

FACTS AT A GLANCE

Kidney Transplantation in Texas

Texas Legislative Council May 2004

Kidney Transplantation in Texas

Prepared by Carey Eskridge Research Division Texas Legislative Council for State Representative Glenda Dawson

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Introduction

This publication is intended to serve as a primer on the issues central to transplantation policy and to provide background on the organ donation, procurement, and allocation process and statistical data relating to kidney transplants in Texas as compared to the rest of the nation. Following a brief overview, the publication highlights federal legislation and United States Department of Health and Human Services (DHHS) rules relating to the Organ Procurement and Transplantation Network (OPTN) and the United Network for Organ Sharing (UNOS) and describes the organization and functions of those entities; reviews the current kidney allocation process in Texas, relevant state programs, and major legislation filed in and enacted by the Texas Legislature; explains the federal approval process for state legislative modification of the organ allocation process; and provides information related to technical policy issues.

A glossary of technical terminology, additional resources, and references are provided as appendixes to the publication. Data contained in the publication are based on OPTN data available as of March 12, 2004, unless otherwise noted.

Overview

The primary function of the kidneys is to remove waste from the body through the production of urine. Kidneys also help regulate blood pressure and volume and maintain the chemical composition or electrolyte balance of the blood. All the blood in a person's body passes through the kidneys almost 20 times every hour.

Kidney (or renal) failure occurs when the kidneys are no longer able to remove waste and maintain the electrolyte balance of the blood. Acute renal failure is characterized by the sudden inability of the kidneys to excrete waste, concentrate urine, and conserve electrolytes. Acute renal failure is often associated with trauma, burns, acute infection, or obstruction of the urinary tract. Chronic renal failure is the progressive loss of kidney function and is characterized by the kidneys compensating for the damage by hyperfiltration or excessive straining of the blood. End-stage renal disease is a complete or near-complete failure of the kidneys to function and usually occurs when chronic renal failure progresses to the point where kidney function is less than 10 percent of the normal function. Dialysis and kidney transplantation are the only treatments for end-stage renal disease.

As of February 27, 2004, there were 83,529 patients awaiting an organ transplant in the United States, with almost 5,500 in Texas. The vast majority of those patients—68 percent (56,864) nationwide and almost 70 percent (3,784) of those in Texas—are awaiting kidney transplants.

While advances in medical technology have increased patient and graft survival significantly, the demand for organs far exceeds the supply. In 2003, 991 patients received kidney transplants in Texas, but additions to the waiting list for kidneys in Texas have increased by at least 10 percent each year since 1997—reaching a high of 15.5 percent (1,844 candidates) in 2002. This critical and growing need for organs is evidenced most obviously by the fact that last year 5,419 patients died in the United States while awaiting an organ for transplant.

Meeting the demand for kidneys with such a limited supply of organs is fundamental to the technical and policy decisions facing the transplant community. As a result, health care officials and legislators have devoted considerable attention to promoting organ donation programs and improving the allocation process. These policy decisions are nuanced by the need to allocate organs fairly but effectively.

Much of the technical policy governing organ donation, procurement, and allocation in the United States is established by the federal government in collaboration with the national OPTN, a private, nonprofit organization composed of hospitals that perform transplants, organ procurement organizations (OPOs), independent histocompatibility laboratories, and certain medical, scientific, and professional organizations; voluntary health and patient advocacy organizations; and members of the general public, including patients awaiting transplantation and donors. The following is a brief explanation of the history, organization, and function of the OPTN, legislative and regulatory changes that have affected the network's operation and organ allocation policy, and current kidney allocation policy guidelines and the organ allocation process in Texas.

The Organ Procurement and Transplantation Network

The National Organ Transplant Act (NOTA) of 1984 governs the allocation of organs for transplantation in the United States. The act established the national OPTN. In 1986, DHHS solicited contract proposals for the operation of the OPTN. The initial contract was awarded to UNOS, which has administered the OPTN under contract with the Health Resources and Services Administration of DHHS since September 30, 1986.

The OPTN facilitates the organ matching and placement process; develops procedures for organ recovery, distribution, and transportation; and maintains the nation's 24-hour organ transplant waiting list and related databases. UNOS develops, monitors, and enforces policies and guidelines that govern the organ procurement and distribution process, including minimum procurement standards for OPOs and the patient waiting list and acceptance criteria. The policies are a result of collaborative development that includes a federally required public comment process, input from the transplant community, and approval by the UNOS board of directors.

