

Department of Health and Human Services  
**OFFICE OF  
INSPECTOR GENERAL**

**THE DISTRIBUTION OF ORGANS  
FOR TRANSPLANTATION:  
EXPECTATIONS AND PRACTICES**



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# EXECUTIVE SUMMARY

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## PURPOSE

The purposes of this study are to: (1) clarify expectations governing organ distribution practices in the United States, (2) determine the extent to which actual practices are in accord with expectations, and (3) offer recommendations that facilitate close accord between expectations and practices.

## BACKGROUND

In April 1990, 20,171 people in the United States were awaiting an organ transplant. This number has risen sharply in recent years as the demand for transplants has grown much faster than the supply of available organs.

In this report, we focus on the distribution of cadaver organs from the point of procurement to the point of transplantation. Although the report addresses all organs, we pay particular attention to the distribution of kidneys because they account for about 75 percent of organ transplants and about 84 percent of those awaiting a transplant.

The report is based primarily on an analysis of a data base consisting of the 17,556 individuals in the United States who were waiting for or received a first kidney transplant between October 1, 1987 and March 31, 1989. In addition, it draws on an on-site review of the operations of organ procurement organizations in California, Florida, Wisconsin, and Pennsylvania; on interviews with many individuals involved with the field of organ transplantation; and on a review of pertinent literature and documents.

## EXPECTATIONS

*Congress and professional leaders envision the development of organ distribution practices that are equitable to those in need, carried out in accord with a national system, and based on the cooperation of transplant professionals. More specifically, they expect:*

1. each person on a transplant waiting list to have an equal opportunity to receive a transplant, subject to established medical criteria;
2. organ distribution to occur in accord with a national system adhering to uniform policies and standards; and
3. transplant surgeons and other transplant professionals to work together cooperatively in the best interest of all patients waiting for transplants.

## **FINDINGS**

*While there has been progress, current organ distribution practices fall short of congressional and professional expectations in each of the three areas.*

### **1. Equity**

The access of patients to donated organs remains unequal in some important respects.

- ▶ Blacks on kidney waiting lists wait almost twice as long as whites for a first transplant, 13.9 months compared with 7.6. Such a differential remains even when blood type, age, immunological, and locational factors are taken into account.
- ▶ Patients at some transplant centers wait much longer than those at others. At 15 of the 202 transplant centers reviewed, the waiting time for a first kidney transplant was 18 months or over; at 79 it was less than 6 months.
- ▶ Highly sensitized patients—those whose immune system makes it difficult for them to receive organs—wait almost 4 times as long for a kidney transplant as all other patients, 32.4 months vs. 8.6.

### **2. National System**

There has been considerable progress in establishing a national system grounded in uniform policies and standards for the distribution of organs. However, organ distribution remains heavily controlled by the individual transplant centers and confined primarily within the individual service areas of 72 Organ Procurement Organizations (OPOs).

### **3. Cooperation**

The development of the Organ Procurement and Transplantation Network (OPTN) is a significant cooperative achievement of transplant professionals and others. Yet at the transplant center and OPO levels, the sense of local ownership that some transplant professionals have towards organs they have procured impedes the development of an equitable and national system for the distribution of organs.

## RECOMMENDATIONS

### *The Public Health Service (PHS)*

The PHS, in collaboration with the OPTN, should issue regulations to require that each OPO (1) establish a single, unified list of patients awaiting transplantation and (2) distribute donated organs to those patients on a first come first served basis, subject to established medical criteria.

The PHS, in collaboration with the OPTN, should issue regulations to require that each transplant center and donor hospital in an OPO service area adhere to the centralized organ distribution policies of the OPO governing that area.

The PHS, in collaboration with the OPTN, should support the development of medical practice guidelines addressing organ transplantation.

The PHS should fund a demonstration effort incorporating the following two features: (1) the establishment of a single, unified waiting list including all patients awaiting an organ transplant in a number of OPO service areas and (2) the mandatory distribution of donated organs to those patients on a first come first served basis, subject to established medical criteria.

### *The Health Care Financing Administration (HCFA) and the Public Health Service*

The HCFA and the PHS should support research efforts that could help reduce racial disparities in organ allocation.

Before granting Medicare recertification to an OPO, HCFA, in collaboration with PHS, should assure that the OPO is distributing organs equitably among patients, according to established medical criteria.

Before granting Medicare recertification to an OPO, HCFA, in collaboration with PHS, should assure that the OPO is conducting a rigorous, soundly based organ procurement effort.

### *The American Society of Transplant Surgeons (ASTS) and the American Society of Transplant Physicians (ASTP)*

The ASTS and the ASTP should conduct their own inquiries of the factors leading to longer median waiting times for blacks than whites awaiting a kidney transplant and of any actions their associations should take to help reduce this disparity.

## COMMENTS

Within the Department of Health and Human Services, we received comments from PHS, HCFA and ASPE. The PHS and HCFA agreed with the recommendations directed to them. The ASPE raised a number of concerns about the recommendations.

Outside the Department, we received comments from the ASTS and ASTP and numerous other organizations, including the United Network for Organ Sharing, the American Society for Histocompatibility and Immunogenetics, the Association of Organ Procurement Organizations, the North American Transplant Coordinators Organization, the New England Organ Bank, and the South-Eastern Organ Procurement Foundation.

In response to our recommendation directed to ASTS and ASTP, the ASTP indicated that it recently completed a study addressing the differential access of blacks and whites to organ transplantation. The ASTS noted its readiness to (a) define medical indices of patient suitability for being placed on transplant waiting lists, (b) develop an allocation scheme that addresses all (racial included) factors that affect organ transplantation, and (c) delineate standards to assess OPO activity and performance.

In appendix D, we present the detailed comments of each of the organizations and our responses to them.

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# INTRODUCTION

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In this report, we focus on the distribution of organs to the more than 20,000 people who have been determined to be medically suitable candidates for an organ transplant and are now awaiting a donated organ.<sup>1</sup> We examine the distribution process, from the point that an organ is procured to the point that it is transplanted.<sup>2</sup> We pay particular attention to the expectations and practices governing the actual selection of the individuals who will receive an organ transplant.<sup>3</sup>

Throughout the report, we emphasize the distribution of kidneys. We do that because kidney transplants account for about 75 percent of all organ transplants and because about 84 percent of the individuals on transplant waiting lists are awaiting a kidney transplant.<sup>4</sup>

At the same time, we believe that most of the basic issues addressed in the report are of equal significance to the distribution for transplantation of hearts, livers, and other organs. In large measure kidney procurement and distribution practices have provided and will continue to provide the framework for practices governing these other organs.<sup>5</sup>

The basic purposes of our study are threefold: (1) to clarify expectations governing organ distribution practices in the United States, (2) to determine the extent to which actual practices are in accord with expectations, and (3) to offer recommendations that facilitate close accord between expectations and practices.

