at 70 mm Hg of pressure.

The infusion pressure may be approximated by raising the I.V. pole about one meter above the decedent and/or by providing pressure bags as an adjunct. The Line Placement Team will monitor the flush solutions for continued inflow and outflow. Flow characteristics and other parameters such as intra-abdominal temperature are recorded on the ROR/MedSTAR Flow Sheet.

Organ Recovery

Organ recovery will not be initiated without consent of the legal next of kin, consistent with current practice. Once preservation attempts are completed and consent for organ/tissue retrieval is obtained, and the recovery surgeon and the Washington Regional Transplant Consortium (WRTC) coordinator are present, the body of the donor will be removed from either the MedSTAR unit or the ICU unit to the operating room. The recovery will be performed using standard technique. Peritoneal lavage will be discontinued at the request of the surgeon.

1. The body will be prepped from the neck to the pubis and draped in the usual fashion.

2. A midline incision is made from the sternal notch (sternal saw required) to the symphysis pubis with bilateral supra umbilical transverse

extensions through the skin, subcutaneous layer, fascia, and muscle to maximize exposure of abdominal organs.

3. The right colon and small bowel mesentery are then reflected to expose the retro peritoneum from the aortic bifurcation to the renal veins. The abdominal organs will be visually inspected, and if they appear well flushed and cool to the touch, a hepatectomy, pancreatectomy and/or a bilateral en-bloc nephrectomy (as approved by the Medical Examiner and family consent), will be performed as described below. The abdominal cavity and kidneys are packed with iced saline slush.

4. A standard en bloc resection, to remove sections of the inferior vena cava and aorta with both kidneys in continuity is used. The entire gastrointestinal tract, spleen, and inferior portion of the pancreas are mobilized by dividing the celiac axis and the superior mesenteric artery, exposing the entire retroperitoneal region. The inferior vena cava and aorta are clamped below the renal vessels with vascular clamps, and the vessels are divided.

Lumbar tributaries are secured with metal clips and are divided. The kidneys and ureters are freed from their surrounding soft tissues. The ureters are divided distally at the iliac artery bifurcation. The suprarenal aorta and inferior vena cava are clamped and divided below the diaphragm. The vessels and kidneys are removed from the surgical field, and the aorta and vena cava stumps are ligated.

5. After removal, the kidneys are moved to the back table and are placed in a saline slush where they are immediately re-flushed with cold (8°C) Viaspan solution. Careful inspection, measurement and separation, are carried out on the back table. Cultures of the abdominal fluid, the ureter tips and the organs and the basin containing sterile slush will be obtained and sent to the microbiology laboratory. A wedge biopsy will be obtained of the removed organs and sent to surgical pathology for both a frozen and permanent section.

6. The kidneys are then placed in the hypothermic pulsatile perfusion machine for transport to the MRI/HUH Organ Perfusion laboratory for monitoring and evaluation.

7. After kidney perfusion has begun, the abdominal lymph nodes and spleen are removed for use in tissue typing.

8. The incision is closed with heavy running suture.

A video tape may be made at the request of the Medical Examiner of the initial incision and the recovery. The recovery surgeon will verbally note any pertinent observations. This tape will be labeled with donor name and date and will be sent to the Medical Examiners Office as requested. Finally, other tissues donated (e.g., corneas, heart valves, skin, bone, etc.) by the next-of-kin will be procured by the appropriate tissue agencies. All relevant

parameters and interventions will be recorded. The OPO on site coordinator will observe the surgical recovery and record the anatomy of the kidneys. Photos of the recovered organs may be taken for documentation purposes.

