

Organ Procurement and Transplantation Oversight: Who is looking out for patients?

**August 15, 2006, 1:30 – 4:30 p.m.
State Capitol, Room 4202**

Purpose

This hearing will examine organ procurement and transplantation oversight. In the past several years, there have been growing problems with hospital transplant programs in California. These problems include shortages of medical and administrative staff, a shortage in the availability of organs, low transplantation volumes, lapses in leadership and oversight, ethical breaches resulting in improper transplants, and poor patient survival rates. Recent relevant newspaper articles are summarized below. The hearing has been organized to answer the following questions: What organizations are involved and how does the process work? Which government agencies are responsible for oversight of organ transplant centers? How are these centers managed? Are the problems unique to California? What are the causes of the problems? What are the medical and ethical issues associated with organ procurement and transplantation? Is there a need for stronger state regulation, monitoring and enforcement?

Recent Press Articles

- **July 2006:** The Los Angeles Times (LA Times) reported that the liver program at **University of Southern California (USC) University Hospital** (owned by Tenet Healthcare Corporation and managed by USC School of Medicine) in Los Angeles has one of the highest death rates in the nation, with twice as many patients as expected dying after their surgeries. The survival rate at USC's liver center, the third-largest program in the state, has steadily dropped since 2002, and hit a low of 75.8%. USC performed three times as many liver transplants in 2005 as St. Vincent Medical Center and the University of California, Irvine (UCI) combined in the recent years. According to Dr. Rick Selby, the program director, USC's numbers suffered because of a higher number of extremely ill patients who also suffered from kidney failure. However, the article indicates that Loma Linda University Medical Center's program treats a much higher proportion of very sick patients than USC and had a survival rate of 98%.
- **June 2006:** The LA Times reported that 20% of the 236 transplant centers across the nation failed to meet minimum standards for patient survival or performed too few operations to ensure competency. When these programs fall short of meeting Medicare guidelines, Medicare rules mandate no sanction, but require that the programs turn themselves in. The

- federal Centers for Medicare and Medicaid Services (CMS) has the authority to pull certification for funding from these centers but rarely does.
- June 2006: The LA Times also reported that geographic inequity is inherent in the U.S. transplant system. The U.S. is divided into 58 territories, each with its own supply of organs and separate waiting list. California is divided into four territories, each managed by an Organ Procurement Organization (OPO). To protect local access to organs, most donated within a territory go to patients waiting there, even if sicker patients are waiting elsewhere. This design has led to significant disparities, because supply and demand are not evenly spread across the country or the state. In large metropolitan areas, disease rates are higher which increase the need for organs, but donor recruitment is difficult. At the same time, transplant centers in less crowded territories are often choosier about who is placed on their waiting list. In California, waiting times for organs vary significantly between small geographic distances depending on what OPO waiting list the patient is on. The article also reports that it is feasible to have another system in which organs are regularly moved across territory lines to the sickest patients, given advances in transportation technology. For instance, when stored in ice-cold preservation solution, livers suffer no significant damage in the first 12 hours after harvesting. However, current legislation and regulation does not force organ-rich territories to share and, as a result, “the system has evolved into a collection of self-interested fiefdoms.” For example, the longest lines for livers nationally are in the territories surrounding New York, Los Angeles and San Francisco, which together account for 30% of all patients waiting for livers nationwide. The article stated that fewer than 2% of patients are savvy or wealthy enough to leave town and join waiting lists in other territories.
- May 2006: The LA Times reported that **Kaiser Permanente Northern California** "endangered patients" awaiting kidney transplants by "forcing them into a fledgling program unprepared to handle the caseload." During its first full year of operation in 2005, Kaiser performed 56 transplants, but twice that many people on the waiting list died. The LA Times article also stated that in 2004 Kaiser told more than 1,500 patients on the kidney transplant waiting list in northern California that it would no longer pay for treatment at contracting hospitals outside of Kaiser. Other problems cited were paperwork errors, doctors and administrators providing misleading and inaccurate information, poor notification to patients, and delays and problems associated with the transfers. The LA Times reported in a follow-up article in August 2006 that **Kaiser Permanente** is in the process of closing their kidney transplant center, but transfer of patients from Kaiser to University of California, Davis (UC Davis) and University of California, San Francisco (UCSF) will not be completed until the end of 2006.
- December 2005: The LA Times reported that **St. Vincent Medical Center** had a "higher-than-expected" mortality rate between January 2002 and June 2004 among patients in its kidney transplant program, prompting insurers (Aetna and Humana) to stop sending kidney transplant patients to the hospital. According to the LA Times, 36 patients died within one year of surgery during that period – 15 more than would normally have been expected. Data reported by the Scientific Registry of Transplant Recipients (SRTR), the federal contractor with responsibility to track and report organ procurement and transplant data, also indicated that 25% of the kidneys accepted for transplant in 2004 at St. Vincent were of marginal quality and had been refused by other transplant programs.
- November 2005: The LA Times reported that 32 patients at **UCI Medical Center** died awaiting liver transplants after the hospital turned down viable organs due to staffing

