

THE ACCESS OF DIALYSIS PATIENTS TO KIDNEY TRANSPLANTATION



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TO KIDNEY TRANSPLANTATION

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This Report

Entitled "The Access of Dialysis Patients to Kidney Transplantation," this report is based on a comprehensive study conducted to help the U.S. Department of Health and Human Services and other interested parties gain a better understanding of the effectiveness, efficiency and equity of organ acquisition practices in the U.S.

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MAJOR FINDINGS

- o Although kidney transplant surgeons report that at least 20 to 25 percent of the dialysis population is medically suitable for a transplant, only 10 to 11 percent of that population is on a transplant waiting list.
- o A major factor contributing to this differential is the failure of some dialysis facilities to provide their patients with a full and fair opportunity to receive a transplant.
- o Across the country, a number of dialysis facilities have transplant referral rates well below the national average. Some of these are large facilities with 80 or more patients.
- o Under Medicare conditions of coverage, dialysis facilities are required to develop patient long-term care plans that designate suitable treatment modalities for patients. The oversight of this requirement by State survey agencies and ESRD network organizations has been spotty and often ineffectual.
- o A Medicare requirement notwithstanding, it appears that transplant surgeons are not regularly involved in reviewing patient long-term care programs. Further, the patients' own role in this process tends to be minimal and passive.
- o A number of considerations support the case for significantly increasing the number of referrals for kidney transplantation, even at a time when close to 10,000 individuals are already reported to be awaiting a transplant. Among them are the following:
 - Precluding a patient the opportunity for a transplant is unethical, regardless of the length of a waiting list.
 - Non-sensitized dialysis patients are likely to receive a transplant quickly.
 - Increased waiting lists would reduce the likelihood of cadaver kidneys being discarded or provided to foreign nationals.
 - The supply of cadaver kidneys may increase significantly in the near future.
 - Low referral rates can add to Medicare costs.

RECOMMENDATIONS

- HCFA should require that network organizations prepare and disseminate, annually, a report that indicates, by dialysis facility, the proportion of patients on a transplant waiting list.
- HCFA should ensure that intensive oversight is given to dialysis facilities having transplant referral rates appreciably below the network average. In particular, the network organizations should be required to conduct thorough medical records reviews of such facilities and be authorized to prescribe corrective action plans.
- HCFA should ensure that State survey agencies conduct a thorough and more outcome oriented review of the Medicare condition of coverage concerning patient long-term programs and patient care plans.
- HCFA should require that as a condition of reimbursement for routine dialysis, a facility must have for each patient a written long-term program and a written patient care plan signed by the patient, a nephrologist, and a transplant surgeon.
- HCFA should work with the Public Health Service to encourage the American Society of Transplant Surgeons (ASTS) to provide some guidance on which dialysis patients are medically suitable candidates for kidney transplants.

INTRODUCTION

Dialysis is a life-saving process. It is also a debilitating one. Each year it exerts a significant toll on the physical, social, psychological, and financial well-being of patients. Each year close to one-fourth of those taking the three-times-a-week treatment die.

In a 1980 study, we examined the impact that dialysis has on the life style of patients. We heard patients describe the loss of physical strength, the dietary restrictions, the disruptions to their marriages and social life in general, and the weariness associated with their continued dependence on a machine. Further, we found that the impact on their employability was "dramatic and far-reaching." Of 160 patients we met who were working full-time when their kidneys failed, only 29 (18 percent) were working full time and 22 (7 percent) part time at the time of our discussions.

It is understandable then, why the dialysis patients expressed considerable interest in kidney transplantation. Even the most skeptical and cautious among them tended to see in transplantation the possibility of a "cure-all," of a chance for a normal life once again.

In recognition of the opportunity transplantation afforded for improving the quality of life for renal patients and for reducing long-term costs for the Medicare-funded End Stage Renal Disease (ESRD) program, Congress, in 1978, passed legislation providing greater financial incentives for transplantation. In particular, this involved the enactment of provisions (1) authorizing payment in full for the reasonable expenses of kidney donors and (2) extending program coverage for kidney recipients from 12 to 36 months following transplantation.

These provisions did provide some stimulus. But the major increase in transplantation came a few years later in response to significant advances in transplantation technology and immunotherapy. Particularly notable was the widespread introduction in November 1983 of cyclosporine, a powerful immunosuppressive drug.

These developments led to considerable improvements in transplantation results, particularly with respect to transplants involving the use of cadaver kidneys. By the mid 1980s, the one year patient survival rate for those having a cadaver kidney transplant was averaging about 93 percent; the one year graft survival rate about 75 percent. For those having living related transplants, the comparable averages were about 96 and 88 percent.

Accordingly, for many individuals whose kidneys have failed, transplantation provides a viable treatment option. Although there are still risks and limitations, they are much less pervasive than was the case when we conducted our study only 7 years ago.

Since then the interest in transplantation has increased greatly among both the professional and patient communities. From 1980 to 1986, the annual incidence of kidney transplantation increased 63 percent, from 4,697 to 7,695.

Yet, in the midst of this change, we have found that across the country there are still a number of dialysis facilities that do not afford their patients with a full and fair opportunity to pursue the option of transplantation. This is so despite the fact that Medicare ESRD program regulations require each dialysis facility to develop a "written long-term program representing the selection of a suitable treatment modality (i.e., dialysis or transplantation) and dialysis setting (e.g., home, self-care) for each patient."

