



Problems in Transplantation— Ethics, Education, and Expansion

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First, let me begin by expressing my gratitude to you, the membership, for the honor and privilege to serve as your president this past year. I also want to say thanks to all who have helped me discharge this duty, especially all the past presidents and members of the Council—and particularly to Oscar Salvatierra, H.M. Lee, and Robb Corry for their wise and generous advice on some difficult problems, as well as Barry Kahan, Bruce Reitz, and Andy Novick. Special thanks go to Wes Alexander and John McDonald who worked so hard at the ever-increasing job of secretary and treasurer in spite of their demanding academic and clinical duties. I know I speak for all of you when I express my gratitude to Jerry Rosenberg and his committee for the beautiful job they have done in preparing this meeting's program. Likewise, we are all indebted to the local organizing committee, especially its chairperson Olga Jonasson, for the magnificent job they have done in organizing this meeting—and this at a time when Olga has had so many obligations with the National Task Force. Time does not permit me to publicly thank all of the committee chairmen and their members individually for their work; I have tried to express my personal gratitude at their meetings yesterday. Finally, I would like to acknowledge the thoughtful, professional, and expert work of Janet Wright and her organization in handling the day-to-day affairs of the society and our annual meeting. We are lucky to have them.

I had hoped to talk to you today about a scientific subject—namely, the use of donor antigen to modulate the allograft response, an area of long-term interest to me, and one that I think should and will be the next application of clinical immunosuppression. This subject I will leave for a later talk because I want to focus today on three problems I see facing the transplantation community in general, and the American Society of Transplant Surgeons in particular. These are the general concept of ethical practice in transplantation, the education of the transplant surgeon, and the expansion of the clinical practice of organ transplantation.

Ethics in Organ Transplantation

First, I will discuss at some length certain ethical considerations in transplantation. You are no doubt aware of the recent significant negative publicity generated in the public media concerning access to organ transplantation, exportation of organs, preferential treatment of certain recipients, and other equally disquieting matters. As your representative, I was repeatedly asked (and sometimes verbally assaulted by the media, including all the networks and most major papers) for ASTS's stand on this or that issue relative to ethics or practice. I had to state that for many of the issues raised there was no official stand that I could articulate for the society. I had my opinions, but they were just my own. Frankly, I did not feel the urgency to elaborate Society guidelines. I thought then, as I do now, that the overwhelming majority of our members act ethically with the welfare of their patients as their foremost consideration. Furthermore, a law had been passed making a felony of the purchase and sale of organs, and the international Transplantation Society had already dealt with a number of important ethical issues and published their guidelines. Likewise, the task force was at work and it was going to address access to organ transplantation. I also thought that media attention, particularly that as motivated by sensationalism as this was, would abate—and it did. But the incident that identified to me an urgent need for an ASTS statement of guidelines came one day in a phone call from one of our members. He told me that his university president wanted to contract to do cadaver transplantation for a significant number of foreign nationals and that he, the transplant surgeon, was under great pressure to cooperate in this for “the good of the university.” The transplant surgeon wanted help in the form of the official stance of ASTS in this matter, and unfortunately there really was none. Incidentally, this university was not in a city with a major league baseball or football club. It seemed to me that, if academic, institutional, or administrative pressures could be brought to bear on transplant surgeons in areas of ethical consideration, ASTS should provide some shield of protection.

Guidelines for Organ Transplantation

Accordingly, your Council at its mid-winter meeting discussed in detail the need for written guidelines on certain aspects of transplantation practice. A set of guidelines was elaborated, for the most part through the enormous efforts of Jim Cerilli, chairman of the Ethics Committee; they were discussed and eventually approved by the Council and mailed to the membership for vote. We have 331 members in ASTS, and 192 replied, an excellent reply rate for a mail ballot; there were 183 affirmative votes and only 7 dissenting votes (2 abstentions). Thus, 95% were in favor of these guidelines. I want to review these guidelines briefly and identify what I think is the particular significance of each one, fully acknowledging that this is an imperfect document.

1. The supply of transplantable organs is a national resource and procurement is almost exclusively fiscally supported through federal funding. Therefore, the distribution and assignment of organs to patients must be determined by medical criteria and cannot be

influenced by other considerations, such as political influence, monetary exchange, or center favoritism.