Our methodology is based on four major lines of inquiry:

- A statistical analysis of a data base consisting of the 17,556 individuals in the United States who were waiting for or received their first kidney transplant between October 1, 1987 and March 31, 1989.<sup>6</sup> The analysis focuses on demographic and other factors associated with the length of time waiting for kidney transplantation (see appendix A for a detailed description of data used in the analysis);
- case studies of four large organ procurement organizations and affiliated transplant centers in California, Florida, Wisconsin, and Pennsylvania;<sup>7</sup>
- interviews with representatives of national organizations involved with the field of organ transplantation, government policymakers, public and private researchers, and transplant professionals;<sup>8</sup> and
- a review of pertinent literature and documents concerning organ procurement, distribution, and transplantation.<sup>9</sup>

## BACKGROUND

In 1984, after congressional hearings which addressed the inadequate supply of organs being made available for transplantation and the often unfair systems for distributing those that did become available,<sup>10</sup> Congress passed the National Organ Transplant Act. Among other things, the legislation prohibited the buying or selling of organs and called for the Department of Health and Human Services (HHS) to provide by contract for the establishment and operation of an Organ Procurement and Transplantation Network (OPTN) and to establish a Task Force on Organ Transplantation (hereafter referred to as the Task Force).<sup>11</sup>

Congress mandated that the Task Force be composed of 25 members and stipulated the categories of members to be appointed by the HHS Secretary. In addition to 4 ex-officio members representing various parts of HHS, it specified that there were to be 12 from the organ transplantation field (9 of whom must be physicians or scientists); 4 who as a group had backgrounds in law, ethics, health care financing, and the social and behavioral sciences; 3 from the general public; and 2 from the health insurance field. Congress instructed the members to develop recommendations on how to achieve more effective, efficient, and equitable systems for organ procurement, distribution, and transplantation.

In April 1986, the Task Force issued its report to Congress. The recommendations set forth in the report provided the stimulus for subsequent legislation in 1986 and for the initiation of the OPTN called for in the 1984 legislation.<sup>12</sup>

In September 1986, the Public Health Service (PHS) contracted with the United Network for Organ Sharing (UNOS)<sup>13</sup> to develop the OPTN. One year later, PHS and UNOS agreed to a 3-year contract for UNOS to operate the OPTN. The contract calls for the OPTN to:

- improve the effectiveness of cadaver organ procurement and distribution;
- improve and increase the access to an optimal organ transplant;
- improve the system for sharing renal and extrarenal organs so as to: (1) facilitate matching; (2) improve the access to transplantation of patients whose immune system makes it difficult for them to receive an organ; (3) improve the outcomes of organ transplantation; and (4) decrease the wastage of organs;
- assure quality control by the collection, analysis, and publication of data on organ donation, procurement, and transplantation;<sup>14</sup>
- maintain and improve professional skills of those involved in organ procurement and transplantation; and
- maintain an OPTN governance entity or board elected by a majority vote of all OPTN members.

The OPTN board, much like the prior Task Force's membership, is a diverse one, but one in which transplant professionals are heavily represented. Among the 34 members of the board, 17 are physicians, and 15 of the physicians are transplant surgeons.

In 1986, Congress passed legislation that had far reaching impact on organ procurement and distribution practices throughout the country. On the basis of this legislation:

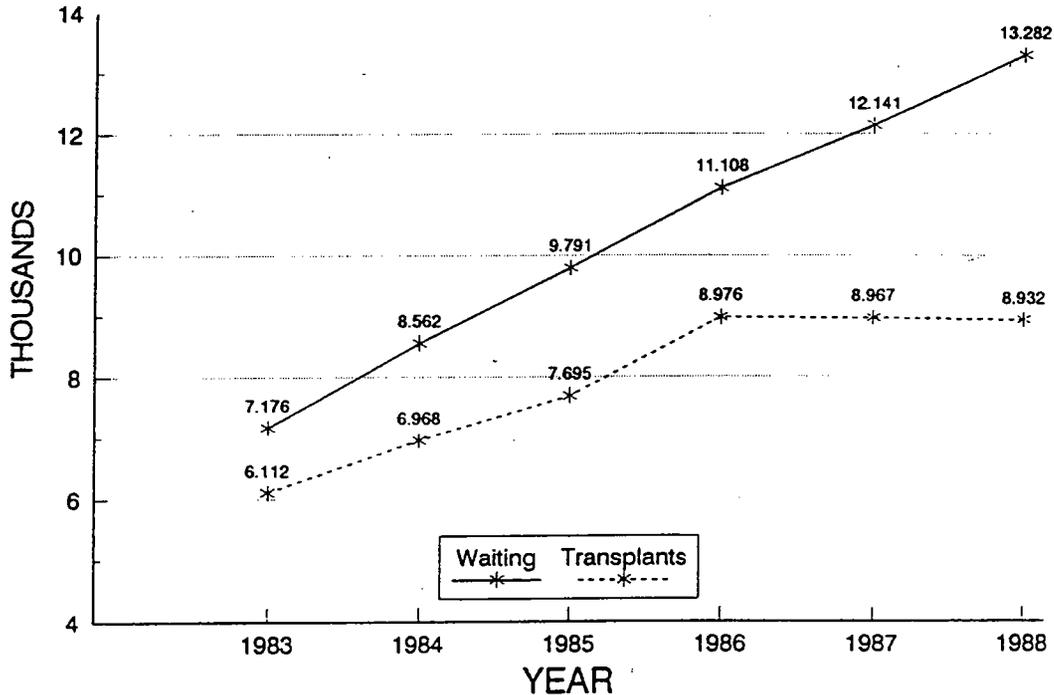
- HHS had to delineate organ procurement service areas throughout the country and designate a single organ procurement organization responsible for each area (previously, in many areas of the country OPOs were competing with one another for the procurement of organs);
- OPOs had to be members of and abide by the rules and requirements of the OPTN;
- OPOs had to adhere to performance standards established by HHS;
- hospitals with transplant centers, as a Medicare condition of participation, had to be members of the OPTN and abide by the rules and regulations of the OPTN; and
- all hospitals, as a Medicare condition of participation, had to develop written protocols for identifying potential organ donors and for notifying an OPO of such donors.<sup>15</sup>

In the midst of this legislative activity, there were continued advances in transplantation technology and immunosuppression therapies, resulting in improved patient outcomes. As transplantation became an increasingly accepted treatment for organ failure, third party coverage for the costs of the procedure became increasingly common. At the Federal level, the Medicare program had long covered the costs of kidney transplantation as part of the near universal coverage accorded to individuals with end stage renal disease (ESRD).<sup>16</sup> However, in 1987 it made heart transplantation a covered service for Medicare beneficiaries<sup>17</sup> and in March 1990 issued a draft regulation proposing coverage of liver transplants in adults under certain circumstances.<sup>18</sup>

