



Role of Kidney Transplantation and its Implementation

JAMES CERILLI, 1980–81

Today I wish to present to you my views of transplantation, discussing some of its problems emphasizing those that this society can help alleviate. Thus, the major thrust of this talk will be to present how I feel this society can and should impact on certain current problems in transplantation.

Transplantation, like most surgical disciplines, began as a highly research-oriented clinical program. The initial results in the few centers that performed transplantation in the early and mid-1960s, if one reviews those results today, were extremely encouraging. Living related donor graft survivals were 60% to 70%, cadaver graft survivals approximately 40%, and technical complications quite reasonable. The number of surgeons performing transplantation was limited and each had extensive experience in the dog laboratory. Without doubt, the major problem with transplantation at this time was an unacceptably high mortality rate.

Research efforts during the 1960s were very productive in solving some problems, but with others failed dismally. We must recognize these failures, and ask ourselves why we were so ineffective in solving some very important questions. For example, efforts in organ preservation remarkably improved the management of patients with end-stage renal disease by making cadaver transplantation logistically more efficient and more convenient. Certainly, the ability to preserve kidneys for 24 to 36 hours took cadaver transplantation from the rare and unusual into a more routine form of care. In contrast, however, our efforts in other directions were not so productive. Is it not disappointing that despite 20 years of investigation into antilymphocyte globulin, we still have not been able to standardize this product and to determine the best method of production and administration. Certainly, 20 years of investigation of such an important agent should have compiled more information than is currently available. Is it possible that, had this society been the catalyst for large, cooperative, carefully directed studies, such a question might have been answered? There is little question that this society must play a major role in stimulating cooperative studies of this type;

this responsibility becomes more important as the delivery of transplantation services becomes increasingly fragmented.

As transplantation evolved, it developed within a limited number of research-oriented institutions and its applicability was limited by the lack of funding. The passage of the HR-1 legislation in 1972 changed that very dramatically, and unquestionably we are still feeling its impact. Now, for the first time, patients could be cared for literally without regard to cost, and, because of this, the number of centers performing transplantation rapidly exploded. Many transplant surgeons have commented that during the mid-1970s transplantation results appeared to deteriorate. This was attributed to many causes; however, it is my belief that one of the fundamental causes of this deterioration was the rapid increase in the number of transplantation units that often were directed by surgeons with little or no background or formal training in transplantation. Directors of many units were physicians whose background in administering immunosuppression was limited and whose technical training was meager. Individuals established transplantation programs simply by beginning to do transplants, and this clearly was one of the major reasons that transplantation results deteriorated. For this reason, as well as others, I have for several years had a major interest in the formalization and certification of transplant training programs and during the past year have tried to bring this objective to fruition. The significance of these attempts will be discussed later in this address.

Unquestionably, during the past three to four years, results in transplantation have improved. Primarily owing to the contributions of several of the members of this society, there has been a significant decrease in patient mortality. We must all very clearly understand that without this decrease in mortality, transplantation as a clinical tool for end-stage renal disease was clearly in jeopardy. However, the fact that not all centers have achieved this decrease in mortality not only affects patients receiving care in specific centers, but is detrimental to the entire discipline of transplantation: such results are widely quoted by our colleagues who question the role of transplantation.

There are many factors that contribute to an unacceptable mortality, morbidity, and graft survival, but I wish to mention a few of the more obvious. There are still centers that do not use mixed lymphocyte cultures to evaluate living related donors. The value of mixed lymphocyte culture for living related donor transplantation in my mind has been proven beyond any question, and to perform living related donor transplantation without mixed lymphocyte culture analysis is clearly wrong. Second, many centers still routinely perform bilateral nephrectomy when there is little documentation that this is of value and patients who reject their grafts are left with the disabilities of severe anemia and anuria. Third, immunosuppression is still used much too aggressively in many centers. Fourth, the technical complications in many centers are inexcusably high and inexperienced individuals often perform this procedure under poor supervision. While clearly we must train individuals to carry on this discipline, inadequate supervision of poorly trained personnel must be condemned. This is true not only for the transplant operation itself but also for the donor. Improper procurement of cadaver grafts leads to increased patient morbidity and mortality. This is not a procedure to be delegated to an unsupervised surgical resident.

