

ORGAN ACQUISITION COSTS: AN OVERVIEW



**OFFICE OF INSPECTOR GENERAL**  
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#### This Report

Entitled "Organ Acquisition Costs: An Overview," this report was conducted to gain a better understanding of (1) the extent and nature of Medicare expenditures on kidney acquisition and (2) the overall efficiency and economy of the kidney acquisition systems that exist across the U.S.

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## EXECUTIVE SUMMARY

PURPOSE: To gain a better understanding of (1) the extent and nature of Medicare expenditures on kidney acquisition and (2) the overall efficiency and economy of the kidney acquisition systems that exist across the United States.

### MAJOR FINDINGS:

- o During FY 1985, Medicare expenditures on kidney acquisition and transplantation were an estimated \$240 million. Of that total, \$102 million, about 43 percent, was for kidney acquisition.
- o Renal transplant centers (RTC's) accounted for about one-half of all the kidney acquisition expenditures; independent organ procurement agencies (IOPA's) for about two-fifths. However, when only cadaver acquisitions are considered, the IOPA's are dominant. Of the estimated \$76.5 million in Medicare funds spent on cadaver kidney acquisition in FY 1985, IOPA's accounted for about 54 percent; RTC's 36 percent.
- o There is widespread variation in the per kidney acquisition cost of providers. In one large city dominated by two RTC's, one had an average Medicare expenditure of \$9,363 per transplant in FY 1985 compared with \$17,902 for the other.
- o Most kidney acquisition providers are not functioning in a very efficient or economical manner. They tend to devote relatively little attention to identifying possible cost savings and sometimes tolerate unnecessary duplication and waste. As a result, a substantial portion of the Medicare funds spent on kidney acquisition are being spent unnecessarily.
- o Pretransplant laboratory costs, which account for at least 20 percent of Medicare expenditures on kidney acquisition, have been growing rapidly and are subject to little control. This is particularly troubling because it was found that:
  - o There is widespread variation in pre-transplant testing procedures, terminology, and costs.
  - o There is a sharp increase occurring in laboratory costs being incurred by those on transplant waiting lists.
  - o There is unnecessary duplication of pretransplant testing.

- o Kidney wastage rates, though declining, remain high especially for hospital organ procurement agencies (HOPA's). For FY 1985, the overall wastage rate was an estimated 13.8 percent--16.6 percent for HOPA's and 11.7 percent for IOPA's.
- o Kidney wastage adds significantly to kidney acquisition costs. If, in FY 1985, the wastage rate were 5 percent instead of 14 percent, the acquisition cost per cadaver transplant would have been \$1,381 less per kidney transplant--\$13,199 instead of \$14,580.
- o Fiscal oversight of kidney acquisition costs is extremely limited. This is especially so with respect to the costs incurred by RTC's.
- o Among those working on the front lines of organ procurement, there is widespread recognition about the looseness of the kidney acquisition cost center of RTC's. As one transplant surgeon said: "There's a lot of padding in the hospital kidney acquisition costs."

RECOMMENDATIONS:

- o HCFA should amend the current Diagnosis Related Group (DRG) for kidney transplantation (DRG 302) to include all costs associated with acquisition as well as transplantation. Further, as soon thereafter as possible, it should take the same approach with respect to heart, liver, and any other type of organ transplant that might be covered under Medicare in the future.
- o In determining the Federal payment rate for the kidney acquisition component of the transplant-acquisition DRG, HCFA should ensure that it (1) takes into account the unnecessary costs reflected in current kidney acquisition expenditures, (2) is based on the cost per kidney transplanted rather than retrieved, and (3) includes living related as well as cadaver acquisitions.
- o HCFA should begin full implementation of the transplant-acquisition DRG's as soon as practical.
- o HCFA should support some demonstrations of a capitated approach to Medicare reimbursement for kidney transplantation and acquisition.

## INTRODUCTION

As the number and type of Medicare covered organ transplants have increased, the cost of acquiring organs has become an increasingly important one for the Federal government. In this report, we aim to promote a better overall understanding of this cost. In so doing, we focus on kidney acquisition costs because, as we address in Appendix I, most of the experience and data are in that area. The implications, however, extend to organ acquisition and transplantation in general.

Kidney acquisition costs cover a wide variety of pretransplant services. These services include different kinds of laboratory tests involving both donors and potential transplant recipients. They include diverse activities associated with the organ acquisition process, such as transportation, organ preservation, and professional and public education. And, they include a broad range of functions directly associated with the surgical removal of organs from donors.

The Medicare program pays for these services on the traditional reasonable cost basis in accordance with procedures spelled out in detail in a July 1974 Medicare Intermediary Letter (74-23). As stipulated in the Letter, all Medicare reimbursement for procurement (acquisition) is to the renal transplant center (RTC) performing the transplant. That center establishes a standard acquisition charge for living related donors and one for cadaver donors; after the close of the hospital's fiscal year, the charges are aligned with actual costs and any necessary adjustments are made.

All procurement costs borne by donor hospitals, independent organ procurement agencies (IOPA's), and independent laboratories (IL's) are passed on to a RTC for payment. Typically, this means that the bills are provided directly to a RTC. However, in the case of a donor hospital working with an IOPA, the IOPA reimburses the hospital on the basis of its standard charges for the procedures performed and then incorporates this payment in its charge to a RTC.

In 1983, when the Health Care Financing Administration (HCFA) was establishing the Medicare prospective payment system for hospital inpatient services, it was planning to include kidney acquisition services in Diagnosis Related Group (DRG 302), which also included inpatient services associated with kidney transplant surgery. However, HCFA decided that because of the "unique characteristics of organ procurement activities and the desirability of maintaining an adequate supply of kidneys," kidney acquisition costs would be reimbursed in the traditional fashion, outside the prospective payment system. This meant that RTC's could pass through for Medicare reimbursement 100 percent of their kidney acquisition costs, as long as they were covered and reasonable.

Since 1983, the incidence of and interest in kidney transplantation has increased greatly. With the introduction in November 1983 of cyclosporine, a powerful immunosuppressive drug, and significant improvements in graft survival rates, kidney transplantation has become increasingly prominent and popular. From CY 1983 to 1985, the annual incidence of kidney transplants increased 26 percent (from 6,112 to 7,695) and transplant waiting lists increased by 36 percent (from 7,176 to 9,791). During the same period, the number of Medicare certified IOPA's rose by 50 percent (from 36 to 54), IL's by 35 percent (26 to 35), and RTC's by 14 percent (156 to 178).

Obviously, during this period of substantial growth there has been a major increase in kidney acquisition costs. But, because of fragmented, incomplete, and sometimes incorrect data bases, strikingly little is known about the extent or nature of these costs.

In this report, the third in a series of reports concerning organ acquisition systems, we examine the Medicare costs being incurred for kidney acquisition. First, by piecing together strands of data from different sources, we seek to offer some reasonable estimates of the scope and dimensions of these costs. Second, on the basis of extensive field work and the review of scores of materials (see Appendix I), we aim to provide some insight on the overall efficiency and economy of the kidney acquisition systems that exist across the United States. Finally, we close with some recommendations directed to HCFA.

## FINDINGS

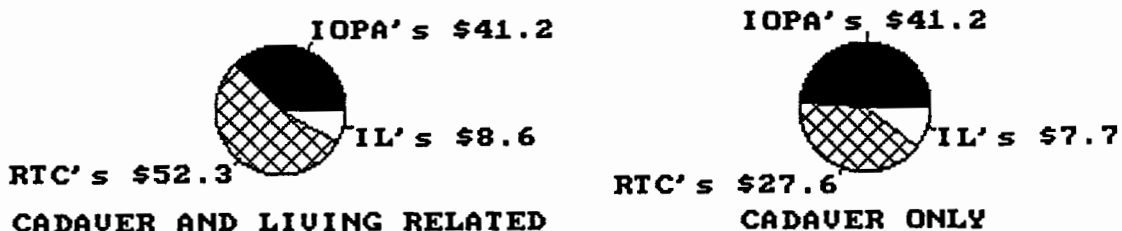
### THE COST PICTURE

We estimate that during FY 1985, the Medicare program spent about \$240 million on kidney acquisition and transplantation. About \$138 million of that was for transplantation (DRG 302). The remaining \$102 million, about 43 percent of the total, was for acquisition. For each transplant performed, the average Medicare expenditure was about \$20,000 for inpatient expenses associated with the operation and about \$14,800 for acquisition costs.<sup>1</sup>

The \$102 million expenditure was incurred by three major types of providers: renal transplant centers (RTC's), independent organ procurement agencies (IOPA's), and independent laboratories (IL's)<sup>2</sup> Among them, the RTC's accounted for the most sizeable portion of Medicare kidney acquisition expenditures. As indicated in the chart below, they accounted for an estimated \$52.3 million of such expenditures, slightly more than one-half of the total. This money covered a wide range of acquisition costs associated with both living related and cadaver transplants. (Here and subsequently, the expenditure or reimbursement totals are Medicare totals for FY 1985 unless otherwise noted.)<sup>3</sup>



**CHART I**  
**ESTIMATED MEDICARE KIDNEY**  
**ACQUISITION EXPENDITURES, FY 85 (In Millions)**



**SOURCE: Transplant Center Cost Reports and Aetna**

When the universe is narrowed to expenditures for only cadaver transplants, which represented about 76 percent of all transplants, the RTC's are much less prominent. In this sphere (see chart above), RTC's spent an estimated \$27.6 million in Medicare funds, a little more than one-third of the total. In contrast, IOPA's, which retrieve kidneys only from cadaver donors, spent an estimated \$41.2 million, about 54 percent of the total Medicare reimbursement for the acquisition of cadaver kidneys. Independent laboratories, which do work primarily for IOPA's, but also RTC's, received an estimated \$7.7 million (about 10 percent) in reimbursements.