Paralleling the above developments has been a steady increase in the number of transplantation programs. By April 1990, there were 250 medical institutions in the United States operating organ transplantation programs.<sup>19</sup> There were 72 HHS designated OPOs that in various ways and to varying degrees were involved in the procurement and distribution of organs to be transplanted in these institutions.<sup>20</sup>

From the perspective of patients awaiting an organ transplant, these developments are of profound importance. They present the opportunity for a medical intervention that can significantly improve their physical well-being or, indeed, save their life. Yet, because the demand for transplants has risen much faster than the available supply of organs, the opportunity is one that will be long delayed or never achieved by many of these patients. While there has always been a gap between the supply and demand, it widened appreciatively between 1986 and 1988 (figure 1), and on the basis of preliminary data, it appears that trend continued in 1989.<sup>21</sup>

**FIGURE 1**  
**Growth In Kidney Transplants And In The Number Waiting For Transplants**  
**1983 - 1988**



Source: ESRD Facility Survey, HCFA, BDMS

In the pages that follow, we address the expectations and practices governing how donated cadaver organs<sup>22</sup> are made available to the more than 20,000 people now awaiting them. We start by identifying the fundamental expectations which Congress and professional leaders<sup>23</sup> have set forth. Then, in our findings section, we indicate the extent to which these expectations are reflected in practice. In so doing, we find some disturbing discrepancies. We close by offering a number of recommendations on how these discrepancies might be eliminated or at least narrowed.

## EXPECTATIONS

*Congress and professional leaders envision the development of organ distribution practices that are (1) equitable to those in need, (2) carried out in accord with a national system, and (3) based on the cooperation of transplant professionals.*

From statutes and supporting documents, HHS and OPTN policies, the final report and other documents of the Task Force on Organ Transplantation, and our own extensive interviews, we found extensive and clearly stated support for the three above-noted expectations. We found that

the realization of each of these expectations was widely regarded as essential to the underlying legitimacy and continued advancement of organ transplantation.<sup>24</sup> Each is briefly explained below.

- ***Congress and professional leaders expect each person on a transplant waiting list to have an equal opportunity to receive a transplant subject to established medical criteria.***

There is a clear trail of authoritative congressional and professional expressions that provide the underpinning of the above expectation. The trail begins with the National Organ Transplant Act of 1984. In that legislation, Congress specified that an OPO must “have a system to allocate donated organs among transplant centers and patients according to established medical criteria.”<sup>25</sup> In an accompanying report, the Senate Labor and Human Resources Committee added the following: “An equitable policy and system is necessary so that individuals throughout our country can have access to organ transplantation when appropriate and necessary.”<sup>26</sup>

Two years later, the Task Force reinforced Congress’ expectation governing the equitable allocation of organs and defined it more specifically. In its final report, it stated the following:

*“The Task Force recommends that selection of patients both for waiting lists and for allocation of organs be based on medical criteria that are publicly stated and fairly applied. The Task Force also recommends that the criteria be developed by a broadly representative group that will take into account both need and probability for success. Selection of patients otherwise medically qualified should be based on length of time on the waiting list.”<sup>27</sup>*

Then, in 1988, Congress once again addressed the matter of organ distribution. It amended the 1984 legislation to clarify that in allocating organs according to established medical criteria an OPO must act “equitably” and must focus strictly on the allocation among patients, not transplant centers.<sup>28</sup> In a report accompanying the amendment, the House Committee on Energy and Commerce noted that concerns had been raised about OPOs being “in a position to show favoritism to patients of a particular transplant facility.” While the committee indicated it had no knowledge of any particular instance of such favoritism, it added that it expected “the Secretary to monitor the allocation of organs closely.”<sup>29</sup>

Thus, the clear intent of Congress is that organs be distributed fairly without regard to such factors as a transplant candidate’s income, sex, race, or residence and without regard to the transplant center at which that candidate expects to receive a transplant. In one way or another, nearly all the individuals we interviewed in the course of this study supported this congressional intent.

In expressing its expectations on how an organ distribution system should function, Congress, in the 1984 legislation, singled out one group that it felt needed special attention if it were to receive a fair opportunity for a transplant. Specifically, in calling for the OPTN to develop “a national list of individuals who need organs” and a “national system... to match organs and individuals on the list,” it indicated that particular attention should be given to “individuals

whose immune system makes it difficult for them to receive organs.”<sup>30</sup> In so doing, it recognized that for these highly sensitized<sup>31</sup> individuals, the opportunity to receive a medically suitable organ increases as the size of the available pool of donors increases.

Yet, Congress did not accord the highly sensitized with an actual preference, nor do professionals in the transplantation field agree on how much, if any, preference they should receive in distributing organs.

- ***Congress and professional leaders expect organ distribution to occur in accord with a national system adhering to uniform policies and standards.***

The 1984 legislation was a response to the informal and fragmented practices then characterizing the distribution of organs in many parts of the country.<sup>32</sup> It recognized that it was in the public interest to develop more formalized and systematic mechanisms guiding organ procurement, distribution, and transplantation throughout the country. In this regard, the legislation enjoyed widespread support among the organ transplant community.

Thus, as already noted, the legislation called for the OPTN to establish one nationwide list of individuals awaiting transplantation and “a national system” that would allow for donated organs to be quickly matched with medically suitable candidates on that list. Congress called for the OPTN to develop this capability through the use of computers and in accord with established medical criteria.

In calling for a national system, Congress essentially sought two outcomes: (1) the development of some common rules to which all OPTN members were bound and (2) the development of the technical capability to distribute organs nationally, expeditiously, and in accord with explicitly stated criteria. Yet it did not mandate any such national distribution, and it specifically stated that a national list and a national system could be established in regional centers instead of in one central location.

The Task Force reinforced the importance of developing a national system and urged the adoption of “uniform policies and standards by which all will abide.”<sup>33</sup> Such policies and standards, it indicated, should address matters such as the acceptability of an organ for transplantation, the acceptable length of organ preservation time, and the desirable degree of tissue matching between donor and recipient. The Task Force noted that while diverse practices and protocols were to be expected during the pioneering years of transplantation, “at this point in the evolution of organ transplantation, sufficient data have been developed to allow for the establishment of certain standards of practice.”<sup>34</sup>

- ***Congress and professional leaders expect transplant surgeons and other professionals to work together cooperatively in the best interests of all patients waiting for transplants.***

Such an expectation is one that would apply to any complex human endeavor. Yet, it is an important one to include here because it is so integral a part of the framework of expectations characterizing not only organ distribution, but also organ procurement and transplantation.

