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# Regulating Heart and Liver Transplants in Massachusetts: An Overview of the Report of the Task Force on Organ Transplantation

by George J. Annas, J.D., M.P.H.

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Organ transplantation has been a favorite topic of health lawyers since its inception. Organ procurement was addressed with the adoption of the Uniform Anatomical Gift Act in all fifty states, and "brain death" has been recognized both judicially and legislatively across the country. Nonetheless, it is now apparent that the major problems in organ transplantation are not legal and thus neither are their solutions. Heart and liver transplants are extreme and expensive interventions that few individuals can afford and few hospitals can offer. In an era of economic scarcity, how (if at all) should organ transplant procedures and other extreme and expensive treatment be introduced into the health delivery system?

Although it seems reasonable to expect federal leadership to establish a limited number of high-quality transplant centers, federal efforts to date have focused almost exclusively on trying to help the scattered organ procurement agencies become more efficient. By default, the individual states have had to develop their own policies. A number of them, like California and Connecticut, have concentrated on Medicaid reimbursement requirements. Ohio has worked to develop a statewide "consortium" approach. But until late 1984, only Mas-

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sachusetts had established a statewide public task force to make recommendations concerning how heart and liver transplants should be introduced. The Massachusetts Task Force grew out of a recommendation, made by Dr. Harvey V. Fineberg's earlier Liver Transplantation Task Force, that

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a broadly based public group examine the social issues involved with transplantation technology. The Massachusetts experience is important not only because it is the first state to utilize the strategy of a public task force, but also because of the strong medical institutions in Massachusetts, the vigorous use of determination-of-need mechanisms to regulate the introduction of liver and heart transplants, and the almost overwhelming desire of at least four Boston hospitals to do liver transplantation and of four Boston hospitals to do heart transplantation. Indeed, at times the political aspects of whether one hospital or more than one hospital should do either of these procedures have eclipsed all of the other critical issues involved in using these extreme and expensive technologies.

The complete set of recommendations, as well as the Task Force's charge and a description of its process, is included in the sections of the

Final Report reproduced in this issue of *Law, Medicine & Health Care*. The recommendations themselves went to public hearing on November 5, 1984, and on November 27, 1984, the policy-making body of the Massachusetts Department of Public Health, the Public Health Council, unanimously adopted the recommendations as official Policy Guidelines and used the Report itself as explanatory text for the Department in reviewing determination-of-need applications for organ transplantation.

## Major Conclusions

Although sometimes lost in bland prose, several significant conclusions were reached by the Task Force, which structured its set of recommendations. The basis of the Report can be stated in one long sentence. Because transplants are extreme and expensive procedures that nevertheless do not cure disease but replace the patient's underlying disease with a lifetime of immunosuppression, and because introducing transplantation into the current cost-constrained health care system threatens to displace other, higher priority health care services (including services to the Medicaid population and the poor), transplants should not be performed at all unless they are done on those who are likely to benefit from them, unless the total cost is controlled, and unless resources are not diverted from higher priority care. In fleshing out this basic principle, the Task Force concluded that public regulation would be ineffective if the burden of proving health care priorities was placed on the Department of

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Public Health. Accordingly, the Task Force recommended that the analysis of health care priorities begin with a *presumption that all currently offered health care services have a higher priority than organ transplantation.* Therefore, any hospital applying to perform transplants should have the burden of demonstrating that "transplantation has a higher priority than any other currently available health service from which organ transplantation diverts funds and/or support systems."