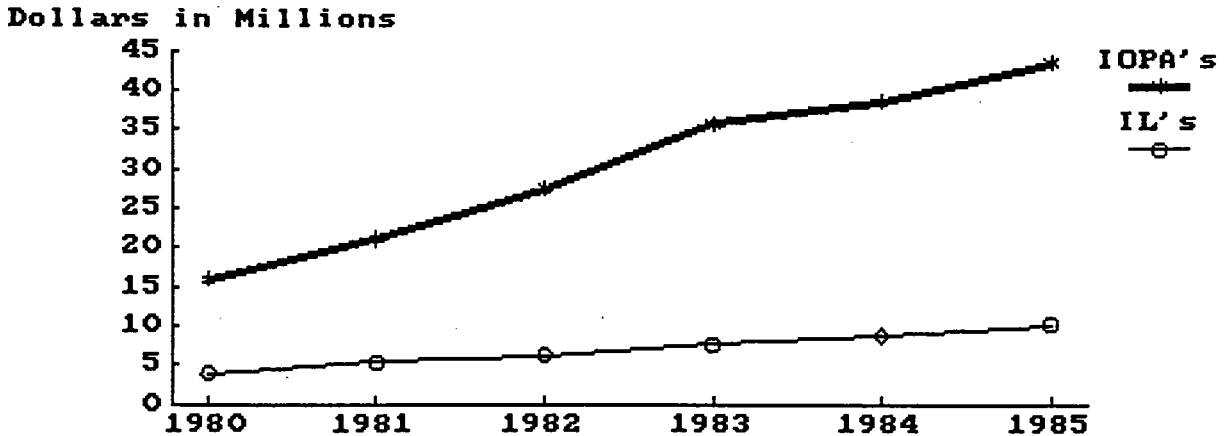
Among the 178 Medicare certified RTC's at the end of 1985, some were actively involved in procuring organs directly rather than working strictly through IOPA's. These RTC's, often referred to as hospital organ procurement agencies (HOPA's), represented slightly less than one-third of all RTC's and slightly more than one-third of all kidney transplants performed in 1985.<sup>4</sup> Yet, during FY 1985, we estimate that they accounted for about 47 percent of the \$102.1 million Medicare reimbursement for kidney acquisition.<sup>5</sup>

Do IOPA's then tend to be more efficient and economical than HOPA's? Perhaps, but the cost data is not differentiated sufficiently to determine the costs for comparable activities and thus, to reach any definitive conclusions. For instance, IOPA per kidney acquisition costs generally do not include the full costs for laboratory work. Indeed, their costs for such work are sometimes borne by HOPA's, thereby adding to the latter's acquisition costs.

Unfortunately, there is insufficient historical data available on RTC's to offer much information on trends in the extent or nature of kidney acquisition expenditures. All that is available is the data compiled by Aetna on the IOPA's and IL's. As indicated below, it shows a considerable increase from 1980 to 1985 in both IOPA and IL expenditures. During that period, while the number

of active IOPA's increased from 20 to 43 and the annual number of kidneys procured by these IOPA's increased from 1,817 to 3,961, total IOPA reimbursable costs (the amount reimbursable by RTC's) increased from \$15.9 million to \$43.4 million. Simultaneously, while the number of active IL's rose from 23 to 31 their total reimbursable costs jumped from \$3.9 million to \$10.1 million.

**CHART II**  
**TOTAL REIMBURSABLE COSTS, IOPA's and IL's**  
**FY 1980 - 1985**



SOURCE: Aetna

There is also insufficient data to draw upon to make many useful generalizations about kidney acquisition cost components. For instance, from the RTC cost reports, we cannot determine the amount spent in acquiring living related kidneys compared with that of cadaver kidneys.

However, from the RTC cost reports and the somewhat more detailed (and accurate) IOPA cost reports, we can decipher two sizeable categories of expenditure. One concerns operating overhead; the other laboratory expenses.

First of all, with respect to operating overhead, the IOPA cost reports for FY 1985 indicate that the reimbursable cost for operating overhead is about \$21 million. (This includes all of the "general service cost centers," such as equipment depreciation, plant maintenance, employee health and welfare, and administrative costs.) With the total reimbursable cost for that year at \$43.4 million, the overhead rate is thus almost 100 percent. Comparable data is not readily obtainable for the RTC's.

Second, in regard to laboratory costs, it can be determined that at least \$20 million of the estimated \$102.1 million in Medicare expenditures for kidney acquisition in FY 1985 were for various pretransplantation lab tests.<sup>6</sup> These include three major

categories of tests: for HLA (human leukocyte antigen) typing of potential donors and potential recipients, for the crossmatching of serum from potential donors and recipients, and for ongoing antibody screening of potential recipients.

Finally, in filling out the overall cost picture, it is important to indicate that even though exact cost comparisons are not possible with the current data base, there are widespread variations in the per kidney acquisition cost of different providers, even in the same community. For instance, in one major metropolitan area where two RTC's conduct the great majority of transplants, one of them had an average Medicare expenditure of \$9,363 per transplant for FY 1985 compared with \$17,902 for the other. In another major urban area having 4 large transplant programs, the Medicare cost per transplant in FY 1985 ranged from \$11,289 to \$24,161. (In both these areas, the data is based on audited cost reports.)

Why is there such variation? A key factor certainly is quantity. Providers acquiring a larger number of kidneys have more opportunities to achieve economies of scale. But there are also many other factors that help to explain differential costs and charges. Among them are variations that exist in (1) the wastage of acquired organs, (2) the proportion of non-renal organs being acquired; (3) the number of individuals on a transplant waiting list; (4) the type of preservation being used; and (5) the extent of administrative overhead costs.

#### COST CONCERNS

In a financial sense, kidney acquisition systems are now an anomaly. While the health care system in general is facing major pressure to become more cost conscious, they remain by and large free of such pressure. This is because kidney acquisition costs continue to be reimbursed by Medicare on a "reasonable cost" basis. As long as the costs incurred are covered and considered reasonable, Medicare is obligated to pay for them.

As we became more familiar with the kidney acquisition systems across the United States, it became increasingly apparent to us that most of them were not functioning on a very efficient or economical basis. Although many providers were quite effective in procuring kidneys, most seemed to devote little attention to identifying possible cost savings. Worst yet, we found numerous indications of duplication and waste. Quite clearly, a substantial portion of the Medicare funds spent on kidney acquisition are being spent unnecessarily.

This finding is of particular concern for two reasons. One is that kidney acquisition systems tend to be the same ones being relied upon to procure hearts, livers, and increasingly, other organs and tissues. With Medicare now covering heart and liver transplants (the latter are only for children under 18 years of age), the potential financial vulnerability thus extends beyond the acquisition of kidneys.

The second reason is that the financial stakes are increasing. The number of individuals receiving kidney transplants and the number awaiting such transplants have been rising sharply, as we documented in the introductory section of this report. In the years ahead, the increases are likely to continue and may even intensify as "routine request" laws begin to take hold. (At this writing, at least 26 states have passed such laws.) Thus, before the end of the decade, Medicare expenditures for organ acquisition could very well approach the \$200 million level.

The key question, then, is: on what specific grounds do we base our finding that kidney acquisition systems tend to be run without sufficient attention to costs? While there are many particular examples that support the point, there are three major ones that have broad based applicability throughout the country. The first concerns a functional area of expenditure: pretransplant laboratory services. The second concerns a phenomenon associated with organ procurement: organ wastage. The third concerns a vital managerial component: fiscal oversight. Each is addressed below.

### Laboratories

As indicated earlier, pretransplant laboratory costs account for at least \$20 million (or 20 percent) of all Medicare expenditures on kidney acquisition. At many RTC's and IOPA's, these costs represent one-third or more of their standard acquisition charge.

Although there is little national information on how these costs break down, we do know that they have been growing rapidly and have been subjected to little control. The seriousness of the matter is suggested by a transplant coordinator at a large RTC who commented as follows:

"We spend more than \$1/2 million a year on laboratory tests. Much of it is unnecessary. But no one here gives a damn because it's a 100 percent Medicare pass-through."

Upon analysis, we find that there are three major elements that serve to make the current situation a troublesome one. They are addressed below.