Kidney Preservation

The kidneys are placed on a hypothermic pulsatile perfusion machine in the operating room and then transported to the Medlantic Research Institute (MRI)/Howard University Hospital (HUH) Organ Preservation Lab for perfusion and evaluation. The kidneys will be perfused with a commercially available solution modified for the NHBD kidney and used in standard ex-vivo kidney perfusion. Appropriate parameters for kidney function and status such as temperature, flow rates, pH perfusion pressures, and resistances will be measured and recorded over the next four to six hours, to determine organ suitability for transplantation. Patient history prior to injury, hemodynamic parameters prior to death, warm ischemic time, cannulation and flush characteristics, biopsy and perfusion characteristics are used to determine the viability of the kidneys and to assess the potential suitability for transplant. Once the kidneys have been deemed suitable for transplantation by the MRI/HUH Organ Preservation Lab Co-Medical Directors and the OPO Medical Director, the OPO Coordinator will be notified so the kidneys maybe placed as per UNOS policies. Placement will not take place until the kidneys are on pump for a minimum of 6 hours. In the event that one or both of the MRI/HUH Co-Medical Directors are unavailable for consultation, the organ recovery surgeon will be responsible for organ suitability evaluation and communications with the OPO Medical Director.

Kidney preservation will be performed according to the MRI/HUH Organ Preservation Lab's Standard Operating Procedures, under licensure from the District of Columbia Department of Consumer and Regulatory Affairs. Post perfusion photos of the kidneys may be taken for documentation purposes.

Community Education

One of the most important factors in the success of the Rapid Organ Recovery Program is effective community education. The primary concern of the participants of the 1993 consensus conference was that of community education and awareness of the Rapid Organ Recovery Program. To this end, the Office of Decedent Affairs has planned and conducted more than 30 educational presentations in the community with post presentation evaluations using a survey to assess public attitudes toward the Rapid

Organ Recovery Program. Media coverage of the program has been extensive. Presentations have been made to the D.C. City Council Members as well as the mayor, all of whom expressed support for the program. A program brochure is made available to potential donor families and the community at large. The brochure has been developed by the community oversight committee.

Facilities and Equipment

The placement of preservation lines will take place within the WHC. Potential donors will remain in MedSTAR/ICU until operating room time is coordinated. All necessary line placement equipment and supplies are available in a specially designed cart in MedSTAR and each ICU. Organ recovery will take place in a WHC operating room. Kidneys will be placed in the Medlantic Organ Preservation Lab's perfusion pump while in the OR and transported to the MRI/HUH Organ Preservation Lab for preservation and evaluation. The MRI/HUH OPL is fully equipped and ready to perfuse and evaluate ROR kidneys. No additional equipment is needed.

Collaborators/Consultants

These costs are reimbursable and are outlined in the OPO billing agreement when organs are recovered and transplanted.

Conclusion

The recovery of organs from the deceased cardiac donor will clearly increase the supply of available organs for transplantation. It has been shown that the recently deceased cadaver is a medically acceptable source of organs for transplantation. By utilizing this donor source both the number of patients waiting for cadaveric transplantation, and the time these individuals must wait for such a transplant will be reduced. Further, a wider pool of potential matches for those patients with uncommon HLA antigens will be available. In addition, more patients and bereaved families will now have the unique opportunity to gain solace from organ donation.

We have, in the past year, shown that kidneys recovered using this technique can be successfully transplanted by our program. Major steps have been taken to insure compliance with the recommendations made by the participants of the Consensus Conference and the community oversight committee. Several other transplant centers are now exploring the possibility of utilizing kidneys from NHBDs. However, only a handful of transplant centers in the U.S. have actually recovered and transplanted kidneys from this donor population.

All charges incurred in the evaluation and procurement of these kidneys for transplant are paid through an agreement with the OPO either through standard billing mechanisms or direct OPO billing from the Medlantic Research Institute Transplant Research Center.

Addendum 2006. While successful in recovering and transplanting kidneys from the uncontrolled donor, the resources needed and the labor intensity eventually could not be sustained as a single center effort. The community accepted the concept of initiating preservation pending consent with appreciation. Consent for organ recovery was obtained in just over 50 percent of the cases.

