Textbook of Organ Transplantation

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CHAPTER 143

National Healthcare Policy, Transplant-specific Statutes, and the Future of Organ Transplantation

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Introduction

During the past century, transplantation and health policy in the US have evolved in ways inconceivable to previous generations. From the first successful kidney transplant performed in Boston, Massachusetts in 1954, to the first successful liver transplant in 1967, to the establishment of the first organ procurement organization (OPO) in 1968, to the 1980 Uniform Determination of Death Act, and to the first successful face transplant in France in 2005, transplantation has changed dramatically. Health policy too has evolved tremendously, from the establishment of Medicare and Medicaid in 1965 and the adoption of employer-based private health insurance, to the current healthcare climate in which healthcare expenditures exceed 17% of the Gross Domestic Product (GDP). Technology has advanced, health insurance coverage has expanded, and delivery systems have improved so that more Americans have access to healthcare than ever before. The Patient Protection and Affordable Care Act passed in 2010 will continue to reshape the healthcare landscape through policies aimed at expanding coverage, implementing market reforms, improving healthcare quality through payment incentives and other demonstrations, and containing costs. These reforms will undoubtedly affect all areas of healthcare, and have important implications for transplantation.

The purpose of most existing transplantation policy is fourfold: to protect the health of recipients and donors, to preserve dignity and protect autonomy throughout the transplantation process, to enhance efficiency in organ allocation, and to ensure equity in availability and allocation of resources. The future of transplantation policy is a broad topic beyond the scope of a single chapter. However, in this chapter, we address a number of key challenges central to the future of transplantation policy, including: implications of health reform for patients and providers, and meeting a growing demand for organs through donation incentives. Given the marked variability of specific laws worldwide, this chapter is presented from a North American perspective, with specific examples from the U.S. legal system. However, the general themes facing transplantation in the U.S. are reflected in similar legal statutes in most developed countries. Additional discussions on national oversight in general, and cultural variability as it relates to transplant policy and practice, can be found in Chapters 128 and 139, respectively.

Legal and regulatory structure of transplantation in the U.S.

The U.S. transplant system is composed of a network of transplant centers, donor hospitals, OPOs, and ten geographic regions for the purposes of allocation of organs. Each donor hospital is situated within a single geographic region and assigned to a specific OPO (Figures 143.1 and 143.2). Organ donation and transplantation policies are dictated by the Organ Procurement and Transplantation Network (OPTN), which currently contracts with the United Network on Organ Sharing (UNOS) to frame and administer transplantation policies. The Division of Transplantation (DOT) of the Health Services and Resources Administration (HRSA) (a branch of the Department of Health and Human Services (DHHS)), provides federal oversight of the OPTN (Figure 143.3).

Significant changes in transplantation policy have taken place over more than 20 years. For example, the organ allocation algorithms have been devised and revised, criteria for donors and recipients have been expanded, and process, quality and outcomes standards have been established and enforced by the Centers for Medicare and Medicaid Services (CMS). Although some standards have been universally applied, others, such as OPO policy allocation variances, were granted regionally or on an individual basis, creating a patchwork of protocols [1]. Currently, UNOS policy efforts are aimed at reconciling variances and at amending allocation algorithms to better achieve equity and efficiency. Other initiatives involve changes to the kidney allocation rules [2], inclusion of the Kidney Donor Profile Index (KDPI) score in UNet, initiatives to prevent transmission of donor diseases, and for liver transplantation patients, tiered regional sharing to facilitate wider sharing for critically ill patients with MELD/PELD scores above 35 [3].

Despite central oversight for transplantation, laws and rules governing the transplantation process are layered and somewhat fragmented. The legal and regulatory policies that shape transplantation are framed at four levels, in order of most to least granular: UNOS policies, federal regulations, and state and federal laws.

UNOS rules provide detailed instructions and operational protocols for the OPTN, OPOs, and transplant hospitals. UNOS is a private, non-profit organization that is contracted by the OPTN to manage organ transplantation, donation, allocation, and distribution nationally. UNOS rules dictate how transplant data is

transmitted, stored, and disseminated between hospitals, OPOs, and UNOS. UNOS also maintains a national database. UNOS is tasked with managing the national waiting list, running the matching algorithms, and overseeing the public process for continuously monitoring and improving organ allocation. Finally, UNOS is charged with promoting awareness and education related to organ donation and transplantation.

Just as UNOS rules provide practical guidance for transplant providers, federal regulations and CMS requirements also provide concrete direction for the OPTN, OPOs, and transplant programs by clarifying key principles and procedures.

At a higher level, state laws define the donation process. These have been amended to include criteria for declaring death, donor consent requirements, composition of donor registries, the scope of public education programs, and benefits for living donors. In contrast, federal laws govern national processes such as organ procurement, allocation, transplantation, and anatomical gifts. Federal laws outline the principles and constraints at the highest and broadest level; they establish the OPTN and guidelines for OPOs. For example, the federal laws establishing the OPTN stipulate that it is responsible for coordinating, monitoring, and implementing organ transplantation policies and procedures at the national level, while OPOs, which are local or regional organizations are responsible for retrieving organs and notifying potential recipients under the supervision of the OPTN [4]. The sections below discuss in greater detail these types of laws and regulations, as they pertain to organ transplantation.

**UNOS**

While the federal laws and regulations dictate the framework of the OPTN and its relationship with member OPOs and transplant centers, UNOS is responsible for many of the policies that dictate the action of the OPTN and its members [5]. UNOS has been the organization that administers the OPTN through a contract with DHHS since 1986. While UNOS and the OPTN are legally distinct, they have the same Board of Directors and the same policies.

UNOS is tasked with ensuring that organs are procured and allocated as expeditiously and as fairly as possible through the Organ Center. The Organ Center matches donors with recipients and manages distribution of organs using UNet, a nationwide transplant computer system. UNet maintains information about all wait listed patients. Once the donor organ information is put into UNet, it generates a list of ranked potential recipients for each organ type. Finally, when a match is made and the potential recipient’s transplant hospital agrees to receive the organ, the organ is delivered by the corresponding OPO. Importantly, UNOS monitors the matching process and ensures adherence to organ allocation policies. The UNOS Evaluation and Quality Department also

Figure 143.1. Current UNOS Region Map (Reproduced from http://optn.transplant.hrsa.gov/members/regions.asp)
 monitors OPTN members, OPOs and hospitals, and ensures that they are compliant with rules and that they can receive CMS benefits. As efforts to promote paired kidney exchange nationally increase, UNOS may play a role in coordinating a united national system.

In addition, UNOS develops policies for the OPTN. Policy proposals are developed by UNOS committees, distributed as initial briefs, and circulated for public comment.

UNOS then incorporates the public comments and submits the final proposal for approval by the Board of Director to become UNOS/OPTN policy. UNOS has 22 committees: Ad Hoc Disease Transmission Advisory, Ad Hoc International Relations, Ethics, Executive, Finance, Histocompatibility, Kidney Transplantation, Liver and Intestinal Organ Transplantation, Living Donor, Membership and Professional Standards, Minority Affairs, Operations and Safety, OPO, Pancreas Transplantation, Patient Affairs, Pediatric Transplantation, Policy Oversight, Thoracic Organ Transplantation, Transplant Administrators, and Transplant Coordinators. The Board of Directors can also submit approved proposals to the Secretary of HHS, and if approved, the policies are incorporated into

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Figure 143.2. Current OPO region map (Data from Penhoet, E. D. et al., Organ Procurement and Transplantation, Washington, D.C., National Academy Press, 1999.)
official regulations. Most of the committees, including the Board of Directors, are comprised of elected members representing the transplant community. These members include: transplant clinicians and coordinators, histocompatibility experts, OPO representatives, voluntary health organizations, medical or scientific member organizations, and public representatives (including transplant candidates, transplant recipient and families, living donors and families). The Board of Directors is comprised of 41 members and is responsible for overseeing the policy development for UNOS. The diversity of the committees is critical to ensure that all voices and interests present in the transplant community are heard during the policy-making process.

Finally, UNOS has an important role in maintaining public trust and promoting organ donation and transplantation. It provides information and support for patients and their families, as well as for donors. Similar to the Scientific Registry, UNOS collects and distributes information on organ transplantation from UNet. Along with the states, UNOS also promotes the need for organ donation.

**Federal regulations and CMS requirements**

**Federal regulations**

These federal laws are supplemented by federal regulations on organ transplantation in Title 42, “Public Health” of the Code of Federal Regulation 42 CFR Part 121 [6]. Effective March 16, 2000, DHHS implemented the “Final Rule”, which established the organizational structure and regulatory framework of the OPTN. All OPTN members must comply with the Final Rule, and to future policy amendments added by UNOS, the OPTN, and HHS.

**Title 42 Section 121**

Describes requirements for transplant programs, guidelines for organ procurement, regulations of the OPTN, and allocation of organs.

**Title 42 Section 121.4**

Outlines policy guidelines for the OPTN Board of Directors. These include equitable distribution of organs, testing to avoid the spread of infectious diseases, reduction of inequities caused by socioeconomic status, and training of transplant surgeons and physicians.

**Title 42 Section 121.5**

Establishes listing requirements for an OPTN member. There are three main rules. The member transplant hospital may list a person only for a designated transplant program. The transplant hospital must place individuals on the waiting list as soon as they are deemed eligible to be candidates for transplantation. The OPTN member must pay a registration fee for each transplant candidate placed on the waiting list.