There is widespread variation in pretransplant testing procedures, terminology, and costs. This is a long-standing phenomena that to some extent is unavoidable in this dynamic, rapidly changing field. Yet the degree of variation that currently exists appears to be hard to justify. Aetna, in a May 12, 1986 memo to independent laboratory directors, noted that there may be as many as 47 different crossmatch tests being employed. Further, drawing on 1984 data, it indicated that the cost per test for the labs it covered ranged from \$33 to \$264. At one extreme, Lab A did 799 renal tests for which it was reimbursed

\$210,739 for an average cost per test of \$264. At the other Lab B did 7,998 tests and received \$268,113, for an average of \$34 per test. Aetna added that at present:

" . . . . there is no mechanism to determine if these laboratories do a comparable amount of work and simply count "tests" differently, or if Laboratory B actually performed 10 times the work done by Laboratory A at only a 27% increase in costs."

Even for those tests that appear to be identical, one finds extensive variation in the reimbursement rates. Antibody screens, for instance, range from \$40 a test to as much as \$175. Similarly, HLA A,B and C typing ranges from \$44 to \$150. One lab has a menu of 36 different types of tests, each with its own reimbursement rate. Another does not differentiate the tests and costs for billing purposes and instead has a standard laboratory charge of \$2,000 for each locally transplanted kidney.

In this situation of extreme diversity, Aetna, the Medicare intermediary for the independent laboratories, is in poor position to determine whether laboratory costs are, in fact, reasonable. Recognizing this reality, it recently established a task force of laboratory representatives in an effort to achieve some standardization in the nomenclature and to find ways of determining a laboratory's efficiency.

This effort is an important one, addressing significant issues, but the prospect for any significant results in the near term appears limited. Moreover, it does not involve the RTC based laboratories, which are overseen by whatever Medicare fiscal intermediary is responsible for the parent hospital. No comparable effort involving these laboratories is underway.

There is a sharp increase occurring in laboratory costs being incurred by those on transplant waiting lists. The precise rate of increase cannot be determined, but it is clear that these costs are rising at an accelerated level. Mainly this is because of the growing size of transplant waiting lists (from 5,072 in 1980 to 9,791 in 1985) and because of the fact that an increasing proportion of the lists is composed of highly sensitized individuals (those with a high level of preformed antibodies). Thus, as of June 6, 1986, 40 percent of the 8,610 individuals on the national waiting list of the United Network for Organ Sharing (UNOS) had a Panel Reactive Antibody 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.

These two developments--the increasing demand for kidney transplants and the increasing proportion of highly sensitized individuals--add to laboratory costs in numerous ways. For new transplant candidates, laboratories conduct tissue typing tests to determine their HLA (human leukocyte antigen) specificities.

For those on the waiting lists, laboratories typically conduct monthly antibody screens to determine any changes in a candidate's level of antibodies. Then, when a donor kidney becomes available, laboratories usually conduct crossmatch tests involving serum obtained from the donor and from various candidates with compatible blood types. Indeed, in many regional consortia, the protocol calls for such crossmatches to be conducted on all highly sensitized candidates with compatible blood types.

Thus, the accumulated costs for laboratory tests can become quite significant, particularly for RTC's with large numbers of sensitized patients on their waiting lists. At most centers, it appears there are individuals who have been on a waiting list for years and whose chances of obtaining a transplant grow increasingly remote. At one such center, a laboratory director noted: "The vast majority of tests here are done on individuals who never get a transplant."

To get a better sense of the financial consequences of this situation, let's consider a highly sensitized individual who has been on a transplant waiting list for three or more years, as is probably the case for at least 15 to 20 percent of those on such lists. Aside from the initial tissue typing costs, that individual may generate costs averaging about \$80 a month for monthly antibody screening and about \$300 a month for HLA crossmatching. Over the course of a year that totals \$4,560; over three years--\$13,680.

The underlying point here is not that such individuals should be removed from the list. Rather, it is that a sizeable ongoing expenditure has developed with little notice and with hard questions seldom being asked about how these expenditures might be curtailed without compromising the humanitarian objectives of transplant programs. For instance, are more crossmatch tests being conducted than are necessary? Is once a month antibody screening needed for everyone? (Some RTC's now conduct these tests every second or third month for some individuals.) Are there some individuals on transplant lists who, for all practical purposes, are no longer viable transplant candidates and who should be removed from the lists?

There is unnecessary duplication of pretransplant testing. In many areas, RTC's have agreed to use a single laboratory for all their pretransplant work. This has afforded the opportunity to achieve some economies of scale and to expedite the organ acquisition process. In other areas, however, RTC's have refused to participate in such cooperative efforts and have continued to operate their own laboratories.

At its worst, this situation can involve numerous RTC laboratories that exist in the same metropolitan area and that regularly duplicate one another's work. Such a situation, which is

not precluded under current reimbursement rules, was especially striking in one large metropolitan area that otherwise features a highly effective centralized organ procurement operation.

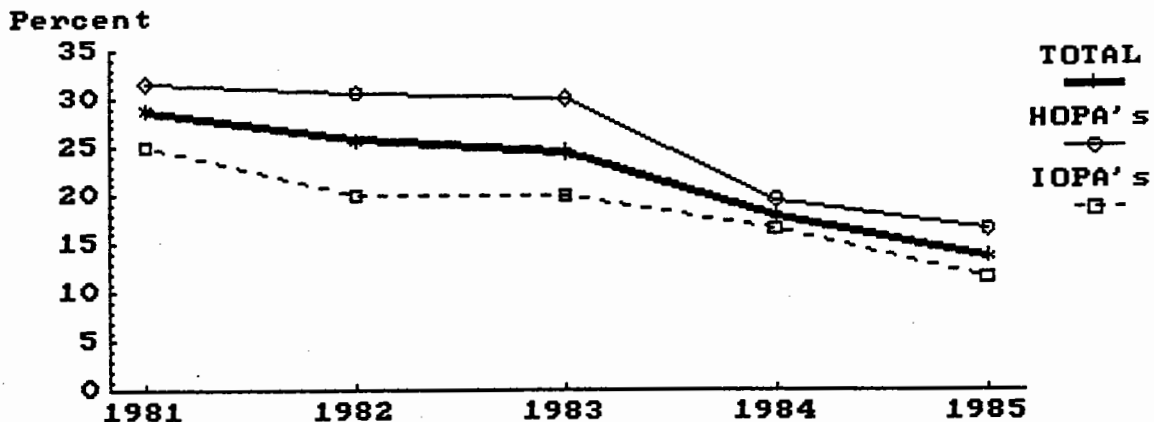
That metropolitan area has five RTC's, each of which is a medical school teaching hospital which operates its own tissue typing laboratory. In harvesting (obtaining) kidneys, each of the RTC's has agreed to the following protocol: The RTC that harvests the kidney packs five boxes with a tube of blood, lymphnodes, and spleen serum from the cadaver donor and sends them to the five RTC tissue typing laboratories. Each laboratory then conducts its own HLA typing of the donor serum and its own crossmatching of that serum with individuals on its own waiting list. The process not only adds significantly to Medicare kidney acquisition expenditures in the area, but can add up to eight extra hours to the organ procurement process, meaning that kidneys are sometimes transplanted as much as eight hours later than would be the case if there were a single, consolidated laboratory operation.

When asked why this situation is tolerated, a director of one of the laboratories said, "We can't trust the work of the other labs." The transplant surgeons who comprise the board of the IOPA that procures kidneys for each of the RTC's have not been inclined to tackle the issue--apparently feeling that it reflects a delicate balance of power that is best left alone. Further, another laboratory director asserts that the surgeons have actually discouraged the lab directors from communicating too closely with one another because in the highly competitive situation that exists, they are reluctant to give away any secrets.

#### Kidney Wastage

The chart below shows that during the 1980's there has been significant progress in reducing the rate of kidney wastage in the United States--both for hospital organ procurement agencies (HOPA's) and independent organ procurement agencies (IOPA's). Improved organ acquisition systems, a decreased reliance on the national sharing of kidneys, and an increased readiness to transplant older kidneys appear to be major factors contributing to this progress.<sup>7</sup>

**CHART III**  
**WASTED CADAVER KIDNEYS AS PERCENT OF**  
**CADAVER KIDNEYS RETRIEVED**



**SOURCE:** HCFA Facility Survey and Aetna

Yet, the more significant point may be how high the wastage rate remains: 13.8 percent overall, 16.6 percent for HOPA's, and 11.7 percent for IOPA's. As Dr. Jeffrey Prottas of the Health Policy Center at Brandeis University has indicated, the United States rates have been much higher than European rates--by margins of 50 to 75 percent.<sup>8</sup>

The cost consequences associated with this wastage are significant. If in 1985 the cadaver kidney wastage rate (the proportion of harvested kidneys that were not transplanted) had been 5 percent instead of 14 percent, the kidney acquisition cost per cadaver transplant would have been \$13,199 instead of \$14,580--a savings of \$1,381 per kidney.<sup>9</sup> This is in line with Prottas' estimate, based on 1982 data, which is that between \$1,000 to \$1,800 of the cost of each kidney transplant can be attributed to unused kidneys.<sup>10</sup>

Moreover, each additional transplant performed results in savings over time in Medicare End Stage Renal Disease Program (ESRD) costs, by reducing the level of costs incurred by those on transplant waiting lists and even more so, by reducing the number that would otherwise be receiving dialysis treatments. Thus, a 5 percent wastage rate in 1985 would have meant that about 550 additional transplants would have been performed. Over a five year period, these additional transplants would have yielded an estimated Medicare cost savings of at least \$41.2 million.<sup>11</sup>

Why, then, is the wastage rate in the United States so high? Prottas' 1984 study identifies poor donor management, surgical error, poor preservation, and sharing/matching problems as possible sources of wastage. In comparing the Europe and United States situations, he explains:



". . . the Europeans have a far more standardized and centralized system for matching donors with potential recipients. The U.S. computer system of kidney recipients is fine as far as it goes, but it operates without agreed upon standards and without the routine sharing of specimens to permit pre-testing of donors and recipients for compatibility. As a result it is often hard to place organs that cannot be used locally, and once placed it is sometimes found that they are not immunologically acceptable only after the organ has been shipped across the country."<sup>12</sup>

This conclusion is supported in an article written by G. M. Williams et al. and published in the February 1985 issue of Transplantation Proceedings. Entitled "Renal Transplant Wastage: An International Problem," the article focuses on 565 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 the great majority of these kidneys (68 percent) "failed to be transplanted in the U.S. because of our inability to identify non-sensitized recipients." Among the remaining 32 percent, about one-half were lost because of problems the authors regarded as "preventable" and one-half because of what they term as an aggressive procurement attitude (i.e., a readiness to harvest kidneys even though the potential viability of those kidneys may be questionable).