shortages. The transplant program closed and later was found to have had inadequate staff training, poor monitoring of transplant patients, and irregular reviews of patient care. In addition the center had a 69% rate of patient survival compared to the Medicare guidelines which require a minimum survival rate of 77% for payment.

- September 2005: The LA Times reported that the Medical Board of California launched an investigation of the liver transplant program directors at **St. Vincent Medical Center** in Los Angeles after reports that a patient (a Saudi national) who was 52nd on a regional transplant waiting list received a misappropriated liver ahead of other patients who were much higher on the waiting list. The Royal Embassy of Saudi Arabia paid St. Vincent \$339,000 for the transplant and hospital stay, which is about 25 to 30% more than what insurance or U.S. government programs would have paid. St. Vincent's staff was found to have falsified documents concealing the improper transplant. According to SRTR data, St. Vincent allocated about 8% of its donated livers to foreign nationals since the program was created in 1995, higher than the 5% guideline set by the United Network for Organ Sharing (UNOS), the federal contractor which administers the nation's Organ Procurement and Transplantation Network (OPTN). While the article points out that 8% of *livers* were allocated to foreign nationals, St. Vincent indicates that it has allocated fewer than 5% of *all* organs received to foreign nationals. UNOS policies do not specify punishments for exceeding its guidelines.
- March 2005: The Sacramento Bee reported that health insurers began declining to cover heart transplants at **Sutter Memorial Hospital** because of low program volumes. Insurers terminate small transplant programs based on the hypothesis that "the more [procedures] you do, the better you do it, so they [insurers] use a minimum volume requirement and an outcome requirement." In a follow-up story, the LA Times reported in November 2005 that the California Department of Health Services (DHS) had revoked Sutter Memorial's certification to perform heart transplants.
- May 2003: The San Francisco Chronicle reported that the **California Pacific Medical Center** halted its heart transplant program due to a shortage of surgeons, requiring over 30 patients on the facility's transplant list to seek transplants elsewhere.

Organ Transplant Statistics

According to the official U.S. Government web site for organ and tissue donation and transplantation, www.organdonor.gov, on average 74 patients receive organ transplants daily in the U.S. However, 18 patients die each day waiting for transplants. In 2005, a total of 28,107 transplants were conducted in the U.S., of which 3,243, or 11.5%, were done in California. Although the number of surgeries has grown steadily since 1988, a total of 92,544 patients across the nation are still waiting for organs as of August 9, 2006. Of these patients on the national list, roughly 21% or 19,411 patients are from California.

National Administration of the Organ Procurement & Transplantation Process

The national system grew out of federal legislation in 1984 to regulate what had become a free-for-all competition among kidney surgeons. The legislation sought to increase donations, prevent organ trafficking, and distribute organs "equitably among transplant recipients according to established medical criteria." In turn, the legislation has spurred the creation and adoption of a number of detailed processes and policies governing the national system, including the National Organ Transplant Act (NOTA) of 1984 and the OPTN Final Rule, which was last amended in 1999 and codified in 42 Code of Federal Regulations (CFR) Part 121. These

policies are developed in a public-private partnership with input from organ transplant and procurement professionals, in conjunction UNOS and the OPTN Board of Directors.

OPTN. In accordance with NOTA, the purpose of the OPTN Final Rule was to help achieve the most equitable and medically effective use of human organs donated for transplantation. Toward this end, the Final Rule establishes performance goals intended to bring about:

- 1) Standardized criteria for placing patients on transplant waiting lists;
- 2) Standardized criteria for defining a patient's medical status; and,
- 3) Allocation policies that make the most effective use of organs, especially by making them available whenever feasible to the most medically urgent patients who are appropriate candidates for transplantation.