Inadequate training also affects cost, a third and major issue in the management of patients with end-stage renal disease. With the emphasis now placed on maximum cost-effectiveness in all federal programs, a close look is being taken at the relative benefits of transplantation and dialysis. Without question, the cost-effectiveness of transplantation is significantly superior to that of dialysis. This fact needs to be publicized, defended, supported, and brought to the attention of responsible persons in federal and local government. Transplantation is cost-effective, however, only when performed properly and accompanied by low mortality and low morbidity. Properly performed, the cost of 100 transplants followed for 10 years, even assuming that only 60% of the grafts functioned and attributing all dialysis costs of rejected grafts to transplantation, would yield a savings of over \$15 million over the cost of center dialysis for 10 years on the same 100 patients. That is an enormous cost benefit. However, the cost/benefit advantage can even be heightened by the elimination of technical errors in the operating room, loss of kidneys from irreversible acute tubular necrosis because of poor donor procurement programs, high mortality rates because of over-aggressive use of immunosuppression, and the management of patients by relatively inexperienced, poorly trained people.

Now these issues define certain problems that should be addressed at this time and can be solved with the help of this society. First, transplantation is not as yet identified as a discrete surgical discipline. Second, the results of transplantation are, unfortunately, still inconsistent. Third, organ supply is inadequate. Fourth, end-stage renal disease expenditures are excessive.

Transplantation must develop into an identifiable discipline. This is difficult when many nephrologists have a valid complaint that many transplant surgeons refuse to see patients preoperatively, or that patients are seen by a fellow or by a transplant surgeon who has other clinical interests with a higher priority. Transplantation surgery will not gain identity as a discrete discipline as long as referring physicians have this very valid complaint.

Second, transplantation will never become an identifiable discipline until training programs with established standards are certified. I attempted to establish with the American Board of Surgery, the American College of Surgeons, and the Residency Review Committee of the American Medical Association (AMA) the formal review and recognition of transplantation training programs. I have endeavored to work through these historical and established administrative channels to accomplish formal recognition of transplantation training programs. However, it is clear that the administrative systems for review of training programs is too rigid and will not encompass the discipline of transplantation under their supervisory umbrella at any time in the foreseeable future. Therefore, it is necessary and mandatory that this society assume responsibility for the quality of transplantation postgraduate education. I have endeavored to establish this concept during the past year and believe that we must have certification of transplantation surgical training programs with periodic review of these programs. Many centers have applied for certification through ASTS and will probably be certified. However, I have asked the Education Committee to

establish high standards, and it is possible that some centers will not be approved until the quality of their training programs is improved.

In addition to assessing the quality of transplant programs, there must be some assessment as to their proper quantity. The number of transplant surgeons in the country must meet the clinical and research needs of the country, yet not exceed these needs so that skills cannot be maintained and also improved. According to present estimates, approximately 6,000 transplants should be performed per year. About 4,000 are now being performed and about 150 transplant surgeons easily meet this clinical responsibility. Clearly, about 10 to 15 well-trained surgeons per year should be adequate to meet future clinical needs. These surgeons must be highly trained in the technical aspects of transplantation and must also have a knowledge of transplantation immunology so that they can continue to advance the field and improve results. I repeat, the society must assume a role of leadership in ensuring quality education.

Another serious problem to which I have already alluded is that of inconsistent results. Two years ago, I appointed a standards committee to evaluate what should be reasonable clinical results in 1980. As you know, seven centers believed to be adequately staffed with trained personnel were reviewed. At these centers, cadaver transplantation is being performed with a one-year graft survival of approximately 55% to 60%; living related donor graft survival of approximately 78%, and mortality in both groups of approximately 5 to 10%. Our recent experience at Ohio State since 1977 shows that cadaver graft transplantation has been performed with a mortality rate of 3% and a one-year graft survival rate of 65%. Certainly, transplant centers whose results are not at least as good as those obtained in the American Society of Transplant Surgeons survey must rapidly reassess and change their methodology or cease offering transplant services. The only exception to this should be centers evaluating new techniques and methodology that may incur short-term poor results.

