

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**THE ACCESS OF FOREIGN NATIONALS
TO U.S. CADAVER ORGANS**



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AUGUST 1986

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This Report

Entitled "The Access of Foreign Nationals to U.S. Cadaver Organs," 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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TABLE OF CONTENTS

Major Findings.....	ii
Recommendations.....	iii
Introduction.....	1
Foreign Nationals Receiving Transplants in the U.S.....	2
Incidence.....	2
The District of Columbia.....	5
Implications.....	7
Exporting Cadaver Kidneys to Other Countries.....	12
Implications.....	13
Recommendations.....	15
Appendix I: Background and Methodology.....	19
Appendix II: Methodology for Medicare Cost Savings Estimates.....	22

MAJOR FINDINGS

- o An estimated 300 foreign nationals received a cadaver kidney transplant in the U.S. in 1985. This represents 5.2 percent of the cadaver donor transplants performed in the U.S. in that year.
- o In a divided vote, the Task Force on Organ Transplantation, established by the National Organ Transplant Act of 1984, recently recommended that no more than 10 percent of the transplants at any center should be provided to foreign nationals. This recommendation could have the unintended effect of legitimizing a higher incidence of transplants for foreign nationals at centers now functioning well below the 10 percent level.
- o In the District of Columbia, foreign nationals received about 22 percent of the 181 cadaver kidney transplants performed in 1985. This is especially striking because (1) the incidence of dialysis in the District is more than twice the national average and (2) a major military hospital, which is located in the District and which performs transplants for military personnel and dependents from all over the world, is no longer accepting additions to its transplant waiting list. The shortage of kidneys is cited as a basis for this policy.
- o An estimated 200-250 kidneys were exported from the U.S. to other countries in 1985.
- o Medicare policy does not require that foreign receiving centers pay the full acquisition cost of exported kidneys. As a result, the Medicare program is, in effect, subsidizing much of the acquisition cost of kidneys sent to other countries.
- o There are a number of unfortunate implications associated with foreign national access to U.S. cadaver kidneys. Among them are the following:
 - For U.S. residents, the number of kidneys available is reduced and the average waiting time increased.
 - National organ sharing is discouraged. The availability of foreign nationals on a waiting list provides a disincentive to sharing.
 - Medicare costs are increased.
 - Organ donation is jeopardized.

- Foreign nationals, on average, are more quickly serviced.
- Post-transplant care is jeopardized.
- Valuable outcome data is lost.

RECOMMENDATIONS

- o HCFA should undertake efforts to help ensure that cadaver kidneys are not offered to foreign nationals unless it has been determined that no suitable U.S. recipient can be found.
- o HCFA should undertake efforts to help ensure that kidneys are not exported to other countries unless it has been determined that no suitable U.S. recipient can be found.
- o When kidneys are sent to other countries, HCFA should prohibit Medicare reimbursement for any of the acquisition costs of those kidneys.

These recommendations, if carried out, would allow for an estimated 500 additional Medicare beneficiaries to receive a cadaver kidney transplant during 1987. The Medicare cost savings generated in that year would be an estimated \$37.5 million over 5 years.

INTRODUCTION

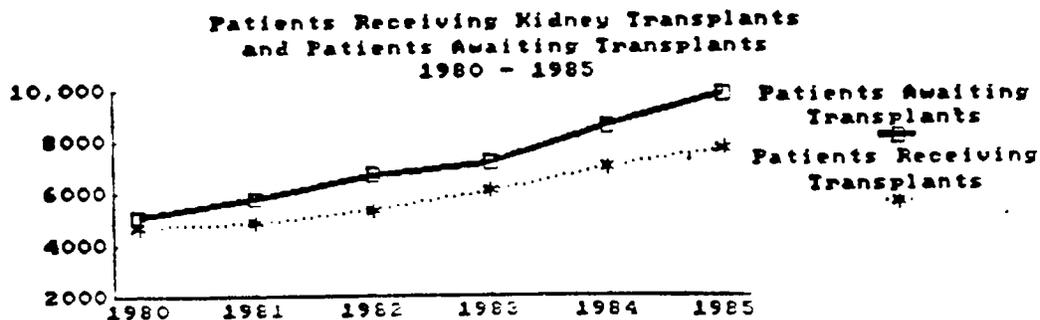
Recent advances in transplantation technology and immunotherapy are ushering in a new era of multiple organ and tissue recovery. Instead of excising just kidneys, organ recovery teams are increasingly removing hearts, heart valves, livers, pancreases, bone marrow, cornea, and other tissue. This development adds to the significance, complexity and visibility of the acquisition process. It also makes it especially important that the more established kidney acquisition process functions in an efficient, effective, and equitable manner, for, in large measure, that process is serving as a model for organ acquisition generally.

