

Oversight and Review

***Abstract.* The committee concluded that achieving the goals of the National Organ Transplant Act requires an active federal role in review and oversight, and that this should be in collaboration with representatives from all those involved in transplantation, including patients, donor families, physicians and nurses, OPOs, and transplant centers. To assist in this activity there needs to be independent scientific review and better performance measures for various aspects of the system. In addition, data about the system must be reliably and regularly gathered, independently assessed, and made widely available.**

In conducting its review, the committee concluded that oversight and review of the nation's organ procurement and transplantation system needs to be enhanced to improve the system's accountability to the public and to ensure that it operates effectively in the public interest. The committee's concerns cut across the individual issues specified in its charge and relate in general to all organ transplantation, not just liver transplantation. The committee addresses these matters—the role of the federal government and the need for improved data—separately in this final chapter.

ROLE OF THE FEDERAL GOVERNMENT

The federal government, as well as the transplantation community, has a legitimate and appropriate role to play in ensuring that the organ procurement and transplantation system serves the public interest, especially the needs and concerns of patients, donors, and families affected by it. The committee learned of numerous instances in which weak governance tends to undermine the effectiveness of the system. Specifically, responsibilities are dispersed throughout the system, creating impediments to oversight and review. Weak oversight has compromised accountability at all levels, permitted poor procedures for data collection and analysis to persist, and allowed the system to operate without adequate assessment of performance.

The committee acknowledges that many aspects of organ procurement and transplantation require effective arrangements and decision making at a local level. However, a more centralized mechanism for oversight and review would improve the quality assurance that donors and recipients deserve. This is not to say that the federal government should be making medical judgements regarding

individual patients, or that DHHS ever intended to do so, but rather that its responsibility is to ensure that the policies that guide the operation of the system are equitable and well-grounded in medical science.

Vigilant and conscientious oversight and review of programs and policies are critically important to ensuring accountability on the part of the OPTN and other participants in the organ procurement and transplantation system. The Final Rule appropriately places this responsibility with the federal government. The committee believes that this is an important aspect of the Final Rule and a charge that should be pursued by the federal government in close cooperation with the full range of participants in the transplant community.

Some of the activities that could be undertaken in a more proactive manner include, but are not limited to, assessing the equity of access to transplantation, including fairness across socioeconomic, racial, and ethnic groups, and monitoring short- and long-term patient outcomes.

Performance Measures

The various participants in the transplantation system (including the federal government) and the general public would be better served if there were a comprehensive set of reliable, informative, and patient-centered performance measures for the various key components of the overall system of organ procurement and transplantation. As noted in Chapter 2, the Health Care Financing Administration (HCFA) has established performance measures for OPOs. However, the General Accounting Office (GAO) and others have noted several improvements that could be made in these measures to focus them more sharply on the most important determinants of effective performance and improve their fairness among the OPOs (GAO, 1997). The committee believes that the standards for successful performance could be raised to a higher level.

HCFA has also established performance standards that transplantation centers must meet to be eligible for Medicare reimbursement. The committee believes it would be appropriate for the independent scientific review board (see Recommendation 8.2), to review these measures and standards on a periodic basis to make sure they are consistent with current medical science and are as useful as possible to patients and policy makers.

The committee also believes that the OPTN should be rigorously evaluated against performance measures. The committee recognizes that some of these measures would necessarily be process-oriented but urges that, to the degree possible, they focus on patient outcomes and on the equity of the overall system in serving the needs of America's diverse population.

A few summary statistics that could be used to assess outcomes might include: (1) transplantation rate by medical status; (2) pre-transplant mortality rate by medical status; (3) post-transplant mortality rate by medical status; (4) median waiting time in the status 1 category; and (5) graft survival as a function of such variables as cold ischemic time and donor characteristics. The improved

data collection and analysis (Recommendation 8.3) and the independent scientific oversight called for in this chapter (Recommendation 8.2) would facilitate the development and reporting of such performance measures.