**Title 42 Section 121.6**

Outlines the determination of suitability of organs donated for transplantation. The OPTN member retrieving the organs must assure that laboratory tests and clinical examinations of potential donors are performed to identify any contraindications for donor acceptance. The OPTN shall have standards to prevent the acquisition of organs from HIV infected individuals. The transplant programs must also establish criteria for organ acceptance and provide them to the OPTN and OPOs.

**Title 42 Section 121.7**

Explains the identification of an organ recipient, allocation of the organ, and transportation to the recipient. The OPTN member must use the OPTN computer match program, with its organ specific allocation criteria, to identify and rank potential recipients. The OPTN member arranges for the transportation of the organ to the transplant hospital. If the transplant hospital rejects the organ, the OPTN member must offer the organ to the next most eligible recipient.

**Title 42 Section 121.8**

Establishes guidelines for the allocation of organs and performance goals. The allocation policies must be based on sound medical judgment, preserve the transplant program’s right to decline an organ, be organ specific, and avoid wasting organs. Performance goals to ensure equitable allocation include standardizing the criteria for determining the suitable candidates, setting priority rankings.
expressed through objective and measurable medical criteria and distributing organs over as large a geographic area as possible.

**Title 42 Section 121.11**
Requires the OPTN and the Scientific Registry to use a system for managing information about transplant candidates, recipients, and donors. This section establishes rules for rigorous reporting and record keeping through the HHS Secretary, the OPTN, the Scientific Registry, and the OPOs. Information must also be provided to the public on the performance of transplant programs.

**Title 42 Section 121.12**
Establishes the Advisory Committee on Organ Transplantation (ACOT) for opinions on proposed OPTN policies and any other issue the Secretary deems necessary.

**Title 42 Section 482.90**
Requires transplant centers to ensure that a prospective living donor receives medical and psychosocial evaluation, to document the living donor’s suitability for donation, and to document informed consent.

**Title 42 Section 482.92**
States that, if a center performs living donor transplants, the transplant surgeon and at least one other licensed healthcare professional at the transplant center must verify that the donor’s blood type and other vital information is compatible with transplantation immediately before the removal of the donor organ(s) and prior to the removal of the recipient’s organ(s).

**Title 42 Section 482.94**
Requires transplant centers to write patient management policies including patient care policies for the pretransplant, transplant, and discharge phases of transplantation, and donor management policies for living donor evaluation, donation, and discharge.

**Title 42 Section 482.98**
Requires transplant centers to identify either an independent living donor advocate or an independent living donor advocate team to ensure protection of the rights of living donors and prospective living donors.

**CMS requirements**
Requirements fall into three categories: data submission, outcomes measures, and process measures. CMS final regulations (published March 30, 2007) became effective June 28, 2007, establishing conditions of participation (CoPs) for hospital-based transplant programs. These requirements focus on outcomes largely reflecting the clinical experience, quality of care, and resources available at the transplant center. Although CMS did not cede sole jurisdiction over transplant centers to the OPTN, in an effort to fulfill CMS’s own role in ensuring patient safety, the additional CoP requirements are meant to complement existing OPTN rules. The data submission requirements largely mirror those of the OPTN (e.g. that 95% of all OPTN-required forms be submitted directly to CMS for all transplants within 90 days of the OPTN’s required deadline). Outcome measures are meant to ensure patient and graft survival that is within the appropriate threshold (estimated by Scientific Registry of Transplant Recipient’s [SRTR] data). Outcomes falling below the expected threshold will be deemed inadequate and thus may face penalties or sanctions. In addition to these initiatives, CMS instituted process measures, affecting patient and living donor selection and protection of rights, organ recovery and receipt, patient and living donor management requirements, waiting list management, detailed quality assessment and improvement requirements. Important changes include providing potential donors with complete information regarding the short and longer term risks of donation, opportunities for withdrawing from donation, and implications for future insurance coverage [7].

**State laws**
State laws are fairly uniform and generally govern the donation process, including: education and outreach initiatives, donor consent and donor reimbursement, donor registries, and designation of death. There are numerous state laws that govern donation. The major ones are briefly described below:

**Uniform Anatomical Gift Act**
The 1968 Act (and its periodic revisions) establishes criteria for donation of organs for the purposes of transplantation and donation of cadavers for medical research and education. The Act describes how the donation process might take place, designating who is eligible to donate the body after death, who has the right to use the body, and the priority list of persons that may donate the body if there is no preference against donation. The Act was revised in 1987, specifying that documentation of a desire to be an organ donor is sufficient for organ procurement (without consent of next of kin), and that witnesses are not required for documentation. The Act also mandates Routine Inquiry (questioning of patients about their organ donation preferences upon admission to a hospital) and Required Request (request from a deceased patient’s next of kin in the event that donation preference was not indicated). The Act also prohibits trade of organs, which reiterates the federal ban enacted in 1984 [8]. The National Conference of Commissioners on Uniform State Laws (NCCUSL) has drafted this Act in an attempt to harmonize the law between states.

Recently, all 50 states and the District of Columbia adopted first-person consent laws (also called “First Person Authorization” or “donor designation” to force the honoring of donor intentions. First person consent laws mandate that the indication of an adult’s intent to donate on any legally binding document, such as a driver’s license, donor card, or online registry be upheld, even against their family’s expressed wishes. This legislation frees the OPOs from securing consent from families to donate their loved one’s organs, to informing the family of the patient’s wishes to become an organ donor and educating the family about the process [9].

Many states have also created computerized donor registries. Revisions of state anatomic death acts allowed people to declare their intention to donate by enrolling in state donor registries, facilitating the identification of potential donors by OPOs. Elements of effective donor registries include: donor designation is considered legally binding consent; consent for tissue donation is included; individuals can enroll through a dedicated website; State Department of Motor Vehicles (DMV) enrolls donors via driver’s license and ID card applications and renewals; no follow-up step required for State DMVs or online enrollment; State DMVs export donor records to registry database; organ, eye, and tissue recovery agencies can effectively access donor designations. Other initiatives include the establishment of the National Minority Organ/ Tissue Transplant Education Program to increase the rate of donation by minorities, the formation of the Organ Donation Breakthrough Collaborative to raise the rate of recovery of organs in
Table 143.1. State initiatives to promote organ donation

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Participating hospitals, efforts to increase retrieval of organs from cardiac death donors as well as brain death donors, and provision of financial subsidies to donor families, such as contributions to funeral expenses in Pennsylvania [10]. All states recognize the driver’s license as a document of gift. Finally, most states subscribe to the same ways of determining death. These states base their definitions on the NCCUSL’s Uniform Determination of Death Act.

Although there is consensus among states on areas defined above, state laws diverge in some important ways. Some states have anatomical gift funds meant to increase public awareness and encourage organ donation. These initiatives will be discussed below under “Promoting Organ Donation.” Some states have laws aimed at removing disincentives to donation, primarily by addressing the financial burden associated with donation. These initiatives may include: paid leave for state employees, a requirement for private employers to provide unpaid leave of absence for organ donation, and tax credits if the donor received paid leave or tax deductions for unpaid donation expenses. The location of donor laws within state codes also varies (Table 143.1).
Federal laws
Federal laws in the U.S. dictate the legal structure of organ transplantation, and are primarily found in Title 42 of the United States Code, which is called “The Public Health and Welfare” [11]. These laws frame the American system of organ transplantation by establishing the OPTN, the SRTR, defining how organs may be transferred between persons, and assisting federal employees who become organ donors. Further on in this chapter details the three sections and several subsections that together comprise the federal framework for transplantation.

Title 5 Section 6327 of the United States Code
Describes provisions for federal employees donating an organ. The Code states that an employee of any executive agency is entitled to a leave from work without a loss of pay to serve as a bone marrow or an organ donor. This supplements state laws to reduce disincentives and costs associated with organ donation.

Title 42 Section 273
Establishes the roles and structures of transplantation organizations. Section 273 requires that the OPO be a non-profit organization under the jurisdiction of the Secretary for Health and Human Services, and ensures equitable allocation and efficient procurement. OPOs must maintain connections with local hospitals and together identify and consent potential donors. Section 273 also describes federal funding for OPOs, the geographic areas that OPOs must serve, and the policies that they must follow to be reimbursed. Title 42 Section 273a outlines evaluations of the long-term effects associated with living organ donations.

Title 42 Section 274
Establishes the OPTN as the main national entity governing the procurement, allocation, and transplantation of organs. The OPTN must first establish membership criteria and medical criteria for the allocation of organs, then establish a national list of individuals requiring organ transplantation and a national system, including a telephone service, to help match organs and individuals on the list. The OPTN must assist OPOs in the nationwide distribution of organs. And finally, it must carry out studies on how to improve organ procurement and allocation. UNOS has had the contract for the operation of the OPTN since its establishment.

Section 274a
Establishes the Scientific Registry as a national database on organ transplantation that includes national transplant statistics, transplant center-specific reports, and transplant research resources.

Section 274b
Establishes general provisions for grants and contracts.

Section 274c and 274d
Establishes administration and report.

Section 274e
Prohibits the buying and selling of organs. Organs must be given as gifts without payment. While living donors may receive reimbursement for the costs of giving, only those who provide the necessary services involved in transplantation may receive payment. The Charlie W. Norwood Living Organ Donation Act of 2007 clarified that paired donation is not deemed valuable consideration, ensuring that criminal penalties are not applied to human organ paired donation.