From the earliest efforts to enlist the support of potential donors and donor hospitals to the post transplant efforts to improve patient outcomes, successful performance requires the cooperative efforts, often under very strict time pressures, of a wide range of professionals. These include but are by no means limited to transplant coordinators, nurses, social workers, neurologists, nephrologists, transplant surgeons, immunologists, and OPO administrators. While each of these participants have their own particular interests, they must work together effectively as trustees of organs for all the persons awaiting a transplant.

It was in recognition of the complex nature of this collaborative effort that Congress called for the unusual approach of a private body, the OPTN, having a strong role in shaping the national system. Congress and professional leaders saw the OPTN and, to a lesser degree, the OPOs themselves as forums for developing policies and protocols buttressed by broadly based consensus.

# FINDINGS

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*While there has been progress, current organ distribution practices fall short of congressional and professional expectations in each of the three areas.*

Almost every individual with whom we conversed, whether in highly structured telephone interviews or in the halls outside of operating rooms, regarded the establishment of the OPTN as a substantial accomplishment. In various ways, they indicated that it provided a foundation for the development of an equitable national system rooted in cooperative professional relationships. Yet, upon questioning, these same individuals were quick to point out that such a system has not yet been achieved. Our review of the OPTN data reinforced this conclusion.

The three more specific findings that follow indicate how current practices fall short of each of the three sets of expectations addressed earlier.

## EQUITY

► *The access of patients to donated organs remains unequal in some important respects.*

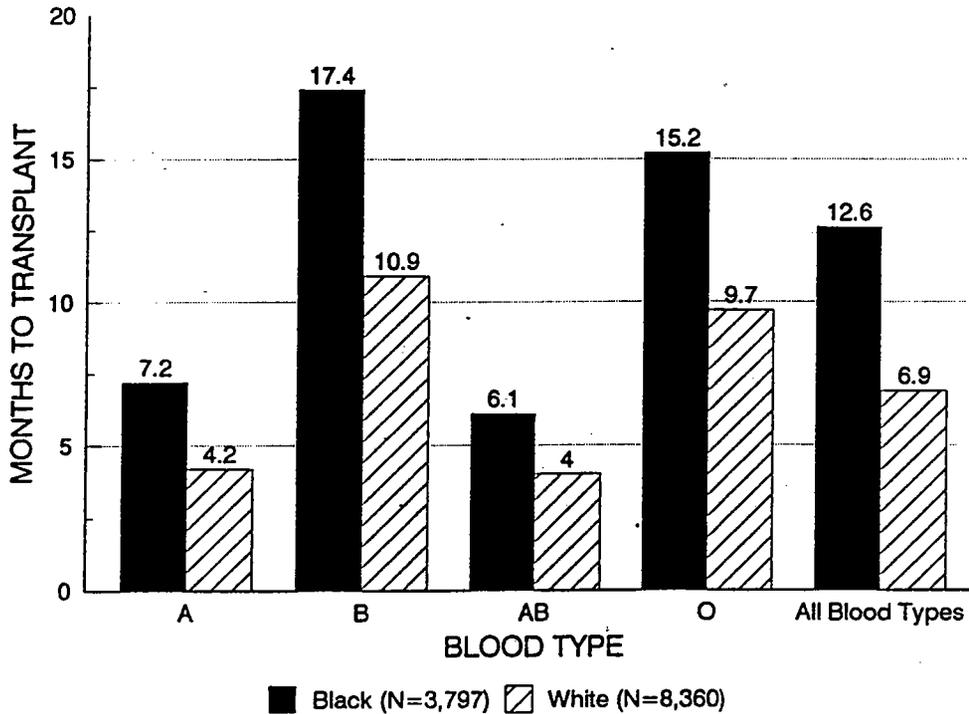
Our primary patient data base, as indicated earlier, concerns the 17,556 individuals in the United States who between October 1, 1987 and March 31, 1989 were waiting for or actually received a first kidney transplant. In analyzing the data, we found that in three respects there were significant disparities in the access that these individuals had to kidney transplants. The disparities related to an individual's race, transplant center, and level of sensitization.

**Race:** First, with respect to race, we found that blacks were waiting almost twice as long as whites for their first kidney transplant. In particular, we found that the median waiting time for blacks was 13.9 months, compared with 7.6 months for whites (see appendix B, table B-3).

In seeking to explain this substantial difference, we were informed by professionals in the transplantation field that medical considerations involving blood type, level of sensitization, and/or age might account for some or all of the gap. However, we found that these considerations accounted for little of the difference. For each blood type, blacks who are not highly sensitized<sup>35</sup> and are between 18 and 64 years of age waited significantly longer than whites for their first kidney transplant. For all blood types combined, the median waiting time for non-highly sensitized blacks 18 to 64 years old was still nearly twice that of comparable whites, 12.6 months compared with 6.9 (figure 2). Not surprisingly, therefore, blacks have been receiving only about 23 percent of all cadaver kidney transplants,<sup>36</sup> while they represent about 30 percent of those on kidney transplant waiting lists.<sup>37</sup>

FIGURE 2

**Estimated Median Waiting Times To First Kidney Transplant  
By Race And Blood Type  
October 1, 1987 - March 31, 1989**



*Note: Ages 18-64, Not Highly Sensitized (i.e., PRA <=75)*

*Data Source: OPTN Contractor*

*Data Analysis: OIG/OEI*

Thus, on the basis of the above-noted analysis and of a proportional hazards analysis<sup>38</sup> wherein we examined the independent effect of race, holding age and blood type constant, we are unable to explain the longer waiting time of blacks on the basis of blood type, level of sensitization, and/or age.

In seeking other possible explanations, we considered that there might be some kind of locational effect. We sought to determine if the longer median waiting time of blacks existed throughout the country or if it were concentrated at certain centers and/or certain parts of the country.

In this regard, we conducted two additional analyses. Both involved a calculation of the mean ratio of black recipients' median waiting time to that of white recipients for each transplant registration center. With this approach, a ratio greater than 1 indicates that blacks waited longer,

on the average, than whites. (See appendix A for further elaboration on the calculation and the analyses summarized below.)

In the first analysis, we calculated the average ratio for registration centers in each of 10 regions of the country. We found that in two regions (New England and the Plains States), the ratios were considerably lower than in the others and that the median waiting time for blacks and whites was about the same. In the other regions, blacks waited longer, with the ratios ranging from 1.25 to 2.74.

In the second analysis, instead of parts of the country, we focused on the percent of blacks on waiting lists. More specifically, we performed a regression analysis of the percent of blacks on a registration center's<sup>39</sup> waiting list against the ratio. We found that the ratio of blacks' median waiting time for a first transplant to that of whites was not affected by the percent of blacks on the waiting list of a center.