In this report, the second in a series of reports concerning organ acquisition systems, we examine this problem of limiting patient access to transplantation, a practice which some refer to as "sequestering." We address the nature and dimensions of the problem, the causes, and the implications. We close with some recommendations addressed to the Health Care Financing Administration (HCFA) in the U. S. Department of Health and Human Services (DHHS).

THE PROBLEM

". . . even more pressing than the problem of non-Americans receiving kidneys is the problem of many Americans being dialyzed who are not being considered for transplantation."

The above comment was part of prepared testimony submitted by Paul I Terasaki, Professor of Surgery at the UCLA School of Medicine, to the House Subcommittee on Investigations and Oversight of the Committee on Science and Technology. The testimony was presented in November 1983 at hearings which the Subcommittee held on the procurement and allocation of human organs for transplantation.

In the nearly 3 years that have passed since those hearings, we have found that the problem remains. Although transplant surgeons report that at least 20 to 25 percent of the dialysis population is medically suitable for a kidney transplant, HCFA data indicate that only 11.5 percent of that population is on a

transplant waiting list. Taking into account the duplications reflected in the waiting list data, the actual proportion of dialysis patients awaiting a transplant is probably closer to 10 percent.

Why is there such a differential between the proportion of suitable candidates and the percent actually awaiting a transplant? Certainly patient choice is a factor. Some patients, of their own volition, prefer not to have a transplant, which, after all, does involve some risks. Some may be reluctant to give up their time slot for regular dialysis treatments. Others may have some interest in a transplant, but because of the distance to the transplant center may conclude that it is not a realistic alternative. Some studies carried out by ESRD network organizations suggest this factor as a possibility.

But clearly a major factor responsible for the differential is the failure of some dialysis facilities to keep their patients adequately apprised of the transplantation option and to suggest that option to the appropriate candidates. This assessment was offered to us by many surgeons, nephrologists, transplant coordinators, and network directors from different parts of the country.

Most were quick to clarify that in their areas the phenomenon was not widespread -- that most dialysis facilities and referring nephrologists were quite conscientious in informing patients of treatment options and in referring them for transplantation. The problem, they added, tended to involve a small number of facilities, some of which were quite large and some of which had consistently low referral rates over the years. In a few cases, the problem appeared to be more widespread involving much of the dialysis community in a particular locale.

To get a better sense of the scope of the problem, we examined data on referral patterns of each of the dialysis facilities located in three different ESRD networks. The networks are in three different parts of the country: New England, the South and the West. In each case, we had visited one or more cities in the network.

In each of these areas we found extensive variation in the degree of attention given to transplantation by dialysis facilities. While some regularly had referral rates of 15 percent or more, others were consistently at levels well below the national average of 11.5 percent. Following is some capsule information on the three networks and the findings concerning them.

Network #4

- This network covers 13 counties in southern California, including Los Angeles and Orange counties. As of December 1985, it included 106 dialysis facilities, which had 6,204 patients, 9 percent of whom were on transplant waiting lists.
- In 31 of the facilities, 5 percent or less of the patients were on transplant waiting lists. Ten of these facilities had 80 or more patients.
- One dialysis facility with 117 patients had only one individual awaiting a transplant. Another, with 181 patients had only 4 on a waiting list. Since 1981 that facility consistently has referred only 1 to 2 percent of its patients for transplantation.

Network #18

- This network covers Alabama (except for one county), Mississippi, Tennessee, and selected counties in Arkansas, Georgia, Missouri, and Virginia. As of December 1984, it included 79 dialysis facilities, which had 4,284 patients, 9 percent of whom were on transplant waiting lists.
- In 26 of the facilities, 5 percent or less of the patients are on transplant waiting lists. These include 5 of the 18 facilities with 80 or more patients and 14 of the 22 in Mississippi.
- One facility with 205 patients had only 5 awaiting a transplant.

Network #28

- This network covers Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont. As of December 1985, it included 40 operating dialysis facilities, which had 2,744 patients. During 1985, 9 percent of the patients had a kidney transplant. (Data on percentage of patients on transplant waiting lists were not readily available.)

- o In 8 of the facilities, 5 percent or less of the patients received a transplant in 1985. Two of these facilities had 80 or more patients.
- o One facility, with 253 patients had only 8 of its patients receive a transplant in 1985. In another facility that maintained a patient census of about 50 in 1984 and 1985, none of the patients received a transplant during that period.

It is important to recognize that the presence of some facilities having low transplant referral rates in these networks is not unique to these networks. The same phenomenon is likely to be found in all or nearly all the networks.

In some instances, of course, the medical condition and/or age of the patients may very well explain the low incidence of referral. In many other facilities, especially larger ones having 80 or more patients, patient characteristics are much less likely to provide a satisfactory explanation.

THE CAUSES

Why, then, aren't more dialysis patients who are likely candidates for transplants being considered for transplants? Indeed, in view of the widespread reports on the successes of transplants, why aren't the dialysis patients themselves urging that they be considered for transplants?

In actuality, dialysis patients are becoming more informed and assertive in this regard. That is in part responsible for the fact that from 1980 to 1985 kidney transplant waiting lists have increased from 5,072 to 9,781, from 9.7 percent of the dialysis population to 11.5 percent.