If in the coming years, the wastage rates continue to decline as they have in the recent past, the problem would be largely resolved. But this is far from assured. Indeed, some suggest that the easy progress has been made and that continued progress is unlikely without some significant initiatives.

It is also important to take into account how wastage rates might be reduced. If they were to be reduced through less aggressive procurement approaches, then the gains might be offset by the loss of transplants that would otherwise have occurred.

Nevertheless, it appears to be the case that with sufficient commitment, wastage rates can be much lower without any adverse effect on organ retrieval efforts. This is most especially true for RTC's, which now discard at least one out of every six kidneys they retrieve themselves.<sup>13</sup>

### Fiscal Oversight

Fiscal oversight of kidney acquisition systems is extremely limited. It seldom involves a search for ways in which acquisition efforts might be carried out in a more efficient or economical manner. Instead, it concentrates on matters of

verification--assuring that identified costs were in fact incurred and eligible for reimbursement. And even in that context, its effectiveness is often questionable.

The fiscal oversight that does occur tends to be much less consequential for the RTC's than the IOPA's. In part this may be because the organ procurement efforts of the former tend to have less managerial direction than the latter. In a 1982 survey, for instance, Prottas found that RTC procurement programs tended to receive only one-sixth of an administrator's time while IOPA's generally received much more than that.<sup>14</sup>

However, of greater significance is that the oversight that Medicare intermediaries exert over RTC's tends to be minimal. For these intermediaries, the review of a hospital's kidney acquisition cost center tends to be one small part of their overall review of that hospital's Medicare costs. Because of that and because they have little or no information available to compare the acquisition costs, their audits of kidney acquisition costs are seldom exacting.

Among those involved on the front lines of organ procurement--the transplant coordinators, surgeons, laboratory directors, and others--there is a widespread recognition about the looseness of a RTC's kidney acquisition cost center. In one major metropolitan area where a number of RTC's dominate organ procurement, a group of surgeons representing these RTC's are considering establishing a centralized IOPA in place of the RTC procurement efforts. However they are reluctant to give up the financial advantages of the current situation. As one of them said, "We all know that there's some softness on what's in the hospital's kidney acquisition cost center."

In another area, a transplant surgeon remarked: "There's a lot of padding in the hospital's kidney acquisition costs. Personnel time devoted to other matters is often included in the kidney acquisition cost center." Similarly, a surgeon in yet another area said, "There's a certain amount of bootlegging that goes on in ESRD programs with non-renal accounts."

Perhaps the strongest testimony in this regard was offered by the administrative director of an IOPA that used to be a procurement program within one of the nation's largest teaching hospitals.

He said:

"When we were part of the hospital, fiscal oversight was much more lenient. The fiscal intermediary paid little attention to our operation. Now, as an independent organ procurement agency, we're subject to much more oversight."

This relative neglect, however, is not always to the benefit of a RTC's organ acquisition efforts. As a hospital's administration seeks to maximize Federal reimbursement for the kidney acquisition cost center, the benefits may very well flow to other departments or to the hospital as a whole, rather than to the kidney acquisition component per se. One hospital tissue typing laboratory director emphasized this point when he said, "Just because we're reimbursed 100 percent doesn't mean the 100 percent comes back to us. The financial office keeps as tight a stronghold on us as on other departments." Similarly at the same RTC where the chief transplant surgeon said there's a lot of "bootlegging" going on with the ESRD account, the finance office has imposed strict controls on hiring, travel, and purchases. The finance director rationalized this treatment as follows:

"We want to make sure they're efficient, so that we'll be ready for any tightening up by the Federal government. I don't manage their account any differently-- even though it's a pass-through."

In the sphere of the IOPA's and IL's, the oversight tends to be somewhat more comprehensive and consequential. Stronger managerial direction contributes to this situation to some extent, but tends to be constrained by the understandings reached by surgeon dominated boards. For instance, in the example noted earlier where five hospital laboratories regularly duplicate one another's work, the IOPA executive director seems to have insufficient authority to alter this practice.

Also responsible for the somewhat more vigorous oversight of the IOPA's and IL's, is that Aetna has served as the single fiscal intermediary for them for more than seven years and in doing so has built up considerable expertise about kidney acquisition costs. Its audits of IOPA's and IL's appear to be more extensive than those that other intermediaries conduct on RTC's. Drawing on its considerable experience in the area, Aetna has established certain cost control measures such as limits on payments made for professional education and for the surgical excision of kidneys. Further, the laboratory task force that it established, has as one of its objectives the identification of means for determining the overall efficiency of a laboratory operation.

But even in this sphere of IOPA's and IL's, it is important to recognize that initiatives fostering efficiency and economy are taking place basically at the margin, having little overall impact. Thus, with respect to escalating laboratory expenditures, for instance, Aetna is still a long way from even being able to compare the services being performed, let alone to determine if their costs are "reasonable."

## RECOMMENDATIONS

Given the situation described in the previous pages, we feel that it is imperative for the Federal government to take action that fosters greater efficiency and economy in Medicare funded kidney acquisition systems.

That could be done under the current reasonable cost framework of Medicare reimbursement. Under that framework, cost limits could be established for a variety of particular activities or, indeed, for acquisition activity as a whole. Further, stricter determinations could be made of covered services, concerning, for instance, the type of preservation techniques used or laboratory tests performed.

However, it is important for the Federal government to take an approach that is less regulatory and interventionist in nature and that offers providers stronger incentives for efficiency and economy. In that regard, we expect that over time a capitated approach to financing is most desirable and should therefore be developed. In the more immediate sense, we regard a prospective payment system that allows for some area-based differences in costs as the most desirable approach to reimbursement. It encourages cost savings without getting the Federal government enmeshed in medical and organizational complexities. And, it can be accomplished quickly.

Thus, as our basic recommendation, we offer the following:

- o HCFA should amend the current DRG for kidney transplantation (DRG 302) to include all costs associated with acquisition as well as transplantation. Further, as soon thereafter as practical, it should take the same approach with respect to heart, liver, and any other type of organ transplants that might be covered under Medicare in the future.

Three years ago when the Medicare Prospective Payment System (PPS) was established, it was quite proper to exclude kidney acquisition costs from that system. With the hospital cost report data on kidney acquisition costs being incomplete and unreliable, there was insufficient data available to determine how to calculate a DRG incorporating those costs. Moreover, with most kidney acquisition programs still quite fragile, there was good reason to be concerned that cost generated pressures might jeopardize efforts to retrieve organs.

However, at present that rationale is not as persuasive. First of all, the relevant cost data is now available. HCFA has revised that portion of the hospital cost reports that concerns kidney acquisition so that it provides more detail and captures

all kidney acquisition costs (including those of IOPA's and IL's). Thus, the FY 1985 hospital cost reports, for the first time, identify overall Medicare reimbursable costs for kidney acquisition.

Second, kidney acquisition programs have matured and the public has become more accustomed to organ donation. Although there is still a shortage of kidneys, the widespread movement to establish hospital "routine inquiry" procedures concerning organ donation could exert a considerable stimulus to the supply of cadaver organs in the years ahead. At least 26 States have already passed legislation calling for hospitals to develop "routine inquiry" procedures. Further, the Omnibus Budget Reconciliation Act 1986 included a provision requiring all hospitals participating in Medicare and Medicaid to establish protocols for encouraging organ and tissue donation.

Third, in considering why it is now more reasonable to include kidney acquisition costs under the DRG for kidney transplantation, it is important to recognize that the Medicare expenditures for kidney acquisition have increased significantly during the past three years and are likely to continue to climb, perhaps at an even faster rate in the years ahead. The financial stakes are thereby greater and, as we have noted, some worrisome vulnerabilities have emerged. A DRG incorporating transplantation and kidney acquisition would address these vulnerabilities and help ensure that both transplantation and acquisition are conducted efficiently and economically.