With respect to cadaver kidney transplants, on which this report will concentrate, the improvements in patient outcomes have been striking. One year patient survival rates are now averaging about 93 percent. One year graft survival rates are averaging about 75 percent, with some centers reporting results well above the 80 percent level. In the late 1970s, in contrast, cadaver kidney graft survival rates were averaging only a little over 50 percent.

A major factor behind these gains was the widespread introduction in November 1983 of cyclosporine, a powerful immunosuppressive drug. Studies have shown that the use of cyclosporine has been responsible for increasing one year graft survival rates by anywhere from 8 to 12 percent and has been particularly valuable for patients who are highly-sensitized (i.e., have a high level of preformed antibodies) and who have received a kidney with a low antigen match.

Accordingly, there has been a considerable increase in the level of kidney transplantation occurring in the U.S. From 1980 to 1985, the annual incidence increased from 4,697 to 7,695, an increase of 63.8 percent. During this period, cadaver transplants increased from 72.9 percent of the total to 75.6 percent.

However, while the number of transplants rose, the demand for transplants increased even faster (see chart). During the 1980-1985 period, the number of people awaiting kidney



transplants across the country jumped from 5,072 to 9,791, an increase of 93 percent.

In this kind of situation, where the demand is greater than the currently available supply, access to that supply becomes a key matter of public policy. This report addresses that access issue with respect to foreign nationals. It looks first at the phenomenon of nonresident aliens coming to the U.S. to receive transplants. It then turns to the practice of exporting cadaver kidneys from the U.S. to other countries. Finally, it closes with three recommendations concerning Federal policy.

FOREIGN NATIONALS RECEIVING TRANSPLANTS IN THE U.S.

INCIDENCE

For more than a decade, foreign nationals have been coming to the U.S. to receive a kidney transplant. At first, most would come with a living related donor. But as the success with cadaver organ transplants increased, the proportion of foreign nationals receiving such organs rose. Currently, it seems that at least 90 percent of the transplants performed on foreign nationals in this country involve a kidney removed from a cadaver.

Those who have traveled to the U.S. for a kidney transplant have usually done so to gain access to a more skilled technology than is available in their own country. But a number of other propelling factors have also been involved. These have included religious and/or cultural principles that restrict the use of cadaver organs in their own country. They have also included active solicitation by a few U.S. transplant centers seeking to supplement their domestic activity. Over the years the individuals who have received transplants in the U.S. have come from countries all over the world, with the significant concentrations recently from Saudi Arabia and Greece.

For many years, this practice attracted little attention. However, as the demand for transplants began to increase, it became increasingly visible and controversial. In November 1983, the House Subcommittee on Investigations and Oversight of the Committee on Science and Technology gave major attention to the transplantation of nonresident aliens as part of a broader set of hearings on organ procurement and allocation. Subsequently, the media began to focus on the issue and heightened public awareness.

Most prominent in this regard was the Pulitzer Prize winning series of reports published by The Pittsburgh Press, first in May 1985 and then in November 1985. These covered a wide

range of issues, among which were the exporting of U.S. cadaver kidneys overseas and the transplanting of foreign nationals in this country. The latter involved allegations of wealthy foreign patients being given preference for transplants at the major transplant center in Pittsburgh.

There is no clear indication of the incidence of kidney transplants performed in the U.S. on foreign nationals or of the impact of the widespread publicity on the level of such transplants. The Health Care Financing Administration (HCFA) of the U.S. Department of Health and Human Services (HHS) does collect annual data from all 178 Medicare certified transplant centers. This data distinguishes transplants on Medicare recipients from those on non-Medicare recipients, but it does not break down the latter category. In addition to transplants paid by or on behalf of foreign nationals, the non-Medicare category can include transplants for individuals covered by the Veterans Administration, Medicaid, and private insurers. (A 1981 amendment calls for Medicare to serve as a secondary payer for all transplants performed during the first year of a beneficiary's coverage under the End Stage Renal Disease Program.)

Given the lack of data and the heightened congressional interest in the matter of transplants for foreign nationals, both HCFA and the American Society of Transplant Surgeons (ASTS) conducted surveys of transplant centers in 1983. The HCFA data, based on (often incomplete) responses from 137 of 157 centers, identified 122 nonresident aliens receiving transplants in 1981, 137 in 1982, and 79 in the first 6 months of 1983.

The ASTS data, based on responses from 82 centers, identified 142 nonresident aliens having transplants in 1982. Further, it indicated that 117 (82.4 percent) of these individuals had cadaver transplants and that only eight centers accounted for 50 percent of these 117 transplant operations.