Section 274f
Permits grants for the reimbursement of travel, subsistence, and appropriate incidental non-medical expenses incurred by living donors. These grants can be provided to states, transplant centers, and qualified OPOs. Section 274f-1, 274f-2, 274f-3, 274f-4 contain rules regarding public awareness, studies and demonstrations, grants, and studies and reports relating to organ donation and the recovery, preservation, and transportation of organs.

Multiple levels of oversight are needed to ensure that the transplantation system not only functions effectively and efficiently in allocating scarce resources in acute situations, but also that it upholds the ethical principles of fairness, equality, efficiency, and transparency. To this end, the rules and regulations promote organ donation as a public good while protecting individual autonomy in donation decisions. The laws protect the equal rights of citizens and prevent discrimination in organ allocation. Finally, the laws protect the dignity of human life, and prohibit commodification and trade of organs.

Implications of the Patient Protection and Affordable Care Act (PPACA)

Implications for patient care
The passage of the Patient Protection and Affordable Care Act (hereafter PPACA) (P.L. 111-148) presents the single largest piece of healthcare legislation since the passage of Medicare and Medicaid in 1965. A massive piece of legislation with many goals, PPACA has two main aims: expanding access to health insurance and limiting the growth in healthcare costs and reform the delivery system. One of the primary goals of health insurance is to improve access to healthcare for many Americans, including the 50.7 million uninsured and the 25 million underinsured [12]. To this end, the Act aims to increase insurance coverage to 32 million Americans by 2019 (16 million from Medicaid expansions, and 16 million from insurance exchanges and expansions of private insurance). The major provisions affecting transplant patients in the PPACA seek to expand coverage and reduce exorbitant costs associated with receiving needed healthcare. The Act attempts to do this in a number of ways, most notably, through insurance expansions (both private and public) and through reducing the financial burden of healthcare, especially for those who need it most and cannot afford it. Insurance expansions are a vital part of the PPACA and are achieved using a number of mechanisms. For private insurance, the Act institutes an individual mandate to purchase health insurance, establishes a competitive insurance rate for individuals and the small-group market, and requires employers to “play or pay” with respect to provision of health insurance. More important for vulnerable populations, the Act provides significant funding for Medicaid expansions and subsidies for private insurance for those qualifying. Implementation of the law is staggered, with major milestones taking place between 2012 and 2018 (Figure 143.4). We detail provisions of the PPACA that relate to insurance expansions and regulation of the insurance market further on.

Increased access to care and lower cost liability through insurance expansions and insurance regulation

Private market expansions
PPACA mandates that all citizens and legal residents buy and maintain insurance or face a financial penalty that will be gradually
phased in through 2016. The individual mandate, or “minimum coverage requirement,” requires that persons over the age of 18 obtain health insurance, either through their employers or through the state-run health insurance exchanges or public insurance programs if they cannot afford insurance otherwise. Starting in 2016, those who do not have insurance will be assessed at $695 per year, or 2.5% of their income, whichever is higher. Exemptions are available for those who cannot afford insurance.

The rationale for the mandate (and non-discrimination measures) is to reduce moral hazard and adverse selection in the insurance market. Although the goal is to reach universal coverage, persons demonstrating extreme financial hardship, those for whom purchasing insurance would exceed 8% of income, and those with religious objections will be exempt from the mandate. Native Americans would be exempt due to their coverage by the Native American Health Service, and incarcerated persons would be exempted as well. Although PPACA has many implications for healthcare systems and patients beyond the scope of this chapter, we focus our discussion on the potential implications for transplant patients and providers.

Mandating that individuals purchase insurance has been politically and legally controversial. Those opposed to the mandate have stated that it is unconstitutional on the grounds that the federal government oversteps its boundaries by applying undue coercion onto individuals by requiring them to purchase health insurance. In a nearly unprecedented case with three days of Supreme Court arguments, 26 states, the National Federation of Independent Business, and numerous individuals argued that the mandate interferes with personal liberties. The Obama Administration argued that the right to regulate interstate commerce is granted to Congress in the US Constitution, and that this right extends to the case of health insurance. Furthermore, lawyers on behalf of the Administration argued that the individual mandate is a necessary step to achieving universal coverage and preventing discrimination, goals sanctioned by the Constitution and government. In the June 2012, the Supreme Court delivered a final ruling in this case, upholding the individual mandate, leaving much of the law in tact. However, the Court ruled against the right of the federal government to require (or even very strongly incentivize) states to expand Medicaid programs. This may severely impede the likelihood

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**Figure 143.4.** Timeline of US health reform implementation.
of achieving universal coverage while keeping the costs of premiums affordable.

On the employer side, consistent with a “pay or play” model, employers with more than 50 employees will be required to provide insurance, and a voucher to employees whose income falls within 400% of the federal poverty level. The exchanges are meant to facilitate affordable health insurance options for those not covered by employers, remedying the problem of unaffordable insurance premiums in the current small-group insurance market. To further ensure affordability for those in need, credits are available based upon income level from 133–400% of the Federal poverty level (FPL). The credits are indexed to keep total premium payment for individuals at a reasonable level (2% of income for <133% of FPL to 9.5% of income for 300–400% of FPL).

**Essential benefits package**

PPACA establishes an essential health benefits package (termed essential health benefits) that is mandatory for:

1. Health plans offered to individuals and small groups (both in or out of the affordable insurance exchanges);
2. All plans offered in the exchanges; and
3. Medicaid plans.

This benefits package includes ten categories: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care [13]. This package covers at least 60% of the actuarial value of the benefits, restricts cost sharing to current Health Service Administration limits, and is generally inline with the employer plans. The essential benefits package, which became effective January 1, 2014, also tasks the Secretary of HHS to define and update the benefits package annually through a transparent and public process.

**Public insurance expansions**

Medicaid expansion is a key feature of PPACA meant to provide coverage for low-income and vulnerable populations and is likely to positively impact transplant and pretransplant patients. The Act extends Medicaid to nearly all individuals under the age of 65 with incomes up to or below 133% of the federal poverty line. For many low-income adults without children, as well as parents at 133% of the poverty line, this expansion marks the first time that insurance coverage is readily available. The federal government will pay 100% of all newly eligible Medicaid patients in financial year (FY) 2014 through FY2016, 95% in FY2017, 94% in 2018, 93% in 2019, and 90% for 2020 and beyond. The federal government has committed additional transition-making funds to assist states that have expanded Medicaid coverage for adults at least 100% of federal poverty. Although the federal government will pay a very high share of the Medicaid costs in all states, uptake may vary. This is in part due to differences in state policies and their support for the Medicaid program, and partly due to the constrained funding environment and deficits facing many states during difficult economic times. Geographic disparities in Medicaid coverage are likely to augment existing geographic disparities in organ transplantation, and may impede transparency among patients in understanding eligibility and projecting costs associated with care. In particular, lower Medicaid uptake in states with high incidence and prevalence rates of hypertension, diabetes, chronic kidney disease, and substance abuse are likely to exacerbate geographic disparities in organ transplantation.

**Relevance to transplantation**

Lack of insurance has long been linked to lower rates of transplantation [14–16]. Continued access to care over the life course has the potential to improve health of patients with end-stage renal disease (ESRD) and other chronic conditions that can lead to organ failure by facilitating early diagnosis, and helping patients to better manage their chronic conditions. Furthermore, patients with “pre-existing conditions” can often feel job locked leading to underemployment because they are hesitant to transition to a different job where their insurance coverage may suffer. This is particularly true of patients who have received a transplant and are worried about losing coverage for immunosuppressive drugs. These patients often face a difficult choice between rejoining the workforce and suffering loss of coverage, or applying for disability [17]. For these persons, the promise of insurance is in and of itself, life improving by increasing jobs open to them and reducing anxiety surrounding loss of coverage. Access to insurance and a lower financial burden associated with needed healthcare is likely to solve these problems, resulting in better health and quality of life for transplant (or pretransplant patients).

Expanded Medicaid coverage should increase access to transplantation, offer coverage for uninsured patients in the post-transplant period, and reduce organ loss due to medication non-adherence. Beyond these implications for transplant recipients, expanded coverage will also likely help patients with end-stage organ failure by enhancing their access to transplant services at an earlier stage, leading to better care and more equitable access. This is likely to be particularly important for patients suffering non- kidney organ failure. Unlike patients with ESRD who receive a Medicare entitlement, patients with organ failure, such as those with chronic liver disease, are likely to benefit greatly from this insurance expansion.

Greater access to referrals and chronic care may lead to more patients being listed for transplant. This could lead to proliferation of the waiting list, accompanied by an absolute decline in outcomes for wait-listed patients (e.g. deaths on the waiting list, wait time, etc.). In this sense, increasing access to care will only remedy the situation insofar as there is care to be provided. Without a corresponding increase in the organ supply, longer waiting times and greater use of marginal organs will likely occur and increase the cost of transplant [18]. It is worth noting, however, that while this is a potential outcome, it is unclear whether increased insurance coverage will actually lead to more equitable referral and listing. Some studies suggest that, despite improved coverage, disparities remain [17,19]. Lack of private insurance (in the presence of Medicaid) has been a demonstrated barrier to receipt of quality and timely care for transplant patients [19]. As such, increased access, while alleviating some burdens, is unlikely to solve all of the healthcare difficulties facing transplant patients. Quality and performance measures aimed at providing equitable care are still needed in order to achieve this outcome.

