POLICY FORUM: PUBLIC HEALTH

# Waiting for Organ Transplantation

**Robert D. Gibbons,* David Meltzer, Naihua Duan, and the other members of the Institute of Medicine Committee on Organ Procurement and Transplantation**

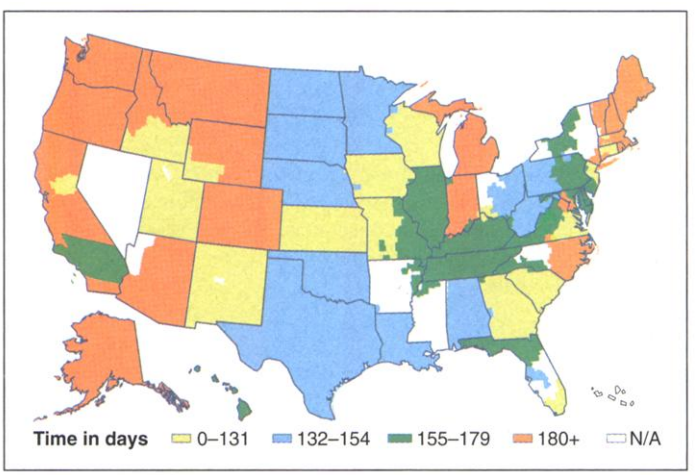
Since the enactment of the National Organ Transplant Act of 1984, the number of people receiving organs has increased annually. In 1998, more than 21,000 Americans were transplanted with a kidney, liver, heart, lung, or other organ. Currently, approximately 62,000 people are waiting for an organ, and a name is added to the national waiting list every 16 minutes (*1*). Moreover, although the number of donors has increased steadily since 1988, donation rates are not growing as quickly as demand (*2*). As a result, approximately 4000 Americans die each year waiting for a solid organ transplant (*1*).

In recent years, a debate has arisen regarding the fairness of the current system of organ procurement and transplantation. This is based on the argument by some that the current system results in great disparities in waiting time across geographic areas within which organs are primarily allocated (*3*) (see the figure, right), and provides minorities and poor patients with less access than whites of higher socioeconomic status.

In response to these concerns, the U.S. Department of Health and Human Services (DHHS) published a regulation termed the "Organ Procurement and Transplantation Network; Final Rule" in April 1998 to "assure that allocation of scarce organs will be based on common medical criteria, not accidents of geography" (*4*). The stated principles underlying the Final Rule include establishing more effective federal oversight, increasing public access to information, implementing consistent medical listing criteria, placing emphasis on medical need, and reducing geographic disparities in waiting times.

Issuance of the Final Rule generated considerable controversy in the transplant community, especially with respect to liver transplants. Concerns were expressed that its implementation would increase costs, force the closure of small transplant centers, adversely affect minority and low-income patient access, discourage organ donation, and result in fewer lives saved.

In October 1998, the U.S. Congress suspended implementation of the Final Rule for 1 year to allow further study of its potential impact. During that time, Congress asked the Institute of Medicine (IOM) to review current Organ Procurement Transplantation Network (OPTN) policies and the potential impact of the Final Rule. The IOM study was completed in July of 1999 (*5*). In the following, we provide an overview of our analysis of records for approximately 33,000 patients on waiting lists for liver transplants from 1995 to 1999.




Median waiting times for liver transplants from 1998 to 1999, all status groups. [From (*5*), courtesy of the National Academy Press]

The OPTN classifies liver transplant patients into the following status groups according to disease severity and expected survival without transplant: status 1 (includes patients who are most severely ill having an average life expectancy of one week), status 2 [patients who are less ill, recently divided into severe (2A) and less severe (2B)], and status 3 (patients needing transplantation but not at high risk of imminent death). A major concern regarding the current system is that organs that could be used for the most severely ill patients are in fact used for less severely ill patients. Indeed, analyses of transplant rates by status showed that only 52.4% of the status 1 patients were transplanted, whereas 9.2% died while waiting for a transplant and the remainder shifted to a different status, including status 7 which is "too sick to transplant" (see table, p. 238). Meanwhile, many status 2B and 3 patients received organs. No significant effects of race or gender were observed, indicating that the system is equitable for women and minorities once they are listed.

To refine our analyses, we performed a comprehensive statistical analysis of variations in waiting times and mortality across organ procurement organizations (OPOs), and the consequences of OPO size on these measures. Complete details of the model are presented in the IOM report (*5*). Analysis reveals the strengths and weaknesses of the current system and clear direction for change.

