UpDate is a section that will report developments in health policy issues and scheduled conferences of relevance to the field. In this issue we offer an update of organ transplantation policy.

A Review Of Organ Transplantation Policy

In the last five years, the field of organ transplantation has grown at a dramatic rate. The number of kidney transplants performed in the United States increased 43 percent between 1981 and 1984, heart transplants increased almost sevenfold, and liver transplants over elevenfold. As the success rates for these procedures have improved, the number of medical centers that have become involved in organ transplantation has burgeoned, driving up the number performed.

The federal government, from President Reagan on down, and some states and private interests have been enthusiastic about promoting this form of high-technology medicine. But while the technology of organ transplantation pushes ahead, the health policy directing its path lags behind, mired in a debate of who should pay for the new transplant procedures and where policymaking authority should lie—with the federal government, state legislatures, the medical community, or the private sector. This article gives a brief update on the year-old National Organ Transplant Act and takes a look at transplantation policy.

Federal Role

Since 1972, Medicare has financed through its End Stage Renal Disease (ESRD) program, kidney transplants and dialysis for individuals with end-stage kidney disease. The cost of this program has risen from $184 million in 1974 to a projected $2.3 billion in 1985, far exceeding the estimates given at the time the program was initiated. This cost escalation has generated serious concern among many legislators as they consider coverage of extrarenal transplants. The average cost of a heart transplant today is $57,000-$110,000, a kidney transplant is $25,000-$30,000, and a liver transplant costs $135,000-$238,000, depending on complications, medication, graft rejection, readmissions, geography, and other factors.

The Health Care Financing Administration (HCFA), wary of the financial implications of extending coverage for the transplantation of
other organs, but interested in the phenomenon and unable to ignore such a high visibility issue, commissioned the National Heart Transplant Study to evaluate the state of heart transplantation and the feasibility of funding these procedures under Medicare. The report, which the Department of Health and Human Services (HHS) released in May 1985, projected that the number of Medicare-eligible recipients for heart transplants would be very small. Since one criteria for transplantation is to be under 55, very few Medicare patients would qualify. The cost to Medicare would be $2 million to $3.5 million (in 1983 dollars) per year from 1985 to 1989 and involve 30-40 patients. In addition the report states, “when compared specifically with kidney transplantation with regard to cost-effectiveness, heart transplantation does not seem to be clearly more expensive per recipient from HCFA’s point of view. But compared with the cost-effectiveness ratios of other medical technologies that have been evaluated, heart transplantation appears to fall at the high end of costs.”

At present, all signs indicate that Medicare will provide coverage for its beneficiaries in need of a heart transplant. In August 1985, the Public Health Service (PHS) submitted a document to HHS which said, in essence, that heart transplants are safe and efficacious and could no longer be termed “experimental” and thus should be funded. This resulted in a joint memorandum from the PHS and HCFA to the Secretary of HHS which centered on two issues: the conditions of coverage and how it should be put into effect. If the Reagan administration accepts this recommendation and is prepared to implement it, eligibility criteria will be strict, probably limiting coverage to Medicare patients under age 55, even though some centers are reportedly transplanting patients up to age 59. This could have serious cost implications for Medicare, although the limited number of organs available will still largely control the number of procedures performed. The number of transplant centers eligible for Medicare reimbursement will be limited, as well, to those which have performed twelve procedures a year for at least three years.

Despite this concern over cost, federal interest has been substantial as reflected in the enactment of the National Organ Transplant Act (Public Law 98-507) by an overwhelming majority of Congress. Signed into law by the president in October 1984, the law evolved from a series of hearings called by Sen. Albert Gore, Jr. (D-TN) in 1983 when he was a member of the House and chairman of its Science and Technology Subcommittee on Investigations and Oversight. Gore became interested in transplantation when a Tennessee constituent sought his help in securing an organ. The hearings dealt with many of the legal, ethical, economic, and social issues of transplantation.

The main features of the law would prohibit the sale of organs; establish a task force to examine the issues and make recommendations; require
establishment of a national computerized organ recipient registry and network of procurement centers to provide a more efficient system of matching donors to recipients; and authorize $25 million in grants over a three-year period to private, nonprofit organizations involved in organ procurement. An Office of Organ Transplantation was created under the Health Resources and Services Administration of HHS to administer the act.

To date, the National Task Force on Organ Transplantation, formed in January 1985, has met seven times. Nine of the twenty-one members are physicians and scientists eminent in fields related to organ transplantation, while the remaining include procurement agency administrators, and representatives from the fields of law, ethics/theology, health care financing, and social and behavioral science, the general public, and the health insurance industry. The task force was charged with reporting to Congress and the Secretary of HHS its recommendation for the federal funding of immunosuppressive medications, drugs which help prevent the body from rejecting a transplanted organ. This was an issue that legislators were unable to resolve in debate on the legislation. The task force has also developed a model organ procurement and transplantation network, and will prepare a final report evaluating the feasibility of a national computer registry, reimbursement of extrarenal transplants, the problem of equal access to organs, and the importance of designating which transplant centers the federal government will agree to reimburse for treatment of Medicare patients.

In a report presented to Congress in October 1985 on immunosuppressive therapy issues, the task force recommended that federal funds be provided for immunosuppressive medications for financially needy Medicare patients who are eligible for transplantation. If approved, this recommendation would be precedent setting in that Medicare currently does not pay for self-administered, outpatient prescription drugs. The issue of drug coverage was primarily spurred by the development of the drug, cyclosporine, which costs patients $5,000-$7,000 each year, while conventional immunosuppressive drugs average $1,000-$2,000. Cyclosporine has, however, markedly improved the rates of transplantation success. According to the report, if cyclosporine is used indefinitely following kidney transplantation, the cost to Medicare’s renal dialysis and transplantation program would rise. However, if Medicare pays for the drug for only three years, corresponding to current renal transplant coverage, there would be no difference in cost to the program. If cyclosporine is discontinued after six months, substantial savings could be achieved. The medical community has not yet reached concensus on how long the drug must be continued to be effective.