The secretary of DHHS has oversight of the OPTN and final authority for the network's policies and procedures. Perhaps the most important statutory responsibility of the secretary is to ensure that the OPTN distributes organs "equitably." However, the secretary is also charged with acting on "critical comments" that relate to how the OPTN carries out the network's duties. This means responsibility for the system evolving on par with improvements in technology and medical science and changes in the various demographics served by the OPTN. The secretary issues regulations as necessary to address these ongoing challenges to the effective and efficient operation of the OPTN.

Congress has made a number of significant amendments to NOTA that have been responsible for shaping the OPTN into a national organ-sharing system focused on fair and equitable allocation of organs. In 1986, it passed the Omnibus Budget and Reconciliation Act, which added as a condition for participation in Medicare and Medicaid a requirement that hospitals that perform transplants be members of and abide by the policies, rules, and requirements of the OPTN. The same was required of OPOs in order to be eligible for reimbursement of organ procurement costs under Medicare and Medicaid. This effectively requires participation in the OPTN by those institutions and immediately expanded the compass of the network.

Responding to these and other congressional amendments directing change to the scope of operation for the OPTN, the secretary of DHHS has issued several rules relating to federal oversight of the processes by which the OPTN allocates organs, such as medical criteria for patient listing, medical urgency listing ("status" definitions), and organ allocation policies. Effective March 16, 2000, DHHS adopted a final rule governing several aspects of the operation of the OPTN. The stated purpose of the rule was to improve allocation of organs for transplantation by establishing certain performance goals to be achieved by the OPTN.

Congressional and regulatory requirements are administered by UNOS in the form of policy guidelines issued to OPTN members. UNOS has developed separate organ allocation policies for each type of organ, including kidney and kidney/pancreas allocation. Kidney allocation in Texas is conducted according to these guidelines.

The Organ Allocation Process in Texas

When a kidney is donated, a complex organ-matching process involving one of the most sophisticated databases in the world is initiated. The procuring organization accesses a central computer operated by UNOS, enters information about the donated organ, runs a matching program, and, based on the results, coordinates the appropriate procuring and transplanting surgical teams. The organ matching program generates a list of potential transplant candidates ranked according to a point system based on medical and other criteria. This system awards points according to the current allocation policy algorithm and includes criteria such as blood type, histocompatibility antigen (human leukocyte antigen—HLA) tissue match, the time the patient has spent on the waiting list, panel reactive antibody (PRA) level, the medical urgency of the patient, whether the patient is under 11 years of age, and whether the patient has donated a vital organ in the past. (See "Technical Policy Issues" for further explanation of blood type matching, HLA matching, and PRA.)

Except for mandatory-share kidneys, donated organs are first offered to patients in the area in which they were donated before being offered to patients in other parts of the country. A mandatory-share kidney is a perfectly matched donor kidney that is mandated by law to be shared with a matching patient. If a kidney donated to an OPO in Texas perfectly matches a patient on the OPTN waiting list who lives in Florida, the organ is offered to that patient first. If the patient accepts the organ and the organ is exported from the Texas OPO, a credit is awarded to the exporting OPO and a debt is imposed on the receiving OPO. The OPTN maintains a national accounting system known as a payback list. If a donor kidney is not a mandatory-share organ, it is first offered to the payback list to erase any debts. If no debt is owed, the kidney is then offered to the highest ranked patient on the local waiting list (maintained by either the alternative local unit or the OPO), then to patients in the entire service area of the OPO, and finally to patients in the entire UNOS region. The United States is divided into 11 UNOS regions. Texas and Oklahoma constitute Region 4.

There are 59 organ procurement organizations nationwide. While most states have only one OPO, Texas has three: LifeGift Organ Donation Center (Houston, Fort Worth, Lubbock, Amarillo); Southwest Transplant Alliance (Dallas, El Paso, Corpus Christi, Galveston, Beaumont, Temple/Tyler); and Texas Organ Sharing Alliance (Austin, San Antonio, Waco, San Angelo, Laredo, Rio Grande Valley). The Southwest Transplant Alliance and LifeGift Organ Donation Center are each subdivided into a number of federally approved alternate local units (ALUs)—smaller, distinct geographic areas for patient listing and organ procurement and distribution. The Texas Organ Sharing Alliance operates with a single waiting list that serves all patients in the federally designated area for the entire organization.

Organ procurement organizations are required to be certified by the Centers for Medicaid and Medicare Services (CMS), formerly the Health Care Financing Administration. In addition to being a member of and abiding by the rules of the OPTN, an OPO must meet specific standards set by DHHS to remain certified by CMS and receive reimbursement from Medicare and Medicaid.