**Insurance regulations**

Reducing the financial burden and uncertainty associated with paying for care is key to achieving universal coverage. PPACA has been relatively successful at limiting abusive insurance practices, including restricting access, unpredictably increasing costs, and denying claims. Together, these provisions protect the consumer
and aim to reduce the often-ruinous consequences of adverse health shocks.

Private sector reforms such as the elimination of pre-existing condition clauses will likely benefit transplant patients and increase coverage rates among this population. Similar to increasing insurance coverage, defraying the costs of healthcare may result in earlier specialist referral, improved access to transplant evaluation and listing, reduced risk of non-adherence from loss of drug coverage, and improved continuity of care. In particular, elimination of pre-existing condition clauses and annual spending caps may help patients whose immunosuppressive drug Medicare coverage is expiring and those who cannot afford to seek care.

Annual spending caps per enrollee and lifetime limits have also been mechanisms facilitating abusive behavior by insurance companies. These constraints have been particularly injurious for chronically and acutely ill patients, such as those with organ failure, whose annual healthcare costs are substantial. Limits on insurance coverage have transferred the cost burden to the patient, many of whom are forced to liquidate all assets or are driven into bankruptcy in order to pay medical bills [20,21]. For transplant patients in particular, the burden continues even after receiving a transplant. Rodrigue et al. surveyed 333 liver transplant and 318 kidney transplant recipients who were at least one year post-transplant asking whether transplantation caused financial problems, whether income had changed since transplantation, what resources they used to pay for transplant-related expenses, and what their out-of-pocket monthly expenses were. The authors found that 41% of patients reported financial problems after transplantation, and nearly half reported lower monthly income over a year post surgery than in the year preceding transplantation. Average out-of-pocket expenses were estimated to be $47,660 in 2007; this figure has likely increased since. Rodrigue et al. found that patients primarily relied upon savings and credit cards to cover these expenses, however, in the currently constrained lending environment and prolonged recession, patients are likely to face even greater difficulty in paying for care. Provisions to reduce the cost of care, such as elimination of annual spending caps and lifetime limits per enrollee are critical to transplant patients. These patients often experience extended and repeated hospitalizations in addition to requiring expensive medication indefinitely, and as a result, exceed both annual and lifetime limits, resulting in significant financial burden [22].

PPACA also allows for parents to retain their adult children on a family insurance plan up to the age of 26 and limits coverage waiting periods to 90 days. This policy took effect for insurance plan renewals beginning on September 23, 2010. As with the other provisions, this will help transplant patients (and those potentially needing a future transplant) gain and maintain access to care, in particular for younger patients between the ages of 18 and 26 years. Young adults are the age group least likely to have health insurance. This group has benefited tremendously from PPACA, as 18–24 year olds were the only age group to experience a significant increase in the percentage with health insurance, from 70.7% in 2009 to 72.8% in 2010 [23]. Despite the ongoing recession, the two-percentage point increase in coverage for 500,000 young adults aged 18–24 is largely attributable to the PPACAs provision to extend coverage until age 26. Since the fraction of insured adults was stable or decreasing among other age groups, this two-percentage point increase almost certainly reflects the effects of the extension of dependent coverage to age 26.

Effective June 21, 2010, legal immigrants who have resided in the U.S. legally for more than five years or U.S. citizens with pre-existing conditions who have been uninsured for more than six months became eligible to participate in a state managed and underwritten temporary high-risk pool, subsequently replaced by state health insurance exchanges. Premiums will be established based on the standard population and can vary no more than 4 to 1 based on age, geographic area, and family composition. The Act also limits out-of-pocket spending to $5950 for individuals and $11,900 for families, excluding premiums, (on a graduated basis) for families under 400% of the federal poverty level [24]. Up-front deductibles are limited to $2000 for individuals and $4000 per family for plans in the small group and individual market. This will help to assuage the fear of many transplant patients that a 10% or 20% co-payment or high deductibles will exclude them from access to transplantation. Many transplant recipients may be eligible for these plans. However, potentially low reimbursement rates and high costs of organ acquisition may pose a problem for providers, and may pose barriers to access for vulnerable patients [25,26].

PPACA also attempts to reduce administrative costs of healthcare and redirect health insurance costs to pay for healthcare. The Act addresses this partially through instituting a new medical loss ration and premium rate reviews. The Act requires health plans to report the proportion of premium dollars spent on clinical services, quality, and other related healthcare costs, and provide rebates for the amount of premium spent on administrative costs that is over 15% in large group market plans and 20% in individual and small group market plans. Reporting of medical loss ratio was effective in 2010, with the rebate provision effective in January 2011. Additional oversight was included to ensure appropriate increases in premiums. Significant abuses have taken place, with premiums for family coverage having increased by 50% across states, and employee annual share of premiums increased 63% between 2003 and 2010. Were premiums to continue to increase at the rate observed prior to the enactment of PPACA, the average premium for family coverage is estimated to increase by 72% by 2020, to nearly $24,000 [27]. Many insurance regulations in the PPACA are aimed at slowing premium increases, in particular a review process for examining increases in insurance premiums and a requirement for the justification of all increases. Since 2010, all increases in insurance premiums must be approved by the states.

It is likely that these provisions will reduce the cost of care for transplant patients and will increase access, particularly for young patients who may have been uninsured. It will likely also improve quality of life, as young patients may feel more freedom since they will be able to relocate or pursue a different job without fear of losing insurance. However, quality of care and choice of provider may suffer somewhat. Transplant services are often financed as a “carve-out” from medical/surgical premiums because of their high cost and need for highly specialized services. Given heightened scrutiny of the fraction of premium dollar spent on clinical services and restrictions in increasing premiums, it is possible that transplantation coverage may be somewhat limited. Ultimately, transplantation coverage is largely contingent upon the health insurance market (because carve outs are financed by reinsurance) and regulations that more directly relate to transplantation. Depending on the level of reimbursement, plans offered to individual and small group markets and the high-risk pool may restrict choice, reducing care options for transplant patients.

Immunosuppressive drug coverage:
Although kidney transplantation has proven to be superior to dialysis for improving patient survival rates and quality of life and is
cost-effective, its long-term success depends upon ongoing treatment with immunosuppressive drugs. An initial kidney transplant costs Medicare an average of $110,000. Immunosuppressive medications cost $15,000 to $20,000 annually. This is compared to the annual cost of $75,000 for dialysis treatment in the case of premature transplant failure as well as the cost of repeat transplantation. The Medicare extension of funding for immunosuppressive medication for kidney transplantation from one to three years reduced costs and income-related disparities in outcomes [28]. Economic analyses confirm that providing lifetime funding for immunosuppressive medications would lower overall costs by $200 million annually [17]. In addition, long-term survival rates are higher in countries that provide continued immunosuppression. Furthermore, patients experiencing premature transplant failure due to loss of immunosuppression must revert back to dialysis, thereby experiencing poorer outcomes at greater expense. Premature transplant failure is the fifth leading cause of initiation of dialysis in the US [29]. The 2-year mortality rate for patients whose transplants fail is worse than the mortality rate among patients with a functioning transplant and even that among age-matched patients who have never received a transplant.

Transplant failure can result directly from non-adherence to immunosuppressive drugs, which may be due to inability to pay. This link is difficult to confirm using prospective research since transplant recipients are unlikely to admit to poor adherence [30]. However, in a 2010 survey, more than 70% of US kidney transplantation programs reported that their patients had an “extremely serious” or “very serious” problem paying for immunosuppressive medications, and 68% reported deaths and graft losses attributable to cost-related non-adherence [29]. Ensuring lifetime access to these medications with kidney transplants would save lives and reduce the total cost of treating patients with ESRD [29].

Prior to PPACA, in the US, Medicare rules end immunosuppressive drug coverage three years after kidney transplantation for all Medicare patients below 65 years of age or those with work-related disabilities. Upon returning to work and losing disability status, many transplant recipients also lost coverage of their medications. The Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2011 is a proposed amendment to the Social Security Act that would grant lifelong coverage of immunosuppressive medications to all kidney-transplant recipients in the US [29]. Currently, lifetime coverage of immunosuppressive drugs is thought to be afforded largely through various provisions in PPACA. Access to immunosuppressive drugs is provided through the high-risk pool (Pre-Existing Condition Insurance Plan), as well as through private insurers who can no longer exclude enrolled patients or institute annual spending caps or lifetime limits. The Act also prohibits discriminatory practices such as exclusion of pre-existing conditions and the lifetime caps on spending. These practices, in particular, have negatively affected transplant patients because they have impeded their ability to receive care, including vital coverage for immunosuppressive drugs beyond the 3-year period covered by Medicare following transplantation.

PPACA also includes Medicare reforms that will result in better drug coverage by closing the “donut hole.” Effective starting in 2010, Part D enrollees with any spending in the “donut hole” (coverage gap) will receive a rebate ($250). Subsequently, in 2011 enrollees with spending in the coverage gap will receive a 50% discount on brand-name drugs (provided by the pharmaceutical industry). Medicare coverage is phased in beginning in 2011 to 2013 for generic and brand name drugs, respectively, purchased in the gap. Part D enrollees will ultimately be responsible for 25% of the cost of drugs (brand-name and generic) purchased in the gap by 2020. PPACA also reduces the catastrophic coverage threshold by 2019. Despite these policies, patients may still have outstanding expenses due to the high costs of immunosuppressive drugs, and as such, a special provision addressing the need for full coverage of immunosuppressive drugs may still be needed.