The first guideline identifies cadaver organs as a national medical resource that should be dispensed only on the basis of medical criteria without political, financial, or other potentially corrupting influences. Although some quibbled over describing cadaver organs as a national resource, all agreed that the basic tenet of this guideline was correct and something we could live with.

2. There must be no shipment of transplantable organs to foreign countries by an organ procurement organization or individual unless there is verifiable evidence that a concerted attempt has been made to place these organs somewhere in the U.S. Such evidence must include the referral of the organ to a national center for organ distribution if regional patients are not available for its utilization.

The second guideline clearly affirms ASTS's opposition to exportation of cadaver organs from the U.S.—regardless of a profit or nonprofit motive—unless verifiable efforts to use the organ in the U.S. have been made. This is current practice in both our national sharing networks and will be standard practice when the national network is established under the Organ Procurement and Transplantation Act—which it soon will be. There were no significant objections to this.

3. The active recruitment or encouragement of foreign nationals for the sole purpose of transplantation in the U.S. is inappropriate and unacceptable to the American Society of Transplant Surgeons.

The third guideline was designed to address the problem I identified initially. Specific contracting of groups of foreign patients by individual centers could clearly lead to disadvantages to the regional patients of the center or the national patient pool, by sheer numbers or by the financial pressure that a single large patient referral source can exert, as it does in so many areas of medicine. The guideline also renders unacceptable advertising and guaranteeing of cadaver organs within certain lengths of time, which have encouraged foreign nationals to seek organs in the U.S. in the past. No one had trouble with this guideline.

4. Organs made available for transplantation in the U.S. should be preferentially transplanted into citizens of this country, individuals residing permanently in the U.S., and foreign nationals under specifically defined conditions. The transplantation of any organ into an individual who comes to the U.S. for the express purpose of receiving a transplant is acceptable for humanitarian reasons, providing such transplants constitute a very small percentage of organs transplanted at a given center. This percentage must not exceed, on average, 5% per year of the organs transplanted at any single center.

Foreign nationals who are on the transplant waiting list of a center in the U.S. must reflect the religious, ethnic, and economic profile of their country of origin. The patient or the

responsible financing agency must be charged for transplantation services on the same basis as citizens of the U.S.

The first half of the fourth guideline definitely states citizens of this country should receive cadaver organs procured in the U.S. preferentially. It does not exclude cadaver organ transplantation for foreign nationals categorically—as some of our members wanted—for a number of reasons, including the realizations that a human being is a human being, that many countries do not yet have complete transplant capabilities, that many foreign nationals have been treated in the hospitals of the transplant center for years for the very disease that now brings them to require transplantation, that foreigners donate organs when they die in the U.S.—and for numerous other reasons reasonably described as humanitarian. The Council realized that, practically, these transplants should constitute a small percentage of any center's activity. One could have endless ethical discussions pro and con about the concept of identifying a specific numerical limitation (here 5%) for foreign nationals. Nevertheless, identifying a numerical limitation acknowledges preference for citizens of the U.S., restores flagging public trust in the transplant community, and provides you, the society and its Council and Ethics Committee, with a reasonable monitoring mechanism and a behavioral yardstick. I might add that the recently completed task force report addressed this problem and similarly recommended a numerical limitation of 10% for foreign cadaver kidney transplants and heart and liver transplants only if no recipients were identifiable in the U.S.

The second half of the fourth guideline shown here attempted to ensure that foreign nationals who were accepted at a center would not be restricted to the wealthy and privileged of a country. It was a naive attempt, difficult to interpret, and clearly in retrospect undefinable and uninterpretable. This statement requiring transplanted foreign nations to reflect the religious, ethnic, and economic profile of their country might be the first part of the guidelines to be modified by future Ethics Committees. On the other hand, the requirement that everyone should be charged the same is appropriate and important, and again reinforces the public trust that financial inducements for foreign transplants have been removed or minimized.

5. The use of living related donors is currently accepted because of the shortage of cadaver organs, and because current long-term results with living related donors are better than with cadaver organs. The use of living related donors must assure (A) proper informed consent with adequate documentation, (B) proper donor psychological and medical follow-up, (C) absence of financial profit by the donor, and (D) no known coercion of the donor or family.

The fifth guideline identifies standard practice for living related kidney transplantation. It was included because some members expressed concern that with the current good results of cadaver transplantation, living related transplantation might be considered unnecessary, obsolete, and not peer practice by people not acquainted with the field. Clearly it still is peer practice; obviously we all eagerly await the day when use of living related donors will not be necessary.