Once again, therefore, we are unable to explain the substantially longer median waiting time for blacks. Our analyses indicate that although there are some locational variances, the longer median waiting time for blacks is widespread, not confined to a few parts of the country or to a few transplant centers or organ procurement organizations.

There are numerous other factors that we were not able to analyze that might help account for the disparity. What would appear to be the most consequential of these is that typically organ allocation systems are at least partially based on human leukocyte antigen (HLA) matching.<sup>40</sup> In response to our draft report (see appendix D), the American Society for Transplant Surgeons explained as follows how this practice might disadvantage blacks: "Since most donors are white, whites are more likely to have better HLA matches than blacks with a given donor; thus, among potential recipients the proportion of whites first offered a kidney could be greater than the proportion of whites waiting, because of the increased probability of a good match."

Another possibly important factor is the economic status of the candidates. Although nearly all kidney transplant candidates are Medicare covered individuals, those who are not can be subject to financial costs which in some way inhibit their access to a transplanted kidney. Further, even for Medicare covered individuals the Medicare program does not cover the cost of immunosuppressive drugs for more than one year after the transplant and does impose certain coinsurance and deductible requirements. The associated costs can be substantial and conceivably can hinder access.

Still other considerations that might help explain the difference are (1) the patient's medical condition and/or willingness to accept a donor organ when it is offered, (2) the extent of the social support available to the patient, (3) the fact that some patients are on multiple waiting lists, and (4) the factors used to determine who is actually placed on a kidney waiting list in the first place.

In a recent report on black-white disparities in health care, the American Medical Association's Council on Ethical and Judicial Affairs identified different rates of kidney transplantation as an indication of broader disparities in medical treatment offered to blacks and whites. It further

noted that it was “unlikely” that medical factors alone accounted for the fact that whites were more likely to receive a kidney transplant.<sup>41</sup>

After reviewing disparities in various medical treatment decisions, the Council concluded that in part they “may reflect the existence of subconscious bias.”<sup>42</sup> It elaborated as follows:

*“This is a serious and troubling problem. Despite the progress of the past 25 years racial prejudice has not been entirely eliminated in this country. The health care system, like all other elements of society, has not fully eradicated this prejudice.”<sup>43</sup>*

In our study, we found no information to indicate that racial prejudice contributed to the differential in black-white waiting time. Yet, considering the statement of the AMA Council, we must recognize that it is possible that to some degree the differential may reflect such prejudice and “subconscious bias.”

Finally, the longer median waiting times of blacks are especially significant since blacks have much higher rates of kidney failure than whites. Although blacks account for only about 12 percent of the U.S. population,<sup>44</sup> they account for 34 percent of dialysis patients in the End Stage Renal Disease Program.<sup>45</sup>

At the same time, it must be noted that blacks are less inclined to donate organs than are other groups. In 1988, only about 8 percent of all cadaver kidney transplants involved the use of a kidney from a black donor.<sup>46</sup> The possible explanations for this situation are many and complex,<sup>47</sup> but certainly among them must be the relatively small number of black procurement coordinators working for the organ procurement organizations.<sup>48</sup> In this regard, the president of the American Society of Transplant Physicians, in commenting on our draft report (appendix D), made an observation that warrants serious consideration by all those associated with the field of organ transplantation. It is as follows:

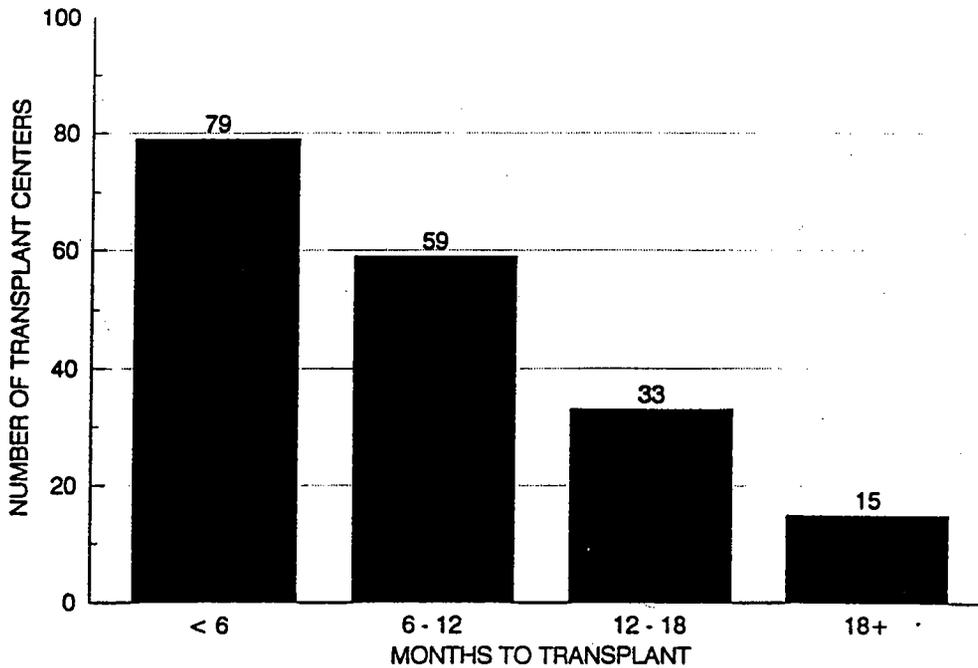
*“Some years ago we hired a black social worker in our ESRD program. Related donor transplantation, which had previously been negligible in blacks in our program, rose substantially soon after he took on the position. I strongly believe that cadaver organ donation in blacks would increase significantly if black families were approached by black organ procurement coordinators. Therefore, I would like to suggest that the OPO be strongly encouraged to train and hire black transplant coordinators. This effort could be coordinated through NATCO and AOPO.”*

**Transplant Center:** A second major respect in which we found patient access to organs to be unequal concerns the transplant center at which the patient was registered. For the October 1987 through March 1989 period, the median patient waiting time for a first kidney transplant ranged from a low of less than 1 month at one center to a high of 71 months at another. Among the 202 centers reviewed, the median waiting time at 79 was less than 6 months for non-highly sensitized patients; at 15 it was over 18 months (figure 3). Such wide variations existed even among centers in the same OPO service area.

From our proportional hazards analysis, we also found that the size of a center's waiting list had some effect on how long a patient had to wait for a transplant. Thus, for instance, a patient awaiting a first transplant in a center with 25 registrants had a 7 percent better chance of receiving one at any point in time than a patient in a center with 100 registrants (see appendix B, table B-5).