In October, the task force also recommended creation of a model Organ Procurement and Transplantation Network (OPTN). The task
force said that the network should be national in scope and administered by a private, nonprofit entity. The network would coordinate regional activities; improve organ matching and procurement; gather, maintain, analyze, and publish data pertaining to all facets of organ transplantation; and set national policy and monitor performance of member organizations.

The task force intends to submit its final report on organ donation, procurement, and the transplantation process by March. The factor of limited organ donors is one of great concern to the field as it looks at issues of equity and the continued growth and development of transplantation. At a recent conference on the medical, ethical, and economic aspects of organ transplantation held at the Cleveland Clinic, Olga M. Jonasson, chief of surgery at Cook County Hospital in Chicago and chair of the National Task Force on Organ Transplantation, said, “If we’re going to increase the number of transplants, we’re clearly going to have to increase donors.” In trying to increase the number of organs donated, she said, “the single largest barrier is the failure of physicians referring patients.”

While the law authorized $25 million in grants to organ procurement agencies over a three-year period, the president’s 1986 budget requested no money for this purpose. The activities of the office and the task force are currently supported by funds appropriated to the PHS. Executive director of the task force and staff liaison to the Office of Organ Transplantation, Linda D. Sheaffer, acknowledged in an interview that “for budgetary reasons we have concentrated on the task force” rather than the other functions designated by the transplant act.

The Office of Organ Transplantation sees its role at present as primarily that of educator and catalyst. “We’re like a clearinghouse, in some respects,” said Harvey R. Vieth, the new and second director of the office, in an interview. “The real role of the office is in education. . . . It would be presumptuous of us to take money and start a massive program.” Vieth cautioned that since the field of organ transplantation is complex and dynamic and since there is controversy even among the “experts” over the best policy directions to take, the federal government should not be too eager to regulate the existing systems of procurement and provision. “If the experts can’t come up with a solution to the problems, how can we dictate what to do?” he questioned.

Senator Gore, however, has criticized the administration for delaying implementation of the new law. At a recent news conference, Gore said, “they (the administration) have totally failed in addressing the problems of thousands in our nation who require life-saving organ transplant surgery. Their foot-dragging in implementing the law, and their continued insistence that voluntary groups and private organizations can solve this societal problem—a problem that requires a national solution—is inexcusable. . . .”

In response, Vieth countered that the administration could not act until it had the reports and recommendations of the task force. “I think we’re
right on track. The fact that the task force is taking longer (than one year to present its final report) shows that the issues are difficult,” he said.

Regarding the role the federal government should take in directing transplant policy, and reflecting the administration’s views, Vieth favored less federal regulation and more freedom on the part of states and the private sector to develop systems that work best in their particular area. The field of transplantation, Vieth said, is “predominantly a private sector involvement. I don’t think we want to interfere in any way with the mechanism that’s out there.” He raised the concern that overregulation “could interrupt the development of technology.”

State Role

State legislators, frustrated at the lack of guidance from the federal government, are beginning to address on their own the complex issues of setting up efficient, equitable guidelines for procurement, provision, and payment of organ transplants. A number of states, including Maryland, Massachusetts, California, Pennsylvania, Wisconsin, and Iowa have set up task forces to examine the issues. Oregon, New York, New Jersey, and California have recently enacted laws to improve the availability of organs by requiring physicians to ask families of “brain dead” patients about possible donation. Ohio has developed a joint public/private sector commission to coordinate coverage and service delivery among private insurers, purchasers, and providers within the state.

Historically, states have looked to the federal Medicare program as a guide of whether to pay for transplants under Medicaid. However, as the federal government increasingly delays its funding decisions by labeling certain transplant procedures as “experimental,” and as states have begun to receive pressure, often from the media, to pay for the procedures, they have begun to set up their own financial guidelines. A recent survey by the Intergovernmental Health Policy Project and HCFA reports that nine states are either reviewing or developing reimbursement policies, seventeen states have no formal policies, though fifteen of these have paid on a case-by-case basis, twelve states have explicit policies to follow Medicare’s lead in paying for transplants, though nine of these have or are willing to consider paying for procedures that Medicare terms “experimental.”

As David Hollister, a Michigan state legislator who oversees the state’s welfare budget, said in an interview, “We are only beginning to understand the ramifications (of organ transplants). We hopefully look to Washington for actions, but the feds will not take the lead.” As the technology of transplantation races ahead and political pressure to pay for the increasingly successful transplants mounts, states are having to make quick decisions. “We are dealing with this in a vacuum,” continued
Hollister. At present, “the budget frames the issue (of Medicaid payment for transplants) and this tends to skew the issue.”

Woodrow Myers, Indiana’s state health commissioner, agreed in an interview that “it would be better for the feds to take a more aggressive role than they’re doing now. . . . Because the feds have dropped the ball and the states have to pick it up, it is much less efficient-each state forming individual task forces.” He acknowledged that “the National Organ Transplant Act was a step in the right direction, but it’s not enough.” The fact that organ transplants are such technologically advanced, intensely emotional procedures requires the federal government to play a large role in regulating their use and development, Myers asserts. However, Indiana and other states are not going to wait around for the federal government to act: “We are at a point where we can use this technology and the feds are not going to stop us from doing what needs to be done,” Myers said.

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NOTES

2. Ibid.
4. Task Force on Organ Transplantation, “Report to the Secretary and the Congress on Immunosuppressive Therapies” (October 1895), 15.