Knowing that they would be reimbursed a given amount for each transplant performed, hospitals with transplant programs would have a strong incentive to address the hard cost-relevant questions that now tend to be ignored. Would it be less expensive to acquire kidneys themselves or to acquire them through an independent organ procurement agency? Are pretransplant laboratory tests being performed in the most efficient manner possible and are they all necessary? Are there economies that can be achieved by working together more closely and cooperatively?

In this changed financial environment, it is quite likely that in the metropolitan area having five competing and duplicative hospital-based tissue typing laboratories, the RTC's would find a way to consolidate their laboratory operations, which now account for more than one-third of their acquisition costs. In the area where an IOPA has a kidney acquisition charge of about \$13,000, about one-half of which is for administrative overhead, the RTC's would almost certainly press the IOPA to reduce its overhead costs or find an alternative, less costly way to procure kidneys. In the State where some newly established RTC's are establishing their own organ procurement programs rather than working through a well established IOPA serving the area, these RTC's might very well reconsider their actions.

Some individuals who recognize the need for greater cost control still feel that including kidney acquisition within the transplantation DRG would be unfair. They note that IOPA's have been more effective than RTC's in procuring organs and favor a separate DRG for kidney acquisition that would apply to IOPA's as well as RTC's. They suggest that our approach, with its focus on the RTC's, would enable RTC's to benefit at the expense of IOPA's.

We do not expect that would generally be the case. As suggested above, many RTC's may be confronted with a financial incentive to work through IOPA's, which may be less costly. Further, IOPA's and RTC's are not as separate as it may appear. The IOPA board of directors is typically dominated by transplant surgeons from one or more RTC's in the area. A single DRG focusing on the RTC's would encourage the RTC's to exert more leadership in the area of kidney acquisition and would make them more clearly and fully accountable for overall financial management in this area.

Our approach is also in accord with two other important realities. One is that it is only the RTC that absorbs all the various costs associated with kidney acquisition. The other is that there are some spillover effects between acquisition and transplantation costs. An example is in the area of kidney preservation. Although ice preservation has become the dominant practice, some surgeons argue that machine preservation, though more costly, maintains the kidneys in a healthier state. This, they add, means that transplant costs are likely to be less than with ice preservation because the transplant is likely to take hold quicker, meaning that the need for post-transplant dialysis is less likely and that the patient is likely to be discharged more quickly. Thus, some increase in acquisition cost may result in a decrease in transplantation cost. A DRG linking the two areas would enable an RTC to realize the savings.

Given that, there are still a number of important details that HCFA would have to address concerning the implementation of the proposed DRG. Among the most significant of them would be those involving the determination of the Federal payment rate for the kidney acquisition component to be added to the DRG for kidney transplantation. In that regard, the FY 1985 hospital cost reports provide the data base for determining the proper rate. As we noted earlier, these reports indicate that the average Medicare expenditure per transplanted kidney was about \$14,800.

If the proposed DRG were to be derived on a "budget neutral" basis, as was the case when DRG's were introduced in 1983, then this \$14,800 total could provide the basis for the add-on. But a budget neutral reimbursement system would only incorporate the inefficiencies we have found into the new system. While there would be incentives over time to eliminate them, we feel that they can and should be eliminated from the start.

Another issue in determining the payment rate is deciding whether to calculate it on the basis of cost per acquired kidney (transplanted and wasted) or per transplanted kidney. Some feel that the former is preferable because it is less likely to discourage organ retrieval efforts. We prefer the latter approach because we feel it provides a stronger incentive to reduce wastage and because RTC's, on their own accord, have considerable interest in maintaining as high a level of transplantation as possible.

Still another payment-related issue concerns whether acquisition costs for living related and cadaver organs should be included in the same DRG. We feel that they should be combined because here again there are spillover effects between the two cost areas and because we seek to encourage efficiencies for the transplant program as a whole. Moreover, it is not clear that the differential between the two types of cost is sufficient to warrant separate treatment.

Thus, in accord with the above discussion, we offer the following recommendation:

- o In determining the Federal payment for the kidney acquisition component of the transplant-acquisition DRG, HCFA should ensure that it (1) takes into account the unnecessary costs reflected in current kidney acquisition expenditures, (2) is based on the cost per kidney transplanted rather than retrieved, and (3) includes living related as well as cadaver acquisitions.

Finally, there is the matter of timing--both in the sense of when the proposed DRG's would be implemented and whether or not there would be a staged implementation period. When the DRG's were first implemented in 1983, the statute called for a three year transition period during which "a declining portion of the total program payment will be based on a hospital's historical costs in a given base year and a gradually increasing portion will be based on a regional and/or national Federal rate per discharge." With respect to our proposed modification of the kidney transplantation DRG, we feel that such a lengthy transition period would be unnecessary, given the comparatively limited scope of the change involved and the compelling need to introduce greater efficiency to the field of organ acquisition. In view of that consideration and the fact that HCFA would have to consider a number of other factors associated with the proposed DRG's, such as the basis for any waivers and the role of the Medicare fiscal intermediary for the IOPA's and IL's, we offer the following recommendation:

- o HCFA should begin full implementation of the transplant-acquisition DRG's as soon as practical.

Many of the transplant coordinators, surgeons, and IOPA and laboratory directors with whom we met were quite supportive of the concept of a DRG for organ acquisition. At the same time, they and others raised concerns about unintended effects that could be associated with it. In the quest to achieve savings, some RTC's, they noted, might be inclined to take a more conservative posture toward organ retrieval, to downplay immunological considerations that can have consequences for the long-term viability of a transplant, to become too restrictive in determining who is allowed on a transplant waiting list, and to show even less interest in obtaining kidneys through the national network.

Just as with the DRG system in general, there must be regular oversight to assure that the payment mechanism does not trigger harmful, unintended results. The peer review organizations, the hospital peer review committees, the End Stage Renal Disease network organizations, the State survey teams, and the newly forming national network organization each provide forums for such oversight. The establishment of national standards for organ procurement would also provide an important safety valve.

In summary, we feel that the establishment of transplant-acquisition DRG's, along the lines addressed above, offers a prime opportunity for a policy initiative that can save Medicare dollars without adversely affecting the quality of care. The scope of the savings is, of course, impossible to determine precisely, but reasonable estimates can be made.

In that regard, we have two bases for estimated savings for the proposed kidney transplantation-acquisition DRG. One concerns those savings that would result from the substantially reduced wastage rates which a DRG would almost certainly generate. We estimate that in its first year, the new DRG would be responsible for a reduction of at least 5 percentage points in the overall rate of kidney wastage. This reduction, during that one year, would generate an estimated Medicare cost savings of \$30.1 million over a five year period.<sup>15</sup>

A second category of savings would be that represented by increased efficiency and economy in organ acquisition systems and by a Federal payment that takes this into account. In that context, if the Federal Medicare payment per transplant were reduced from an estimated \$14,800 to \$14,000, about 5 percent, the first year Medicare cost savings would be \$7.4 million.<sup>16</sup> Thus, without even considering any cost savings associated with heart or liver acquisition, the inclusion of organ acquisition in



the Medicare prospective payment system would generate in its first year an estimated Medicare savings of at least \$37.5 million. (\$30.1 million plus \$7.4 million).

Simultaneous with the development and implementation of the DRG's as noted above, we feel that some consideration should be given to how a capitated financing/reimbursement approach might be applied to organ transplantation and acquisition. In this regard, a demonstration effort involving a few experienced renal transplant centers would be particularly desirable. It would afford an opportunity to gain some valuable insights about the workings and impact of such a system.

Accordingly, we conclude with the following recommendation:

- o HCFA should support some demonstrations of a capitated approach to Medicare reimbursement for kidney transplantation and acquisition.

Such demonstrations might involve providing the RTC with a capitated amount per transplant that would cover acquisition, transplantation, and certain post-transplantation costs for up to three years. With the post-transplant care included in the capitated payment, the RTC would have a significant stake in the longer term viability of a transplant.

## 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 1984-1985 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 16 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, 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 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 third of a series of reports presenting the findings and recommendations of the study. The first report, issued in August 1986, is titled "The Access of Foreign Nationals to U.S. Cadaver Organs." The second, issued in November 1986, is titled "The Access of Dialysis Patients to Kidney Transplantation."

In each of these reports primary attention is 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 United States, 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 United States 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

### METHODOLOGICAL NOTES

We include this section to inform the interested reader about the assumptions and approaches used to obtain our estimated numbers. It is directed primarily to those already knowledgeable about the existing data bases concerning organ procurement costs. We stress that in some cases the estimates rest on a stronger foundation than others. We also urge that the reader recognize that we focus on Medicare expenditures rather than overall costs and that we reconcile data from different reporting periods. Thus for instance, we develop fiscal year estimates for the transplant activity data compiled on a calendar year basis by the annual HCFA Facility Survey. We do that in order to compare it more directly with the cost data that is compiled on a fiscal year basis.

We recognize the imperfections in this methodology. At the same time, we feel that the resulting estimates, inexact as they are, add valuable clarity to a cost picture that was heretofore extremely blurred.