Such differences in waiting time have developed because few transplant centers have joined together to develop a common list of transplant candidates and then to distribute donated organs to those candidates on a first come first served basis, subject to medical criteria. Some have joined together to establish a common list, but the criteria they have developed governing the distribution of donated organs are apt to devote as much or more attention to the distribution of organs among centers as among patients. For instance, many transplant centers across the nation participate in an OPO approved arrangement where for each pair of cadaver kidneys they retrieve, they keep one for one of their own patients and give one to the common pool. The kidney donated to the pool is then made available to another transplant center in the service area, usually in accord with some rotational arrangement.

**FIGURE 3**  
**Estimated Median Waiting Times To First Kidney Transplant**  
**By Transplant Center**



*Data Source: OPTN Contractor*  
*(October 1, 1987-March 31, 1989)*  
*Data Analysis: OIG/OEI*

***Level of Sensitization:*** Finally, as professionals in the transplant field would expect, we found that the highly sensitized patients had considerably less access to donated organs than did others on transplant waiting lists. Even some of the professionals, however, might be surprised at the extent of the difference. During the 18-month period we examined, the median time that the highly sensitized waited for donated kidneys was almost 4 times that of all others, 32.4 months compared with 8.6.

From the available data, we cannot determine whether or not this difference has widened or narrowed in recent years. However, the data do indicate that proportionately more women are highly sensitized than men and for that reason tend to have longer waiting times than men.<sup>49</sup>

## NATIONAL SYSTEM

***There has been considerable progress in developing a national organ distribution system grounded in uniform policies and standards. However, organ distribution remains heavily controlled by the individual transplant centers and confined primarily within the individual service areas of the 72 Organ Procurement Organizations.***

Only a few years ago, some transplant centers that could not use an organ they retrieved would, on the basis of private conversations and informal arrangements, send that organ to another center. That center might be in the same State, in another State, or, for that matter, in another country. That is no longer allowed. The OPTN requires that centers and OPOs have formally stated criteria governing the distribution of organs and that OPOs use the national organ center for distributing any organs that they cannot use within their individual service areas. The organ center then distributes such donated organs, in accord with established criteria, to individuals on a national waiting list it maintains.

In this and many other respects, the OPTN, as several of the individuals we interviewed indicated, has been a positive force in the development of a national system characterized by uniform policies and standards. It has provided a valuable forum for bringing together diverse interests and multiple viewpoints and, where possible, for forging common approaches based on the national interest. It has established a computerized national waiting list as Congress mandated.<sup>50</sup> And, in the sphere of kidney transplantation, it has required that all donated kidneys which match perfectly with a candidate on the national list<sup>51</sup> be made available to that candidate, wherever he or she may reside in the United States.

The above are significant achievements. Yet, in considering these and others that could be cited, it is important to recognize that the actual distribution of organs from donors to recipients remains highly localized. It is localized, first of all, in the sense that through the OPTN's "local use" policy, the 250 transplant centers are allowed to retain almost all of the organs that they have retrieved.<sup>52</sup> They enter into cooperative agreements with an OPO or other centers only at their own will. Indeed, if they so wish, they can make arrangements concerning the distribution of organs with a donor hospital and/or an OPO in a service area other than the one in which they are located.

Secondly, as would be expected from this local use policy, the distribution system is also localized in the sense that most organs procured within a service area never leave that area. Only about 22 percent of all the kidneys retrieved are distributed nationally, through the OPTN organ center.<sup>53</sup> This share, which includes perfectly matched kidneys that OPOs are mandated to distribute nationally and the larger number of other kidneys which they voluntarily make available to the national pool, has not changed appreciably in recent years.

Whether or not the share of organs that is distributed nationally should be increased is a matter of much debate within the transplant field. The debate centers around the extent to which tissue matching should be used to determine who receives donated organs. One camp emphasizes that transplant recipients whose tissues, or, in particular, whose identified human leukocyte antigens (HLA), are well matched with those of the donors will have improved outcomes, both in terms of their physical well being and the life of the transplanted organ. Thus, the proponents of this viewpoint point out that an organ distribution system that allows for recipients to be matched with a large pool of potential donor organs, either in a few regions of the country or, better yet, nationally, will enhance patient outcomes and provide for the best use of a scarce resource.

The other camp, while not necessarily discounting the gains from HLA matching, stresses that similar or even better outcomes can result by using proper drug regimens and by minimizing the time during which a retrieved organ is held in storage prior to transplantation. Thus, the advocates for this position call for minimizing the national distribution of organs and confining distribution to a far more limited geographic scale, one that is no larger than an OPO service area and perhaps even smaller.<sup>54</sup>

## COOPERATION

*The development of the Organ Procurement and Transplantation Network is a significant cooperative achievement of transplant professionals and others. Yet at the transplant center and OPO levels, the sense of local ownership that some transplant professionals have towards organs they have procured impedes the development of an equitable and national system for distributing organs.*

Just as the OPTN has been a constructive factor in the development of a national organ distribution system, so too has it been an important reflection of the readiness of many diverse interests to work together cooperatively. The same can be said of many of the OPOs.

Yet, among many transplant professionals and transplant surgeons in particular, there remains a sense of ownership of donated organs they have retrieved. This orientation inhibits further cooperative achievements and, as we have already noted, impedes the development of a more equitable system for distributing organs among patients.

By a "sense of local ownership" we mean that in the course of procuring organs, many transplant professionals, instead of viewing themselves as trustees of donated organs for all transplant candidates in the United States, regard themselves more as agents for patients associated with a particular transplant center or residing in a particular service area.

Thus, as rationale, we often heard that in order for transplant surgeons to have sufficient incentive to carry out the demanding work of procuring organs, often during the middle of the night, they must have some assurances that their patients (and their particular programs) will derive some benefit from the effort. As further rationale, we also heard that the incentive to donate organs might diminish if residents of a particular OPO service area found that organs donated in their area were being sent to other areas that are less successful in obtaining donated organs.<sup>55</sup>

The latter rationale was expressed as follows by the OPTN's Organ Procurement and Distribution Committee in response to a physician's recommendation that organs be allocated on a national basis, irrespective of local or regional needs:

*"The Committee pointed out that it is widely recognized and accepted that organ procurement is enhanced by local use. Organ donation is a 'donation.' Those who raise money for transplant recipients report that donations are highest where there are local patients waiting for organs. Furthermore, it is inequitable to force efficient OPOs to by-pass their own patients to subsidize the inefficiency of other OPOs."*<sup>56</sup>

Such concerns, along with the reservations about the benefits of tissue matching, have been extremely influential in limiting the geographic scope of organ distribution. They provide the basis for the "keep one—share one" type of kidney distribution system described earlier. And they offer the rationale for the "renal payback system" that the OPTN now applies in regard to kidneys that OPOs are mandated to donate to the national pool. Under that system, a transplant center receiving such a kidney must subsequently return one to the offering transplant center or OPO.<sup>57</sup> Such an arrangement was necessary to maintain support for the perfect match requirement, even though that requirement affects only about 8 percent of all cadaver kidneys transplanted.