## Waiting Time

The public discussion concerning inequities in waiting times has focused on variations in overall median waiting time across the 63 OPOs. However, patients awaiting liver transplant differ in their need for transplantation. The regional inequity asserted to exist on the basis of the median waiting times, which has been the focus of public attention, is produced by pooling data on patients of all status levels. However, waiting times vary from a few days for status 1, to months in status 2, to potentially years in status 3. As more than half of the patients on the list are status 3, the overall median waiting time provides little information regarding the equity of the system for patients with more critical need for transplantation (i.e., status 1). In fact, our analysis demonstrated that for patients listed in status 1, the median waiting time distribution varies little across geographic regions. Moreover, a significant amount of the variation in waiting times for status 3 patients may result from differences regarding when they are placed on the transplant list, as the hope of early allocation can be an incentive for patients to be placed on the waiting list as early as possible.

## OPO Volume and Size

Although OPO size played no role in transplantation or mortality rates for status 1 patients, a significantly larger fraction of the aggregate number of transplanted organs go to status 2B and 3 patients in smaller OPOs (serving 4 million patients or less) than larger ones (serving 9+ mil-

*R. D. Gibbons is a Professor of Biostatistics, University of Illinois at Chicago, Chicago, IL 60612. E-mail: rdgib@uic.edu. IOM Committee Members: D. Meltzer, N. Duan, Edward E. Penhoet (Chair), Nancy N. Dubler, Charles K. Francis, Barbara Gill, Eva Guinan, Maureen Henderson, Suzanne T. Ildstad, Patricia A. King, Manuel Martinez-Maldonado, George E. McLain, Joseph E. Murray, Dorothy Nelkin, Mitchell W. Spellman. Project Staff: Andrew Pope, Sarah Pitluck.

lion (see the table). This suggests that the current system is less able to meet the needs of the most severely ill patients because it routinely uses organs to transplant less severely ill patients in smaller OPOs. We recommend that at least 9 million people be included in an organ allocation region to maximize the chance of transplantation for the most severely ill patients (*6*).

### The Effect of Sharing

We further examined this by analyzing results of several regional and statewide sharing arrangements among two or more OPOs, most typically for status 1 patients. Our analysis of these "natural experiments" revealed that sharing significantly increased the status 1 transplantation rate from 42% without sharing to 52%, lowered average status 1 waiting times from 4 to 3 days, and decreased status 1 pretransplantation mortality from 9% to 7%. Not surprisingly, sharing significantly decreased the rate of transplantation for less severely ill patients. For example, among small OPOs that serve a population of 2 million or less, status 3 transplantation rates decreased from 31% for OPOs that did not share to 6% for those that did share, making more organs available for more severely ill patients. Although sharing decreased status 3 transplantation rates, we did not find a concomitant increase in their pretransplantation mortality. We also found that broader sharing was not associated with closure of the smaller centers and, in fact, was associated with higher donation rates.

### Waiting Times and Transplant Need

We also focused on the relation between waiting time and the likelihood of receiving an organ transplant or dying while waiting. For status 1 patients, the rates were constant over the first 12 days of waiting at approximately 15% for transplantation per day and 3% for mortality, but for status 2B and status 3 patients, both rates decreased rapidly over time. For status 2B, transplantation rates decreased from 12% to 5% per month over a 12-month period, whereas pretransplant mortality rates decreased from 3% to 0.3% per month. For status 3 patients, transplantation rates decreased from 4% to 0.05% per month over a 12-month period, and pretransplant mortality rates decreased from 2% to 0.2% per month. Thus, waiting time is inversely related to medical need in the less severely ill patients and should therefore not be used as a criterion for transplantation in status 2B and 3.

### Post-Transplantation Survival

The benefits of transplantation depend in large part on a patient's survival afterwards. Not surprisingly, in patients transplanted in 1998 and 1999, mortality risk was highest immediately after transplantation, declined over time, and was lowest in patients transplanted in status 2B and 3. However, patients in small OPOs had increased risk of mortality relative to those in larger OPOs (*7*). The reasons for increased mortality rates associated with smaller OPOs are not clear. A question of serious concern is whether this increased mortality is a consequence of the smaller number of procedures performed by the centers in smaller OPOs.