The OPTN links donation and transplantation system professionals and member organizations participate in the decision-making process through representation on committees and on the Board of Directors. Both HRSA and UNOS have representation on the OPTN Board. Every transplant center, OPO, and histocompatibility laboratory in the U.S. is an OPTN member. As of August 13, 2006, 257 transplant centers, 58 OPOs, 155 histocompatibility laboratories, ten voluntary health organizations, such as the American Diabetes Association, 12 general public members, including ethicists and donor family members, and 24 medical professional/scientific organizations, such as the American Medical Association, have OPTN membership.

HRSA. The Health Resources and Services Administration (HRSA) manages and administers the federal OPTN and SRTR contracts. National transplantation policies are developed by the OPTN Board of Directors for approval by HHS and HRSA. Under regulations that took effect March 16, 2000, HHS made it clear that organ transplantation policies will continue, as before, to be developed by the transplant community under the auspices of the OPTN Board of Directors and UNOS.

According to the OPTN Final Rule, the Secretary of HHS has the sole authority to establish conditions of participation in Medicare and Medicaid. The Final Rule also states that “no OPTN policies are legally binding “rules or requirements” of the OPTN... unless they have been approved by the Secretary.” Furthermore, a 1999 Institute of Medicine (IOM) report cited in the Final Rule commentary made five major recommendations, including that HHS “exercise the legitimate oversight responsibilities assigned to it by NOTA and articulated in the final rule, to manage the system of organ procurement and transplantation in the public interest.”

Finally, Section 1138 of the Social Security Act requires hospitals that perform organ transplants to be members of, and abide by the rules and requirements of, the OPTN as a condition for participation in Medicare and Medicaid for reimbursement for organ transplants. Thus, the oversight role of the Secretary of HHS becomes two-fold, as HHS oversees both HRSA and CMS (CMS oversees Medicare and Medicaid).

UNOS. UNOS surveys transplant centers and OPOs every three years. However, UNOS does not have the authority to terminate a transplant program; rather, their responsibility is to bring a program into compliance. To this end, UNOS employs a peer review process in which an OPTN member found out of compliance with federal guidelines is brought before their “peers” who

serve on the UNOS Membership & Professional Standards Committee (MPSC). The MPSC reviews the qualifications, medical outcomes and professional conduct of OPTN members, and ensures that clinical transplant centers, independent organ procurement agencies, and independent tissue typing laboratories meet and remain in compliance with UNOS Criteria for Institutional Membership.

SRTR. The SRTR contract is administered by the Arbor Research Collaborative for Health with the University of Michigan and supports the ongoing evaluation of the scientific and clinical status of organ transplantation in the U.S. Their responsibilities include designing and carrying out rigorous scientific analyses of data and disseminating information to the transplant community. The U.S. organ transplantation system employs evidence-based allocation policy development through collaborative efforts between the transplant community, the SRTR, and the OPTN.

CMS. CMS oversees data submission, outcome measure and process requirements that transplant centers must meet to participate as Medicare-approved centers. To qualify for Medicare funding, transplant centers must meet the following minimum requirements:

<u>Type</u>	<u>Number of Transplants</u>	<u>Survival Rate</u>
Heart	12	73%
Lung	10	69%
Liver	12	77%

Donor Matching System

Transplant centers, laboratories, and OPOs are all involved in the organ sharing process. A patient in need of an organ must first undergo evaluation at a transplant center. Based on the evaluation and the individual transplant center's criteria for accepting a patient for transplant, the transplant team determines if the person is a good candidate for receiving an organ. Viable candidates are then placed on the center's waiting list in the UNOS database.

Waiting times for organs vary widely and are based on multiple factors, including patient medical status, the availability of donors in the local area and the level of match between the donor and recipient. The variation is based upon many patient-specific factors, including patient health status, blood type, medical urgency, and time on the waiting list. In addition, there are external factors such as type and availability of organs, the number of transplant centers drawing from each OPO, as well as the transplant center's own criteria for accepting organ offers. Organ acceptance policies vary by center and are subject to the determination of the physician/surgeon.