Texas Legislative History and State Programs

The Texas Kidney Health Care Act (Chapter 42, Health and Safety Code) was passed by the 63rd Legislature to establish a comprehensive program "to direct the use of resources and to coordinate the efforts of the state" relating to the prevention and treatment of chronic kidney disease or end-stage renal disease (ESRD). The act established the Bureau of Kidney Health Care in the Texas Department of Health. The bureau provides payment for certain ESRD-related medical services, including dialysis, travel for dialysis and transplant procedures, and payment for certain drug therapy through the Medicaid Vendor Drug Program. To qualify for benefits, a prospective patient must be receiving regular chronic renal dialysis treatments or be a candidate for a kidney transplant and must meet certain other eligibility requirements, including Texas residency. The types of benefits available to each patient depend on the patient's treatment status and eligibility for benefits from other programs such as CMS programs or private insurance.

The 76th Legislature passed two major pieces of legislation affecting kidney transplantation. Senate Bill 673 established the Anatomical Gift Education Program (Chapter 692, Health and Safety Code), which is designed to educate Texas residents about anatomical gifts, organs and tissues that can be used for transplantation. The program is partly funded through a voluntary \$1 additional fee for the issuance or renewal of a driver's license or identification card by the Texas Department of Public Safety. According to the comptroller's office, the voluntary driver's license fee for anatomical gift education generated \$0 in state fiscal year (SFY) 1999, \$1 in SFY2000, \$1,726 in SFY2001, \$162,450.75 in SFY2002, and \$336,566 in SFY2003.¹ The Bureau of Kidney Health Care and the Anatomical Gift Education Program are the two major state programs related to kidney health.

The other major piece of legislation passed by the 76th Legislature was Senate Bill 862, which required the Texas Department of Health to establish a public multidisciplinary task force on organ allocation. The task force was directed to examine the technical and policy issues surrounding the organ allocation policy in Texas and to develop and implement an optimum organ allocation policy for Texas. The Senate Bill 862 task force submitted its report to the governor and the 77th Legislature in December 2000. The report assessed policy issues related to the organ allocation system, including federal guidelines, patient survival rates, transportation issues, and medical urgency.

The task force made two recommendations specific to kidney allocation. First, the task force proposed changing the geographic areas of allocation, independent of the federally designated OPO service areas, to establish new organ allocation areas. Second, the task force unanimously suggested creating two pools of patients—one consisting of patients who had been on the waiting list for longer than three years and the other of patients with a PRA of greater than 19 percent (see "Technical Policy Issues" below for further explanation of PRA). The task force also made several recommendations for legislative and regulatory action, including (1) the creation of a presumed consent law; (2) general revenue funding to authorize the payment of certain funeral expenses of an organ donor; (3) a 30-day paid leave of absence for state employees who donate organs; (4) mandatory donor education in medical and nursing schools and a required advanced course in donor education to complete a residency in neurology or neurosurgery; and (5) the integration of organ donation education with information provided by hospitals and legal professionals to individuals considering living wills, advanced directives, and other end-of-life decisions.

During the 77th Legislature, three bills were filed relating to organ donation. Two of the bills were directly related to the recommendations of the Senate Bill 862 task force. Senate Bill 363 related to a leave of absence for state employees donating an organ or bone marrow. Senate Bill 1477 related to a number of the task force's recommendations. Neither Senate Bill 363 nor Senate Bill 1477 passed the legislature in 2001. The third bill, Senate Bill 154, became effective May 18, 2001. The act required the commissioner of education to provide certain information relating to anatomical gifts in the curriculum of each driver education and driving safety course.

The 78th Legislature saw significant legislative activity relating to organ donation and allocation. Eight bills relevant to kidney transplantation were filed, with four of these bills becoming law: House Bill 89, Senate Bill 160, Senate Bill 1225, and Senate Bill 1226. Three of the bills related to the recommendations of the Senate Bill 862 task force and corresponded with legislation previously filed during the 77th Legislature. House Bill 89 related to paid leave of absence for state employees who serve as organ donors, and Senate Bill 160 related to the education of health care providers and attorneys about anatomical gifts and the information provided by attorneys to clients seeking legal advice for end-of-life decisions. Senate Bill 1226 related to the formation of a statewide kidney-sharing pool. (See "Federal Approval of State Legislative Action" for more on Senate Bill 1226.)

Senate Bill 1225 related to the removal of an organ or tissue from a decedent who died under circumstances requiring an inquest. Under previous law, if a designated organ donor or a person whose family has given consent for donation died and an inquest into the person's death was required, a medical examiner was the only person with the authority to permit the removal of organs or tissue from the decedent. Senate Bill 1225 authorized a justice of the peace, a county judge, or a licensed physician designated by a justice of the peace or county judge to permit the same action. In addition, if the medical examiner, justice of the peace, county judge, or designated physician denies the removal of the organ, the bill required that person to provide an explanation of the decision to the qualified OPO and to the person who consented to the donation.