But there are two major factors that serve to constrain patient initiative in seeking out the transplantation option. One is that those with unsuccessful transplants typically return to the dialysis facility and share their frustrations with the other patients, while those with successful transplants are seldom if ever seen again.

More significant perhaps is the other factor - the dependence and deference that generally characterize the patients' relationship with their nephrologists. From the onset of their kidney failure, which often causes considerable disorientation and anxiety, patients usually become accustomed to following the direction and advice of their nephrologists on matters concerning their treatment.

As noted earlier, it appears that most nephrologists are quite conscientious in considering the best treatment plan for their patients and that many are becoming increasingly inclined to recommend transplantation. On the basis of medical considerations, however, some still seem to have major reservations about transplantation and are likely to take a very conservative approach in determining its appropriateness for their patients. Instead of the previously cited 20-25 percent of the dialysis patients being prime candidates for transplantation, they may regard 5 to 10 percent as a more appropriate level.

Notwithstanding that there is room for disagreement on the basis of medical considerations, many individuals, including a number of transplant surgeons, feel that other considerations often loom behind a nephrologist's lack of enthusiasm for transplantation. In particular, they refer to financial considerations. By referring a patient for transplantation, they note, nephrologists take the chance of losing income in a newer facility trying to get established, a proprietary one owned by nephrologists, or one having a difficult time maintaining its caseload, this financial factor, some feel, may be particularly important.

Nephrologists are quick to deny such assertions. But many of them do express concern that patients who receive a transplant often become "captured" by the transplant surgeons -- that is, they don't refer the patients back to the nephrologists for post-transplant care concerning their renal disease. Surgeons tend to respond that they are best suited to manage the drug regimen for the patients and to identify early signs of impending graft failure.

Given that a dialysis facility is required in Medicare regulations to develop patient long-term care plans that designate suitable treatment modalities for patients and that involve transplant surgeons in the process, one might well ask how a facility, for whatever reasons, could deny its patients full and fair access to transplantation. The answer is that the oversight of this requirement has been spotty and often ineffectual, particularly, it appears, during the past year or two.

The responsibility for oversight is that of the State survey agencies and the ESRD network organizations. The State agencies review dialysis facilities as part of the Medicare survey and certification process to assure that they are in accord with Medicare conditions of participation. The network organizations are responsible under Medicare regulations for fostering the quality and appropriateness of patient care, including "the use of those treatment settings most compatible with the successful rehabilitation of the patient."

The State survey teams, first of all, review ESRD facilities about every other year. From HCFA's Medicare/Medicaid Automated Certification System (MMACS), we found that over the past 2 years, 183 or 12 percent of the 1503 dialysis facilities reviewed

were found to be deficient in meeting the Medicare standard concerning a patient long-term care program. (This standard and another concerning patient care plans together constitute a "condition.") We have not determined the exact nature of the deficiencies found across the country. But for one State having a significant number of these deficiencies, we learned that most involved a failure to have a written long-term care program in the patient's file.

This data and our review suggest that some States give a good deal of attention to whether or not proper procedures are followed in determining a patient's treatment modality. But in 24 States no facilities at all were found to be deficient with respect to the above noted standard and in 14 others only 2 or less were identified as deficient. In one heavily populated urban area, where referral for transplantation has been a significant problem, the State survey team cited only two facilities, during the past 2 years, for being in violation of the standard.

Further, even where deficiencies are identified and corrective action subsequently taken, it does not necessarily have a notable effect on the rate of referral, since the thrust of the State review is on process elements rather than outcomes. Illustrative is the experience in one State where the State survey team awhile back raised concerns about how transplant surgeons were not adequately involved in preparing patient care programs. This led to an arrangement whereby the dialysis facilities would regularly send medical records to a transplant surgeon, who would review them and then send them back to the facility with his comments about the suitability of a transplant. In assessing that process, the surgeon told us how he seldom heard back concerning any of the cases he reviewed.

As a rule, it appears that transplant surgeons are not regularly involved in reviewing patient long term care programs. And when they are involved, it tends to be in a distant and rather passive way as noted above. Rarely, it seems, do the nephrologist, transplant surgeon, and other professionals meet with the dialysis patient, as a team, to discuss treatment options. One factor that may tend to discourage such practice is that transplant surgeons are not allowed to bill Medicare for consultation services for dialysis patients considering a transplant. Such services are regarded as part of the nephrologist's monthly capitation payment. Any payment to the surgeons must be made directly by the nephrologists.

Network organizations, as noted, also have a role in overseeing dialysis facilities. Over the years, many of them, have devoted considerable attention to the adequacy of dialysis facility practice in alerting patients to transplant opportunities. Through surveys, medical record reviews of individual facilities,

patient education, and other initiatives, they have been instrumental in improving referral rates for transplantation (as well as home dialysis). In many cases, peer review and pressure seem to have had some effect in changing the practice of those with unusually low rates. In cases where they haven't, the network organizations haven't been able to do much about it.

During the past 2 years, as a result of budgetary cutbacks, the network organizations appear to have become less active and effective in this area. In a number of cases, the financial restrictions have led to reductions in the scope of studies undertaken, medical records reviewed, and informational material prepared.

THE IMPLICATIONS

The most important implication associated with the finding that many dialysis patients who are suitable transplant candidates are, in fact, not being considered for a transplant is, of course, quite clear. It means that they are being deprived of an opportunity to improve the quality of their life. A national study conducted recently by the Batelle Human Affairs Research Centers and funded by HHS found that "transplant recipients consistently reported a higher objective and subjective quality of life than patients undergoing any form of dialysis." Precluding this opportunity to a dialysis patient is an unethical and irresponsible practice, regardless of the length of a waiting list. This is reason enough for attempting to eliminate the practice.