6. *The use of living, nonrelated donors is acceptable only under specifically defined circumstances that include a documented “emotional relationship” between donor and recipient and a medical situation necessitating prompt transplantation. When living, nonrelated donors are used, there must be documented informed consent, lack of monetary exchange in excess of reasonable donor costs, and an assurance of proper donor medical and psychological follow-up. Because, at this time, the overall clinical results and benefits of using living, nonrelated donors are still unknown, such transplantation must be conducted with the approval of the respective center’s Committee on Human Experimentation.*

The American Society of Transplant Surgeons, while recognizing the occasional appropriateness of living, nonrelated donor utilization and the current justification for the use of living related donors, is committed to the goal of an adequate supply of cadaver organs with a graft success equivalent to that of living related donors, thus ultimately eliminating the need to use healthy living donors.

The first part of the sixth guideline affirms that nonrelated living donors—whether the transplant is done with DST, cyclosporine, or something else—may be an acceptable alternative to cadaver kidney transplantation. It requires that a documented emotional relationship between donor and recipient and a special medical need be conditions for use, and it sets up barriers to the mere buying of organs from external sources. This guideline is designed to oppose opening the flood gates to use of living nonrelated kidneys from donors whose motives are less than altruistic or whose circumstances, economic or otherwise, might force them to donate their organs against their will. However, the guideline has been discussed for at least a year, and several members honestly object to the description of this procedure as experimental and the requirement for Human Studies Committee participation. With new and more complete experience, this objection seems valid and the Ethics Committee might consider modifying or deleting the statement that nonrelated living donor kidney transplantation should be conducted with approval of the institution’s Human Experimentation Committee.

The second half of this guideline restates the ASTS commitment to develop cadaver transplantation to such a level that living nonrelated donors would not be required, a noble and noncontroversial goal.

7. *The Ethics Committee of the American Society of Transplant Surgeons will review complaints against individual surgeons and/or centers regarding alleged breaches of ethical practice. The Ethics Committee will present its findings to the Council of the American Society of Transplant Surgeons who will decide upon appropriate disciplinary action, which may include censure by or expulsion from the American Society of Transplant Surgeons if violations of ethical practice are confirmed. The governing board of the facility utilized by the offending member for the purpose of transplantation will be notified in writing if such disciplinary action is taken.*

The seventh guideline squarely states that ASTS will concern itself with alleged breaches of ethical practice. It identifies the role of the Ethics Committee in investigating these alleged breaches, confirms the right of ASTS to exercise disciplinary action, and asserts its intention to inform appropriate institutional administration of any disciplinary actions it has taken.

I emphasize that these guidelines are not perfect, but they are certainly a starting point from which a great scientific society can fulfill its professional responsibilities. They should be reviewed and changed as scientific progress and clinical practice mandate modification. Indeed, if organs become plentiful, some guidelines may be rendered obsolete and others strengthened. I think that if we follow them and take adherence to them seriously, our ethical problems and public concern and distrust will be things of the past.

Education of the Transplant Surgeon

The education of the transplant surgeon is another area of concern. Please note I said *education*, not *training*. It implies that the individual is taught or trained to react in a defined way or to do things only in a defined manner. It connotes a shade of anti-intellectualism that some people attribute to certain areas of surgery in general. Certainly in the beginning, transplant surgeons were the opposite of this concept in every way. They were the eggheads of surgery—talking about genetics, immunobiology, inbred strains, tolerance, enhancement, haplotypes, public antigens, private antigens—and more recently, lymphocyte subsets, killer cells, suppressor cells, helper cells, lymphokines, IL-1, IL-2, interferon, and so on. In the early days a young resident surgeon invariably went off to a basic science laboratory, frequently not related to a surgical department, to study some aspect of immunobiology, and only after that experience would he or she take up clinical transplantation studies and activities. With the increased success of all organ transplants, especially with the use of new, more effective immunosuppressive agents, many young residents bypass the basic science year and plunge into clinical organ transplantation. Whatever basic immunology they learn is picked up along the way. The chance to immerse themselves in immunologic studies is missed along with the many lifelong good habits of sophisticated scientific experimentation that they could apply to their clinical studies throughout their professional careers. Basic science immunologic preparation combined with surgical skills invariably made the transplant surgeon the leader of the transplant unit. I am concerned that, as we get away from basic immunologic education requirements, the transplant surgeon can become the “sewer-in” of the organ and not the unit leader and contributor. I remind you that in other countries where it has not been the frequent practice for the surgeon to be prepared in immunobiology, the leader of the transplant unit is frequently a nonsurgeon who has prepared in immunology. My admonition is clear; as clinical organ transplantation expands and our young people go into it, we should emphasize and reinforce—and even require—a basic science investigational experience as part of the transplant surgeon’s education. This could be obtained in a basic science department or as part of a qualifying research-clinical