Of the bills introduced during the 78th Legislature that did not pass, House Bill 2111 is noteworthy and relates to the recommendation of the Senate Bill 862 task force regarding presumed consent. The bill provided that a person 18 years of age or older would be presumed an organ donor on death. This concept shifts responsibility for action from those who wish to donate organs to those who wish *not* to donate organs and is based on the premise that a majority of the population supports organ donation. The presumed consent paradigm has been in effect in certain European countries for over a decade.

Federal Approval of State Legislative Action

As explained above, the federal government, through the DHHS and UNOS, has oversight of the organ distribution and allocation policy in the United States. There are three types of modifications that can be proposed to a region's organ distribution or allocation systems:

- An alternate point system, also known as a variance, alters the system by which patients are assigned points for criteria such as blood type, HLA match, and PRA levels, among others.
- A sharing arrangement is an arrangement between two or more OPOs to share organs. Essentially, a sharing arrangement requires the participating OPOs to operate from a single, shared waiting list.
- Alternative local units (ALUs) are usually subdivisions of an OPO that function as distinct areas for organ procurement and distribution. Multiple OPOs, entire states, UNOS regions, or other geographic areas can also qualify as an ALU.

(Note: Certain modifications of organ distribution and allocation procedure may qualify under more than one of these categories; for instance, there may be an ALU that is also considered a sharing arrangement.)

A UNOS member—an OPO or transplant center—must submit an application to UNOS for approval of any plan to modify the organ distribution or allocation procedure in the member's service area through a variance, sharing arrangement, or ALU. The UNOS approval process requires that the application for modification be considered by the appropriate UNOS region before being reviewed by the applicable UNOS organ-specific committees and the UNOS board of directors. Certain criteria must be met by the proposed modification, and all alternate point assignments (variances), sharing arrangements, and ALUs must be programmed into the UNOS computer before implementation.

Senate Bill 1226 (Chapter 926, Acts of the 78th Legislature, Regular Session, 2003) became effective June 20, 2003, and is a clear modification to the kidney allocation procedure in Texas. The bill added Subchapter R, Chapter 161, Health and Safety Code, Allocation of Kidneys Available for Transplant, to form a statewide kidney-sharing pool to be made up of 20 percent of the kidneys from deceased donors of each blood type. Kidneys in the pool are to be used for redistribution to patients who have been waiting the longest for transplantation. Patients with low panel reactive antibodies and who, in terms of accumulated waiting time, constitute the top 20 percent of all patients waiting for transplantation are eligible for the pool. As one of those patients receives a transplant, the patient's place in the pool is to be taken by the next longest waiting patient.

The requirements of the UNOS approval process complicate the effective implementation of state legislative acts that modify organ allocation policy. If a state's law requires a change in allocation policy by the OPOs and transplant centers operating in that state, the affected organizations and institutions must coordinate their efforts and apply for UNOS approval of the appropriate type of policy modification: variance, sharing arrangement, or ALU. Technically, the applicants must secure 75 percent approval for the modification by the affected OPOs and transplant centers. However, this requirement does not prevent certain OPOs or transplant centers from adopting the new policy in an effort to comply with state law.

Responding to the requirements of Senate Bill 1226, two proposals by two different OPOs have been submitted to UNOS Region 4 for consideration. These proposals will likely begin the UNOS committee review process in May 2004.

Technical Policy Issues

With so much of the UNOS guidelines directed by medical science, there are any number of scientific procedures that invariably enter into any discussion related to transplantation and organ allocation policy. There are three such technical issues that are of particular importance to the point system that ranks patients on the waiting list and that affect organ distribution: the HLA system, Panel Reactive Antibody (PRA), and blood typing.

The HLA System

"Histocompatibility" refers to the compatibility between an organ donor and an organ candidate as measured by the number of HLA antigens shared between them. Histocompatibility antigens or HLA (human leukocyte antigens) are proteins on the surface of every cell with a nucleus in the human body.

The body's immune system uses HLA antigens to distinguish between foreign and nonforeign substances, such as bacteria, viruses, and parasites. The immune system can recognize the HLA antigens of other people's cells and build antibodies to the foreign antigens to defend the body against the foreign cells, thus causing the rejection of a transplanted organ or tissue (graft). There are three HLA antigens that seem to be most important for transplantation: HLA-A, HLA-B, and HLA-DR.