I recently spent a day discussing the current status of transplantation with some members of Congress, their staffs, and representatives of the Rand Corporation who frequently serve as their consultants. It was discouraging to hear their concepts of the role of transplantation relative to dialysis in the care of patients with end-stage renal disease. Their data are 5 to 6 years outdated. Nevertheless, they accurately indicate that many transplantation centers have poor results. That this assessment is accurate is demonstrated by the fact that in the recent survey to which most of you responded of 81 centers, the overall one-year mortality rate for cadaver transplants was 18%. Thus, it is clear that centers whose programs do not meet previously described standards need to reevaluate their methods and to cease performing transplants until clinical results can be improved. Uniform results must be achieved rapidly if we are to maintain transplantation surgery as a discipline and if we are to meet our moral and medical obligations to patients with end-stage renal disease. Now the question arises as to whether or not there is an optimal system to maximize the possibility of administering the best possible quality care to patients with end-stage renal disease. It is my view that one of the important requirements for the delivery of medical and cost-effective transplant services is encouragement of the concept of regionalization of transplant services. Unlike dialysis, geographic proximity of the patient in

the transplant centers is not an important factor in the development of optimal transplant services. It is very difficult for small units to maintain skilled personnel and facilities of the same quality as large units doing open-heart surgery and other complicated forms of surgery. It has also been demonstrated by a screening of more than 80 transplant centers in this country (unpublished observations) encompassing over 3,000 transplants, that centers performing fewer than 15 transplants per year had a 40% to 100% higher mortality rate depending on donor source than centers performing more than 30 transplants per year. Thus, it is my view that it is difficult to maintain the skills of medical and paramedical personnel necessary to maintain quality transplantation in centers performing fewer than 30 to 40 transplants per year.

This is an important issue and clearly must be definitively established or refuted for the discipline of transplantation in this country. The Health Care Financing Administration is in the process of evaluating the relationship between the size of the transplantation or dialysis units and cost and medical effectiveness. I have pledged the cooperation of this society and all its members to this study.

I am sure you are all aware of the close interrelationship between the federal government and our ability to deliver transplant services because of the Medicare legislation. However, new legislation, if enacted, will have an equal but unfortunately deleterious effect on us now. Our goals of maintaining outstanding research and training programs, quality care, and cost containment in transplantation are being threatened by current efforts toward deregulation that is being supported by the Reagan administration. The administration's current goal is to remove the health planning agencies that have been ineffective in regulating end-stage renal disease and to eliminate the networks that have been reasonably effective in some areas. The goal is to relinquish regulatory powers to the states. In some states, this may prove to be successful, but in most states it will be disastrous. There is no financial motivation for most states to be cost-effective, unless the source of the end-stage renal disease dollars is transferred from the federal government to the state government. Therefore, when an application for a dialysis unit or a transplantation unit is reviewed by the state, the political aspects will supersede the medical or cost-effective aspects. The federal government will continue to pay the bill through Medicare, while the states will be deciding the size of that bill. Therefore, costs will escalate, dialysis and transplantation units will proliferate, and quality of care will suffer because of fragmentation of services.

An additional consequence will be, I firmly believe, a worsening of the problem of the sequestration of patients on dialysis because small dialysis units in small communities are marginally cost-effective. To improve cost-effectiveness, they must increase their pool of center dialysis patients. To accomplish this, they must decrease the flow of patients into transplantation, chronic ambulatory peritoneal dialysis, and home dialysis. Therefore, in my view, deregulation of end-stage renal disease programs will encourage proliferation of units which will inhibit proper use of transplantation services.