Coverage for living donors

PPACA may also positively impact the health of living donors post donation, as well as potential donors hoping to donate. High rates of no insurance coverage, the transient nature of insurance, and restrictions on pre-existing conditions may have served as deterrents for donation. Lack of follow-up care for living donors may have also been a deterrent. Lack of coverage for long-term donor follow-up may be particularly important due to the relaxing of certain donation criteria (e.g., mild hypertension and higher BMIs). The long-term consequences of donation are unclear for these donors, and coverage for comprehensive follow-up may be both important to their physical and mental health. Insurance expansions may also help living donors, whose long-term follow-up, at least within the 2-year period following transplantation, will be covered by Medicare and is likely to be covered under private insurance as well. A recent study by Kher et al. examining reimbursement rates for donor follow-up at a single center, suggests that private insurance and Medicare reimburse follow-up for donation at rates similar to reimbursements for recipients [31]. This suggests that insurance coverage for donor follow-up should not pose a significant barrier to care.

Importantly, given that people could become donors at any time, increasing coverage, expanding preventative health services and encouraging healthy behaviors is likely to increase the pool of potential donors. This is especially true for previously uninsured populations, many of whom are young and healthy, who may not have considered donation due to lack of insurance. The Act promotes preventative care by eliminating cost sharing on recommended preventive services delivered by Medicare and all new insurance plans; providing an annual free wellness visit under Medicare, contributing more federal Medicaid matching funds to states that offer evidence-based prevention services and requiring coverage of tobacco cessation services for pregnant women in Medicaid; and promoting community preventative services by supporting grants [32].

The transplant community, including professional societies, have embraced living donation and have advocated for supporting living donors. The American Society of Transplantation (AST) has publicly called for policies providing health insurance to donors to address the short- and long-term effects of living donation [33]. Although the recipient’s policy typically covers donor-related expenses for a limited time before and after transplantation, the donor is exposed to significant risk by not being guaranteed his or her own insurance. First, the long-term health consequences of donation are not well understood, and as a result, donors may experience a health event related to donation after the recipient’s insurance coverage period has expired. Second, if the recipient dies or loses insurance, the donor will also lose coverage. This could result in substantial medical expenses, often totaling thousands of dollars. Prior to PPACAs provision banning exclusions due to pre-existing conditions, donors suffered a further risk that any future medical need might not be covered if it could be tied in any way to donation. With great uncertainty related to future access to medical
care and potentially high out of pocket expenses, living donors might be dissuaded from undergoing surgery. Universal coverage for donors, granted either through the PPACA or through a separate tailored provision, is likely to help alleviate fears surrounding donation and may encourage donors to come forward.

Implications for transplant providers

Reimbursement

Expanded Medicaid coverage through PPACA is likely to increase the number of individuals with access to transplant services (both pre and post-transplant). Furthermore, if this insurance expansion encourages living donation by making living donors more inclined to donate after being insured, then PPACA may indeed increase the number of transplants. As insurance coverage expands through Medicaid and state-run health exchanges, reimbursements for specialists, in this case transplant centers, will likely decrease. This shift in payer mix may lead to revenue deficits, particularly for centers in large, urban regions with long waiting times and those that use a higher proportion of expanded criteria organs [34].

PPACA establishes an Independent Payment Advisory Board (IPAB) to advise the President and CMS using cost-effectiveness analysis. Although this is in line with PPACA’s mission to improve efficiency and decrease waste in healthcare, many specialists and surgical organizations have voiced their concern about the potential of President-appointed IPAB to influence Medicare coverage decisions. It has been widely suggested that the IPAB is likely to increase funding for primary care and decrease reimbursement of specialist care [35]. This means transplant and potential transplant patients may have better management of chronic disease and potentially earlier referral and better screening. However, it likely will reduce access to specialized transplant services at the same time. Although the need for Disproportionate Share Hospital (DSH) payments as offsets is debatable depending on the rate of insurance uptake among the uninsured and underinsured and the reimbursement rates offered by safety net payers, Medicare generally provides DSH for large academic medical centers that treat an indigent patient population. Under health reform, hospitals are likely to lose 75% of DSH. Finally, the complexity of transplant patients, infection and readmission may be more common than in other patient populations. This may be construed as “poor quality care,” defined by Medicare as high rates of readmission and infection, resulting in lower reimbursement. One way to help both outcomes and reimbursement is through better risk adjustment and enhanced integrated care (perhaps through Accountable Care Organizations).

Restrictions on insurance premiums may lower reimbursement and limit patient choices. These restrictions may increase the market power of large networks, which may limit access to certain transplant centers and may also reduce reimbursement for transplant providers. Thus, restrictions on the overall cost of insurance plans may potentially increase the patient base, but restrictions on high-cost, high-benefit plans will likely decrease reimbursement and choice [18].

Quality improvement

PPACA also addresses stabilization of the sustainable growth rate, creation of medical homes, shift to episode of care reimbursement (already familiar in transplantation), and development of comparative effectiveness research in an attempt to improve the delivery system and enhance healthcare efficiency. The Act also attempts to improve quality by incorporating pay-for-performance incentive mechanisms. Many studies have demonstrated that physicians and hospitals are responsive to such incentives, and this model has been used successfully across a number of clinical domains [36–38]. In PPACA, two provisions aimed at integrating pay-for-performance became effective in 2012: the first provides incentives for the formation of accountable care organizations (ACOs), and the second links payment to quality outcomes, supplying hospitals with financial incentives to improve quality of care.

Accountable care organizations

ACOs promote care coordination and quality improvement by focusing especially on disease prevention, disease management, reducing redundancy, and ultimately reduction of unnecessary hospital admissions. Cost-saving is achieved if ACOs provide high-quality care at lower costs to the healthcare system, in which case the ACOs receive a fraction of the costs saved.

ACOs encourage a disease management approach to healthcare delivery, by linking providers and provider payment (ambulatory, hospitals, nursing and ancillary care facilities) in a defined way to an episode of care. The expectation is that greater communication and ownership over the patient experience will enhance quality care and decrease costs. In many ways, transplant care is a pioneer in this approach, since many of the services surrounding transplantation are integrated and involve a number of different specialties, centers, and routine follow-up care. Transplant centers have acted essentially as medical homes, integrating a number of medical and surgical subspecialties, and even incorporating emergency department visits for patients under their care. Bundled payments, which often accompany discussions of ACOs, will be familiar to transplant centers that have been reimbursed in this way for some time. Provisions aimed at developing the Medical Home Care Models and expanding the Federally Qualified Health Centers may also serve transplant recipients in providing long-term care [34].

The American Society of Transplant Surgeons (ASTS), although supportive of developments proposed in the ACA, suggests that CMS take special care to ensure that Medicare and ACO patients with expensive healthcare needs, such as transplantation, receive proper information about their care options and are not dissuaded from pursuing transplantation [39]. ACOs may have to overcome disincentives to provide such information, particularly if a transplant center is not included in their network.

Pay for performance

The second main quality-related provision incorporates pay-for-performance (P4P), which entails “linking payment to quality outcomes”, and offers hospitals financial incentives to improve quality of care. The provision requires public reporting of hospital performance, beginning with measures related to heart attack, heart failure, pneumonia, surgical care, and nosocomial infections. Public reporting requirements will extend to discharges effective October 1, 2012.

P4P has two main components: the first rewards physicians for outcomes meeting a quality threshold, and also often for demonstrating improvement. The second component involves public reporting of outcomes in an effort to increase transparency and information in the market, and facilitate consumer-driven demand. The provision is structured at the hospital or group level, meaning that for physicians individual returns are not directly linked to individual effort. Instead, physician returns depend on the group or hospital quality improvement. Such a structure is risky in that it creates a “free rider” problem, where certain physicians can experience benefits without improving their own quality.
The structure of the incentives is also important. Rewarding absolute quality thresholds can have negative consequences, such as discouraging physicians with complex patients. Without proper risk adjustment, this could exacerbate disparities and lead to fewer physicians accepting patients with severe medical needs. In such a system based on absolute performance, low performers, even those demonstrating significant improvement, would not receive any rewards. In a system rewarding improvement, high performers would not be incentivized to maintain high performance because they would not be rewarded for that. Risk adjustment is crucial, as are both relative and threshold performance incentives. For transplant physicians, this is of particular importance given the range of patients and geographic variation in availability of standard criteria organs. Furthermore, given the importance of equity to transplantation policy, special attention should be paid to incentives and their potential negative consequences.

PPACA is also focused on process-based measures. Process of care measures are intended to improve how care is being delivered, not simply the outcome. Incorporating process measures somewhat mitigates the gaming problems associated with outcome-based quality measures. The timing of incentives (end of the year versus continuous) as well as the relative size of incentives (at least 5% of the capitated salary) will also be important [40,41]. P4P incentives must be carefully structured and implemented. It is currently unclear with these incentives, as they are included in PPACA, will achieve their desired outcome.

Meeting a growing demand for organs through donation incentives
A third area of developing transplantation policy involves stimulating organ donation through incentives and increased public awareness. The current waiting list for kidney transplants has more than 85,000 people, but donated organs allow only about 17,000 transplants each year. Approximately 4500 people die each year while waiting for a kidney transplant, and an additional 33,000 join the list [10]. The growing number of patients on waiting lists is increasingly disproportionate to the supply of donor organs. While the use of organs from donors dying from cardiac death has increased over the past decade, with such donors now exceeding 10% of the total, UNOS policies intended to facilitate the use of expanded criteria donor kidneys (making a second transplant waiting list available for kidneys recovered from older and sicker donors) have met with mixed success [1]. Currently, about 60% of kidney transplants come from deceased donors. Forty percent of kidney transplants are from living donors, with the proportion of living donors increasing in recent years [42].