Each person inherits a relatively unique set of these three HLA antigens from each parent, for a total of six antigens. Among the criteria used to determine an organ's compatibility with a prospective transplant candidate are the results of two tests performed by a histocompatibility lab. The first test is tissue typing or HLA typing, which determines the HLA type of each potential donor and of each potential organ candidate before the candidate is placed on the OPTN waiting list.

The second test is known as crossmatching and detects antibodies that a potential candidate may have to the antigens in the donor organ. A "positive" crossmatch means antibodies are present and the donor and candidate are incompatible. A "negative" crossmatch means the donor and candidate are compatible. References to a six antigen match or a zero antigen mismatch relate to the three HLA antigens a person has inherited from each parent. A six antigen match or zero antigen mismatch between a donor and potential organ candidate is a "perfect" match.

Human leukocyte antigen typing figures rather prominently into the national point system developed by UNOS for determining a patient's rank on the waiting list, particularly for cadaveric organs. Candidates with no HLA-A, HLA-B, and HLA-DR mismatches are given priority, followed by candidates with the fewest mismatches of the HLA-B and HLA-DR antigens. Increased long-term patient and graft survival rates of transplants using organs with six antigen matches and zero antigen mismatches ("perfect" matches) are documented. The mandatory share policy and highest waiting list priority for candidates who have a "perfect" match organ are based on evidence of this higher survival rate.

There is controversy regarding the use of HLA matching apart from the mandatory share policy, and some organ procurement organizations (such as LifeGift in Texas) do not use HLA matching as a determinant for kidney allocation in their service areas. The racial inequity in kidney transplantation and longer wait times for African American candidates have been attributed to the HLA system. Although African Americans constitute 13 percent of the general

population,² they currently account for almost 37 percent of the waiting list for kidney transplants.³ This disparity creates a smaller pool of potential donor organs from African American donors and means that African American candidates rely on organs from Caucasian donors even though HLA antigens between Caucasian and African American candidates do not match as well.

A recent study published in *The New England Journal of Medicine* concluded that "[r]emoving HLA-B matching as a priority for the allocation of cadaveric kidneys could reduce the existing racial imbalance by increasing the number of transplantations among nonwhites, with only a small increase in the rate of graft loss."⁴

Panel Reactive Antibody (PRA)

Panel reactive antibody (PRA) is basically the measure of a potential organ candidate's sensitization to the antigens of the general population. It specifically relates to the percentage of cells from a panel of blood donors against which a potential candidate will make or has antibodies. Panel reactive antibody is considered a reflection of the percentage of the general population against which a potential candidate's immune system would react negatively by building antibodies to fight the foreign antigens present in the transplanted organ or tissue. Patients with a high PRA are referred to as highly sensitized. The more sensitized a patient is to the general population and, therefore, the donor pool, the more difficult it is to find an organ for transplantation. Sensitization may be the result of antibodies created because of pregnancy, a blood transfusion, or a previous transplant. Highly sensitized patients have the highest priority on the waiting list, but are technically the least likely to find a suitable donor.

Blood Typing

Simply put, except in the case of "perfect" match or mandatory share organs: (1) blood type "O" kidneys must be transplanted only into blood type "O" patients; and (2) blood type "B" kidneys must be transplanted only into blood type "B" patients.

Notes

¹The revenue code for the voluntary driver's license fee for anatomical gift education (Section 521.421(g), Transportation Code) is 3041. The code is found in the Comptroller Manual of Accounts available on-line at <u>http://window.state.tx.us/fm/pubs/cma/04-05/cmav2_2004.pdf</u>. The revenue figures for revenue code 3041 are found in the Texas Annual Cash Reports available on-line at <u>http://window.state.tx.us/comptrol/san/fm_manuals/crtoc.html</u>.

²J. McKinnon, *The Black Population in the United States: March 2002*. U.S. Bureau of the Census, Current Population Reports, Series P20-541 (Washington, D.C., 2003).

³2003 Annual Report of the U.S. Scientific Registry of Transplant Recipients and the Organ Procurement and Transplantation Network: Chapter VI. Kidney and Pancreas Transplantation. Rockville, MD, and Richmond, VA: DHHS/HRSA/OSP/DOT and UNOS.

⁴J. P. Roberts, et al., "Effect of Changing the Priority for HLA Matching on the Rates and Outcomes of Kidney Transplantation in Minority Groups," *New England Journal of Medicine* 350, no. 6 (February 5, 2004): 545-551.

Appendixes

Appendix A: Glossary

Allocation: The system of ensuring that organs are distributed to patients who are in need of a transplant.

Alternative Local Unit (ALU): Normally, the local unit for allocation purposes is the OPO. Alternative local units are usually subdivisions of the OPO that function as distinct geographic areas for organ procurement and allocation. All ALUs must be approved by UNOS.