Because of the incomplete information, this data cannot be relied upon to provide a full accounting of the incidence of transplants for nonresident aliens in the early 1980s. Yet, it helps provide the basis for a reasonable estimate if one takes into account that there were 441 non-Medicare transplants in 1982 and 496 in 1983, and that these non-Medicare totals included relatively few Veterans Administration, Medicaid, or private insurer covered transplants. Such an estimate might be an annual level of 200-250 cadaver transplants. Considering that there were

3,681 cadaver transplants in the U.S. in 1982 and 4,328 in 1983, this 200-250 estimate results in 5.4 to 6.8 percent of all cadaver transplants in 1982 and 4.6 to 5.8 percent in 1983.

Since this survey activity and the November 1983 hearings, a number of transplant centers on their own initiative have developed more restrictive policies concerning the transplanting of foreign nationals. Typically, these involve specifying that U.S. residents will be given priority consideration for cadaver donor transplants.

But, because other centers have become more accommodating to foreign nationals (usually without any explicitly stated policies), it does not necessarily follow that the annual level of transplants for foreign nationals has decreased during the past 2 to 3 years. In fact, it may have increased.

The HCFA data suggest that such an increase is quite possible (see table below) as the annual level of non-Medicare transplants in 1984 and 1985 increased to almost twice that of 1983. Some of this increase is accounted for by a jump in the number of non-Medicare covered transplants for those recorded as having Medicare applications pending (275 in 1984 and 375 in 1985). Some is probably also explained by the implementation of the secondary payer provision referenced earlier. But it would still appear that a substantial number of the nearly 1,000 non-Medicare transplants in 1985 were for foreign nationals.

KIDNEY TRANSPLANTS, BY MEDICARE AND NON-MEDICARE COVERAGE
(Calendar Years 1981-1985)

Year	TOTAL Transplants	Medicare	NON- Medicare	MEDICARE AS Percentage Of Total
1981	4885	4421	464	90.5
1982	5358	4917	441	91.8
1983	6112	5616	496	91.9
1984	6968	6029	939	86.5
1985	7695	6698	978	87.0

Source: Health Care Financing Administration

Taking into account the above noted factors, we estimate that 300, or less than one-third of all the non-Medicare transplants in 1985, were for foreign nationals receiving a transplant obtained from a cadaver donor. This represents 5.2 percent of the 5,819 cadaver donor transplants that took place in the U.S. in that year.

Perhaps even more notable is that two recent developments provide a good basis for assuming that this rate will remain about the same in the years ahead or may even increase. One serves to legitimize a rate of transplantation for foreign nationals at 10 percent per center; the other at 5 percent.

The 10 percent maximum comes from the Task Force on Organ Transplantation, which was established by the National Organ Transplant Act of 1984 and which recently issued its final report. On a divided vote, the Task Force recommended that transplants for nonresident aliens not comprise more than 10 percent of the transplants at any particular center (but that non-renal organs should not be offered for transplantation to such individuals unless no other suitable recipient can be found). They specified that this policy should apply until the soon to be established national organ procurement and transplantation network has had an opportunity to review the issue.

The 5 percent maximum comes from the American Society of Transplant Surgeons (ASTS). In a recently adopted set of guidelines, the ASTS stated that the percent of transplants for nonresident aliens "must not exceed an average 5 percent per year of the organs transplanted at any single center."

Both of those pronouncements were meant to have an inhibiting effect on the incidence of transplants for foreign nationals. The Task Force, for instance, established the 10 percent cap with the idea of reducing the level of foreign national activity at the few transplant centers now functioning at a higher than the 10 percent level. But by lending authority and credibility to a level of 5 or 10 percent, both these entities may, however inadvertently, be providing a rationale for many centers now performing below these levels, to become more inclined to conduct transplants for foreign nationals.

THE DISTRICT OF COLUMBIA

As suggested above, the incidence of transplantation for foreign nationals varies across the country. While 7.9 percent of all individuals having transplants in the U.S. in 1985 had neither existing nor pending Medicare coverage,

the proportion in some states was considerably higher. As examples, Massachusetts had a rate of 15.5 percent; Tennessee - 13.0 percent; Louisiana - 11 percent and New York - 11.3 percent. Illinois, which had a rate of 12.9 percent in 1984, dropped to 3 percent in 1985. Similarly, California declined from 18.7 to 8.2 percent during the same period.

In recent years, by far the highest rate of non-Medicare transplantation has been in the District of Columbia. (Here and subsequently, in referring to the non-Medicare category, we are excluding from consideration those individuals who have had transplants and have Medicare applications pending.) In 1985, non-Medicare transplant patients accounted for 31 percent of all those receiving kidney transplants within the District, up from 24.6 percent in 1984. Three of the five transplant centers in the District performed 30 percent or more of their transplants on non-Medicare patients (see table below).