It should be noted that some transplant professionals do not view the organs they procure as belonging to their transplant program or even their OPO service area, and are in fact opposed to the OPTN's renal payback system and other such payback systems operating within OPO service areas. An indication of this point of view and the rationale behind it is offered in the following excerpt from a letter sent to the OPTN in February 1989 by a transplant surgeon who is the medical director of an OPO.

*"Establishing a payback system also creates the illusion that a kidney is the property of a given OPO. Clearly, we need to foster the notion that organs for transplantation are a national resource which should be used in the most efficient and successful manner possible. They are not anyone's individual property."*<sup>58</sup>

It should also be noted that the rationales supporting the ownership argument rest on fragile foundations. We found no valid statistical basis to support the contention that organ procurement will diminish if transplant centers and/or OPOs are not given some payback for procured kidneys. And, contrary to the OPTN Committee's suggestion that communities do not expect to supply organs to other parts of the country without a reasonable return, we found that in a national public opinion poll, commissioned by the OPTN itself, over 75 percent of the

respondents disagreed with the statement that “donor organs should go to someone in the area where the donor lived.”<sup>59</sup>

# RECOMMENDATIONS

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During the 1980s, there has been tremendous progress in the field of organ transplantation. At the beginning of the decade, kidney transplantation was still a poor alternative for the great majority of dialysis patients, and heart and liver transplants were in the very early experimental stages. By the end of the decade, kidney transplants had become a well established protocol for a significant proportion of dialysis patients, with close to 9,000 such transplants being conducted on an annual basis in the United States. Similarly, heart and liver transplants had advanced well beyond the experimental stages, with more than 3,000 such transplants being carried out annually in the country.

In this milieu of rapid medical advance, there has also been substantial advance in the development of complex organizational systems responsible for the distribution of organs, from the point of donation to the point of transplantation. This advance is reflected in the increasing sophistication of OPO operations and in the establishment of the OPTN as a policymaking and oversight body.

Yet, in the midst of this progress, we have found that there are some disturbing disparities between the stated expectations governing organ distribution and the practice realities. This is most especially the case with respect to the expectation that subject to medical criteria those on transplant waiting lists should have equal access to transplants and the reality that in some respects the access is quite unequal. As the number of individuals awaiting a transplant increases, this disparity becomes an increasingly serious matter warranting national attention.

In making our recommendations, we do not impose our own or others' judgments about the three stated sets of expectations. A reexamination of the desirability of some or all of those expectations may be warranted, but is beyond the purview and data base of this study.

Thus, we regard the expectations as given. Each is the product of long deliberation among a broad base of participants, and each is rooted in law. In our recommendations, we focus on the practice realities and on how they might be modified to reflect more closely the three sets of expectations.

We direct our recommendations primarily to PHS and HCFA and focus primarily on the equity issue. Each agency has responsibility for addressing this issue: PHS, through its oversight of the OPTN, and HCFA, through its oversight of Medicare and Medicaid expenditures in general and its certification of OPOs in particular. We conclude with a recommendation to the American Society for Transplant Surgeons and the American Society for Transplant Physicians.

## THE PUBLIC HEALTH SERVICE

*The PHS, in collaboration with the OPTN, should issue regulations to require that each OPO (1) establish a single, unified list of patients awaiting transplantation and (2) distribute donated organs to those patients on a first come first served basis, subject to established medical criteria.*

What this means is that each transplant center located within an OPO's service area would register its own transplant candidates on one unified list maintained by the OPO. Each donated cadaver organ that then becomes available for transplantation in that service area (except for those mandated by the OPTN to be distributed nationally), would then be offered to patients on that list in the order that they have been registered. The only basic exceptions would be those warranted in accord with established medical criteria (which, as we note subsequently, must be stated more explicitly).

With this approach, the emphasis would be on equitable access among patients, not among transplant centers. Transplant centers would not "own" any organs that they or others have procured. All distribution of organs would be based on the OPO's list, not individual centers' own lists. The result would be a system that is much more in accord with congressional intent, as expressed in 1984 and clarified in 1988.

*The PHS, in collaboration with the OPTN, should issue regulations to require that each transplant center and donor hospital in an OPO service area adhere to the centralized organ distribution policies of the OPO governing that area.*

If the first recommendation is to achieve its objective of a more equitable, patient based system, the above recommendation must also be carried out. If it were not, transplant centers would be able to undermine the first come first served approach by making organ distribution arrangements, as some now do, with a donor hospital and/or an OPO outside the service area in which they are located.

In this context, it is absolutely essential that OPOs, not transplant centers, be regarded as the engines of the organ distribution system. They should have the authority to shape and oversee distribution policies in their service areas, in accord with guiding Federal requirements, and they should be held accountable for the exercise of this authority. In guiding the equitable distribution of organs, they must assure that the focus is on the equitable access of patients, not transplant centers.

*The PHS, in collaboration with the OPTN, should support the development of medical practice guidelines addressing organ transplantation.*

Our recommendation calling for OPOs to distribute donated organs on a first come first served basis responds to the National Organ Transplant Act's requirement that organs be allocated equitably among patients. It also responds to the Act's injunction that organs be allocated in accord with "established medical criteria."

Herein lies a certain problem. There are differences among professionals in the field concerning the proper scope of medical criteria and how such criteria should be applied at a time when there is a considerable shortage of donor organs. These differences involve, among other things, the degree of emphasis that should be given to age, sensitivity level, and HLA matching in distributing organs. Further, it is possible that the application of such criteria, at least in so far as they apply to HLA matching, can contribute to the inequitable allocation of organs among blacks and whites.<sup>60</sup>

Thus, it appears that further examination of the content of these criteria and some resolution concerning them is relevant to any concerted national effort to reduce the racial and other disparities indicated in this report. In short, it is important to have a clearer definition of just what is meant by the widely used term "medical criteria."

In that regard, PHS can make a valuable contribution by supporting the development of transplant practice guidelines, based on medical outcomes, that would serve as an authoritative and useful reference point both for practicing professionals and for oversight bodies responsible for assuring that organs are in fact being distributed equitably.

If in the effort to establish practice guidelines it emerges that certain choices concerning organ allocation are in essence societal ones more than medical ones, then they should be identified as such and be addressed by the OPTN, the Department of Health and Human Services, and perhaps even the Congress.