Antigen: A foreign substance, such as a transplanted organ, that triggers the body to try to destroy it. This response may lead to the production of antibodies, which try to destroy the antigen.

Cadaveric Donor: A person who has been declared "brain dead" and whose family has offered one or more organs to be used for transplantation.

Candidate: A person who is waiting for a transplant.

Crossmatching: A blood test done before the transplant to see if the candidate will react to the donor organ. If the crossmatch is "positive," the donor and candidate are incompatible. If the crossmatch is "negative," the transplant may proceed. Crossmatching is routinely performed for kidney and pancreas transplants.

End-Stage Renal Disease: Also known as chronic kidney failure. A condition in which patients need dialysis treatments or a transplant to perform the lost functioning of the kidneys.

Graft: (Surgery) tissue or organ transplanted from a donor to a recipient.

HLA System: In transplantation, the HLA tissue types of the donor and candidate are sometimes used to help determine whether the transplant will be accepted or rejected. There are three major genetically controlled groups: HLA-A, HLA-B, and HLA-DR. (See Human Leukocyte Antigen.)

Host OPO: The organ procurement organization that identifies potential donor organs, then manages placement of those organs.

Human Leukocyte Antigen (HLA): A molecule found on cells in the body that characterizes each person as unique. These antigens are inherited from biological parents.

Ischemic Time: Also referred to as cold time or cold ischemic time. The time measured from the point at which blood flow to the organ is stopped in the donor to the time the blood flow to the organ is restored to the recipient.

Match: The compatibility between the donor and the candidate. The more closely they are matched, the greater the chance the transplant will be successful.

National Organ Transplant Act (NOTA): Passed by congress in 1984, established a national system for organ sharing and a scientific registry to collect and report transplant data.

Organ Procurement Organization (OPO): An organization accepted as a member of UNOS and authorized by the Centers for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration, to procure organs for transplantation.

OPO Local Area: Each OPO provides its services to the transplant programs in its federally designated area. An OPO's local service area can include a portion of a city, a portion of a state, or an entire state. When a donated organ becomes available, the list of candidates is generated from the OPO's local service area, with certain exceptions. If a patient match is not made in that local area, regional and national candidates are considered according to their rank on the list.

Organ Procurement and Transplantation Network (OPTN): A private, nonprofit organization composed of hospitals that perform transplants, OPOs, independent histocompatibility laboratories, and certain medical, scientific, and professional organizations. The OPTN is administered under contract with the federal government by UNOS. Its purpose is to maintain the national computerized list of candidates waiting for organ transplants.

Panel Reactive Antibody (PRA): The percentage of cells from a panel of donors with which a potential candidate's serum reacts. The more antibodies in the candidate's blood, the more likely the candidate will react against the potential donor organ. The higher the PRA, the lower the chance of the candidate's receiving an organ that will not be rejected. For example, a patient with a PRA of 80 percent will reject 80 percent of donor kidneys. Patients with a high PRA, also referred to as "highly sensitized," have priority on the waiting list but are less likely to find a suitable organ for transplant.

Payback List: In the U.S. organ transplantation system, organs are allocated locally, regionally, and nationally under different circumstances. If a donated organ is a perfect (six antigen) match for a patient, the organ must be offered to that patient first, even if that patient resides outside the service area of the procuring OPO. If the organ is exported outside the service area of the procuring OPO. If the exporting OPO and a debit is assigned to the importing OPO. The OPTN maintains a national accounting of these exchanges in the form of a "payback list" that must be consulted at the time an OPO procures an organ for transplant.

Renal: Having to do with, or referring to, the kidneys.

Required Referral/Required Request: Legislation requiring hospitals to notify their OPO of all imminent deaths and to consult with a patient's next of kin to request organ donation if the patient is at or near brain death.

Sensitized: When a potential candidate's blood has antibodies. Sensitization is measured by panel reactive antibodies (PRA). Highly sensitized patients are less likely to match with a suitable donor and are more likely to reject an organ than nonsensitized patients.

Sharing Arrangement: When two or more OPOs have a common waiting list or common candidates for a given organ.

Six Antigen Match: A perfect match between a donor and candidate; the donor and candidate share all six HLA-A, HLA-B, and HLA-DR antigens.

Status: The indicated degree of medical urgency for patients awaiting an organ transplant.

Survival Rates: The indication of what percentage of patients are alive or grafts (organs transplanted) are still functioning after a certain period.