CMS specifies quality measures and data reporting requirements that OPOs must meet to have their services covered by Medicare and Medicaid. The OPO becomes involved when a patient is identified as brain dead and classified as a potential donor. The OPO coordinates the logistics, including obtaining consent, between the organ donor's family, the donated organs, the transplant center(s), and the potential transplant candidate. From the moment of consent for donation to the release of the donor's body to the morgue, all costs associated with the organ donation process are billed directly to the OPO. OPOs receive the vast majority of their funds (75% to 95%)

through payments from transplant centers for organs, as provided for in NOTA and the CMS payment regulations.

Donated organs deemed viable for transplant by an OPO are distributed locally first, and if no match is found, they are offered regionally, then nationally. All patients accepted onto a transplant hospital's waiting list are registered with UNOS, where a centralized network links OPOs and transplant centers and assists with the matching, transporting, and sharing of organs throughout the U.S. When donor organs are identified, the OPO matches the organ with potential patients from the UNOS database. For each organ that becomes available, a list of potential recipients is generated and recipients are ranked according to objective criteria (i.e. blood type, tissue type, size of the organ, medical urgency of the patient, time on the waiting list, and distance between donor and recipient). Each organ has its own specific criteria. Ethnicity, gender, religion, and financial status are not part of the computer matching system. The OPO's procurement coordinator then contacts the transplant surgeon caring for the first patient on the match list to offer the organ. Depending on various factors, such as the donor's medical history and the current health of the potential recipient, the transplant surgeon determines if the organ is suitable for the first patient on the list, given the patient's current health status and specific conditions of the available organ. If the organ is turned down, the next listed individual's transplant center is contacted, and so on, until the organ is placed. When an organ is turned down, the OPO is required to report to UNOS the reason for the refusal given by the transplant center by entering a refusal code into the UNOS database.

Once the organ is accepted for a potential recipient, the OPO makes organ transportation arrangements and the surgery is scheduled. For heart, lung, or liver transplantation, the recipient of the organ is identified prior to the organ recovery and called into the hospital where the transplant will occur to prepare for the surgery.

Accreditation

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accredits general acute care hospitals and other health care organizations. According to JCAHO, since the enactment of the Social Security Act in 1965, hospitals with JCAHO accreditation can be deemed to meet the federal Conditions of Participation for the Medicare and Medicaid programs. JCAHO accredited hospitals are surveyed every three years. However, the hospital accreditation survey process does not specifically look at parameters relating to transplant centers. JCAHO is in the process of creating a certification program specific to transplant centers, to begin in 2007.

State Regulation & Oversight

DHS Licensing and Certification program (L&C) is responsible for licensing and surveying health facilities, including hospitals. L&C performs these functions based upon state and federal law and regulations.

There are very few laws or regulations in place in California specific to organ transplantation procedures. However, Title 22 of California Code of Regulations (Section 70351(b)(9) and Sections 70605 through 70613) requires any hospital licensee desiring to establish a renal transplant center to obtain a special permit from DHS. The regulations outline the responsibility and accountability of the hospital with regard to the program and include a requirement that 15 transplants be performed per annum. Health and Safety Code Section 1277(c) requires DHS to

issue the permit when it finds that the staff and the standards of care are adequate and appropriate, and that the special services unit is operated in the manner required in law and regulation. Certification to receive federal Medicare funds for transplant centers other than kidneys is conducted at the federal level. According to L&C, if it receives a complaint against a hospital-based transplant center, the complaint investigation is either conducted under state/federal hospital regulations and/or it is referred to CMS or the appropriate OPO.

California does have a statutory framework related to a statewide organ and tissue registry, which is operated by a nonprofit coalition of the state's OPOs. The law directs DHS to adopt minimum standards for preservation, transport, storage and handling of tissues, and for testing of donors to determine compatibility. The law requires L&C to audit for the existence of organ and tissue procurement procedures for all inpatient hospital facilities.