TRANSPLANT PATIENTS IN THE
DISTRICT OF COLUMBIA, BY
TRANSPLANT CENTER,
TOTAL AND NON-MEDICARE,
(Calendar Year 1985)

Center	Total Transplants Patients	Non-Medicare Patients	
		Number	As % of Total
A	20	9	45.0
B	12	1	8.3
C	70	21	30.0
D	103	34	33.0
E	<u>8</u>	<u>1</u>	<u>12.5</u>
TOTAL	213	66	31.0 (avg.)

Source: Health Care Financing Administration

Our review of three of the transplant centers in the District showed that almost two-thirds of the non-Medicare transplants that occurred in these centers involved foreign

nationals and that nearly all of these transplants involved the use of cadaver kidneys. Thus, when considering that there were 181 cadaver kidney transplants performed in the District in 1985, we find that about 22 percent of those transplants were for the benefit of foreign nationals. Clearly, the nation's diplomatic center is also a center for foreign nationals receiving kidney transplants.

At the same time, the District of Columbia has a higher incidence of dialysis than any state in the nation. This is reflected by the fact that in 1982, the District's Medicare End Stage Renal Disease (ESRD) program incidence rate was 228 per million population. This compared with a rate of 108 for New Jersey, the highest of any State, and of 87 for the country as a whole.

This means that kidneys that would otherwise be available for District residents awaiting a transplant are being offered to foreign nationals.

Similarly, some members of the military and their families are also denied the opportunity to receive a transplant because of the access obtained by foreign nationals. A major military hospital located in the District performs transplants for U.S. military personnel and their dependents from all over the world. As of July 1986, it had a waiting list of 56 and was not accepting any new entrants because of the limited supply of cadaver kidneys.

In perspective, it is important to recognize that while the proportion of foreign nationals receiving transplants in the District is high, so is the overall level of transplant activity compared to that of the States. In 1985, patients who had a transplant accounted for 25 percent of the total dialysis population in the District, compared with a national average of 9.1 percent. This means that when the non-Medicare cases are excluded, the District still has an above average rate of transplants. But it does not follow that District residents are benefitting sufficiently from these transplants inasmuch as two of the five centers are major, high volume centers attracting many patients from surrounding States.

IMPLICATIONS

Many professionals in the transplant field express considerable unease with as heavy an orientation to foreign nationals as exists in the District of Columbia. It is that kind of unease that underlies the limits proposed by the Task Force and the ASTS.

However, many of these professionals also feel that a lesser level of activity, at the 5 to 10 percent level, is not detrimental, and, in fact, is beneficial. Physicians associated with transplant programs are particularly likely to hold this view. It is well reflected in the following comments made at the November 1983 hearings on organ procurement. The first is by Dr. Peter Ivanovich, a nephrologist at the Chicago Veterans Administration Lakeside Medical Center; the second by Dr. Nicholas J. Feduska, a transplant surgeon at the University of California, San Francisco:

"We believe that medicine, like music, should recognize no cultural or national barriers. We can provide a service which, in turn, allows institutions in this country to profit from experience gained from a select group of patients, some with conditions physicians do not normally encounter. In addition, the fees that they help pay defray the costs normally borne by those hospitals and third party payers."

"Most physicians and surgeons take the view that medicine . . . should not be considered in nationalistic terms, that it is a humanistic discipline, and that their services and skills should be made available to all citizens of the world. As long as this is not a problem of substantial magnitude, it might best be left alone."

The call for an international, humanistic approach presents an attractive and important ideal. However, like any ideal it must be examined in terms of associated realities and practical effects. In the present environment, where the U.S. demand for cadaver kidneys exceeds the supply, the application of this ideal involves some realities and effects that clearly undermine its value. At least seven of them deserve serious consideration.

1. Foreign nationals, on average, are more quickly serviced. We did not find or hear of any transplant center that gives priority to foreign nationals. However, many, and probably most, do not have an explicit policy of granting preference to U.S. residents. It is widely noted that among such centers, foreign nationals on a waiting list tend to receive a

transplant more quickly than the U.S. residents. The major reason for this is that fewer of them are likely to be highly sensitized (which means that their chances of receiving an acceptable kidney are higher). During the November 1983 hearings, Dr. Jimmy Light, Director of Organ Procurement and Transplantation at the Washington Hospital Center, explained this reality as follows:

"They (foreign nationals) are a more favorable group to find a kidney for, in the sense that almost all of them are first transplants. Few of them are sensitized so that the cross matches are generally negative and you can accept, if you will, a lesser match."