Regrettably, the regulatory process of the network system has not met expectations. The system is responsible for a too small geographic area, often making objective decisions difficult. Its roles and authority in relation to the health systems agen-

cies and state regulatory agencies have never been defined. The network system's medical review boards are of questionable effectiveness. However, in most states, the networks are currently the only group of well-informed individuals about end-stage renal disease. Their elimination without a concurrent increase in the authority or staffing of the Health Care Financing Administration regional offices, in my view, will be detrimental to patients with end-stage renal disease for the reasons outlined. Although in conflict with the Reagan administration position, both the subcommittees on health of the House Ways and Means Committee and the Senate Finance Committee have retained in their proposals the network concept. I hope that the members of ASTS will communicate to both subcommittees as well as their local Congressional representatives, recommending the preservation of meaningful controls at the federal level to avoid the inescapable problems of costly duplication and inappropriate patient therapy.

Pressures leading to uncontrolled proliferation of transplantation units come not only from the federal government but also from the AMA. The AMA recently passed a resolution that transplant services be delivered in all hospitals capable of providing the necessary medical support. No mention was made of costly duplication or the effect of fragmentation on quality care, education, or research. I have responded to the AMA position on behalf of ASTS, and I suggest that those of you who are members of the AMA who disagree with the position express your disagreement. The AMA position does influence those who determine federal policies toward the end-stage renal disease program.

Still another issue with which ASTS should be involved is the quantity and quality of cadaver kidneys. As the number of hospitals from which we procure kidneys increases, the difficulty of quality control in organ procurement escalates. Our wish to continue a relationship with a community hospital often conflicts with maintaining adequate standards for kidney procurement. Nevertheless, it behooves each of us to recognize that kidney waste is very expensive and that the use of marginal kidneys is clinically unjustified. This society, through its standards and preservation committees, should establish guidelines for organ procurement and utilization with the goal of increasing the efficiency of procurement and decreasing the cost.

The problem of organ procurement extends beyond the relatively narrow problem of the quality of individual kidneys. It is my impression that the whole concept of organ procurement rests on a tenuous and unstable base, requiring continuing and maximum effort by each transplant center to maintain a supply that remains inadequate. Any proposed solution to this problem must not increase the cost of organ procurement, since this is clearly not the time to approach Congress with suggestions that would increase the costs of the end-stage renal disease program. For this reason, I have been working with the staff of Representative Philip M. Crane of the subcommittee on health of the House Ways and Means Committee to introduce a bill in the summer that would provide credits to donors of cadaver kidneys.

The advantages of this bill are clear: (1) The patient receiving the kidney would obviously benefit by receiving an optimal and recommended form of therapy. (2) The donor's family would benefit from the financial sequelae of a tax credit. (3) The gov-

ernment would benefit because the patient receiving the kidney would be removed from dialysis, which costs \$28,000 per year and offers minimal hope of rehabilitation.

In short, if this bill is passed, everybody benefits. The bill obviously does not meet all needs but it is an important beginning to improving, through legislation, the problem of inadequate organ supply. However, to assure passage of the bill, your help is needed. I request and I urge that each of you when you return home to write to the members of the Senate and House subcommittee on health and send copies to Representative Philip Crane and your local representative and senator and ask for support of any reasonable bill that would increase the supply of kidneys. With an outpouring of support, this bill has an excellent chance of passing. Without it, it is doomed to failure. Congress must be convinced that this bill fills a need and only you can establish the need.

Another approach to augment the supply of cadaver kidneys would be to establish the concept in this country of a “presumed consent” rather than an approved consent by specific request. In 13 countries, presumed consent is accepted and kidneys can be removed from a donor unless the donor had at some time specifically objected. I have asked our consultants at Health Policy Alternatives to review the effectiveness of this legislation. This will be a long-term goal and program, but it is the type of activity that I believe ASTS should support.

Clearly, therefore, many problems exist in transplantation that can be addressed by ASTS through cooperation among its members. I have presented several specific examples of activities that should be addressed by the members of the Society that would favorably affect transplantation. They are: (1) support a bill for tax credits for kidney donation; (2) help maintain effective regulation of the end-stage renal disease program; (3) strengthen cooperative research studies; (4) cooperate with the programs to evaluate the relationship between the size of a transplant unit and its quality of care; and (5) support the effort establishing accreditation of training programs by ASTS. I hope you will work together to realize these objectives. Your support, effort, and cooperation are essential if ASTS is to be a meaningful force in these programs that will ultimately improve patient care, which after all is our major responsibility.