Nevertheless, in the current environment where demand for cadaver kidneys exceeds the supply, where close to 10,000 individuals are reported to be awaiting a transplant, one may argue that a significant increase in referrals would yield little net benefit. In fact, one may even argue that it would only serve to raise expectations and add to the laboratory and other costs incurred by those on a transplant waiting list.

We find such a position to be short-sighted and detrimental because it overlooks a number of important considerations. Four are of particular note.

1. Non-sensitized dialysis patients are likely to receive a transplant quickly. Despite the long waiting lists, patients with a low level of preformed antibodies are usually able to have a kidney transplant within a few months of the time they are placed on a waiting list. This is because highly sensitized patients, those who are most difficult to match with a donor kidney, have become an increasingly prominent part of the transplant waiting lists. As of June 1986, 40 percent of 8,610

recipients on the national waiting list of the United Network for Organ Sharing had a Panel Reactive Antibody (PRA) level of 60 percent or more. This means that they were likely to reject at least 6 of every 10 donor kidneys that became available.

Thus many non-sensitized patients who are not on the waiting lists could receive a transplant much sooner than the waiting list statistics might lead one to expect. Moreover, many immunologists and surgeons believe that they would be likely to keep the transplanted kidney longer and have fewer complications than would those who are highly sensitized.

2. Increased waiting lists would reduce the likelihood of cadaver kidneys being discarded or provided to foreign nationals. In accord with recommendations in our first report, HCFA is taking steps to assure that kidneys are not offered to foreign nationals unless it has been determined that no suitable U.S. recipients can be found. In many localities and transplant centers, increased waiting lists would add measurably to the likelihood of suitable U.S. recipients being found.

The same applies to increasing the possibility of a kidney being used. As waiting lists increase, the job of finding a suitable recipient tends to be expedited and simplified. More specifically, the organ procurement agency is more likely to find a suitable candidate in the same vicinity of the donor hospital, thereby saving travel time and reducing the complexity and uncertainty associated with sending kidneys a long distance. This, in turn, reduces the risk of wastage.

This point was well illustrated in an article written by G.M. Williams, et al, that was published in the February 1985 issue of Transplantation Proceedings. Entitled "Renal Transplant Wastage: An International Problem," the article focuses on 575 kidneys that were excised by members of the United Network for Organ Sharing (UNOS) during an 18 month period and that were either discarded or sent overseas. It showed that 393 (68 percent) of these kidneys "failed to be transplanted in the United States because of our inability to identify non-sensitized recipients" (p. 1594). More effective systems for sharing kidneys could help reduce such losses. So, too, could increased waiting lists that would facilitate timely placements of donor kidneys.

3. The supply of cadaver kidneys may increase significantly in the near future. This certainly is not a sure thing. But given the considerable untapped potential of the donor pool and the extensive support being shown for the establishment of hospital "routine inquiry" procedures, it is quite probable. Such procedures would ensure that the next-of-kin of suitable donors are alerted to opportunities for donating organs and tissues.

The Task Force on Organ Transplantation, within its April 1986 final report, strongly endorsed "routine inquiry" and recommended that the Joint Commission on the Accreditation of Hospitals (JCAH) incorporate it as a standard and that HCFA include it as a Medicare condition of participation for hospitals. The JCAH is considering the adoption of a standard of this kind and Congress is considering legislation that would tie in "routine inquiry" with the Medicare and Medicaid programs.

More notable is that at least 25 States already have passed legislation requiring hospitals to establish "routine inquiry" procedures. The great majority of the States passing such legislation have done so in 1986. In those and still other States considering similar legislation, there is considerable optimism that it will increase the level of organ and tissue donations.

Mindful of these developments and the problems he has experienced in receiving referrals from dialysis facilities in his area, one transplant surgeon predicted: "We'll have a surplus of kidneys sooner than we'll have appropriate sized referral lists."

4. Low referral rates can add to Medicare costs. This is most obviously the case if Medicare recipients are deprived of kidneys because they were discarded or given to foreign nationals, or, as speculated above, if the supply of kidneys were to increase substantially (without a concomitant jump in referrals). In such cases the Medicare program could be denied the opportunity of cost savings, since, over time, the cost of dialysis exceeds that of transplantation.

There are also other, more subtle ways in which costs can be affected. One, as noted in the following comment by the director of a tissue typing laboratory, concerns the frequency of collecting serum samples for those on transplant waiting lists:

"Dialysis facilities and transplant centers are in competition. They don't like one another. They don't cooperate. If there were better cooperation, we wouldn't need a serum sample every two weeks. We'd get one only after a blood transfusion."

RECOMMENDATIONS

In the United Kingdom, kidney dialysis now tends to be regarded as a sustaining device, pending a kidney transplant. Nearly all those admitted to the dialysis program are admitted with the understanding that they are candidates for a transplant.

In the United States, where dialysis is a near universal entitlement regardless of medical condition or age, a parallel presumption concerning transplantation would not be desirable. Yet given the significant advances in transplant outcomes and the fact that transplantation is more cost effective than dialysis, an increased emphasis on transplantation would be quite desirable.