During the same hearing, Dr. Light also noted that at The Washington Hospital Center, at that time, the mean waiting time for foreign nationals was 16 weeks compared with 41 weeks for Medicare recipients. In both cases, the waiting time was slightly greater for those with O blood type, and slightly less for those with A blood type.

2. For U.S. residents, the number of cadaver kidneys available is reduced and the average waiting time is increased. Some professionals counter this point by noting that many or most of the kidneys going to foreign nationals would otherwise be discarded. But with close to 10,000 people awaiting kidney transplantation in the U.S., it is difficult to understand why nearly all of the 300 or so cadaver kidneys being transplanted into foreign nationals could not be provided to U.S. residents -- that is, unless a transplant center is disinclined to share kidneys with other centers in its region or in the nation.
3. National organ sharing is discouraged. As we will address in a subsequent report, the extent to which kidneys are being shared on a national basis has been decreasing during the past 2 years. Primarily this is because of the introduction of cyclosporine and its association with improved outcomes, even in a patient with a poorly matched donor kidney. But the availability of foreign nationals on a waiting list clearly provides a further disincentive to sharing. It provides a center with a greater opportunity to use a kidney rather than to send it to another center.

This reality was directly addressed during the November 1983 hearings by Dr. John McDonald, chief transplant surgeon at the Louisiana State University Medical Center and then president of the South-Eastern Organ Procurement Foundation (SEOPF).

In explaining the justification for his own center's policy of not accepting foreign nationals, he commented as follows:

"We are personally fearful that if we had nonresident aliens on our own list that we would use organs locally that we would otherwise have shared with other institutions and thereby in a secondary way deny kidneys to American citizens."

4. Medicare costs are increased. Over time, transplantation not only affords the recipients the likelihood of a healthier and more independent life, but also provides the Medicare program with the opportunity to save money. This is because transplantation, over time costs less than dialysis. Just how much less cannot be definitively determined. However, on the basis of HCFA data on dialysis costs and a recent Rand Corporation study on the cost effects of kidney transplantation, we estimate that for each transplant performed on a Medicare beneficiary in 1985 there was an average cost savings of \$62,000 over a 5-year period. For 1987, we estimate that this savings will increase to \$75,000 (see Appendix II).

If we assume that 275 of the estimated 300 cadaver donor transplants performed on foreign nationals in 1985 were instead performed on Medicare recipients, then, on the basis of the above estimate, Medicare could have saved about \$17 million over 5 years. The opportunity for additional savings would, of course, apply for each subsequent year.

5. Organ donation is jeopardized. Organ donation in the U.S. rests on a fragile foundation. People donate organs with the assumption that the system for distributing them will be a fair one. When they learn that foreign nationals receive organs instead of U.S. residents and that they generally do so in a shorter period of time, they begin to question the fairness of that system and may very well become less inclined to donate. Indeed, in some communities where there has been much publicity about foreign nationals receiving transplanted kidneys, there has been a subsequent reduction in donation levels.

The Task Force, in supporting its recommendation that would allow up to 10 percent of the transplants to be performed on foreign nationals, stated that public concern about foreign nationals receiving cadaver kidneys is directed to policies that reflect "favoritism and injustice not against sharing with non-immigrant aliens per se." Yet such a distinction is not readily drawn. (Is it an injustice, for instance, that foreign nationals are likely to spend less time on the waiting list?) Further, when the media and the public address issues of organ shortage, questions are bound to be raised about the fairness of sharing scarce organs with foreign nationals and about the equity of the processes that determine who among the thousands of potentially interested foreign nationals are actually given access to U.S. cadaver kidneys.

6. Post-transplant care is compromised. Transplant surgeons stress that post-transplant patient care management is a crucial determinant of outcomes. This involves decisions about which immunosuppressive medications to use, in what combinations, and for how long a time. It also involves careful observation for early signs of possible graft failure.

Such oversight is especially critical during the first few months after the transplant, but is important for as long as the transplant lasts. It is generally agreed that foreign nationals, who presumably return to their countries soon after the transplant, have less access to skilled medical oversight than would U. S. residents. This means that their risk of complications and/or graft failure are greater. It also means that the use of a scarce societal resource may be squandered.

7. Valuable outcome data is lost. In the same context, U.S. transplant surgeons lose the opportunity to collect outcome data and to gain critical feedback on the efficacy of particular interventions over time. To varying extents, foreign nationals, then, represent a lost data base. In a dynamic field such as transplantation, where careful analysis of patient outcome data is intricately linked with continued improvement, the loss of such a data base, even for only 5 to 10 percent of the universe, is a serious matter.