The following explanations refer to citations in the textual material:

1] With respect to the Medicare expenditure on transplantation we obtained the \$138 million total from HCFA. The average Medicare expenditure for inpatient services was determined by dividing the \$138 million by 6,904, the estimated number of Medicare reimbursed kidney transplants during FY 1985.

We developed the estimate of 6,904 Medicare reimbursed kidney transplants for FY 1985 as follows. We took the 7,695 transplants reported in the HCFA facility survey for CY 1985 and subtracted from that total the 603 non-Medicare transplants reported in the survey for CY 1985. That resulted in a total of 7,092 Medicare reimbursed kidney transplants for CY 1985. For CY 1984, the comparable total, using the same methodology, was 6,339, 753 less than the CY 1985 total. To obtain an estimated total for FY 1985, we then subtracted 188 (one-fourth of 753) from the CY 1985 total of 7,092. Thus, the estimate of 6,900.

With respect to the Medicare expenditure on kidney acquisition, we developed an estimate of \$102.1 million on the basis of our review of the cost reports of individual transplant centers (RTC's). For the 140 RTC cost reports we obtained, we determined the net amount spent by Medicare by adding the amount on line 56 of the D-6 cost reports. Then, we projected what the total would be for 151 RTC's, if the additional 11 reflected the average net cost of the 140. The 151 total was determined, after discussions with HCFA, to be the number of active RTC's during FY 1985.

Most of these cost reports, it must be emphasized, were unaudited. Thus, some discrepancy is likely between our totals and those that would be obtained subsequently from a full set of audited cost reports.

2] Actually, there is also a fourth major type of provider: donor hospitals. However, the acquisition costs incurred by these hospitals are incorporated in RTC and IOPA cost data and cannot be fully isolated from that data. We estimate that in FY 1985, they accounted for about \$8 million or about 8 percent of overall kidney acquisition expenditures.

We developed that estimate as follows. From Aetna cost report data, we determined that IOPA's paid about \$5.1 million to donor hospitals during FY 1985. We then assumed that RTC's, for the kidneys they retrieved on their own, paid donor hospitals at a parallel level (though it may very well be higher). Thus, since RTC's retrieved about 41 percent of all kidneys retrieved in FY 1985, we increased the \$5.1 million by that proportion. That resulted in a total of \$8.64 million for donor hospitals. We then reduced that total by 5 percent to account for non-Medicare revenue, leaving a total of 8.21 million.

3] For the allocation of expenditures on cadaver and living related, we started with Aetna's FY 1985 total of \$43.4 million in reimbursable cost for independent organ procurement agencies (IOPA's). We then reduced that by 5 percent, since about 5 percent of that would subsequently be reimbursed by non-Medicare sources. Thus, we estimated that the Medicare expenditures on IOPA acquired kidneys was \$41.2 million.

Next, we developed a counterpart estimate for the expenditure on independent laboratories doing pretransplant work. We started with Aetna's total of \$10.1 million in reimbursable cost for FY 1985, reduced that by \$1 million to account for an estimated double counting that appears in the IOPA total, and then another 5 percent to account for non-Medicare revenue. Thus, we estimated that the Medicare expenditure on IL's was \$8.6 million.

Finally to determine the total for RTC's, we subtracted the IOPA and IL estimated totals indicated above from the \$102.1 estimated total for all Medicare kidney acquisition expenditures indicated in Footnote 1. This resulted in an estimated \$52.3 in RTC expenditures.

For the allocation of expenditures on cadaver-only transplants, we subtracted the estimated total acquisition expenditure for living related transplants from the estimated \$52.3 million total for RTC's and \$8.6 million for IL's. On the assumption that living related transplants accounted for about 24 percent of all transplants for FY 1985 (as was the case for CY 1985), we estimated that there were 1,657 living related transplants in FY 1985. We then multiplied that total by \$14,800, the estimated

Medicare expenditure for acquisition per transplant. This resulted in an estimated \$24.5 million for living related acquisition costs.

Thus, subtracting \$24.5 million from \$102.1 million (the estimated total for all Medicare kidney acquisition expenditures) resulted in an estimated total of \$76.5 million for cadaver-only acquisition expenditures. Since IOPA's are involved only with the acquisition of cadaver organs, their total remained at \$41.2 million. For the IL's, we estimated that 10 percent of their \$8.6 million expenditures were on living related donations; thus \$7.7 million for cadaver-only. Finally, we subtracted the total for IOPA's and IL's (\$48.9 million) from the \$76.5 estimated total above to obtain our estimate of 27.6 million in Medicare reimbursed expenditures incurred directly by RTC's for the acquisition of cadaver kidneys.

4] Our number for active HOPA's (57) comes from a compilation made by the Office of Organ Transplantation in the Public Health Service in July 1985.

5] The 47 percent, it should be recognized includes all acquisition expenses--both cadaver and living-related--for these RTC's.

6] We arrived at the \$20 million total as follows: As already noted, Medicare expenditures for IL's were \$8.6. Given that the number of active RTC tissue typing laboratories is at least equal to the number of active IL's and that they perform most of the pretransplant lab work for living related transplants, we assumed that the RTC lab expenditures were at least equal to the \$8.6 total above. Then, we added \$2.7 million, which reflects Medicare expenditures for lab services that are incorporated in IOPA cost reports. Thus  $\$8.6 + \$8.6 + \$2.7 = \$19.9$  million.

7] For the IOPA's, the wasted kidneys include all those identified by Aetna as "non-viable." The percentage is based on only those kidneys reported by IOPA's as procured locally.

For the HOPA's, the wasted kidneys include all those identified by the HCFA facility survey as "not used." This includes kidneys that were either discarded or sent overseas.

Since at least 200 were sent overseas, one might then conclude that the HOPA wastage data provided in this table actually over-represent the number of kidneys actually wasted. But in fact, it may actually under-represent the number, because in our field work we found that some transplant centers consistently under-reported the number of excised kidneys that were not used.

8] "Analysis and Evaluation of the United States Organ Procurement System: Hospital and Independent Agencies Compared." Health Policy Center, Brandeis University, February 1984 (Revised June 1984), p. 50.

9] An estimated 5,247 Medicare reimbursed cadaver transplants were performed in FY 1985 (76 percent of 6,904--see footnote 1). With a wastage rate of 14 percent, 6,101 kidneys would have had to have been procured to account for the 5,247 cadaver transplants. If the wastage rate had been 5 percent, 305 would have been wasted (5 percent of 6,101) instead of 854 (14 percent of 6,101). This represents an additional 549 transplants that would have been performed (854 minus 305) or a total of 5,796 (5,247 plus 549).

Thus, \$76.5 million (the total FY 1985 Medicare expenditure for cadaver transplants) divided by 5,796 equals \$13,199--the kidney acquisition cost per cadaver transplant if there had been a 5 percent wastage rate. \$76.5 million divided by 5,247 equals \$14,580--the kidney acquisition cost per cadaver transplant with a 14 percent wastage rate.

10] See Prottas, p. 49.

11] Each transplant of a Medicare beneficiary generates an estimated five 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).

12] See Prottas, p. 50.

13] We say "at least" because, as noted, it appears that a substantial number of the kidneys that some RTC's harvest and do not use are not reported by them as being wasted.

14] See Prottas, p. 10.

15] 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).

With a wastage rate of 14 percent, organ procurement agencies would have to procure 8,121 kidneys to account for 6,984 cadaver transplants. This involves the wastage of 1,137 kidneys. If the wastage rate were 9 percent, 731 kidneys would have been wasted (9 percent of 8,121) instead of 1,137 (14 percent of 8,121). This represents an additional 406 transplants that could be performed (1,137 minus 731) for a total of 7,390.

By multiplying 406 by \$75,000 (see footnote 11), we obtain the estimated five year savings of \$30.1 million.

16] Here we refer to cadaver and living related transplants because the proposed DRG would encompass acquisition costs for each of them. We base the estimate on the period between October 1, 1987 and September 30, 1988 and assume that during this period the rate of both cadaver and living related transplants would increase at the same rate as between CY 1984 and CY 1985: 10 percent. Such a rate of increase would result in 7,594 Medicare reimbursed transplants in FY 1986 (6,904 plus an increase of 10 percent) and 8,353 in FY 1987 (7,594 plus 10 percent), and 9,188 in FY 1988 (8,353 plus 10 percent).

Multiplying \$14,800 (estimated Medicare payment per transplant in FY 1985 by 9,188 yields \$136.0 million. Multiplying \$14,000 (the estimated per transplant payment noted in the text) by 9,188 yields \$128.6 million. The difference between the two totals--\$7.4 million--is the estimated savings.



### APPENDIX III

#### HCFA, AETNA, PHS, AND ASPE COMMENTS ON THE DRAFT REPORT AND OIG RESPONSE TO THE COMMENTS

We received comments on the draft report from the Administrator, Health Care Financing Administration (HCFA), the Manager of Medicare Administration, Aetna Life Insurance Company (which serves as the single Medicare intermediary for independent organ procurement agencies), the Deputy Assistant Secretary for Health Operations, and Director, Office of Management in the Public Health Service (PHS), and the Assistant Secretary for Planning and Evaluation.