Legislative attempts to increase organ donation aim to increase the supply of potential deceased donors, to increase the pool of potential living donors, and to improve donor conversion. The transplant community and the US government overwhelmingly support the notion that organ donation (especially living donation) should rely on volunteerism and altruism. This is deeply rooted in legislation in the Uniform Anatomical Gift Act (UAGA) and in Section 301 of the National Organ Transplant Act (NOTA) of 1984. NOTA states that, “It shall be unlawful for any person to knowingly acquire, receive or otherwise transfer any human organ for valuable consideration for use in human transplantation” [43]. In this context, “valuable consideration” has been interpreted as a conditional transfer of money or valuable assets between the recipient, donor, and potential broker [43]. In particular, the law serves to prohibit coercion of inducements of any kind for donation, and explicitly bars the purchase or sale of organs. Policies related to stimulating organ donation can be categorized by the intended benefactor: either living or deceased donors; and, by mechanism: financial incentives, material compensation, non-material compensation. The structure and size of potential financial incentives also vary significantly, with some favoring significant market regulation and non-material compensation, compared to others that promote an open and unregulated market for organs where the price of an organ would be regulated solely by the law of supply and demand.

Conflicting views exist about whether financial compensation for organ donation would alleviate the organ shortage and increase supply. Some have argued that the presence of financial incentives would decrease the pool of potential donors because people would no longer feel ethically compelled to donate, viewing the exchange instead as a transaction. In his “Open Letter” to Senator Arlen Specter of Pennsylvania asserting his concerns related to his proposal for the Organ Donor Clarification and Anti Trafficking Act to amend NOTA, Gabriel Danovitch details numerous concerns related to providing incentives, integrating ethical concerns of commodification (detailed in the Declaration of Istanbul) as well as practical concerns. Of note, Danovitch suggests that in countries where financial incentives or payment for donation are introduced, funded donation crowds out voluntary donation. Danovitch cites examples of Israel, Pakistan, and Iran, among other countries which demonstrate this effect [44]. This line of opposition is well established. Policy makers, including several senators and professional societies such as the National Kidney Foundation, along with religious organizations vehemently and successfully lobbied to exclude pilot programs examining the financial incentives for organ donation in the Organ Donation and Recovery Improvement Act ($573), introduced by Senators William Frist and Chris Dodd [45]. Opponents of financial incentives caution that financial incentives could reframe the way the public views organ donation from an altruistic behavior to a normal market transaction. This could lead to (and has in some countries) lower familial and altruistic donation rates.

In contrast, proponents of financial incentives suggest that the distinction is not so stark, and that some level of financial incentives may be both ethical and effective in promoting donation. A common ethical argument supporting financial compensation is that all other stakeholders taking part in the transplant process are compensated and paid for their participation, except for the donor. Other ethical considerations include utilitarian arguments that suggest that everyone would gain from a shorter waiting list and that many lives would be improved by increasing the supply of donors. Some ethicists have gone so far as to argue that restricting the ability to sell one’s organ unfairly constrains autonomy, and in particular harms those of low socioeconomic status who have most to gain from such a transaction [46]. Matas, amongst others, has called for a regulated system that would compensate living donors. He suggests that the system would have six key elements to be administered by OPOs:

1. ban on donor-recipient contact;
2. donor compensation that includes a 1-year $1 million term life insurance policy and guaranteed lifetime healthcare;
3. reimbursement of travel for donation;
4. fixed compensation for leave from employment;
5. fixed payment or tax break;
6. a payment of $500 for completing follow-up evaluation 1-year post-transplant [47].
He argues that such a system would not undermine altruistic donation, but rather would fairly and ethically supplement this pool with more donors who would be adequately compensated and incentivized, without being coerced.

More recently, many professional transplant societies have come to adopt the view that a middle ground might be most appropriate, both ethically and practically. In 2002, the ASTS sponsored a panel of ethicists, OPO leaders, and transplant physicians and surgeons to consider financial incentives. The panel supported efforts to promote a pilot project to examine the effects of funeral reimbursement or charitable contributions in the name of the donor, as a means of expressing appreciation to the donor and donor family [48]. Roth found sustained support for a certain level of compensation among the ASTS membership, stating that, “in an informal poll following a debate on the subject at a recent meeting of the ASTS, a majority of those polled expressed a willingness to contemplate a trial or demonstration project involving compensation for organ donors” (personal communication, Arthur Matas, January 27, 2007) [49]. Other professional societies, including the AAKP, the PKD, the AST, have also expressed support for various types of supports for living donors, but the enthusiasm for financial incentives per se varies significantly [50–52]. Importantly, the politically powerful American Medical Association (AMA) also joined the chorus of support, urging Congress to amend the NOTA of 1984 to permit demonstrations incorporating financial compensation for families of deceased donors. The UNOS/OPTN have also recently called for study of potential financial incentives for organ donation [53].

The political and policy debates have become increasing complex as the organ shortage has grown and the number of stakeholders and number of proposed incentives has proliferated (Figure 143.5). The policy debate surrounding financial incentives often conflates both living and deceased donation, intensifying concerns about exploitation and extending them even to discussions of deceased donation where they may not be relevant. Five main approaches have been suggested for increasing donation using incentives: payments, tax benefit, funeral reimbursement, and charitable contributions on behalf of donors, and medals honoring donors.

Federal legislation
In 1999, the Organ Donor Leave Act (PL 106-56) was passed, granting federal employees paid leave to serve as organ donors. The law grants federal employees up to 7 days for serving as bone marrow donors, and up to 30 days for serving as organ donors [54]. Following a spirited debate surrounding financial incentives and potential commodification of organs, federal legislation, originally introduced by Senators William Frist (R-Tenn) and Christopher Dodd (D-Conn) was passed. In 2001, two bills were introduced in Congress, one proposed offering a $10,000 tax credit for deceased donation and another a $2500 tax refund for living or deceased donation [55,56]. The Organ Donation and Recovery Improvement Act ((PL 108-216), signed into law in 2004, promotes organ donation by allowing reimbursement of travel and subsistence expenses for living donors, supports long-term follow-up of living donors by facilitating a registry, and provides grants to states and public entities [57]. Importantly, this legislation did not overturn the 1984 NOTA ban on buying and selling of organs. Efforts to expand incentives for donation without providing additional financial incentives led to the enactment of two laws in 2007 and 2008. The Charlie W. Norwood Organ Donation Act (PL 110-144) in 2007 [58] paved the way for paired donation, clarifying that it is not considered valuable consideration for purposes of Section 301 of NOTA. The Act also calls for an annual report detailing advancements in understanding the long-term health impacts of living donation. The Stephanie Tubbs Jones Gift of Life Medal Act [59] (PL 110-413) grants the DHHS authority to award organ donors a National medal in honor of their donation.

State legislation
Financial incentives for living donation
States have enacted a set of financial incentives as well. Despite the prohibition of financial compensation for donors stated in the NOTA of 1984, many states afford living donors some benefits to offset the costs and physical or emotional burden of donation. Beginning in 2000, Wisconsin, followed shortly by Maryland, introduced a law that instituted policies granting state employees 30 days of paid leave following organ donation. In other states, this law often is extended to local government employees as well as public school teachers. Some states have expanded this initiative, adding a requirement for private employers to provide unpaid leave of absence for organ donation. Many states further incentivized living donation by passing a second law that grants donors up to a $10,000 tax deduction to compensate costs associated with donation. The actual tax deduction depends on the donor’s marginal tax rate. This varies between states and also depends on income and filing status. The actual monetary value of this deduction depends on the individual’s state marginal tax rate, which depends on the state, as well as one’s income and filing status. As Wellington and Sayre note, “a single filer in Wisconsin with an adjusted gross income of $25,000 faces a relatively high state marginal tax rate because as one’s income increases, the value of the person’s state earned income tax credit decreases. However, Minnesota’s tax system results in more wealthy individuals facing a higher marginal tax rate” [60]. While these examples demonstrate that the value of this benefit varies substantially, in all cases the benefit is relatively small (less than $1500). The transplant community has also called for lifetime insurance benefits for living donors. The ASTS, the AST, and the Declaration of Istanbul have also proposed legislation to provide federally funded lifetime insurance benefits for living donors [48,61]. Although specific guarantees have not been made for living donors, provisions in the PPACA to expand coverage may be enough to encourage donation, likely achieving much the same result as a discrete provision targeting organ donors.

Financial incentives for deceased donation
Efforts to pass legislation related to financial incentives for deceased donation have been less fruitful. According to a 2005 Gallup poll, 95.4% of Americans reported that they “support” or “strongly support” organ donation [62]. Despite this widespread support, less than half of Americans have registered as organ donors [5]. Proposed financial incentives for deceased donation include payments to the donor’s family to defray funeral costs or support designated charities as well as tax credits [63]. In 1999, the Pennsylvania Department of Health proposed offering $300 to families of organ donors to defray funeral costs [60]. However, despite multiple revisions and negotiations, the law was never enacted due to concerns about violating NOTA.