EXPORTING CADAVER KIDNEYS TO OTHER COUNTRIES

Some foreign nationals are able to obtain a kidney from a cadaver donor in the U.S. without even having to travel to this country. In these instances, U.S. transplant centers, independent organ procurement agencies (IOPAs), or the South-Eastern Organ Procurement Foundation (SEOPF)--the nation's largest organ sharing program, send the kidneys to other countries for transplantation there. In recent years, these exports appear to be primarily to England and Japan.

Over the years, SEOPF has been the greatest single exporter of kidneys, as it would regularly send overseas kidneys that could not be placed among its member institutions. But significant numbers have also been exported by individual transplant centers and IOPAs, which, like SEOPF, have developed working relationships with foreign surgeons interested in U.S. cadaver kidneys.

Typically, the exported kidneys have been older ones. They have been removed from brain-dead donors for 40 or more hours and still have not been matched with an appropriate U.S. recipient. U.S. transplant surgeons have been disinclined to use kidneys once they reach this age, but many foreign surgeons have been quite eager to receive and transplant such kidneys. Accordingly, exportation has often been viewed as a way to see that a kidney that would otherwise be discarded is, in fact, used.

As with the phenomenon of foreign nationals coming to the U.S. to receive a transplant, the practice of exporting kidneys became increasingly visible and controversial as the U.S. demand for kidneys began to intensify. The media gave increasing attention to the issue and were instrumental in heightening public awareness of it. They raised difficult questions concerning why, in a time of insufficient supply, kidneys were being sent overseas, especially in view of reports that the outcomes being achieved with these older, exported kidneys were comparable to those of kidneys transplanted in the U.S. They also raised hard questions concerning (1) which individuals were receiving transplants with the exported kidneys, (2) the extent to which U.S. procurement costs were being reimbursed, and (3) the comparatively high kidney wastage rates in the U.S.

In recent years, the annual cost reports prepared by transplant centers, IOPAs and SEOPF have included a count on kidneys sent to other countries. Although these figures are

incomplete and include some double counting, and in some cases, may even be inaccurate, they provide a general indication of the incidence of kidney exportation.

The peak level of activity appears to have been around 1983. At that time, when the U.S. rate of discarded kidneys tended to be more than 20 percent, it appeared that at least 350 and perhaps as many as 400 or more cadaver kidneys were being sent out of the country.

In subsequent years, the number has almost certainly decreased. On the basis of our discussions and review of the cost report data, we estimate that 300-350 kidneys were exported in 1984 and 200-250 in 1985. During this period, the annual number of exported kidneys reported by IOPAs declined from 229 to 111, by SEOPF - from 89 to 63.

Why the decline? The increased U.S. demand and the heightened publicity were certainly contributing factors. So, too, were the improved outcomes associated with the use of cyclosporine and the greater readiness of some U.S. surgeons to transplant older kidneys. These factors have also contributed to a significant reduction in U.S. kidney wastage rates, to a level that now seems about 10-12 percent.

IMPLICATIONS

The 200-250 cadaver kidneys that we estimate were exported in 1985 account for 3.4 - 4.3 percent of all cadaver transplants that occurred in the U.S. that year. If these kidneys were not exported, some, given their advanced age, would certainly have been wasted. But with effective systems for pooling and sharing cadaver kidneys, it is quite feasible to assume that the great majority of these kidneys could be used for transplantation in the U.S.

Thus, while the exporting of U.S. cadaver kidneys does provide a valuable opportunity to some foreign nationals and does foster the international, humanistic ideal referenced earlier, it generates some of the same kind of effects that were also explained. Four such effects are of particular note.

1. For U.S. residents the number of cadaver kidneys available is reduced. In this case, the "opportunity loss" is probably somewhat less than applies to cadaver kidneys transplanted into foreign nationals in the U.S., since the overall incidence seems to be

somewhat less. But nonetheless there is a loss that would appear to be difficult to justify in an environment where there is a shortage of cadaver kidneys.

This is exactly the line of thinking expressed by a British transplant surgeon who has often transplanted U.S. cadaver kidneys into private-pay patients. In its November 1985 series on kidney transplantation, The Pittsburgh Press quoted him as follows:

"I feel very sorry for the patients who are waiting in the United States. It seems absolutely crazy that a country the size of the States, with whatever length of waiting list you have, could ever offer any kidneys away. It doesn't make sense. If these kidneys are so bad, why don't your surgeons just give them away rather than sell them to us? Isn't that a bit like selling a car without an engine?"