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**Limitation is a fair policy so long as we make transplants available to all who are clinically suitable in an equitable manner.**

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On the underlying value issues of fairness and equity, the Task Force concluded that access to a transplant must be "independent of the individual's ability to pay for it." Thus, if offered at all in the system, heart and liver transplants must be considered part of the "minimum benefit package" to which all are entitled. But how could the health care system, which arguably could not handle organ transplants at all, introduce them in a manner that would make them available to everyone? The key is to *restrict the total number of transplants done.* However, this must be accomplished in a manner that optimizes the quality of care and benefit of those procedures actually performed, eliminates arbitrary patient selection excluders (such as income, age, and personal habits), and provides an equitable manner of selecting among suitable candidates when not all can be served. The most crucial element is to define "clinical suitability" for transplantation in a manner that concentrates on benefit to the patient in terms of life style and rehabilitation rather than simple survival. In the words of the Task Force, medical suitability should be an attempt to predict "those who can benefit the most from [transplants] in terms of probability of living for a significant period of time with a reasonable prospect for rehabilitation." Critical to maintaining a

strict definition of "clinical suitability" is the restriction of total system capacity to perform transplants, as explained in the summary of the economics section later in this article.

### **Application of the Report**

The utility of the Task Force Report, its recommendations, and the new Policy Guidelines of the Massachusetts Department of Public Health will face their first test when they are used to determine the public need for a four-hospital consortium to do heart transplants in Massachusetts in early 1985. A separate four-hospital consortium was approved to do liver transplants for a three-year period in January 1984. Conditions were placed on that determination of need, including requirements that the hospital not consider ability to pay or insurance status in patient selection, not reduce Medicaid services as a trade-off for liver transplantation, not reduce free care for non-transplant services below that provided in the most recent fiscal year, and have its liver transplantation protocols reviewed and approved by an institutional review board. The

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members of the Consortium objected to these conditions, and appealed them to the Health Facilities Appeals Board, which ordered a remand on procedural grounds. On remand, the Public Health Council explicitly adopted the conditions, with some modifications, over the objections of the Consortium. The IRB review requirement was modified most significantly to read:

The hospital will have its liver transplant protocols, including consent and withdrawal of consent policies, organ procurement policies, recipient selection policies and confidentiality policies, reviewed and approved by an ethics committee of the Boston Center for Liver Transplantation, which will contain significant

public representation, or by a special board set up for this purpose by the Department of Public Health.

It remains to be seen whether the Liver Consortium can live up to the Policy Guidelines. While the hospitals did not have to satisfy the Guidelines originally, they will serve as minimum requirements for any renewal of their DONs two years from now.

### **Other Sections of the Report**

Portions of the Report not included in this issue are sections on economics, religious views, and the consortium approach. The latter two can be dealt with relatively quickly. The Task Force found no religious tradition that prohibited organ donation or transplantation, and the perspectives included in the Report from the Catholic, Protestant and Jewish traditions were all supportive of organ transplants. As previously mentioned, the consortium approach is primarily a political issue. It was grafted onto the original draft of the Report at the request of the Commissioner of Public Health. In March 1984, Commissioner Bailus Walker asked the Task Force's opinion about the advisability of granting a temporary exemption from determination of need to the Brigham and Women's Hospital, a tertiary care hospital, to do heart transplants. Such a single-hospital exemption was seen as preferable to having multiple hospitals request "emergency waivers" for individual patients while they pursued an institutional DON (this procedure was used for liver transplants in the Commonwealth by the Deaconess Hospital for more than six months). The Commissioner found it impossible to refuse such requests, and the use of emergency waivers in heart transplantation would have undercut any reasonable planning efforts.

The Commissioner's request for advice quickly became politicized, and a loose "consortium" of hospitals was thrown together to provide an alternative to the single-hospital exemption. The Task Force met three times on this issue. At its final meeting on this subject, May 15, 1984, the Task Force appeared for the first time in its en-

tirety. Following a two-hour discussion, which was highlighted by a comment from State Senator Ed Burke that the paper consortium looked more like a "fig leaf" to cover "naked rivalry" among the hospitals, rather than a serious effort at cooperation, the Task Force voted unanimously to recommend a DON exemption for heart transplants in Brigham and Women's Hospital until the end of 1984. In addition, the Task Force voted to attempt to develop guidelines for a "truly cooperative consortium." A summary of guidelines for a "worthwhile consortium" appears in the group's final recommendation.