The "routine inquiry" initiatives that were mentioned earlier reflect an important move in this direction. As we noted, they can provide a significant impetus to the supply of cadaver organs. At the same time, for the reasons we have addressed, the demand side should also be addressed. This was done in 1978, when Congress extended program coverage from 12 to 36 months following transplantation. Now, with transplant outcomes much better than those in 1978 and with thousands of medically suitable dialysis patients not on transplant waiting lists, it is once again time to devote some policy attention to the matter.

In this regard, we urge that HCFA ensure full and effective enforcement of the Medicare condition of coverage requiring that dialysis facilities maintain patient long-term programs and patient care plans. In addition to requiring an up-to-date, written assessment geared to the particular needs of a patient, this condition requires that a transplant surgeon as well as the physician-director (nephrologist) of a dialysis facility and other professionals participate in making that assessment.

HCFA's recent regulatory changes concerning the structure and roles of the ESRD network organizations could help with the enforcement of this important condition. They have the potential of generating more efficient network organizations that are more sharply focused on their statutory requirements concerning the quality and appropriateness of care.

Below we offer five recommendations. Each is directed to HCFA and each can help the network organizations perform their oversight responsibilities more effectively. The first two directly concern network organization activities; the next three do so in an indirect way, but are no less important.

- o HCFA should require that network organizations prepare and disseminate, annually, a report that indicates, by dialysis facility, the proportion of patients on a transplant waiting list.

Such a report should also provide information on the total number of patients of each facility; on certain characteristics, such as whether or not the facility is part of a transplant center; and/or the proportion of patients on a transplant waiting list in the network area as a whole. Moreover, it should be distributed widely to ESRD professionals, patients, State survey teams, and other interested parties.

The report would provide comparative data that could be of considerable value. Most important, perhaps, is that it would serve as a form of peer pressure on those facilities with referral rates below the average and with no plausible explanation accounting for them.

Through a proposed regulatory revision requiring the creation and maintenance of a transplant waiting list by each facility, HCFA is taking an important step in the above noted direction. However, to achieve sufficient impact, we still feel it is important to assure that the proportion of dialysis patients on each list is clear and that this information is widely disseminated.

- o HCFA should ensure that intensive oversight is given to dialysis facilities having transplant referral rates appreciably below the network average. In particular, the network organizations should be required to conduct thorough medical records reviews of such facilities and be authorized to prescribe corrective action plans.

For the laggard dialysis facilities, a greater sense of urgency and seriousness must be conveyed. The above steps would provide that.

There are, of course, some facilities that will have lower referral rates for justifiable reasons -- most notably because of the age and/or medical condition of their patients. Network organizations should have flexibility in determining such facilities and what if any special attention should be given to

them. For those with unjustifiably low referral rates, however, the network organizations should address the problem both in terms of individual cases and the systemic factors that led to the problem. It is with respect to the latter that corrective action plans should be directed.

In cases where more information appears to be needed, HCFA could ask the State survey agency to investigate the reasons for a low percentage of transplants. The network organizations, however, should remain involved and have primary responsibility for identifying and directing corrective actions.

- o HCFA should ensure that State survey agencies conduct a thorough and more outcome-oriented review of the Medicare condition of coverage concerning patient long-term programs and patient care plans.

Through a State agency bulletin, HCFA should alert the States to the fact that many dialysis patients are not adequately informed about transplantation opportunities and should urge the survey teams to give more scrutiny to this issue. In particular, it should ask that the survey teams determine if transplant surgeons have been involved in developing the patients' long-term care programs, as is called for in the regulations. In this regard, it would be helpful to amend the interpretive guidelines issued to State survey teams so that they call for verifying the participation of transplant surgeons. Even more helpful would be to redesign the survey instrument for ESRD facilities so that it is more outcome oriented. This was done recently for skilled nursing facilities and intermediate care facilities. The case for a similar change involving ESRD facilities is no less compelling.

The network organizations could facilitate the State agencies' oversight in this area by providing them with data on the transplant referral rates of dialysis facilities. Similarly, the State agencies could help the network organizations by passing on to them any problems they identify concerning a facility's efforts in developing patient long-term programs and patient care plans.

- o HCFA should require that as a condition of reimbursement for routine dialysis, a facility must have for each patient a written long-term program and a written patient care plan signed by the patient, a nephrologist, and a transplant surgeon.

Except for the signature requirement, this is the same requirement set forth in the condition of Medicare coverage. The rationale for making it a condition of payment is that the level

of importance attached to the practice is raised. The point of requiring signatures is that the participation of the patients and the physicians is more readily documented and audited.

- o HCFA should work with the Public Health Service to encourage the American Society of Transplant Surgeons (ASTS) to provide some guidance on which dialysis patients are medically suitable candidates for a kidney transplant.

Although we recognize that no hard and fast criteria concerning medically suitable transplant candidates could or should be developed, some general statement addressing this matter by an authoritative body such as ASTS would be of considerable value. For network organizations, State survey teams and others, it would provide a useful frame of reference in determining the overall adequacy of a dialysis facility's efforts to alert patients to transplant opportunities.

If these recommendations were to be carried out, we feel they would have a considerable effect in improving the access of dialysis patients to kidney transplantation. They would extend the opportunity for a transplant to many who are now denied that opportunity. And they would contribute to cost savings in the Medicare program.