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Committee and Staff Biographies

COMMITTEE

James F. Childress, Ph.D., is the John Allen Hollingsworth Professor of Ethics and a professor of medical education at the University of Virginia, where he teaches in the Department of Religious Studies and directs the Institute for Practical Ethics and Public Life. He served as chair of the Department of Religious Studies from 1972 to 1975 and from 1986 to 1994, as principal of the University of Virginia's Monroe Hill College from 1988 to 1991, and as co-director of the Virginia Health Policy Center from 1991 to 1999. In 1990 he was named Professor of the Year in the state of Virginia by the Council for the Advancement and Support of Education, and in 2002 he received the University of Virginia's highest honor, the Thomas Jefferson Award. In 2004, the American Society of Bioethics and Humanities bestowed on him its Lifetime Achievement Award. Dr. Childress was vice chair of the National Task Force on Organ Transplantation, and he has also served on the Board of Directors of the United Network for Organ Sharing (UNOS), the UNOS Ethics Committee, the Recombinant DNA Advisory Committee, the Human Gene Therapy Subcommittee, the Biomedical Ethics Advisory Committee, and several data and safety monitoring boards for National Institutes of Health clinical trials. He was a member of the presidentially appointed National Bioethics Advisory Commission from 1996 to 2001. Dr. Childress is a member of the Institute of Medicine (IOM) and a fellow of the American Academy of Arts and Sci-

ences. He is also a fellow of the Hastings Center. He received a B.A. from Guilford College, a B.D. from Yale Divinity School, and an M.A. and a Ph.D. from Yale University. Dr. Childress has cochaired the National Research Council Subcommittee on Use of Third Party Toxicity Research with Human Test Subjects and has served as a member of the IOM Committee on Establishing a National Cord Blood Stem Cell Bank Program and the IOM Committee on Assessing Genetic Risks: Issues and Implications for Health.

Mary Ann Baily, Ph.D., is an associate for ethics and health policy at The Hastings Center. She received a B.A. degree in mathematics from Harvard University, an M.A. in economics from Northwestern University, and a Ph.D. in economics from the Massachusetts Institute of Technology. She has served as a fellow at the Institute for Ethics of the American Medical Association, in which she participated in an educational program in ethics and carried out independent research on ethical issues in managed care. Dr. Baily served as the staff economist for the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. She was a member of the economics faculty of Yale University from 1973 to 1979. Dr. Baily's research interests include access to health care; ethical issues raised by human growth hormone therapy; the implications of human immunodeficiency virus infection, organ transplantation, and Alzheimer's disease for health care financing; the ethics of improving health care quality and safety; and ethical decision making for the genetic screening of newborns. She is a fellow of the Hastings Center and has been a member of the Ethics Task Force of the Society of Critical Care Medicine.

Richard J. Bonnie, LL.B., is the John S. Battle Professor of Law and a professor of psychiatric medicine at the University of Virginia and director of the University's Institute of Law, Psychiatry, and Public Policy. He writes and teaches in the fields of health law and policy; the regulation of alcohol, tobacco, and controlled substances; mental health law and policy; bioethics; and criminal law. He served as associate director of the National Commission on Marijuana and Drug Abuse, as secretary of the National Advisory Council on Drug Abuse, and as a member of two MacArthur Foundation Research Networks in mental health law. He is a member of the IOM and has chaired a number of IOM and National Research Council committees including the Committee on Reducing Tobacco Use, the Committee on Developing a Strategy to Prevent and Reduce Underage Drinking, the Committee on the Risk and Prevalence of Elder Abuse, the Committee on Injury Prevention and Control, and the Committee on Opportunities in Drug Abuse Research.