### Economics

Since it was the cost of these extreme and expensive procedures that initially led to the formation of the Task Force, the Report's economic section and its conclusions are critical to any understanding of the recommendations. The analysis describes the many different ways of determining "costs" of transplants, and uses the specific figures generated by various agencies as examples of how divergent figures are calculated.

In general, hospitals have used only direct costs in the figures they have relied on to support their applications for determinations of need. Figures from the Massachusetts Liver Transplantation Task Force and Massachusetts Blue Cross, on the other hand, utilized fully-allocated average costs. While arguments can be made for both views, the Task Force decided to use fully-allocated-average-costs-for-one-year-of-survival as a benchmark for determining the cost of transplants and comparing it to the costs of other extreme and expensive medical procedures. In computing the costs of heart and liver transplants, the cost of the surgery itself is generally the smallest item, amounting to only about five percent of the cost, for example, of a liver transplant. About one-fourth of the cost is attributable to readmission to the hospital due to complications, and almost one-half of the total is attributable to ancillaries such as laboratory, blood, intravenous lines, radiology, social work, and physical therapy. The most important

cost determiners are the number of ICU days that will be used by the patient and the cost of these days. Fully allocated, average costs will be a function not only of this, but also of the probability of surviving for one year and thus using the ICU bed for a longer period of time (and for additional years, if we want to arrive at average total costs).

Using this model, the Task Force derived costs of \$230,000 to \$340,000 per liver transplant patient alive at the end of one year (using a 70 percent survival rate), and \$170,000 to \$200,000 per one-year survival for heart transplant patients (also using a 70 percent survival rate). Additional years of survival would add from \$10,000 to \$20,000 in costs per year to these figures. Compared to other extreme and expensive medical care examined by the Task Force (including neonatal ICU care, adult ICU care, end-stage renal disease care, hemophilia, bone marrow transplants, and variceal bleeding) on the basis of fully-allocated average one-year costs, the cost of heart and liver transplantation is 4 to 10 times more expensive than any of these. That's the bad news.

The good news is that these procedures can be performed for substantially less than this fully allocated cost to the health care system at least in a state like Massachusetts, which utilizes a prospective revenue cap on individual hospital budgets. Indeed, this cap on prospective total revenue may actually make innovation easier by limiting the costs to the system. A summary of the argument, which is the economic underpinning of the Report, runs like this. First, a significant portion of fully allocated costs goes toward amortization of the physical plant. Thus, if procedures can be "squeezed into" existing capacity without displacing other procedures, this cost will not have to be borne by the system. Second, and most important, since cost is primarily a function of ICU days, and since ICU days are a function of readmission and complications, the cost will be less if readmissions can be lowered. This is likely only if patient selection is kept very strict, i.e., if transplants are given

to only those patients with strong clinical suitability, in the sense of being able to survive the transplant for a significant period of time with reasonable prospects for rehabilitation. Thus, cost becomes a function of patient selection criteria.

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### **In the absence of national leadership on this subject, states are forced to make their individual ways as best as they can.**

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Patient selection criteria, however, tend to expand to include almost everyone in the absence of restraints on the system. This was well demonstrated in the end-stage renal disease program in which universal entitlement has led to universal treatment, whether medically beneficial or not. No one wants to repeat this experience with heart and liver transplantation, and thus no national politician has even suggested that heart and liver transplants be covered by Medicare. Indeed, even though he has made nationwide appeals for livers for children, President Ronald Reagan threatened to veto an organ transplant bill that would have provided federal money to pay the \$6,000 needed annually for cyclosporin to immunosuppress transplant recipients, unless this portion of the bill was deleted—which it was.

Clinical suitability is not an immutable scientific fact, but one that is highly influenced by the environment. It is the Task Force's view that clinical suitability criteria will depend to some significant degree on system capacity. Thus, if system capacity is restricted, the clinical suitability criteria would remain relatively stringent. This would help insure that only good candidates received transplants, and thus that the health care system would not have to be expanded to accommodate large numbers of patients. This would, in turn, ensure a cost-effective transplant program. The conclusion is that in order to maintain a cost-effective program, one must limit volume. And this, of course, makes determination of need a logical regulatory mechanism, one in

which demand is adjusted to system capacity, rather than system capacity being adjusted to demand. The chief architect of this model, and author of the Economics Section of the Final Report, is Professor Marc Roberts of the Harvard School of Public Health.