2. National organ sharing is discouraged. Here, again, the eagerness of foreign nationals to receive U.S. cadaver kidneys can serve as a disincentive to organ sharing within the U.S. When a transplant center cannot readily find an appropriate recipient for a cadaver kidney, it can merely package it in ice and send it off to a foreign institution or surgeon. By contrast, the alternative of striving to find an appropriate placement in the U.S. can be more complex and time-consuming.
3. Medicare costs are increased. This cost effect is twofold. First, for each transplant opportunity lost to a Medicare recipient on a transplant waiting list, the program in 1985 was deprived of an estimated cost savings of \$62,000 over 5 years. Thus, if 200 of the cadaver kidneys sent overseas in 1985 had instead been transplanted into Medicare recipients, the program could have saved about \$12 million over the next 5 years.

Secondly, it is important to recognize that in cases where kidneys are exported, HCFA's policy has been to reimburse all eligible procurement costs, excluding transportation overseas, if such costs are not paid for by the foreign receiving center. It appears that in the great majority of the cases, those costs have not been paid for by the foreign center. If we were to

assume that 150 of the kidneys exported in 1985 were not paid for by the foreign center and that the average procurement cost was about \$9,000 per kidney (including kidneys procured by hospitals and by IOPAs) then the loss to Medicare for that year would be \$1.3 million.

4. Organ donation is jeopardized. The flow of U.S. cadaver kidneys to foreign nationals poses a subtle, but continuing danger to the foundation of trust and goodwill that supports organ donation. This is no less so when foreign nationals receive kidneys in another country than when they come here to obtain them. Moreover, as incidents of this kind are publicized in particular committees, or, indeed, across the nation, the effects can be long-lasting, injecting in many a sense of doubt or even cynicism concerning the equity and reliability of America's system for sharing organs.

RECOMMENDATIONS

In view of the implications discussed in the previous pages, we offer two categories of recommendations. One concerns the transplanting of foreign nationals in the U.S. The other concerns the exporting of U.S. cadaver kidneys.

- HCFA should undertake efforts to help ensure that cadaver kidneys are not offered to foreign nationals unless it has been determined that no suitable U.S. recipient can be found.

Determining the extent to which foreign nationals should have access to kidneys donated in the U. S. is a societal, not a medical decision. Physicians we met with tended to agree with this position and to welcome specific governmental direction on the matter. The recommendation offered above would provide such direction.

It is a practical, straightforward recommendation that could be carried out administratively. It is, in essence, the same recommendation that the Task Force has advocated with respect to hearts and other non-renal organs. Since both renal and non-renal organs are in short supply in the U.S., we don't see why non-U.S. residents should be given greater access to kidneys than to other types of organs.

Further, our recommendation is in line with the position of the National Kidney Foundation and of eight members of the Task Force who filed a strongly stated dissent to the

majority's recommendation that as many as 10 percent of the transplants at a center could be for foreign nationals. We agree with the Task Force minority that "members of the giving community (both American citizens and aliens living in the United States) have a right to expect that their medical needs will be met and that patient selection decisions will not be made to their detriment." A policy based on the above recommendation would help protect this right. It would recognize the reality that there is a shortage of cadaver kidneys and that, through the development of effective systems for sharing, just about all cadaver kidneys that become available can be used by U.S. residents.

Such a policy would be consistent with that established by many other countries, including the United Kingdom. At the same time, it would not be a renouncement of the international, humanistic ideal addressed earlier. It would leave the door open for foreign nationals to receive living related kidney transplants in the U.S. when they have a consenting donor and to receive cadaver transplants when an appropriate U.S. recipient cannot be found. Over time, if the U.S. shortage of cadaver kidneys were to be reduced, the opportunity for foreign nationals to receive such kidneys would be enhanced.

Further, professionals in the transplant field in the U.S. can and should continue to work with their colleagues in other countries, sharing information and technology. This kind of interaction, which can benefit the U.S. as well as other countries, would not be constrained.

Finally from a cost perspective, if the proposed policy were enacted in 1987, the Medicare savings generated during that calendar year above would be an estimated \$22.5 million over a 5-year period (see Appendix II.)

. HCFA should undertake efforts to help ensure that kidneys are not exported to other countries unless it has been determined that no suitable U.S. recipient can be found. Further, when kidneys are sent to other countries, HCFA should prohibit Medicare reimbursement for any of the acquisition costs of those kidneys.

The first part of this recommendation is in accord with a policy change being considered in HCFA. We support this change, but feel that in itself it is insufficient. When a kidney is exported out of the country, we feel it

is essential that the receiving center pay the full acquisition cost for that kidney--just as is already the case for a foreign national who receives a transplant in the U.S. Under present policy, which precludes reimbursement only for the costs of overseas shipment, Medicare is, in effect, subsidizing the cost of exported kidneys.

Enactment of the recommendation, as stated above, would generate in 1987 an estimated Medicare cost savings of \$15 million over a 5 year period (see Appendix II).