Clive O. Callender, M.D., is the chairman of the Department of Surgery and the LaSalle D. Leffall, Jr., Professor of Surgery at the Howard University College of Medicine. Dr. Callender completed his medical training at Meharry Medical College. In the 1970s at Howard University Hospital, Dr. Callender helped develop the first minority group-directed dialysis and transplant center and histocompatibility and immunogenetic laboratory in the United States. In the 1980s, Dr. Callender developed the D.C. Organ Donor Program, a joint program of Howard University Hospital and the National Capital Area National Kidney Foundation. This initial successful local and regional grassroots minority donation effort (1982 to 1988) was followed by the National Dow Chemical Company Take Initiative Program, a mass media campaign that was directed at minority populations and that involved 50 cities and five historically black colleges and universities. The success of these grassroots and media efforts focused on organ donation in African-American populations set the stage for the conceptualization of the National Minority Organ/Tissue Transplant Education Program, which was funded from 1993 to 2006 by the National Institutes of Health, the National Institutes of Diabetes & Digestive & Kidney Diseases, and the National Center on Minority Health and Health Disparities. Dr. Callender served on the IOM Committee on Non-Heart-Beating Organ Transplantation II: The Scientific and Ethical Basis for Practice and Protocols; the IOM Committee on Xenograft Transplantation: Ethical Issues and Public Policy; and the IOM Committee to Study the End-Stage Renal Disease Program.

Raul de Velasco, M.D., is a clinical assistant professor of medicine at the University of Miami Miller School of Medicine, Director, Clinical Ethics at the University of Miami Ethics Programs and Chair of the Baptist Health System Bioethics Committee. He served as medical director of the FMC Kendall Dialysis Center for 27 years. He has served as chair of the Florida Society of Nephrology, Baptist Hospital Nephrology Section, and as a member of the board of directors of the Kidney Foundation of South Florida. Dr. de Velasco received his medical degree and nephrology training from the University of Miami.

James DuBois, Ph.D., D.Sc., is associate professor, department chair, and director of the Center for Health Care Ethics at St. Louis University. He completed a Ph.D. in philosophy at the International Academy of Philosophy in Liechtenstein and a D.Sc. in psychology at the University of Vienna. His research interests include research ethics in behavioral health, bioethics (with a focus on transplantation ethics), moral development and education, and empirical research on ethical issues. He served for 5 years on the UNOS Regional Review Board for Livers and currently serves on the Mid-America

Transplant Services' committee for non-heart-beating organ donation. He is a member of the Ethics Committee and Institutional Review Board at St. Anthony's Medical Center and St. Alexius Hospital (Tenet) in St. Louis, Missouri. He is a member of the Canadian Forum on Donation after Cardiocirculatory Death.

Lewis Goldfrank, M.D., is professor and chairman of emergency medicine, New York University School of Medicine, Bellevue Hospital Center. He is the medical director of the New York City Poison Control Center. Dr. Goldfrank served as president of the Society of Academic Emergency Medicine and chaired the American Board of Emergency Medicine's Subboard on Medical Toxicology. He is senior editor of *Goldfrank's Toxicologic Emergencies*, a standard text in medical toxicology, the eighth edition of which was published in 2006. Dr. Goldfrank is a member of the IOM and chaired both the IOM Committee on Responding to the Psychological Consequences of Terrorism and the IOM Committee for Evaluation of the Metropolitan Medical Response Systems Program.

Sandra Hickey is director of human resources at Georgetown Community Hospital in Georgetown, Kentucky. She is a living kidney donor and is the mother of an organ donor. Ms. Hickey has written and spoken widely on behalf of organ donation efforts. She serves on the State Board of Directors for Kentucky Organ Donor Affiliates (KODA) and on KODA's Donor Family Council.

David Howard, Ph.D., is an assistant professor at the Rollins School of Public Health of Emory University. His research focuses on the use of economics and statistics to better understand medical decision making and its implications for public policy. Currently, Dr. Howard is studying the impact of prognosis on screening and treatment decisions and the role of quality in patients' choice of kidney transplant centers. In previous research he examined the implications of the "sickest first" rule in liver allocation and the role of patient health in surgeons' decisions to accept or reject livers offered through the national allocation system. Dr. Howard received a doctorate in health policy from Harvard University in 2000.

Danny O. Jacobs, M.D., M.P.H., a specialist in gastrointestinal surgery, is chair of the Department of Surgery at Duke University Medical Center. He has served as chairman and Arnold W. Lempka Distinguished Professor of Surgery at Creighton University School of Medicine and was on the faculty of Harvard Medical School. After earning a medical degree at Washington University, St. Louis, Missouri, in 1979, Dr. Jacobs received advanced training in surgery at the University of Pennsylvania School of Medicine.