It should be noted that limitation is a fair policy so long as we make transplants available in an equitable manner to all who are clinically suitable. In this way, we can permit organ transplants to become part of the "minimum benefit package" for Medicare and Medicaid recipients and even for the uninsured, without "breaking the bank." A suggested way to achieve equity of access is outlined in the Report's section, "Patient Selection and Rationing Schemes."

### Conclusions

Is all this merely an academic exercise? Won't the public demand expansion of the health care system to accommodate all who can obtain any conceivable benefit from transplants, no matter what the system costs? Possibly, but the experience with end-stage renal disease has been radicalizing. There are, for example, 80,000 individuals on dialysis in the United States today, yet only about 7,000, or less than 10 percent, are on waiting lists for kidney transplants. Because of the shortage of available organs, physicians have determined that more than 90 percent of all possible kidney transplant candidates are not "clinically suitable." Capacity of the system plays a critical role in this, and if we can directly limit the system's capacity, we not only can limit the system's costs, but also can provide the service to those who can benefit the most from it. A national system which limited heart and liver transplants to perhaps 20 high-quality centers is preferable. But in the absence of any national leadership on this subject, states will be forced to make their individual ways as best as they can. There will be tremendous pressures on the states from the hospitals, the media, and the public who cannot understand why such restrictions on capacity are being imposed. These pressures may be irresistible. But it may also be that these pressures can be

resisted, at least during the 3-year "Phase I" envisioned by the Task Force, and that after this period of limited transplantation and data gathering, we will have learned enough about this issue to be able to make sound public policy that can be persuasively articulated to the public so that the policy is acceptable. So long as the entire procedure is public and perceived as fair, the potential for regulatory success should not be discounted.

My physician friends are fond of quoting the following line from *Hamlet* in describing organ transplantation, "Diseases desperate grown by

desperate appliances are relieved, or not at all." The more appropriate passage for the regulator appears seven lines earlier in the King's declaration: "How dangerous is it that this man goes loose! Yet must not we put the strong law on him. He's loved of the distracted multitude. . . ." (IV.iii) In this context, the man is organ transplantation. The challenge is to put "the strong law on him" long enough to persuade the public that a free-for-all in organ transplantation is reckless, while a controlled system has pay-offs in terms of quality of care, equity, and cost savings.

### Conference on Organ Transplantation

Organ transplantation is becoming one of today's thorniest problems for both individual and institutional health care providers.

To discuss and begin to solve the complex issues, the American Society of Law & Medicine is sponsoring, in April, **Legal & Ethical Issues Surrounding Organ Transplantation** with the American College of Legal Medicine and the National Heart, Lung, and Blood Institute. Seventeen national organizations, including the American Medical Association, the American Hospital Association and the American Council on Transplantation, are cooperating sponsors. The conference will be held April 18-20, 1985, at the Hyatt Regency Crystal City, in Arlington, Virginia.

A special session of the conference will focus on the new legislation giving the federal government a larger role in the formation of policy regarding organ transplantation. What does the Organ Transplant and Procurement Act represent for transplant centers? Who will bear the burden of financing immunosuppressive outpatient therapy? To what extent should the federal government implement medical, ethical, and legal policies on organ transplantation? These and other complex questions will be probed over three days by an outstanding multidisciplinary faculty composed of experts in organ transplantation.

Such a gathering of experts is an event worthy of permanent documentation. Therefore, the conference organizers plan to compile a two-volume textbook that will consist of the proceedings of the conference and an anthology of previously published articles. The text, which will be published with the Health Administration Press of the University of Michigan, will disseminate these important discussions to those unable to attend the conference.

For more information, contact Maureen Shepherd, Conference Registrar, American Society of Law & Medicine, 765 Commonwealth Ave., Boston, MA 02215.