The savings, as suggested earlier, would be generated in a number of ways. In the near term, the most significant would appear to be those associated with a reduction in the number of discarded kidneys. In this regard, we assume that implementation of the above noted recommendations would be responsible for a reduction in the overall rate of discarded kidneys from an estimated 14 percent at present to about 11 percent in 1988. Given that a substantial number of discarded kidneys are lost because of a failure to identify non-sensitized patients, as was indicated in the study cited earlier, this projection would appear to be quite reasonable. Because of the increased number of Medicare recipients who would be able to receive a transplant in 1987 and 1988, the Medicare program would benefit from cost savings that within 5 years would amount to an estimated \$18.3 million (see Appendix II).

APPENDIX I
BACKGROUND AND METHODOLOGY

Over the past few years, the subject of organ acquisition has become an increasingly important and controversial one. Newspaper reports, television news shows, radio talk shows, congressional hearings, and other sources have been raising hard questions about the adequacy of current systems for obtaining and distributing cadaver organs and tissues that will be used for transplantation.

Because of these questions and the Medicare program's significant stake in the condition of the country's organ acquisition systems, the Office of Inspector General has undertaken a broadly based study of these systems. Its overriding purpose is to promote a better understanding of them in terms of their effectiveness, efficiency and equity, and to identify policy directions that might be taken to promote these ends.

The study, which was initiated in January 1986, has involved three major modes of inquiry:

- o Reviews of literature and data bases, including journal articles, books, governmental reports and statistical compilations of public and private organizations. Particular attention has been devoted to the review and analysis of 1984-85 cost reports submitted by HHS certified independent organ procurement agencies and by Medicare certified transplant centers, and to the review of documents and reports generated by the Organ Transplantation Task Force established by the National Organ Transplant Act of 1984.
- o Visits to 17 cities, focusing on reviews of the organ acquisition practices in those cities. These involved discussions with transplant surgeons and coordinators, nephrologists, immunologists, procurement agency directors, fiscal analysts, ESRD network directors and others associated with organ acquisition and transplantation. The cities visited were: San Francisco; Los Angeles; Denver; Chicago; Minneapolis; Memphis; Nashville; Houston; Dallas; San Antonio; Miami; Richmond; Charlottesville; Philadelphia; New York; Boston; and Washington, D.C.
- o Telephone discussions and selected visits with various individuals knowledgeable about organ acquisition practices and issues. These included representatives of organizations, such as the Southeastern Organ Procurement Foundation, and the American Council on Transplantation; many of the members of the task force; academics; and various officials in the Department of

Health and Human Services, most especially in the Public Health Service and the Health Care Financing Administration; and others.

This report is the second of a series of reports that will present the findings and recommendations of the study. Forthcoming reports will address the costs of organ acquisition and the effectiveness of organ procurement and distribution systems, with particular attention to the extent and nature of organ sharing, both within regions and across the country.

In each of these reports primary attention will be given to kidney acquisition. This is because there has been much more experience and activity concerning renal than non-renal organs. Congress has extended Medicare coverage on a near universal basis to those requiring dialysis and transplantation since 1972. During that time more than 50,000 kidney transplants have been performed in the U.S., the majority of which have involved the use of cadaver kidneys.

In the years ahead, however, transplantation of non-renal organs, especially hearts and livers, will become especially prominent given the continued advances in technology and the fact that Medicare now covers liver transplants for Medicare eligible children with biliary atresia and will be covering heart transplants for Medicare eligible individuals meeting specified medical criteria. This prospect for accelerated growth is suggested by the fact that the number of both heart and liver transplants doubled between 1984 and 1985, and from 346 to 719 in the case of hearts and from 308 to 602 with respect to livers. In that period, the number of kidney transplants performed in the U.S. rose from 6,968 to 7,965.

Thus, the problems encountered and lessons learned concerning kidney acquisition have broader relevance to organ acquisition generally. There are some distinguishing characteristics between non-renal and renal acquisition (not the least of which is that non-renal organs must be made available for transplantation much more quickly). But there are also important commonalities, among which is the fact that the same organizations typically handle renal and non-renal acquisition. Accordingly, the findings and recommendations of this study, although focused on kidneys, have significance for organ acquisition in general.

APPENDIX II
METHODOLOGY FOR MEDICARE
COST SAVINGS ESTIMATES

The methodology involves the following assumptions and calculations:

- o We base the estimate on the period between October 1, 1987 and September 30, 1988 and assume that during that period and the preceding periods of October 1, 1986 - September 30, 1987 and October 1, 1985 - September 30, 1986 the rate of Medicare reimbursed cadaver kidney transplants would increase at the same rate that all cadaver transplants increased between CY 1984 and CY 1985: 10 percent. Such a rate of increase would result in 5,772 Medicare reimbursed cadaver transplants in FY 1986 (5,247 plus 10 percent increase), 6,349 in FY 1987 (5,772 plus 10 percent increase), and 6,984 in FY 1988 (6,349 plus 10 percent).
- o We assume that the discard (wastage) rate for FY 1987 will be 14 percent. This is based on estimates of individuals who have studied the matter in depth and on data obtained from Aetna and from the HCFA Annual Facility Survey. See page 10 of our forthcoming report entitled "Organ Acquisition Costs: An Overview."
- o With a 14 percent wastage rate, organ procurement agencies would have to procure 8,121 cadaver kidneys in FY 1988 to account for 6,984 cadaver transplants. This involves the wastage of 1,137 kidneys. If the wastage rate were 11 percent, 893 kidneys would have been wasted (11 percent of 8,121) instead of 1,137 (14 percent of 8,121). This represents an additional 244 transplants that could be performed (1,137 minus 893) for a total of 7,228.
- o Each transplant of a Medicare beneficiary generates an estimated 5-year cost savings of \$75,000 (for an explanation of the methodology used in deriving this \$75,000 estimate, see Appendix II of our August 1986 report entitled "The Access of Foreign Nationals to U.S. Cadaver Organs.")