RECOMMENDATION 8.1: *Exercise Federal Oversight*

The Department of Health and Human Services should exercise the legitimate oversight responsibilities assigned to it by the National Organ Transplant Act, and articulated in the Final Rule, in order to manage the system of organ procurement and transplantation in the public interest. This oversight should include greater use of patient-centered, outcome-oriented performance measures for OPOs, transplant centers, and the OPTN.

Independent Scientific Review

The science of organ transplantation has been continuously evolving and improving, sometimes at a rapid pace. A process for periodic, independent and comprehensive review by a body reporting to the Secretary and not affiliated with the OPTN contractor is needed to help provide objective information and advice for the future directions of the system. Timely, nonpartisan review will assist the Secretary in managing the system in a manner that best serves the public interest and advances the health of the public. An independent, external, scientific review board would help ensure that policies and procedures are evidence-based and guided by the best available medical and scientific precepts. It would also enhance public confidence in the integrity and effectiveness of the system. The independent scientific review board should include a broad spectrum of medical and scientific experts, including epidemiologists and health services researchers, as well as representatives from the community of transplant patients and donor families.

RECOMMENDATION 8.2: *Establish Independent Scientific Review*

The Department of Health and Human Services should establish an external, independent, multidisciplinary scientific review board responsible for assisting the Secretary in ensuring that the system of organ procurement and transplantation is grounded on the best available medical science and is as effective and as equitable as possible.

DATA COLLECTION, ANALYSIS, AND DISSEMINATION

The committee's analysis and deliberations were hampered by a lack of publicly available, comprehensive, and timely data. For this reason, in part, the committee had great difficulty establishing a sufficient baseline of information from

which to make its determinations. Too frequently, important data were either unavailable or were several years old. Although UNOS has been collecting a substantial amount of data, and the UNOS staff responded promptly and fully to committee requests, the committee was puzzled that its requests appeared to be unique or first-time inquiries. The committee believes that the data and analyses it requested were essential to assessing the status and adequacy of the existing system. The fact that these types of analyses are not conducted routinely and made publicly available in a timely manner should be a matter of concern.

Modern computing and information technologies provide mechanisms for facilitating the collection, analysis, and reporting of information essential to the evaluation of the system of organ procurement and transplantation—for example, donor information; OPO and transplant center performance data; biological factors; and, socio-economic and demographic data on patients, outcomes of donation, organ wastage, primary graft nonfunction, transplant outcomes, and patient outcomes. The power of these technologies to process large amounts of information from numerous sites should be employed to improve the system of data collection, and analysis.

In addition, the data that are available need to be shared more widely with the scientific and clinical communities. The lack of access to data has limited the analytical and scientific work being conducted and published. Moreover, this situation has fostered a poorly informed debate over the important issues. Making the raw data available to a broader audience is essential to improving the quality and reliability of analyses that might be used to set policy.

Broader public access to reliable data in a timely manner will facilitate better assessment of such issues as:

- conformity of patient classifications to standardized medical listing criteria,
- effectiveness of organ procurement activities,
- equity of organ allocation and sharing arrangements, and
- graft and patient transplantation outcomes.

Data needs are likely to change over time—requiring continual review and revision. Thus, routine review of the system of data collection and dissemination would help to assure the quality, timeliness, and accuracy of data over time. Review by an external organization, experienced in data management and statistics, but independent of the OPTN contractor and not drawn from the transplant community, could help to ensure the validity, accuracy, and usefulness of the data.

RECOMMENDATION 8.3: *Improve Data Collection and Dissemination*

Within the bounds of donor and recipient confidentiality and sound medical judgment, the OPTN contractor should improve its collection of standardized and useful data regarding the system of organ procurement and transplantation and make it widely avail-

able to independent investigators and scientific reviewers in a timely manner. DHHS should provide an independent, objective assessment of the quality and effectiveness of the data that are collected and how they are analyzed and disseminated by the OPTN.