transplant fellowship in one of the many leadership laboratories of our major clinical transplant centers.

The expansion and success of organ transplantation brings into focus another problem in the education of the transplant surgeon. Institutions are putting together transplant teams for nonrenal organ transplants in which the surgeon's role is strictly technical. This surgeon has had no experience in such subjects as immunobiology, immunogenetics, or management of immunosuppression, and cannot function in a leadership role. ASTS must review and redefine appropriate clinical transplant education to designate the qualified transplant surgeon and what fellowship programs are qualified to achieve this. My own preference is that qualified fellowships include a year of investigational experience and a year of expanded clinical experience in kidney transplantation, as well as in transplantation of one other extrarenal organ. No matter what type of transplantation the fellow intends to pursue, this implies a minimum of two years' laboratory-clinical experience. I further advise that all our fellowship programs be rereviewed by our Education Committee for recertification, and that they be reviewed regularly every two years thereafter once our qualifications are defined.

Expansion of Clinical Organ Transplantation

Elaboration of these more stringent requirements for qualifying as a transplant surgeon leads me to discuss the third problem: proliferation of clinical organ transplant activities. The impetus for transplant center proliferation is multifactorial but includes (1) the obvious success of all organ transplants; (2) the misconceptions that the problems of immunosuppression are over—just sew the organ in and give cyclosporine—and that transplantation is strictly a technical problem that any good surgeon can handle; (3) the decrease in all surgery and the desire, frequently generated by hospital administrations, to get what is euphemistically called the market share of new patients; and (4) the need for many surgeons, even academic ones, to expand into clinical transplantation as their own particular field of interest diminishes in scope and importance. I am amazed at how many GI surgeons propose to transplant the small bowel or pancreas, let alone the liver, without the slightest previous interest or experience in transplantation. In the short term, to stem the tide of proliferation, ASTS should take a forceful role in defining and enforcing what it perceives as appropriate criteria for description of qualified centers, including supporting or expanding the recommendations of the National Task Force for Center Qualification. In the long run, proliferation can only be controlled by enforcing two demanding requirements: that the transplant surgeon in a center must be a graduate of a qualified fellowship program under the expanded requirements I described above, and that no extrarenal organ program can be undertaken in an institution without a qualified kidney transplant program under the direction of a qualified transplant surgeon.

Finally, in a little less serious vein, I would like to mention the *gift of transplantation*. The phrase can mean many things—to the recipient, it is the gift of being saved from morbidity and mortality; to the donor, the chance to give a gift of life to someone; and to the transplant surgeon, the gift of being able to help the patient. To me it

also means another gift to the transplant surgeon. This was brought home to me a couple of years ago when I attended the 50th birthday party of my college roommate who was a successful internist right here in Chicago.

He was bored, disillusioned, and unhappy with his profession, and he announced his semi-retirement. I could not believe it. I felt as if I were just getting started and he was ready to quit. How could two people who started out at the same time in the same profession end up so differently? I concluded it was the particular work I was doing. Transplantation is a vibrant, vital field, ever-changing, ever-challenging, ever-stimulating, ever-accomplishing, with many limitless possibilities to affect all aspects of medicine and surgery—as it already has done and will continue to do. So this is another gift of transplantation, the opportunity it gives us to be continually creative, innovative, and productive. To you younger members, I emphasize this wonderful vitality of transplantation, which is like an unirradiated mixed lymphocyte culture, a two-way reaction. You get from it and you give to it, depending on your hard work and contributions. To you older members who have already contributed so much, I remind you of this continued opportunity, of which I know you will all continue to avail yourselves, perhaps best expressed by a medieval cleric, Bishop Richard Cumberland: “It is better to wear out than to rust out.”