- o Thus, the estimated 5-year cost savings for the 244 additional kidneys that would be provided to Medicare recipients in FY 1988 is \$18.3 million (244 x \$75,000).

APPENDIX III

HCFA, ASH, AND ASPE COMMENTS ON THE DRAFT REPORT AND OIG RESPONSES

We received comments on the draft report from the Administrator, Health Care Financing Administration (HCFA), the Assistant Secretary for Health (ASH), and the Assistant Secretary for Planning and Evaluation (ASPE). These comments were of four major types: (1) general observations about the overall report, (2) reactions to draft recommendations, (3) reactions to specific findings, and (4) concerns about methodology. Below, we indicate the major comments offered in each of these areas and, where appropriate, present our responses.

GENERAL OBSERVATIONS

HCFA indicated that it generally concurred with the findings presented in the draft report. Further, it noted that the Omnibus Budget Reconciliation Act (OBRA) of 1986 (P.L. 99-509) includes several sections that address the subject matter contained in the report and suggested that the Office of Inspector General (OIG) may wish to review these sections. They include: Section 9318--Hospital Protocols for Organ Procurement and Standards for Procurement Agencies; Section 9335(d)--Reorganization of ESRD Network Areas and Organizations; Section 9335(f)--Responsibilities of Network Organizations; and Section 9335(i)--National ESRD Registry.

ASPE noted that the report "raises many valid issues regarding a subject that is of great interest to the Department." It expressed support for the "general conclusion that the option of kidney transplantation must be offered to all eligible patients," but indicated concern about placing onerous reporting requirements on treatment facilities.

ASH's comments focussed on the recommendation directly involving the Public Health Service and on the methodology of the inspection.

REACTIONS TO DRAFT RECOMMENDATIONS

- o HCFA should require that network organizations prepare and disseminate, annually, a report that indicates, by dialysis facility, the proportion of patients on a transplant waiting list.

HCFA reacted as follows:

"In the proposed End Stage Renal Disease (ESRD) regulation revision, we will require the creation and maintenance of a transplant waiting list by each facility. This, plus the proposed expansion of organ procurement requirements via the creation of a new condition of coverage would appear, when coupled with existing criteria, to provide sufficient data to prepare and disseminate an annual report, rather than involve the networks. Development of a national average, rather than a network average of patients referred, could be coupled with appropriate comments on transplant situations and covered in the existing ESRD annual report."

In response, we added a paragraph in the discussion following the recommendation (p.12). In it we note that in requiring a transplant waiting list for each facility, HCFA is taking an important step. However, we also note that we still feel that to assure sufficient impact, it is important (1) to require that each facility specify the proportion of its patients on a transplant waiting list and (2) to disseminate this information widely.

- o HCFA should ensure that intensive oversight is given to dialysis facilities having transplant referral rates appreciably below the network average. In particular, the network organizations should be required to conduct thorough medical records reviews of such facilities and be authorized to (1) prescribe corrective action plans and (2) recommend sanctions for facilities failing to respond.

HCFA reacted as follows:

"Where transplant referral rates appear appreciably below the national average, we could have the State survey agency investigate the reason for such a low average. It appears inappropriate to adopt the concept that the network consider such options as sanctions, etc. Any action with respect to the facilities participation, sanctions, or reimbursement should be restricted to HCFA. To do otherwise would place HCFA in the position of having to defend, upon challenge, network determinations."

In response, we deleted the provisions in the recommendation that called for ESRD network organizations to be authorized to recommend sanctions for facilities failing to respond. While we

feel such authorization could be helpful at some point, we accept HCFA's judgment that it is "inappropriate" at this time.

We have also added a paragraph in the discussion following the recommendation (p.13) that suggests that HCFA could ask the State survey agency to investigate the reasons for a low percentage of referrals from a particular dialysis facility. However, as we indicate in that same paragraph, we still regard it as appropriate and important for network organizations to be given responsibility for identifying and directing corrective actions.

- o HCFA should ensure that State survey agencies conduct a thorough and more outcome-oriented review of the Medicare condition of coverage concerning patient long-term programs and patient care plans.

HCFA reacted as follows:

"We concur with this recommendation and we are currently pilot testing new survey requirements in one State. We expect to implement the new survey requirements in all States by October 1987.

Also, our proposed revision of the ESRD regulation will be directed toward outcomes via a requirement that transplantation and home dialysis assessments become a part of the patient's medical record."

- o HCFA should require that as a condition of reimbursement for routine dialysis a facility must have for each patient a written long-term program and a written patient care plan signed by the patient and the professional team.

HCFA reacted as follows:

"Subpart U, S405.2137 currently provides for a written long-term program and a written patient care plan involving the professional team and the patient. The change being suggested here is that it be signed by the patient and professional team. While we do not object to this for audit purposes, if a signature is to be required, we recommend it be restricted to the transplant surgeon, nephrologist and patient rather than the entire team."