Tissue Typing: A blood test performed before a transplant to evaluate how closely the tissues of the donor match those of the candidate. Tissue typing is performed on all donors and candidates in kidney transplants to help match the donor to the most suitable candidate.

United Network for Organ Sharing (UNOS): The organization operating under federal contract to administer the OPTN and responsible for maintaining the national transplant waiting list.

Variance: An organ allocation methodology for any organ that is different from the standard UNOS national algorithm that determines the point system used to match donated organs with transplant candidates.

Vascular (Vascularized) Organ: A heart, lung, liver, pancreas, kidney, intestine, or other organ that requires the continuous circulation of blood to remain useful for purposes of transplantation.

Waiting List: After evaluation by a transplant surgeon, a patient is added by the transplant center to the national waiting list. Lists are specific to geographic area and organ type: heart, lung, kidney, liver, pancreas, intestine, heart-lung, and kidney-pancreas. Each time a donor organ becomes available, the UNOS computer generates a list of potential candidates based on factors that include genetic similarity, blood type, organ size, medical urgency, and time on the waiting list. Through this process, a "new" list is generated each time an organ becomes available that best "matches" a patient to a donated organ.

Zero Antigen Mismatch: A perfect match between the kidney candidate and kidney donor. There are no antigens the donor has that the candidate does not share.

Source: Definitions adapted from *Transplant Living*. (Richmond, VA: United Network for Organ Sharing, 1999). Available at <u>http://www.transplantliving.org/Community/glossary.aspx</u>. Copyright 1995-2000. United Network for Organ Sharing.

Appendix B: Texas Transplant Centers

- Baylor All Saints Medical Center at Fort Worth
- Baylor University Medical Center, Dallas
- Brackenridge Hospital, Austin
- Children's Medical Center of Dallas
- CHRISTUS Santa Rosa Medical Center Hospital, San Antonio
- Cook Children's Medical Center, Fort Worth
- Covenant Medical Center, Lubbock
- East Texas Medical Center, Tyler
- Harris Methodist Fort Worth Hospital
- Memorial Hermann Hospital, University of Texas at Houston
- Methodist Children's Hospital of South Texas, San Antonio
- Methodist Dallas Medical Center
- Methodist Hospital, Baylor College of Medicine, Houston
- Methodist Specialty and Transplant Hospital, San Antonio
- North Austin Medical Center
- Parkland Memorial Hospital, Dallas
- St. Luke's Episcopal Hospital, Houston
- Scott and White Memorial Hospital, Temple
- Sierra Medical Center, El Paso
- Texas Children's Hospital, Houston
- Transplant Center at Medical City Dallas Hospital
- University Hospital, University of Texas Health Science Center at San Antonio
- University Medical Center, Lubbock
- University of Texas Medical Branch at Galveston

Appendix C: Federal Legislative History

- National Organ Transplant Act (Pub. L. No. 98-507)
- Omnibus Budget Reconciliation Act of 1986 (Pub. L. No. 99-509)
- Balanced Budget and Emergency Deficit Control Reaffirmation Act of 1987 (Pub. L. No. 100-119)
- Omnibus Budget Reconciliation Act of 1987 (Pub. L. No. 100-203)
- Organ Transplant Amendments Act of 1988 (Title IV of Pub. L. No. 100-607)

Appendix D: On-line Resources

http://www.optn.org

The website for the Organ Procurement and Transplantation Network.

The OPTN website also features data reports that can be custom built to display data relating to organ donation and matching, the national waiting list, and transplantation occurring throughout the nation's organ transplant network, including state-by-state comparisons. These reports can be refined to include data specific to organ donors, waiting list candidates, and transplantation survival rates. The reports can be found at: www.optn.org/latestData/viewDataReports.asp

http://www.unos.org

The website for the United Network for Organ Sharing.

http://www.ustransplant.org

The website for the Scientific Registry of Transplant Recipients.

http://transplantliving.org

The website for the UNOS project offering information about transplantation to the general public.

http://www.lifegift.org

The website for LifeGift, the organ procurement organization that services portions of southeast, north, and west Texas, including Houston, Fort Worth, Lubbock, and Amarillo.

http://www.txorgansharing.org

The website for the Texas Organ Sharing Alliance, the organ procurement organization that services portions of south and central Texas, including Austin, San Antonio, Waco, San Angelo, Laredo, and the Rio Grande Valley.

http://www.organ.org

The website for the Southwest Transplant Alliance, the organ procurement organization that services portions of north, west, and east Texas, including Dallas, El Paso, Beaumont, and Temple/Tyler, and portions of the gulf coast, including Corpus Christi and Galveston.

http://www.tdh.state.tx.us/kidney/about.htm

The website for the Bureau of Kidney Health Care in the Texas Department of Health.