The idea of a “futures market” has also been proposed, whereby individuals would receive payment in exchange for the promise of donating their organs after death [64]. As Howard and others have noted, while the concept of a “futures market” is an interesting thought experiment, it would likely require financing out of general
Figure 143.5. Timeline of legislative and policy initiatives related to offering incentives for organ donation in the US.
revenues or tax on hospitals or health insurers [64]. One example of an incentive for a type of futures market can be found in Georgia. Until 2005, Georgia provided a $7 discount on driver's license registration fees to individuals who registered as organ donors. It seems that this small incentive was relatively effective, and in 2005 Georgia boasted one of the highest donor registration rates for organ donation in the US [64]. Although effective, a futures market undermines the validity of the donation designation on the driver’s license because the intent of the registrant is unclear with respect to wanting to donate or simply wanting a discount. As a result, Georgia’s OPO was reluctant to use the Georgia donor registry data while the driver's license discount was in place. Bryne and Thompson, among others, suggest that such a system may undermine familial consent rates as well [65]. Many in the transplant community suggest that, although financial incentives may increase donation rates, the ethical concerns associated with such measures and potential negative implications public perception, public trust, and living donation render them currently undesirable [66].

Mandated choice
The current practice of requiring family consent at the time of organ procurement is problematic because often families are unsure of the donor’s preferences, and even if aware, they may object to donation and refuse efforts by the OPO and clinical team to follow the donor’s expressed wishes [67]. Despite the public’s strong support for organ donation in public opinion polls [68], suggesting that the stress accompanying the decision-making process may be contributing to the rates of family refusal. Mandated choice would compel all competent adults to decide whether they wish to donate their organs after their deaths. People could document their decision via a number of forums, including: driver's license registration, voter registration, or income tax forms. Donor consent would be indicated on the driver’s license or in a state donor register that is accessible at the time of death. For example, in Virginia, three options were available: donor, non-donor, and undecided. In the first six months, 24% were undecided with 31% registering as donors [69]. The main objection to mandated choice is that forcing people to make choices undermines personal autonomy. However, proponents of mandated choice argue that autonomy is actually enhanced because it forces an active decision as opposed to an implied assumption. Mandated choice allows competent adults to make the donation decision for themselves, rather than have it foisted upon them by relatives [70]. Mandated choice may also be beneficial for families too, who often suffer severe stress and internal discord due to donation decisions [71].

Presumed consent
Presumed consent for organ donation attempts to increase organ donation by changing the default option. Changing defaults has been shown to be an extremely effective way to overcome “status quo” bias, where people fail to take action because they are not incentivized to leave the default option. Presumed consent is an opt-out system where, following death, organs can be removed, stored and used in transplant unless a person explicitly refuses to allow such activities. Several European countries such as Spain and Austria have introduced presumed consent. Spain’s presumed consent law is considered somewhat soft, because health providers actively check that the next of kin do not object to organ donation, whereas in Austria the organ recovery proceeds unless it is known that the deceased objected before death. Their law actually provides for preservation without consent; the Spanish norm is to use normothermic extracorporeal membrane oxygenation (NECMO) or cardiopulmonary bypass on donors to keep the organs perfused until family located and consent obtained. Still, Spain has relatively high donation rate of 35.5 per million [72]. Abadie and Gay have estimated that donation rates are 25–30% higher in presumed consent countries [73]. Brazil introduced a system of presumed consent in 1998, but returned to a system of informed consent after a year due to systematic failures. In Brazil, the public lacked trust in the organ donation system, stemming largely from misperceptions that organs would be removed before patients were clinically dead. Brazil also failed to institute a system to allow people to object to donation while alive. Evidence from several studies suggests that presumed consent law is associated with increased organ donation rates, but other factors such as availability of potential donors, infrastructure for transplantation, investment in healthcare, and public attitudes may all play a role [74,75].

The Institute of Medicine has recommended that the social climate be changed before any drastic legislative moves aimed at increasing organ donation [76]. The IOM Organ Donation Committee suggested that the long-term goal would be to create a society so committed to organ donation that such presumed-consent or mandated-choice policies would be acceptable. Professional societies seem to be mostly in agreement. A survey of members of the International Society for Heart and Lung Transplantation (ISHLT) in conjunction with the Foundation for the Advancement of Cardiac Therapies (FACT) found that members overwhelmingly favored indirect over direct compensation as a way of increasing organ donation. This is despite the belief among the majority of respondents that presumed consent is the best way to significantly improve organ donation. The majority also favors the wishes of the individual over the family in determining donor status [63].

Promoting organ donation: interventions
Organ donation involves a few components: first, people must volunteer to be organ donors; and second, families must consent to donation once a donation situation arises. This dynamic decision-making process is complex and is influenced by a number of factors and numerous stakeholders. These include: the potential donor, the donor’s family, the OPO, the clinical staff taking care of the potential donor, and potentially public figures such as religious or community leaders. This section will review a number policy and clinical efforts aimed at overcoming barriers to organ donation (see Figure 143.5).

Deceased donors: increasing public awareness of organ donation
Organ registries might not be sufficient to expand organ donation rates if awareness among the general public remains low. Public education aims to increase organ donation by improving public awareness of transplantation and the need for organ donation [77]. Approaches include public information campaigns using the media, distribution of donor cards, and providing teaching materials for schools [78]. Increasing the opportunities to register as organ donors, such as during driver’s education and licensing, during advance-care planning, and in work, faith, school, and community-based initiatives may help increase the number of potential donors [76].

Changing the social climate would require relieving people of their fears and misconceptions about organ donation and transplantation [79]. Horton and Horton found that lack of religious
support, confusion about the concept of brain death, fragmented healthcare provision by physician teams responsible for the welfare of the donor and recipient, and a mistaken belief that to be valid an organ donor card must be filed with the US Department of Health and Human Services, were associated with organ donor status. The authors found that knowledge of organ donation facts was associated with carrying or requesting an organ donor card, attitudes towards organ donation and willingness to donate their own organs or the organs of a deceased loved one [80].

Willingness to donate also varies by sociodemographic and racial characteristics. Boulewra et al. found that black females were least willing to donate blood (relative to other race and gender groups), whereas black men were least likely to donate organs after death. The authors suggest that mistrust of hospitals and perceived discrimination in hospitals explained much of the racial and gender gap in willingness to donate blood, whereas religious and spiritual beliefs explained the racial gap in willingness to organs after death [81]. Low rates of organ donation among African-Americans has been attributed to: less awareness of transplantation, religious distrust of donation, institutionalized racism and distrust of the medical community, fear of medical abandonment and fear of discrimination [82,83]. Siminoff et al found that, compared to whites, African-Americans reported lower trust in the healthcare system [83] and were more likely to believe that physicians would not try as hard to save lives of donors and that physicians could not be trusted to pronounce death. African-Americans were also more likely to favor compensation for families of donors, such as financial compensation and coverage of funeral expenses. These studies suggest that low levels of trust and lack of awareness and education about the donation process may pose particularly important barriers in minority communities.

Interventions
Despite more research related to identifying barriers to donor registration, few successful interventions have been identified. Given efforts to increase evidence-based policy, HRSA and NIH have committed significant funding to stimulating research promoting organ donation. Future policies may need to incorporate legal and regulatory components of information technology law (specifically internet law), work with various governmental departments, such as the Department of Education and local school committees, and incorporate interdisciplinary teams in order to successfully increase organ donation.

Several studies have highlighted the potential of new media in promoting organ donor registration [84]. Merion et al. studied the effects of an internet-based multimedia intervention (http://www.journey.transweb.org) on donation registration and family notification. The authors found that for the 10884 participants, knowledge improved after completing the educational module. Furthermore, willingness to donate and join a donor registry increased after the intervention. While increases in knowledge were not associated with changes in attitudes, an increase in donation attitude was a significant predictor of donor registry participation and family notification [85]. Thornton et al. examined the effect of an iPod video intervention on donor registration in DMVs in Ohio. They found that viewing the video was associated with increased rates of donor registration. Importantly, they also found that the video was particularly effective among black participants, although it was also effective for other racial groups. This brief video exposure that took place at the DMV was successful in providing information about organ donation and reducing some of the barriers associated with organ donation, particularly amongst minorities [86]. In a recent unprecedented move, the social networking website, Facebook introduced an "organ donor" option allowing their 161 million members in the US (and over 900 million members worldwide) to advertise their organ donation status. The Facebook option will likely be important for two reasons: first, it will increase awareness and likely lead to high rates (at least initially) of donor registration. Second, declaring one's donation status on Facebook serves as a record documenting consent. Although this may not be legally binding, it will serve as a way for the family to identify the patient's wishes when they are not known. Following this move by Facebook, organ donation registries reported a spike in donation registrations. California alone experienced a 700% increase above the typical number of new registrants [87]. Other states reported a tremendous rise in new registrants following this option, including Colorado, Connecticut, Maine, Massachusetts, Michigan, Nebraska, Nevada, New Hampshire, Rhode Island, and Wyoming.

School based health education also presents a promising approach for improving organ donation rates, potentially also among ethnically diverse youth. Tailored interventions also hold promise. Piccolilli et al. demonstrated that a two hour class and two hour session with patients and experts held in eight schools for 17–18 year old students helped increase interest improve attitudes related to organ donation [88]. Using a randomized-control study design, Cardenas et al. found that in a multicultural high school, following an educational intervention, students in the intervention group demonstrated a significant increase in knowledge scores and improvement in willingness to donate [89]. Positive changes in attitudes and willingness to donate occurred independent of ethnicity and gender, in spite of these both being negative predictors of opinion at baseline. These studies suggest that classroom based interventions may be important in promoting organ donation, particularly among young adults.

