



Recommendations Regarding Issues Facing Organ Transplantation

ROBERT J. CORRY, 1986–87

Many previous presidential addresses of ASTS and the Transplantation Society have been concerned with various political and ethical issues facing the transplantation community and the public. My distinguished immediate predecessor stated last year in his Presidential Address that he had hoped to discuss the use of donor antigen to modulate allograft response, but he elected instead to delay this important immunologic topic to respond to the timely political and ethical issues facing transplantation. Perhaps we can look forward to the scientific topic as the subject of his next Presidential Address in Australia. Until a few weeks ago, I had planned to discuss the accumulating evidence that pancreas transplantation stabilizes and prevents some of the secondary complications of diabetes. However, I too have succumbed to the discussion of the pressing issues affecting transplantation currently. While some issues have been at least partially resolved, others have become more diverse and complex and await final solution. Many of these current problems would be simpler had we continued to perform the same number of renal and other organ transplants that were being performed a decade ago or even five years ago. Fortunately, for the patients and transplantation science, results have improved dramatically, and the volume of clinical transplantation has increased substantially. As a result, organ transplantation has been extended in a number of well-known centers to include at least two of the three other primarily vascularized organs—and, in a few institutions, all four organ transplants are being performed.

With the increase in clinical organ transplantation, the continued short supply of organs has become one of the most vital issues facing transplantation today. The short supply is compounded by the fact that success rates have increased by approximately 30% for the kidney, liver, heart, and even the pancreas; this has rendered kidney transplantation the best option for treatment of end-stage renal disease and has removed the other organs from experimental status.

Several measures have already been undertaken to improve the supply of donor

organs for transplantation. Excellent public and professional education programs and audiovisuals have been developed by several organizations. In addition, federal legislation has been passed that requires, by October 1, 1987, as a condition of participation in Medicare and Medicaid programs, the establishment of protocols and procedures for encouraging organ and tissue donation in hospitals, ensuring that families of possible organ donors are made aware of the option to donate. Furthermore, the potential donor hospital must notify the federally certified organ procurement agency. Also, the passage of required request laws has increased donor organ supply in certain areas of the country. All these measures have helped to increase public and professional awareness.

I would like to suggest that ASTS become more active in its support of organizations and associations engaged in professional education and public awareness programs. Heretofore, we have been only mildly supportive of these various efforts to increase donor awareness and acquisition. Our active support of these ongoing programs will lend legitimacy to these efforts. Obviously, in so doing, ASTS will be instrumental in determining which types of programs should be supported. I propose that the Council develop a mechanism to actively endorse effective public and professional education programs regarding organ donation. In addition, the Council should carefully evaluate the possibility of developing a well-organized strategy of professional education regarding donor identification and care.

A more complex issue is the question of which is the correct method of organ distribution and sharing, a discussion in which many of you participated yesterday. Should donor organs stay in local areas and regions, or should they be shared nationally? This issue is particularly sensitive in light of the fact that sharing on a broad scale has been recommended by the National Task Force on Organ Transplantation, as well as by other key individuals and groups. Should matching for kidneys—and, for that matter, other organs—be considered? While ischemic times for nonrenal organs are crucial, should prolonging ischemic times by a few additional hours be the major reason for not sharing kidneys if total ischemic times are below the critical limit? The answers to these questions are, of course, not clear, and evidence can be cited to support either side. For example, in some single-center analyses, the benefit of matching for renal transplants has become less evident—or, in fact, not present at all. Our own program has long advocated sharing, initially based on matching for haplotypes and more recently for DR specificities for cadaver kidney transplantation. Our two-year graft survival since the use of cyclosporine has been 85% for donor-recipient combinations matched for three or more antigens of a possible six, compared with 83% for donor-recipient pairs matched for two or fewer antigens. However, when one looks at far larger numbers, such as the Opelz multicenter data, the effect of matching is clear; six-antigen matches for first kidney transplants have success rates approaching 90%, while poorer matches are a little better than 70%. Also, a retrospective analysis from a single heart transplant center presented in Helsinki by Mr. Yacoub showed that the two-year survival for a 1 DR-matched pair was 84%, compared with a 68% two-year survival for a 2 DR-mismatch. The suggestion that well-matched heart transplants are less likely to develop coronary artery disease, usually associated with chronic vascular

rejection, may be a factor that should be considered in the future if longer storage times become possible.

For the present, it seems to be most logical that kidneys should stay in the local area first. Then, they could be distributed to the immediate region, based on some equitable point system that includes length of time on the waiting list, medical urgency, tissue match, and degree of sensitization. This will assure transplantation of patients within the region and will enhance local and regional education programs. An esprit de corps in these geographical areas will develop. It is unlikely that the same degree of initiative for increasing donor awareness would occur if a large number of kidneys were shipped out of local areas and regions to distant metropolitan areas with large populations. When recipients are not available in the region, kidneys should be shared nationally based on a similar point system. In addition, in the case of a six-antigen match, when all specificities are identified in both the donor and the recipient, we should give strong consideration to the concept of national sharing: results are superior, and the highly sensitized patients would be more likely to receive a transplant than if there is little or no national sharing. Adoption of a policy of sharing for totally compatible matches will require careful monitoring to ensure that the designated recipient actually receives the perfectly matched organ—and, if not, the reasons for choosing another recipient should be documented. If national sharing is adopted, analysis of the data should be performed at least at six-month intervals to determine whether this strategy of sharing based on matching should be continued. For non-renal organs, local and regional allocation should occur in a like manner, based on a point system including the degree of medical urgency. I think a patient with extremely urgent status should receive an organ from the national pool, also with the proviso that a reputable accountability system is adopted. If organ donation were to double, it would be appropriate to institute a program more heavily weighted in the direction of national sharing. In that situation it might be likely that local initiatives would already be maximized and waiting lists would be reduced. In essence, a substantial increase in donor organ supply would lessen the sensitivity regarding whether a high percentage of organs should be kept in local regions or shared nationally. I am confident that the National Organ Procurement and Transplant Network—i.e., the United Network for Organ Sharing (UNOS)—will carry out this complicated task in a highly professional and fair manner.