We agreed with HCFA's reaction and amended the recommendation (p.13) to restrict the signature requirement to a nephrologist, transplant surgeon and patient.

- o HCFA should work with the Public Health Service to encourage the American Society of Transplant Surgeons (ASTS) to provide some guidance on which dialysis patients are medically suitable candidates for a kidney transplant.

HCFA, ASH, and ASPE concurred with this recommendation. HCFA, first of all, reacted as follows:

"We concur with the recommendation that the ASTS provide some guidance regarding criteria for determining medically suitable candidates for transplantation. We would recommend said contact be expanded to include an assessment concerning the reason why older kidneys are refused by American surgeons, yet successfully transplanted by foreign surgeons."

ASPE expressed its support with the following words:

"...I strongly endorse your recommendation that the American Society of Transplant Surgeons be asked to provide guidance on which dialysis patients are medically suitable candidates for kidney transplants. This guidance could be developed in a form suitable for medical professionals and in a pamphlet for patients."

Finally, ASH offered the following reaction and information:

"We concur. PHS will work with HCFA to assist the American Society of Transplant Surgeons to provide guidance concerning kidney transplants for dialysis patients.

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) already has an interagency agreement with HCFA to facilitate the collection and analysis of such data. To this end, NIDDK will establish through a contract, an End Stage Renal Disease (ESRD) data system that will compile data on all types of ESRD patients, including those undergoing hemodialysis, continuous ambulatory peritoneal dialysis, and transplantation. The system will contain types of data which are currently not collected at all or are collected in only a limited way, including data on the etiology of the underlying renal disease, methods of patient treatment and associated patient outcomes, and complications of treatment.

The new ESRD data system will enable tracking of patients through multiple therapies and some comparison of the effectiveness and complications of dialysis and transplantation.

NIDDK expects to award the contract to establish the ESRD data system during this fiscal year. The system should be operational in mid-fiscal year 1988. The data collected and analyzed through this effort may prove useful to HCFA and other agencies and organizations in addressing issues surrounding therapeutic alternatives in ESRD. In addition to the American Society of Transplant Surgeons, the following groups will be involved in the definition of tasks, scope, and workplans for the development and implementation of the data system: American Society of Nephrology; American Society of Pediatric Nephrology; American Society of Transplant Physicians; American Society of Artificial Internal Organs; National Kidney Foundation; Renal Physicians Association; National Association of Patients on Dialysis and Transplantation; American Diabetes Association; and Juvenile Diabetes Foundation International."

REACTIONS TO SPECIFIC FINDINGS

ASH noted that the reasons we cited for the differential between the proportion of suitable transplant candidates and the percent actually awaiting a transplant were not complete (p.3). Specifically, ASH indicated that we did not mention that dialysis patients also elect not to undergo transplantation because they fear giving up their time slot for weekly dialysis or because they cannot pay for cyclosporine.

OIG Response: Upon review, we decided that the concern about giving up a time slot is a pertinent consideration. Accordingly, we noted it on page 3 of the final report. With respect to the concern about the costs of cyclosporine, we did get some comments about how cost considerations might delay transplantation for a patient on a waiting list. However, we did not have sufficient information to determine whether or not it was an important factor in determining whether or not a patient was listed on a transplant waiting list.

ASH indicated that "while an 11 percent referral rate may be low, not all patients on dialysis can be considered for transplantation. For example, the patients may be too sick or have other medical problems that preclude them from being considered for transplantation."

OIG Response: We recognize that not all dialysis patients are transplantation candidates. Accordingly, we note on page 2 of the draft and final reports that "transplant surgeons report that at least 20 to 25 percent of the dialysis population is medically suitable for a kidney transplant."

CONCERNS ABOUT METHODOLOGY

Both HCFA and ASH raise concerns about conclusions in the report being inadequately supported by documentation.

OIG Response: As indicated in Appendix I, the report is based on a careful review of available data sources and on extensive discussions with individuals directly involved with organ acquisition. It is not based on a random sample of dialysis facilities or medical professionals.

Thus, while the findings are not statistically valid according to the precepts of experimental design, they are based on wide-ranging and thorough explorations in a diversity of settings. Such explorations, although not allowing for certainty, do allow for reasoned insights and judgments.

ASH noted that the methodology used to predict Medicare cost savings has two flaws. First, it indicated that the report used the total number of transplants performed in 1985 to predict savings, even though about 25 percent of all transplants are from living related donors. Second, it added that kidney wastage rates have declined considerably in recent years, thereby affecting our estimate on the number of additional transplants that might be performed. In this context, ASH noted that "the Organ Transplantation Task Force found that in some areas of the country the wastage rates are as low as 5 percent."

OIG Response: With respect to the first point, our calculations have been based on the total number of cadaver kidney transplants. They have not included living related transplants. On the second point, in a forthcoming report on organ acquisition costs, we present data that shows that the kidney wastage rate has, indeed, dropped over the past few years but was still at about 14 percent in 1985. Moreover, and perhaps more importantly, we indicate that in some places the number of cadaver kidneys wasted is significantly underreported.

The cost savings data and methodology presented in this final report are somewhat revised to reflect more recent data and to focus on FY 1988 rather than FY 1987. As a result, the savings estimate is increased from \$16.9 million to \$18.3 million.