In addition, Health and Safety Code 7160 required DHS to consult with the Legislature on or before December 31, 1991, to evaluate and make recommendations to improve the effectiveness of organ transplantation for the general public and in minority communities and low-income communities in California. DHS was unable to provide the Committee with a copy of this report and could not confirm if the report was ever produced. The law requires a number of data elements to be included such as:

- 1) The number of persons waiting for organ transplants;
- 2) The number of available organ donors;
- 3) The number of hospitals performing transplants and type of transplants;
- 4) The percentage of medically insured transplant recipients;
- 5) The percentage of Medi-Cal funded transplant recipients;
- 6) The waiting time for transplantation;
- 7) Factors used to determine eligibility for organ transplantation;
- 8) Referral rates of patients to transplant centers;
- 9) The number of persons accepted by transplant centers;
- 10) The cost of recovery, processing, and distribution of the donated organs;
- 11) The cost of transplantation operations;
- 12) The financial impact of an organ donation upon the donor and the donor's family;
- 13) Survival rates of patients receiving organ transplants; and,
- 14) Hospital compliance with protocols for identifying potential organ and tissue donors.

In the 1980s, the Medi-Cal Advisory Committee on Anatomical Transplants (MACAT) established written standards for Medi-Cal coverage for transplants to ensure federal Medicaid payment for organ transplants. According to DHS, at the time no hospitals in California were proficient or experienced enough in performing liver transplants. Since then, Medi-Cal has convened advisory committees for all other solid organ and bone marrow transplants to develop and maintain criteria for facility and patient selection. According to DHS, some third party health care payers also use Medi-Cal's organ transplant criteria to direct their coverage decisions.

Medi-Cal has a special designation (Medi-Cal Center of Excellence) for organ transplantation. To receive this designation, facilities must demonstrate that they have the professional staff and hospital infrastructure that ensures the greatest success for organ transplantations, which are very expensive procedures. Additionally, a transplant center must demonstrate the performance of a specific number of transplants annually and a high percentage of patients must survive at least

one year following the transplant. For liver transplants, centers must perform at least 18 adult transplants per year (or 12 pediatric transplants) and at least 80% of the patients must survive at least one year. For continuing approval as a Medi-Cal Center of Excellence, facilities are responsible for providing DHS with annual performance and survival data as well as information regarding major staff changes in their transplant programs. DHS staff routinely access and review this information from the OPTN data-base. Medi-Cal was among the first to identify compliance problems with UCI's liver transplant program. L&C was invited to participate in an investigation conducted by CMS almost two years after the Medi-Cal findings but declined to attend because of staffing shortages.

DMHC regulates health care service plans and offers consumer assistance to health plan enrollees. DMHC in general does not provide oversight activity in regards to transplant centers. However, special circumstances have led to DMHC's involvement in kidney transplant cases occurring at Kaiser Permanente's Kidney Transplant Program in Northern California. DMHC recently assessed a \$2 million fine on Kaiser and required an additional \$3 million donation to California's organ and tissue donor registry. DMHC found that Kaiser's lack of administrative and clinical oversight of the kidney transplant center resulted in processing delays of patient transfers on the national transplant waiting list.

To date, no other troubled transplant centers have been fined. However, some have either voluntarily given up or involuntarily lost their UNOS designation. Many of the centers highlighted in press reports have suffered from similar administrative and clinic oversight problems in addition to other ethical and performance issues. A significant difference applicable only to Kaiser is that because it is a health plan and a hospital system it has responsibility for coverage decisions and the provision of transplant services for its members. Because of this uniqueness, Kaiser is regulated by both DHS for hospital services and DMHC for health plan services. The other transplant centers are regulated by DHS as licensed hospitals.

Conclusion

There are a number of federal and state rules and regulations in place for governing the nation's organ procurement and transplantation process. However, even with regulations in place, significant variations between transplant centers exist, such as criteria for accepting patients and organs, waiting times and potential for receiving organs between regions. There is a lack of attention and oversight of individual OPOs and transplantation centers to ensure adherence to the federal and state regulations. In California, there appears to be little state-level oversight of hospital transplantation processes. While payors (such as Medicare and Medi-Cal) appear to be reviewing data in making payment decisions, there is little coordination between DHS Medi-Cal and with DHS L&C. In committee staff interviews conducted with the entities involved in the organ procurement and transplant processes, it has become apparent that there is no central agency responsible for receiving and monitoring complaints from patients in this state. California may wish to look to other states for model programs, such as New York, which has licensing requirements for transplant programs, as well as other requirements for patient selection criteria, uniform organ acceptance criteria and continuous quality assessment and improvement.