Another issue is the question of center designation. Since donor supply is limited, it is crucial that every organ should be transplanted to a recipient at a qualified transplant center where good results have been documented. Until recently, there has been a well-established practice of initiating transplant services in comprehensive medical centers, more commonly university-based, where fundamental laboratory and clinical research fuels their development. In the past couple of years, we have had to answer the question of whether or not it is appropriate for the principles of marketplace economics to be a factor in determining the initiation of new transplant services. This trend of proliferation of renal and cardiac transplant services must be governed by a system that assures quality. It is apparent that UNOS has been given considerable authority to establish standards for transplantation programs, histo-

compatibility laboratories, and independent procurement organizations. In essence, UNOS will determine which centers can do which organ transplants, and they are charged with monitoring the results to ensure that these standards are met. By linking Medicare coverage to UNOS membership, there is the remarkable opportunity to ensure quality.

For example, the transplant program must use for its histocompatibility testing a laboratory that meets the standards of the American Society for Histocompatibility and Immunogenetics (ASHI). The clinical transplant program must have eight transplant surgeon on site with a minimum of one year of formal training and one year of experience in an ASTS-approved transplant fellowship program. This individual must be certified by the American Board of Surgery or Urology for kidney transplants, by the American Board of Surgery for liver and pancreas transplants, and by the American Board of Thoracic Surgery for heart and heart-lung transplants. In addition, each center must have on site a qualified transplant physician who is board-certified in internal medicine or pediatrics and has at least one year of specialized formal training in transplantation medicine or two years of experience. Although these criteria for membership adopted by UNOS are less stringent than the criteria recommended by the Task Force or the Ad Hoc Committee consisting of representatives from ASTS, ASTP, and ASHI that met a year ago, they do emphasize quality.

One of the most important tasks facing ASTS is the approval of programs for the training of surgeons in renal as well as extrarenal transplantation. These programs must meet the standards recently developed by the Education Committee led by John Najarian and Gil Diethelm. This committee should move very quickly to evaluate training programs within the next several months, by October 1 it is hoped. In this way ASTS becomes the unofficial credentialing body for approving the training of new transplant surgeons. I believe it is reprehensible today for a young surgeon who is not a graduate of a recognized ASTS-approved program to undertake the direction of a new transplant program. It is equally inappropriate for a surgeon to be performing organ transplants without his or her respective professional boards or their equivalents. I believe the new ASTS Governor of the American College of Surgeons, Oscar Salvatierra, should pursue this issue with the Board of Governors of the American College of Surgeons, and develop a policy statement that fellows of the American College of Surgeons should not perform organ transplants without appropriate credentials and education.

If only those programs that meet the UNOS criteria can perform organ transplants, and the official transplant surgeon at each center is a graduate in good standing of an ASTS-approved program, quality will be assured and inappropriate proliferation of centers will be controlled.

I think it is vital that ASTS and its members remain in a very strong advisory position to UNOS. Many of the officers and leaders of our society are also in leadership roles in UNOS. It is up to them to see that UNOS functions properly and efficiently in this incipient stage of its development. I hope that the members of ASTS, as well as members of ASTP, will continue to play as strong a role in the development and implementation of the policies of UNOS as they do now.

It is important that the surgeons and physicians in this country providing transplantation services to patients continue to be the prime determiners of policies that affect the delivery of this complex branch of medicine. In this regard, it is worthwhile to note that even prior to the implementation of any laws or significant regulation, the physicians entrusted with the care of these patients traditionally offered their best judgment and carried out their duties in a highly professional, successful, and ethically correct fashion—and, as a result, the field has been allowed to develop very rapidly. I know we are all opposed to overzealous federal and state regulation that might stifle appropriate growth and development of transplantation science and clinical advances. However, now that some regulation is here, we must strive to arrive at a partnership with federal and state governments, as well as the other purchasers of these services, to provide the kind of balance that supports high-quality, affordable, and accessible care that permits the same degree of innovation. Even though such a partnership should develop, members of ASTS should provide the leadership and make appropriate and sound recommendations. In essence, we should, in fact, be the policymakers and not the followers in this partnership.

In the process of these changes, most of which are for the public good, ASTS should unite its membership rather than be tempted to form subgroups to work behind the scenes on one controversial issue or another. The leadership in this organization must be made aware of problems as they arise so that they can speak for you, the membership, in a way that is appropriate.

I know there is not one quick and easy answer to these problems. Obviously, many of these issues are controversial enough that it will be difficult for all of us to agree totally on one approach or the other. Nevertheless, I've tried to suggest a few recommendations that I think would be worthy of your consideration for some of these controversial issues. However, I'm sure we all agree on two points: everything should be accomplished in the best interest of the patient, and scientific progress and involvement in clinical care should not be hampered by regulatory measures.

Finally, I'd like to thank all of you who have helped me in the past year in my attempt to discharge my responsibilities. I'd like to particularly include the members of the Council and many of the past presidents. Also, I'm most appreciative of the support and help of my family during the past and previous years.