He has an M.P.H. with an emphasis on biostatistics from the Harvard School of Public Health. Dr. Jacobs' research interests focus on the effects of critical illness and malnutrition on cellular bioenergetics and the use of nuclear magnetic resonance imaging technology to study organ function and metabolism. Clinically, his practice covers a range of general and gastrointestinal surgery, with a special focus on nutritional or metabolic diseases amenable to surgical therapy, including inflammatory bowel disease and obesity. Dr. Jacobs is a member of the IOM.

Cynda Rushton, D.N.Sc., R.N., is an associate professor of nursing at the Phoebe Berman Bioethics Institute and a clinical nurse specialist in ethics and program director of the Harriet Lane Compassionate Care Program at the Johns Hopkins University and Children's Center in Baltimore, Maryland. She also holds an appointment in pediatrics in the Johns Hopkins University School of Medicine. She served as the nurse ethicist at the Children's National Medical Center in Washington, D.C. She received a master's of science in nursing with specialization as a pediatric clinical nurse specialist from the Medical University of South Carolina and a doctorate in nursing with a concentration in bioethics from the Catholic University of America. She has served as the president and the past president of the Association for the Care of Children's Health; on the Board of Directors of the American Society of Law, Medicine, and Ethics; and as the co-chair of the Ethics Work Group of the American Association of Critical Care Nurses. Dr. Rushton received the Pioneering Spirit Award from the American Association of Critical Care Nurses for her work in advancing palliative care across the life span. She is currently chair of Maryland's Council on Quality Care at the End of Life. She is a fellow in the American Academy of Nursing.

David Schkade, Ph.D., holds the Jerome Katzin Chair in the Rady School of Management at the University of California, San Diego, where he teaches negotiation, decision analysis, organizational behavior, and statistics. He has been a visiting senior research scholar in the Woodrow Wilson School of Public Affairs at Princeton University and on the faculties of the University of Chicago, Duke University, and the University of Texas, Austin. Professor Schkade has published on a variety of topics, including his current research interests: the psychology of well-being, loss aversion, and jury decision making. He currently serves on the editorial boards of three major journals and has served on grant review and site visit panels of the National Science Foundation and the Environmental Protection Agency. He received B.A. (mathematics) and M.B.A. degrees from the University of Texas, Austin, and M.S. and Ph.D. degrees in organizational psychology from Carnegie Mellon University. Dr. Schkade has also served on the IOM Committee to

Evaluate Measures of Health Benefits for Environmental, Health, and Safety Regulation.

Debra A. Schwinn, M.D., is the James B. Duke Professor of Anesthesiology and a professor of pharmacology/cancer biology and surgery at the Duke University Medical Centers. She received an M.D. from the Stanford University School of Medicine and completed a fellowship in clinical cardiothoracic anesthesiology at Duke University. Dr. Schwinn has served on the Duke Hospital Ethics Committee and is interested in ethical issues surrounding genetic polymorphisms and their relationship to human disease. Her laboratory examines adrenergic receptor regulation in cardiovascular disease. She was elected to the IOM in 2002.

Keith Wailoo, Ph.D., is a professor at Rutgers University with joint appointments in history and at the Institute for Health, Health Care Policy, and Aging Research. He is an historian of medicine and the biomedical sciences and is the author of *Dying in the City of the Blues: Sickle Cell Anemia* and the *Politics of Race and Health*, *Drawing Blood: Technology and Disease Identity in 20th Century America*; a forthcoming book on race and cancer in America; and numerous other works exploring the intersections of medicine and science with society, politics, and culture in America. Previously, he served for 9 years on the faculty in the School of Medicine at the University of North Carolina at Chapel Hill and received a Ph.D. in the history and sociology of science from the University of Pennsylvania in 1992. In 1999, he received the James S. McDonnell Centennial Fellowship in the History of Science.

STAFF

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