Increasing donor conversion
Awareness of a loved ones wishes, and concordance of family members during the decision-making process is also vital to successful donation [90]. Polls have suggested that a key factor in families agreeing to consent to organ donation at the potential donor's death is whether the potential donor had previously discussed organ donation with his or her family [79]. Siminoff et al. found that prior knowledge of the patients' wishes along with discussions of more topics and had more conversations about organ donation were significantly associated with willingness to donate. Families with greater contact with OPO staff and those who experienced an optimal request pattern also were more likely to donate [91]. Rodrigue et al. examined the relative influence of donor and next-of-kin factors, requestor characteristics, communication processes and satisfaction with the healthcare team on the donation decision [92]. Similarly, they found that prior knowledge of preferences, favorable organ donation beliefs were important, satisfaction with the OPO and healthcare team and timing of requests were associated with donation. These studies suggest that there is a need for a sustained commitment to public education interventions aimed at improving beliefs about organ donation, documenting and discussing donation decisions with next-of-kin, and to improving the request process in hospitals.

Even when a patient has a signed organ donation card, the OPO typically seeks family approval to proceed with donation. Although the Uniform Anatomical Gift Act (1968, revised 1987) states that
a signed organ donation card is sufficient to proceed with donation and serves legally as an advanced directive, requesting consent from the next-of-kin remains standard, largely to avoid lawsuits and unfavorable press. This model may be slowly changing, however, with many states passing legislation establishing “first-person consent” laws. These laws establish that the family cannot supersede an individual’s expressed wish to be an organ donor. Often times in such states first-person consent registries are maintained, often by the Department of Motor Vehicles (DMV). First-person consent laws support patient autonomy, promoting the ideal that patients should be able to choose what the type of care that they will receive and what should happen to their body after they pass. First-person consent may also alleviate a burden from family members wanting to do the right thing in a stressful and difficult circumstance. In this situation, first-person consent laws relieve the family from making the decision while grieving, and reduces the likelihood of familial conflict related to donation. Given the instability of donation decisions made by families (more than one-third of families who made a decision and declined to donate regretted their decision), avoiding this scenario may provide even greater benefit [90,93].

Laws have been passed that require referral of all potential donors to the OPO or request of the families’ permission to obtain organs of potential donors. This requires an effective screening system for identifying potential donors and sharing their information in an expedient way with OPOs. Such systems have required additional hospital development to facilitate donation requests [78]. Demand for organ transplantation may conflict with end-of-life preferences, as organ transplantation may require profusion, receiving or withholding that do not correspond to the patient’s end of life treatment plan. Further research is needed to better develop policies that will allow OPOs to intervene efficiently and expeditiously when needed, while maintaining patient autonomy, dignity, and respect during end of life care.

Given that there are such wide range of consent rates from OPOs and transplant centers (from more than 70% to less than 30% of potential donors), the Institute of Medicine has recommended identifying best practices and disseminating them among the institutions. There should also be research identifying new ways to improve the system and increase donation rates. Organ donation could be coordinated with discussions about end-of-life care. Patients and families should be offered the opportunity to donate as standard end-of-life care. There could also be increased efforts to procure organ donations from cardiac-arrest deaths occurring outside of the hospital. According to one estimate, at least 22,000 people each year who die of cardiac arrest outside of a hospital could be potential organ donors.

The refusal of families to grant permission for donation presents a major impediment to organ donation. Three factors that have helped overcome this barrier. First, decoupling the request for donation from the declaration of brain death to allow the family time to cope with the loss of a loved one and fully understand the concept of brain death. Second, a trained OPO representative along with the clinical team should make the request together. Studies suggest that the clinical team should wait for the OPO representative to discuss donation with the family and chart a course of action. Third, the discussion with the family should be discrete, ideally in a quiet and private setting [94]. In 2003, the Secretary of DHHS launched the US Organ Donation Breakthrough Collaborative to formalize national efforts to improve efficiency and outcomes in organ donation. Housed under HRSA’s Division of Transplantation, the Collaborative included the national community of OPOs and hospitals. Selecting experts from hospitals and OPOs that had a successful record of achieving and sustaining high organ donation rates to serve as faculty, the Collaborative developed best practices [95]. The intervention yielded positive results, with the number of organ donors in Collaborative hospitals rising 14.1% in the first year compared to merely 8.3% increase experienced by non-Collaborative hospitals. Importantly, sustained increases in organ recovery continued into the post Collaborative periods. Between 2003 and 2006, the number of total US organ donors increased by 22.5%, compared to the 5.5% increase measured over the same duration in the immediate pre Collaborative period. Although perhaps not all of the change is due to the Collaborative, studies suggest that dissemination and implementation of best practices gleaned from the Collaborative were a significant factor in this increase [96].

Living donors
Some have concluded that the waiting list for kidney transplant is too long, growing, and unlikely to be substantially reduced by increases in the recovery of deceased donor kidneys. Of the approximately 2.3 million deaths annually in the US, only between 11,000 and 14,000 produce eligible donors under the standard criteria. Removing barriers for living donors can increase the rate of living donations. These include funding to cover their living expenses, travel, lost wages and the costs of care they provide to other family members, assistance for postoperative care of the living donor, encouraging employers to accommodate employee requests to take time off to donate organs [77]. Minorities are far less likely to be living donors as well. Barriers to minority living donation include: unwillingness to donate, medical co-morbid conditions, trust or fear of medical community, loss to follow-up, poor coping mechanisms, financial concerns, reluctance to ask family members and friends, fear of surgery, and lack of awareness about living donor kidney transplantation [82].

The National Living Donor Assistance Center, administered by the Division of Transplantation of HRSA through a co-operative agreement with the University of Michigan and the American Society of Transplant Surgeons (ASTS), aims to provide greater access to transplantation for persons who want to donate, but cannot otherwise afford the travel and subsistence expenses associated with donation [97]. The program states that, it is “authorized by section 377 of the Public Health Service (PHS) Act, 42 U.S.C. § 274f. The specific authority was authorized by the Organ Donation and Recovery Improvement Act (P.L. 108-216) which provided authority to the Secretary to establish this grant program to assist living donors who need financial assistance to help defray travel and subsistence expenses”. In 2006, HRSA awarded the co-operative agreement to the University of Michigan with a subcontract to the American Society of Transplant Surgeons to establish and operate the program, charged with:

1. running a national system to provide reimbursements for “travel, subsistence, and other non-medical expenses that may be authorized by the Secretary, to individuals making living donations of their organs”;
2. establishing governing policies together with HRSA and the transplant community;
3. operating the program effectively including efficient payment to living donors;
4. ensuring continued fiscal health; and
5. monitoring and evaluating the quality of the program.
In October 2007, transplant centers were invited to register for the program on the NLDAC website. Between its inception in 2007 and through July 26, 2010, NLDAC received over 1200 applications and funded 86% of them. The expense for travel and lodging has averaged $2900 per application. Payment is granted in the form of an American Express Controlled Value Card (CVC) to purchase airfare, gas, rental cars, hotel rooms, food and other incidental expenses such as parking [98].

In June 2008, the OPTN/UNOS approved a proposal for a national pilot program with interim implementation that began in October 2010 [99]. 77 transplant centers in four regional networks are enrolling patients and potential living donors in the pilot exchange program that includes two- and three-way exchanges.

**Current policy and transplant tourism**

In 1984, a proposal for kidney sales by a US physician led the National Organ Transplant Act to prohibit monetary compensation for transplantable organs. The prohibition of commodification current policy in the US prevents exploitation. However, data on departures from the US kidney waiting list suggest that from 1987 to 2006, over 335 Americans traveled overseas to obtain kidney transplants. These transplant "tourists" often pay brokers between $15,000 and $150,000 for transplant packages [10]. The current policy thus gives an advantage to those who are wealthy and those with social capital and thus more likely to obtain a live donation. This policy is inefficient due to unrealized willing-but-incompatible donations and losses to potential savings due to these willing-but-incompatible donors. In addition, studies of transplant tourism have found that kidney patients transplanted abroad had a high incidence of serious postoperative infections, although graft survival and function appeared fine [100]. There may also be inadequate communication of information such as immunosuppressive regimens and preoperative information. The extent of commercial transactions and organ theft remains incompletely understood. The WHO estimates that roughly 10% of organ transplants worldwide involve organ trafficking and transplant tourism. Several principles came out of the Declaration of Istanbul World Health Organization Summit on Organ Trafficking and Transplant Tourism. National governments should develop and implement comprehensive programs for the screening, prevention, and treatment of organ failure. Legislation should be implemented to govern the recovery of organs from deceased and living donors, and transplantation, consistent with international standards. Organs for transplantation should be equitably allocated to recipients. The primary objective of transplant policies should be optimal short and long term medical care to promote the health of donors and recipients. Countries and regions should achieve self-sufficiency in organ donation. The World Health Assembly called on countries to prevent the purchase and sale of human organs for transplantation [101].

**Summary**

Transplantation has evolved from an experimental curiosity to one of the most complex of all human endeavors. This complexity is evident in the exceptional number of statutes and the immense regulatory fabric that covers all aspects of the field, from the formal definition of death, to restrictions on who can give the gift of life. Arguably, no field touches on more of the technical, logistical, social and ethical aspects of human existence, as does transplantation. As such, the study of transplantation will forever uniquely reflect the human condition, and in doing so, make this one of the most satisfying of careers.

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