#### HCFA AND AETNA COMMENTS

The HCFA and Aetna comments focused on the recommendations and in both cases tended to be supportive. In a cover memorandum, the HCFA Administrator stated: "We find the recommendations generally to be sound and supportive of our efforts to examine the access and cost issues related to organ procurement." The Aetna representative, who dealt primarily with the recommendations calling for acquisition costs to be included in DRG 302, noted that the recommendation "has many merits." Both respondents, however, raised a number of detailed, operational concerns about how the recommendations would be carried out. Their comments, in full, were as follows.

#### HCFA COMMENTS

##### OIG Recommendation

HCFA should amend the current DRG for kidney transplantation (DRG 302) to include all costs associated with acquisition as well as transplantation. Further, it should take the same approach with respect to heart, liver, and any other type of organ transplant that might be covered under Medicare in the future.

##### HCFA Comments

We agree in principle to a prospective payment approach for kidney acquisition. However, we have some underlying concerns regarding the effect a DRG prospective payment system may have on the supply of kidneys for transplantation. There is reason to believe that kidney transplantations or, for that matter, any other form of organ transplantation would decline if capitation was instituted. Further, many persons believe that the success of the organ procurement program to date has been because of the flexibility of the reimbursement system. We are not as optimistic as the OIG that access to organs, already in short supply, would not be adversely affected by the amended DRG.

A more rigorous OIG analysis of these assertions would be helpful. Since kidney procurement costs represent a significant expenditure to the Medicare program, and other internal organ procurement costs (hearts and livers) are not as significant to the Medicare program, we believe that it is premature to agree to use the same prospective payment approach for all types of organs.

We also have several operational problems that need to be resolved before a DRG system for kidney acquisition could be implemented.

1. A potential problem exists with respect to the use of organ procurement agency (OPA) charges in recalibrating the DRG. Since Medicare is basically the only payor of OPA kidneys, recalibrating the DRG using charges may result in exorbitant charges to Medicare. Currently the Medicare intermediary sets the charge for each institution, but once the cost reimbursement system is abandoned, we would no longer predetermine these amounts. The independent OPA charge to the renal transplant centers (RTCs) becomes a cost to the RTC. Since the cost of organ acquisition would constitute from 33 percent to 50 percent of the DRG amount, an improper OPA charge could dramatically impact on our payment rate.
2. Currently Medicare does not have adequate data to establish a reasonable amount for kidney acquisition in the kidney transplant DRG. Even though the OIG has determined that \$14,800 should be added to the DRG, the report indicates (pages 3 and 4) that the organ acquisition data are inadequate. There is even less data available on organs other than kidneys.
3. We are also concerned about transportation services. Transportation costs are expensive and will influence the overall DRG rate. Some transplant centers use virtually all locally retrieved kidneys while others import kidneys extensively from other areas. It will be necessary to review more closely these costs to determine the impact they have on a DRG.

We will be investigating these issues to determine the potential effects on an amended DRG. Until these questions are resolved, we cannot agree to implement the OIG proposal.

#### OIG Recommendation

In determining the Federal payment rate for the kidney acquisition component of the transplant-acquisition DRG, HCFA should ensure that it (1) takes into account the unnecessary costs reflected in the current kidney acquisition expenditures, (2) is based on the cost per kidney transplanted rather than retrieved, and (3) includes living-related as well as cadaver acquisitions.

### HCFA Comments

Once again, we agree in principle with this recommendation. However, the problems mentioned in the draft report are the very reasons we are unable to implement a DRG at this time. Once we can obtain adequate cost data, we will begin to review the OIG proposals. We would be interested in seeing a cost-benefit analysis of paying only for kidneys that are transplanted, and not all of those which are retrieved. If retrieval is discouraged in cases in which an organ has only a small chance of being successfully transplanted, losing out on that "small chance" may result in unnecessary costs for patients whose transplantation procedures would be delayed further.

If the same DRG price is paid for living-related and cadaver acquisitions, it might be possible that new negative incentives will be introduced. Cadaver acquisitions are less expensive than living-related acquisitions, and paying the same price for both would encourage cadaver harvesting and discourage living-related acquisitions. The potentially harmful effect of this reimbursement change on the quality of transplantable organs deserves further study.

### OIG Recommendations

HCFA should begin full implementation of the transplant-acquisition DRGs as soon as practical.

### HCFA Comments

We agree with the OIG recommendations, but must qualify our response by stating that we currently have data for one year only on RTC organ acquisition services and costs. In a year's time we will re-evaluate our position to determine if the additional data available are reliable enough for use in the DRG. It may be necessary to perform an audit of RTC's costs to ensure adequate data for establishing a DRG.

### OIG Recommendations

HCFA should support some demonstrations of a capitated approach to Medicare reimbursement for kidney transplantation and acquisition.

### HCFA Comments

We currently have a demonstration project with El Camino Hospital in Santa Clara, California that is determining the feasibility of an all-inclusive capitation rate for ESRD services. This rate would include the costs of transplants and kidney acquisition, as well as any other ESRD service that would be required.

Also, we recently received a grant application for a large scale demonstration project to test ESRD capitation, which is under consideration for possible funding.

#### General Comments

- o You should also be aware that we have recently made several changes to improve fiscal oversight of kidney acquisition costs. We have developed a new cost report that allocates costs by organ and identifies offsets, such as revenues collected by an OPA from other payors, which is estimated to save \$1 million. We have advised OPA's that they must increase their efforts to collect revenues from other sources. Finally, we have tightened our requirements to collect revenues for organs that are shipped to foreign countries with estimated savings of up to \$1 million.

As the OIG report indicates, Aetna is the Medicare fiscal intermediary responsible for auditing the cost reports of all independent OPA's. The OIG report states that Aetna has developed expertise in the area of kidney acquisition costs and that its audit of independent OPA's appears to be more extensive than those audits of RTC's conducted by other intermediaries. This infers that further specialization in this area to include the OPA's based in RTC's might be advisable.

We examined this issue in 1985 and decided against designation of intermediaries for RTC-based OPA's because there is no specialized bill processing function. That is, payment for organ acquisition activities is made on the basis of settled cost reports. Also, it is difficult to identify OPA's based in RTC's. Once a hospital is certified as a transplant center, it does not need separate certification to engage in organ acquisition activities. Medicare regulations specify four functions that an entity must perform in order to be classified as an OPA. Some RTC's perform only some of these functions.

- o Some of the problems with wastage of organs that the IG has identified will be addressed once OBRA Section 9318 is implemented in October 1987. These provisions require hospitals and organ procurement agencies to become part of a nationwide organ procurement network.
- o Comparisons with European countries as to the percent of wasted organs may be inequitable because the United States tends to have more stringent standards regarding the number of hours between when an organ is acquired and when it is transplanted.

## AETNA COMMENTS

I wish to thank you for the opportunity to comment upon the report on acquisition costs. As you know, we took part in several meetings with Mr. Yessian during the course of the analysis; and we concur with the majority of the statements made in the report.

The recommendation of placing the acquisition cost in DRG 302 has many merits. Once established, it places the burden of cost containment totally at the RTC level and HCFA is relieved of the day to day cost control efforts. Ultimately, if the RTC cannot break even or produce a profit on a transplant it may decide to leave the field.

There are some considerations that we believe should be taken into account when the DRG proposal is presented.

1. The Prospective Payment System, when fully phased in, will be based upon a national rate adjusted by MSA specific wage indexes. The relative weight for DRG 302 would be consistent for all providers nationwide and, therefore, the only difference between a payment for a transplant in Omaha, Nebraska and Boston, Massachusetts will be the labor wage index.

We question whether this mechanism is equitable given the following:

- A. Kidneys are shared nationwide and the amounts paid by the RTC's vary. Locally procured organs are usually the least expensive and an RTC that relies on imported organs could be at a severe financial disadvantage. For example, all kidneys currently shared through SEOPF cost \$10,500.
- B. The retrieval rates in many areas vary widely from year to year due to poor local economic conditions (less travel), bad publicity which decreases consent, political problems between hospitals, physicians and/or the OPA.
- C. The supply of kidneys, though adequate for non sensitized patients, is limited. It is not a truly free open competitive market. The PPS was designed to function best in a competitive hospital environment where all RTC's have equal access to resources, supplies, and control over their operational policies.

Thus, although a DRG based philosophy would solve many of the concerns the long range effects must be looked at.

2. Although the hospital cost reports have been refined in the analysis of acquisition cost, we believe that it is still inadequate to construct a reasonable DRG weight. Many RTC's do not allocate coordinator's salaries and other costs to extra renal organs; and the use of inaccurate data to establish a weight would be unfair to those centers that have been properly accounting for non renal acquisitions.
3. The problem of wastage does not appear to be directly related to the method of reimbursement. A small percentage of organs are discarded due to surgical error; some have anatomical problems and many are lost due to the lack of recipients.

The lack of recipient issue has several variations. Although the supply is limited, there are adequate numbers for non sensitized patients. In fact, both patients and surgeons have rejected organs because the match was not quite to their liking and a better one would be available soon. Further, the surgeons consistently reject organs over 30 hours old for reasons of liability. Unless the patient is critical, the issues of organ age and typing match play a key roll.