**CHARACTERISTICS OF LIVER TRANSPLANT PATIENTS BY STATUS, 1995–1999***

| | Status 1 | Status 2 | Status 3 |
|---|---|---|---|
| Total patients, 1995–1999 | 5,294 | 14,264 | 26,907 |
| Patients receiving a transplant (%) | 52.4 | 50.2 | 21.3 |
| Patients dying prior to transplantation (%) | 9.2 | 6.1 | 5.2 |
| Post-transplant mortality (%) | 11.1 | 5.0 | 1.9 |
| Male (%) | 54.1 | 59.9 | 58.7 |
| Initial 1-month transplantation rate (%) | | | |
| Large OPOs | | 5† | 3 |
| Small OPOs | | 17† | 9 |
| African American (%) | 11.2 | 8.3 | 6.9 |
| Mean age (years) | 36.3 | 44.9 | 46.1 |
| Mean waiting time (days) | 4.8 | 56.8 | 285.1 |

*Because patients could change status during the sampling period, they may be represented in more than one column. A total of 33,286 patients were counted. †This only represents status 2B patients. [Source (*5*)]

## Discussion

Our analysis does not support objections raised against the DHHS Final Rule. We found no evidence that distributing organs across broader areas might force smaller transplant centers to close. Nor did we find evidence that broader allocation would drive down donation rates. In addition, we found no evidence to support the suggestion that minorities and economically disadvantaged patients would be adversely affected by broader sharing of organs. The evidence suggests that their obstacles to transplantation stem from limited health insurance coverage and other socioeconomic factors.

Additionally, our analysis revealed that once patients are listed for an organ transplant, there are no disparities by race in how long it takes to receive an organ. Furthermore, as concluded in our report, despite objections and arguments from many in the transplant community, the nation's transplant system needs more cohesive and attentive oversight from the federal government aided by an independent scientific review board. Finally, patients, families, health-care providers, and potential donors need much better information about organ transplantation. Timely and more readily available data, which have been independently reviewed for accuracy and relevance, would build confidence in the system's fairness and ensure that it continues to improve.

Results since the IOM report was released have been mixed. DHHS has republished the Final Rule, incorporating analysis and modifications from the IOM report. Nonetheless, the Congress has continued to struggle with the issue. It has further delayed implementation of the Final Rule until next spring. In addition, the House Committee on Commerce has approved a bill (H.R. 2418) which sides with the opponents of the Final Rule and ignores the IOM recommendations for enhanced government oversight.

Although a suitable donor organ cannot be provided for every person who needs one at this time, the improvements we recommend would help ensure that those patients who are in greatest need of a transplant receive the highest priority.

### References and Notes


1. United Network for Organ Sharing (UNOS) Web site (www.unos.org), 1 July 1999.
2. U.S. General Accounting Office, *Organ Procurement Organizations: Alternatives Being Developed to More Accurately Assess Performance* (GAO/HEHS-98-26, Washington, DC, 1997).
3. Under the current system, organs are obtained and allocated by one of 63 local organ procurement organizations, each of which covers a discrete geographic region. Allocation systems vary by organ but generally offer organs to all local patients in order of decreasing severity before offering the organ to any patients from other regions, regardless of the urgency of their need for transplantation.
4. DHHS, Organ Procurement and Transplantation Network; Final Rule [42 Code of Federal Regulations (CFR) Part 121], *Fed. Regist.* **63**, 16296 (2 April 1998).
5. Committee on Organ Procurement and Transplantation Policy, IOM, *Organ Procurement and Transplantation: Assessing Current Policies and the Potential Impact of the DHHS Final Rule* (National Academy Press, Washington, DC, 1999). Available at www.nap.edu/books/030906578X/html/
6. Our review of the literature suggests this should generally be possible within the limits of the length of time an organ can be maintained in the absence of blood flow and still be used for transplantation.
7. Confirmation of this result can be found at the level of transplantation centers in a 1997 study in which transplantation centers doing 25 liver transplants or less per year had 1-year graft survival rates significantly lower than expected given the health status of their patients. [UNOS, *The 1997 Report of the Center—Specific Graft and Patient Survival Rates—Liver Volume* (UNOS, Richmond, VA, 1997), p. 15].


8. We thank A. Harper, M. Ellison, and E. Edwards of the UNOS Research Department for their help in compiling and preparing the data for our analysis. We also thank D. Hedeker of the University of Illinois at Chicago for developing the statistical software (MIXNO) used in our analysis (www.uic.edu/~hedeker/mix.html). We also thank T. Cox for invaluable administrative assistance.