Appendix E: References

Alexander, G. C., and A. R. Sehgal. "Barriers to Cadaveric Renal Transplantation Among Blacks, Women, and the Poor." *Journal of the American Medical Association* 280 (1998): 1148-1152.

American Hospital Association, American Medical Association, and United Network for Organ Sharing. *Required Request Legislation: A Guide for Hospitals on Organ and Tissue Donation*. (Richmond, VA: UNOS, 1988).

Committee on Organ Procurement and Transplantation Policy, Division of Health Sciences Policy, Institute of Medicine. *Organ Procurement and Transplantation: Assessing Current Policies and the Potential Impact of the DHHS Final Rule*. (Washington, D.C.: National Academy Press, 1999).

DHHS (United States Department of Health and Human Services). "HHS Rule Calls for Organ Allocation Based on Medical Criteria, Not Geography: Calls on Private Transplant Network to Develop Policies." *HHS News* (March 26, 1998). Available at <u>http://www.DHHS.gov/news/press/1998pres/980326a.html</u>.

DHHS. "Organ Procurement and Transplantation Network; Final Rule" (42 C.F.R. Part 121). *Federal Register* 63, no. 63 (1998): 16296-16338.

DHHS, Office of Inspector General. *Racial and Geographic Disparity in the Distribution of Organs for Transplantation*. (Washington, D.C.: DHHS, 1998).

DHHS/HRSA/HCFA (CMS). *Roles and Training in the Donation Process: A Resource Guide*. (Rockville, MD: The Lewin Group, 2000).

Eggers, P. W. "Racial Differences in Access to Kidney Transplantation." *Health Care Financing Review* 17 (Winter 1995): 89-103.

Ehrle, R. N., T. J. Shafer, and K. R. Nelson. "Determination and Referral of Potential Organ Donors and Consent for Organ Donation: Best Practice—A Blueprint for Success." *Critical Care Nurse* 19, no. 2 (April 1999): 21-33.

Evans, R. W. "The Socioeconomics of Organ Transplantation." *Transplantation Proceedings* 17, no. 6 (1985): 129-136.

First, M. R. "Cadaveric Organ Procurement—An Overview of Two Aspects: Donor Hospital Networks and Minority Donation." *Transplantation Proceedings* 29 (1997): 70-72.

First, M. R. "Controversies in Organ Donation: Minority Donation and Living Unrelated Donors." *Transplantation Proceedings* 29 (1997): 67-69.

GAO (United States General Accounting Office). Report to the ranking minority member, Committee on Labor and Human Resources, U.S. Senate. *Organ Procurement Organizations: Alternatives Being Developed to More Accurately Assess Performance*. GAO/HEHS-98-26 (Washington, D.C.: GAO, 1997).

Gaylin, D. S., et al. "The Impact of Comorbid and Sociodemographic Factors on Access to Renal Transplantation." *Journal of the American Medical Association* 269, no. 5 (1993): 603-608.

Held, P. J., et al. "The Impact of HLA Mismatches on the Survival of First Cadaveric Kidney Transplants." *New England Journal of Medicine* 331, no. 12 (Sept. 22, 1994): 765-770.

Kallich, J. D., T. Wyant, and M. Krushat. "The Effect of DR Antigens, Race, Sex, and Peak PRA on Estimated Median Waiting Time for a First Cadaver Kidney Transplant." *Clinical Transplantations* (1990): 311-318.

Offermann, G. "What Is a Reasonably Short Ischemia Time in Kidney Transplantation?" *Transplantation Proceedings* 30, no. 8 (1998): 4291-4293.

Pita, S., et al. "The Role of Cold Ischemia on Graft Survival in Recipients of Renal Transplants." *Transplantation Proceedings* 29, no. 8 (1997): 3596-3597.

Siminoff, L. A., R. M. Arnold, A. L. Caplan, B. A. Virnig, and D. L. Seltzer. "Public Policy Governing Organ and Tissue Procurement in the United States." *Annals of Internal Medicine* 123, no. 1 (1995) 10-17.

Ubel, P. A., C. L. Bryce, L. A. Siminoff, A. L. Caplan, and R. M. Arnold. "Pennsylvania's Voluntary Benefits Program: Evaluating an Innovative Proposal for Increasing Organ Donation." *Health Affairs* 19, no. 5 (2000): 206-211.

Washburn, W. K., D. Shaffer, P. Conway, P. N. Madras, and A. P. Monaco. "A Single-Center Experience with Six-Antigen-Matched Kidney Transplants." *Journal of the American Medical Association* 330, no. 3 (1995): 277.