Within a DRG based system, the premise that surgeons would utilize more organs because of reimbursement, and override their concerns on age, typing and liability needs to be investigated.

Whether or not a DRG based system is used the question of an excessive number of laboratories needs to be addressed as well as the frequency and type of tests routinely performed. The DRG may be effective in reducing cost but HCFA will still be the major payor of kidney transplants so that the need to reduce those costs will remain a priority. The Certification and need for the service should be reviewed prior to certifying renal tissue typing labs.

The capitation project approach could be a first step to determine how such a fixed reimbursement system would function as well as provide valuable data to HCFA.

We share your concerns on the cost of organ acquisition, especially the proliferation and duplication of lab tests. If we can provide further comments, please contact us.

## OIG RESPONSE

We recognize that there are various complexities which must be addressed if the recommendations are to be carried out effectively. The specific operational considerations raised in both HCFA and Aetna are reasonable ones. We welcome HCFA's resolve to address them and would be happy to lend whatever assistance possible.

At the same time, we must underscore that kidney acquisition costs continue to increase, that reasonable expenditures continue to be reimbursed on a 100 percent pass-through basis, and that with respect to laboratory expenditures there is little basis upon which to determine if expenditures are reasonable. Further, it is important to take into account that Section 9318 of the Omnibus Budget Reconciliation Act of 1986 requires that as of October 1, 1987 only one organ procurement agency can be eligible for Medicare reimbursement in each service area. It is not clear what kind of effect this development will have on overall costs, but it certainly does appear to be a factor warranting consideration.

We hope that the various operational problems can be dealt with expeditiously enough so that in some fashion a DRG incorporating kidney transplantation and acquisition can be introduced by October 1, 1988. If that is still not found to be practical, then as we note on page 14, we suggest that some cost limits be established under the present reasonable cost framework. At a time when the health care system in general is under considerable pressure to contain costs, we do not feel it is proper for this one segment, despite its overall importance, to remain completely shielded from such pressure.

With respect to the comments on including heart and transplant under a DRG, we agreed that the need for action is not quite as compelling. Accordingly, we have changed our first recommendation to make it clear that the first step should be to include kidney acquisition under a DRG and that heart and liver acquisition be included in a DRG "as soon thereafter as practical."

## PHS COMMENTS

The PHS comments were quite critical of the report with respect to its methodology as well as its findings and recommendations. The comments were divided into those of a general and a technical nature. Some of the latter concerned the need for clarifications, which in two instances we made. Most concerned limitations in the data reported and in the support that exists for our findings and recommendations.

The general comments offered by PHS were as follows.

Our review of the report indicates that the information gathered in the survey is largely anecdotal and is an expression of opinions rather than the result of an analysis of the data collected. The quotes in the report lack credibility since neither the speakers' identity nor a description of his/her relevant level of expertise is disclosed. There is no indication as to how this information was analyzed and used to develop the report's findings and conclusions. The lack of data suggests the need for better data collection and analysis on organ transplantation rather than the propriety of policy formulation at the present time. The report, in effect, recommends the collection of data after implementation of the new payment system, rather than acknowledge a need to first determine the facts needed to formulate such a policy.

The report addresses several medical practice issues, e.g., determining appropriate frequency of testing and defining the number of "usable" kidneys harvested. Since these issues have not been resolved, it is premature to make recommendations on these issues. The determination of proper medical practice is not an area appropriately addressed by administrative bodies of government. These issues might best be resolved by scientific consensus development to ensure optimal transplant outcomes rather than focus on cost effectiveness. From a medical perspective, it is known that careful patient and organ preparation ensure the best transplantation outcome. Considering the cost of a repeat transplantation and costs of alternative therapies (such as dialysis), a successful organ transplant should ultimately prove to be the most cost effective way to treat people afflicted by organ failure, and ensure that its success has a very high priority.

The report states that the findings and recommendations that resulted from the OIG investigation into the cost-effectiveness of kidney transplantation are also relevant to the transplantation of other organs, such as heart and liver. It is also acknowledged that most of the experience and data are in the kidney area and are, therefore, less well developed in other transplant areas. Because each organ has its own transplantation-specific considerations, the report might be more complete with the inclusion of a separate and more detailed discussion of these organ-specific issues. Some of the features that distinguish liver transplantation from kidney transplantation, for example, include fewer available donated livers, a greater patient need (liver patients needing transplants die without a new organ, while kidney patients can survive on dialysis), and a lower level state-of-the-art in transplantation methods. This last factor was mentioned in the report as a valid reason for having a "reasonable cost" pay system for kidney transplantation while optimal methods are still being determined. Other organs that are emerging as new frontiers in transplantation, such as the pancreas, are at an even earlier state of definitive method development.



The report could be strengthened by inclusion of further information about the unintended consequences of procuring and preparing organs for transplantation at a fixed fee. For example, if organs were acquired at a fixed fee, how would this affect the incentive to obtain organs? Would there be a lowered incentive to get organs for older patients or for those with a less than optimal prognosis? Might hospitals act in ways that would be money-saving only at the expense of the welfare of those receiving organ transplant? For example, how would the fixed fee affect a hospital's motivation to fully prepare organs for transplantation, do appropriate tissue typing, and prepare the patient immunologically--that may not be cost-effective at a fixed fee?

Considering kidneys harvested from cadavers and those donated from living relatives together in determining a fixed fee for kidney transplantation could change the balance between the use of live and cadaveric donors since live kidneys are less expensive than those harvested from cadavers. Such changes could have serious repercussions in the ways kidneys are obtained and in the motivation to donate organs.

The report should also include a more complete definition of organ acquisition costs in the executive summary since the broad range of costs covered by the term as it is used in the report may not be readily apparent to those reading only the executive summary.

#### OIG RESPONSE

In reference to the minimal data on transplant areas other than kidneys, we have, as noted earlier, amended our DRG recommendation to call for heart and liver acquisition costs to be included under a DRG as soon as practical after kidney acquisition costs are so included.

With respect to the criticisms of the methodology, we acknowledge, as we did earlier in this report, that there is limited data available on organ acquisition costs. Our study was based on a careful review and synthesis of the available data sources and on extensive, well-documented discussions with individuals directly involved with organ acquisition. We recognize the limitations of this approach. At the same time, we feel that it generated insights that make it quite clear that kidney acquisition is not being handled in an efficient or economical manner and that some policy initiative directed to this reality is warranted.

## ASPE COMMENTS

The ASPE comments reflect support for the position that kidney acquisition costs need to be closely examined, but indicate that the case for including organ acquisition costs under a DRG is not sufficiently developed. The ASPE comments are as follows:

I agree with the IG that kidney acquisition costs, because of wide variations in costs among organ procurement agencies, need to be closely examined. However, I do not agree, based on this report, that HCFA should move quickly to include organ acquisition costs in the DRG for kidney transplantation. I do believe that the Department should make efforts to collect the data which would permit appropriate analyses to make a decision on this matter.

The IG makes strong recommendations based on the findings described in "Organ Acquisition Costs: An Overview." Unfortunately, they are based on "fragmented, incomplete, and sometimes incorrect databases," and widely varying costs which the IG has made no apparent effort to reconcile.

For example, Chart II indicates that kidney acquisition costs have risen dramatically, but the data are, apparently, uncorrected for numbers of kidneys acquired, inflation, or air transportation deregulation (most kidneys are transported by commercial air without the flexibility to take advantage of "super savers").

Furthermore, two of the areas identified by the IG as of particular concern, laboratory costs and costs due to wastage, are somewhat contradictory. The contradiction lies in the tissue typing costs incurred to make a match. A match can reduce wastage (which would otherwise occur from a failure to match) or reduce lifetime (of the patient) transplantation costs by assuring greater compatibility. Some studies show that greater compatibility produces longer organ survival times and less frequent retransplants. While clearly duplicative testing should be avoided, the "secrets" to which the IG alludes are probably differences in technique and equipment which the laboratory directors view as providing better services.

Therefore, I believe that the recommendation should be to gather the data that will permit us to make decisions about more efficient reimbursement methodologies, including the potential for a DRG inclusive of acquisition costs.

## OIG RESPONSE

We agree on the need to collect more information to determine how best to include organ acquisition costs under a DRG. In this report, we attempted to start that process. We feel that we did make an effort to reconcile the "fragmented, incomplete, and

sometimes incorrect data bases." In fact, we believe, it is the only such effort that has been made thus far. Yet, we recognize that more should be done.

Chart II was developed to promote an overall sense of the extent of kidney acquisition expenditures and how they are allocated among renal transplant centers, independent organ procurement agencies, and independent laboratories. This information was not previously available. It took extensive review and synthesis of different data bases to provide it. To connect the numbers for kidneys acquired, inflation, or air transportation deregulation may be desirable, but would take extensive further work and may not even be possible.

Finally, in reference to the comment on how laboratory costs and wastage costs" are somewhat contradictory," we must note that we do not argue against the need for tissue typing. We understand that it is important and that it may contribute to longer organ survival times. Our comments about the duplications and inefficiencies concerning laboratory tests are consistent with that understanding. It is pertinent, we think, to note that in its comments Aetna, which is responsible for reviewing the costs of independent laboratories, reinforces our concern about laboratory costs.