Thus, if both our recommendations were carried out, an estimated 500 additional U.S. residents would be able to receive a cadaver kidney transplant during 1987. That represents an estimated 5-year Medicare cost savings of \$37.5 million. In addition there would be considerable savings in the Social Security disability program, as many of those who would otherwise receive disability payments would be able to lead healthier, more independent lives.

In accord with the study findings and recommendations, the Administrator of the Health Care Financing Administration (HCFA) agreed to do the following:

- o require organ procurment agencies and certified transplant centers to maintain a record of placement efforts for each kidney they export or furnish to a foreign national, which will document efforts to place the kidney with domestic transplant patients;
- o amend its reimbursement rules to ensure that organ procurement agencies and certified transplant centers are reimbursed only for kidneys furnished to Medicare beneficiaries;
- o work with the Public Health Service to encourage the American Society of Transplant Surgeons to reassess the 40 hour standard for viability of cadaver kidneys in light of the success of other countries in transplanting kidneys that have cold ischaemic times in excess of 50 hours; and

- o review standards governing certification of independent OPAs and considering whether they should be strengthened in any way, including extending them to hospital-based OPAs.

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, FL; Richmond and Charlottesville, VA; 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 South-Eastern 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 first of a series of reports that will present the findings and recommendations of the study. Forthcoming reports will address: (1) the extent to which dialysis patients are being informed of transplantation as an optional treatment; (2) the efficiency and economy of kidney acquisition systems; (3) the dynamics of organ supply and demand; and (4) 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, 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 two major components. The first concerns the projected average 5-year Medicare cost for each transplant of a Medicare beneficiary. The second concerns the projected average 5-year Medicare cost for each Medicare beneficiary on dialysis. The Medicare savings is the difference between the two components. Further, we distinguished between savings estimates for 1985 from those projected for 1987. This is because the rapidly changing developments in the field of transplantation call for some different assumptions for those two periods.

First of all, with respect to the methodology for projecting average costs associated with transplantation over a 5-year period, we drew on the work of Jerome Aroesty and Richard A. Rettig, authors of a 1984 Rand Corporation report, based on research funded in part by the National Institutes of Health, and entitled The Cost Effects of Improved Kidney Transplantation. In that report, the authors make different cost projections (all based on 1979 dollars) based on differing assumptions about Government policy and 1-year kidney graft survival rates.

For 1985, we used the authors first policy scenario, which assumes the following: "(1) Current government policy prevails, which limits ESRD benefits to 3 years for successful transplant recipients and restricts coverage of immunosuppressive drugs to inpatient treatment; and (2) treatment costs remain unchanged for all three levels of outcome". In addition, we used the medium level of outcome, which is a 1 year graft survival rate of 74 percent.

On the basis of these assumptions and their analysis of the cost components of transplantation over time, Aroesty and Rettig project average 5-year costs of \$58,000.

For 1987, we used the authors' second policy scenario, which assumes that there will be no change in Government policy concerning coverage but that "new transplantation costs decline 25 percent from baseline costs, a magnitude consistent with results from trials reported by Pittsburgh and Minnesota". The continued advances in the types of medication available and in the use of immunosuppressive drugs generally are leading in many transplant centers to

significant reductions in the length of inpatient hospital stays for transplantation and in the incidence of post transplant hospitalization.

- In addition, because of continued improvements in 1 year graft survival rates, we used an outcome level halfway between the medium outcome level (74 percent) and the high level (89 percent).

On the basis of these assumptions, Aroesty and Rettig's methodology leads to projected average 5-year transplant costs of \$45,000.

Secondly, with respect to the methodology for projecting the costs of dialysis, we draw on HCFA cost data and on analyses of this data by Dr. Henry Krakauer, a HCFA official who, over the years, has studied kidney transplant outcomes and costs in depth. His reviews indicate that 1 year maintenance costs for dialysis patients range between \$25,500 to \$27,900, depending on the age of the patient.

Recognizing that some of these are costs for Medicare covered services that would apply for eligible Medicare beneficiaries, even if they were no longer covered under the ESRD program, we conservatively estimate the annual cost of dialysis to be \$24,000.

Thus, for 1985, we estimate that each transplant of a Medicare beneficiary will generate a 5-year cost savings of \$62,000. This represents \$120,000 for the 5-year cost of dialysis ($\$24,000 \times 5$) minus the 5-year projected transplant cost of \$58,000.

For 1987, we estimate that each transplant of a Medicare beneficiary will generate a 5-year cost savings of \$75,000. This represents \$120,000 for the 5-year cost of dialysis minus the 5-year projected transplant cost of \$45,000.