*The PHS should fund a demonstration effort incorporating the following two features: (1) the establishment of a single, unified waiting list including all patients awaiting an organ transplant in a number of OPO service areas and (2) the mandatory distribution of donated organs to those patients on a first come first served basis, subject to established medical criteria.*

There is much to be gained by regularly distributing organs on a geographic basis larger than that of individual OPOs, of which there are 72 in the country. By allowing for a larger pool of potential donors, larger scale organization would enhance the transplant opportunities of the highly sensitized and allow for better tissue matching between donors and recipients. Also, by bringing transplant centers now in different OPO service areas under one distribution system, it would eliminate the differential access that patients in different OPO service areas now have to organ transplantation.

Yet, some argue that such gains are outweighed by various losses. Among them are the time and financial costs associated with transporting organs longer distances. A carefully constructed demonstration involving multiple OPOs could provide valuable data to inform this debate and contribute to the development of national policy. If, in fact, the benefits of larger scale organization outweigh the costs, serious consideration should then be given to developing larger scale distribution systems throughout the nation and even to reducing the number of OPOs.

## THE HEALTH CARE FINANCING ADMINISTRATION AND THE PUBLIC HEALTH SERVICE

*The HCFA and the PHS should support research efforts that could help reduce racial disparities in organ allocation.*

Building on already initiated efforts, this research agenda should have at least two major thrusts. One should be to conduct a thorough examination of the various factors, medical and nonmedical, that might help explain the differential access to transplantation of black and white transplant candidates. As those factors become understood more clearly, policymakers will be able to take corrective actions with a greater degree of confidence.

The second thrust should be to intensify research efforts to study the immunogenetics of blacks. With blacks accounting for 34 percent of those with kidney failure and 30 percent of transplant candidates, such efforts are of extreme importance. Moreover, as more and better information becomes available about the antigen specificities of blacks, they will be able to participate more fully and equitably in organ distribution systems that involve HLA matching.

*Before granting Medicare recertification to an OPO, HCFA, in collaboration with PHS, should assure that the OPO is distributing organs equitably among patients, according to established medical criteria.*

In the National Organ Transplant Act, Congress clearly set forth its intent that organs be distributed equitably as stated above. Yet, we have found that across the nation the access to organ transplantation remains unequal in some important respects. This is a serious matter which it does not appear can be explained strictly on the basis of medical criteria.

We recognize that a determination of whether or not an OPO is distributing organs equitably is not a simple matter subject to a quick assessment. However, because it is so vital a matter, we think that HCFA must develop some way of making a reasonable judgment on it. In this regard, the PHS, through the OPTN, can be of considerable assistance by providing data, specific to OPO service areas, that indicate the median time of those on waiting lists and that compare the characteristics of those on waiting lists with those receiving transplants. Such data can be useful in identifying outliers and in raising questions that HCFA should address in making recertification decisions.<sup>61</sup> To overlook this matter, or to leave it as a matter for OPOs to certify without any outside review, could impede the development of a more equitable system.

Thus, we urge HCFA to collaborate with PHS to determine the kind of quantitative indicators it should rely upon to help determine if an OPO is adhering to the congressional mandate to distribute organs equitably among patients according to established medical criteria.

*Before granting Medicare recertification to an OPO, HCFA, in collaboration with PHS, should assure that the OPO is conducting a rigorous, soundly based organ procurement effort.*

Disparities in the rate of organ procurement from one OPO service area to another appear to inhibit professional support for the national distribution of organs. The OPTN's Procurement

and Distribution Committee and others we interviewed have suggested that this is because OPOs that are more effective in procuring organs are reluctant to serve as a source of supply for those that are less effective.

To address this concern and to promote organ procurement generally, we encourage HCFA and PHS to examine OPOs with relatively high rates of procurement over a 2- or 3-year period and to determine if there are lessons learned from their efforts that might usefully be shared with other OPOs. However, given the significance of the matter, in terms of both procurement and equity objectives, we also urge that HCFA use the recertification process to assure itself that OPOs are carrying out substantial, well-conceived procurement efforts.

We recommend that HCFA, in collaboration with PHS, identify appropriate indicators of such efforts to help guide its recertification reviews. In this regard, we urge that it give particular attention to its performance standard governing OPO procurement. At present, HCFA has no such standard governing heart or liver procurement, but has one calling for OPOs to procure kidneys at a rate of at least 23 per million population.<sup>62</sup>

Given the growth in the number of heart and liver transplants, it may be a good time to develop a procurement performance standard that applies to them as well as to kidneys. Moreover, it may be more meaningful to base the standard on the number of hospital deaths reported in an OPO service area than on its population level.<sup>63</sup>

#### **THE AMERICAN SOCIETY OF TRANSPLANT SURGEONS AND THE AMERICAN SOCIETY OF TRANSPLANT PHYSICIANS**

*The ASTS and the ASTP should conduct their own inquiries of the factors leading to longer median waiting times for blacks than whites awaiting a kidney transplant and of any actions their associations should take to help reduce this disparity.*

The search for a constructive response to the black-white disparity highlighted in this study should not be limited to governmental entities. All professionals and professional organizations in the transplantation field should be involved in this search. That is particularly important, we believe, with respect to the ASTS and the ASTP, the two national organizations representing physicians associated with organ transplantation.

In any inquiries they undertake, we urge ASTS, ASTP, and other organizations to give careful consideration to practice realities that might contribute, however inadvertently, to the disparities noted in this report. In this context, we urge particular attention to the following conclusion reached by the American Medical Association's Council on Ethical and Judicial Affairs:

*"The social disparities in treatment decisions indicate that inappropriate considerations may enter the decision-making process. The efforts of the specialty societies, with the coordination and assistance of the American Medical Association, to develop practice parameters should include criteria that would preclude or diminish racial disparities."<sup>64</sup>*

# COMMENTS ON THE DRAFT REPORT

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Within the Department of Health and Human Services, we received comments from the Public Health Service (PHS), the Health Care Financing Administration (HCFA), and the Assistant Secretary for Planning and Evaluation (ASPE). In addition, we received comments from many private organizations. These included the American Society of Transplant Physicians (ASTP), the American Society of Transplant Surgeons (ASTS), the United Network for Organ Sharing (UNOS), the American Society for Histocompatibility and Immunogenetics (ASHI), the Association of Organ Procurement Organizations (AOPO), the North American Transplant Coordinators Organization (NATCO), the New England Organ Bank (NEOB), and the South-Eastern Organ Procurement Foundation (SEOPF).

In appendix D, we present the detailed comments offered and our response to them. As indicated there, PHS and HCFA agreed with all of the recommendations directed to them. In response to our recommendation that ASTS and ASTP conduct their own inquiries of the factors leading to longer median waiting times for blacks than whites, ASTP indicated that its Patient Care and Education Committee has already conducted such a study and arrived at findings in agreement with our report. The ASTS responded that it was willing to: (a) Define medical indices of patient suitability for being placed on transplant waiting lists; (b) Develop an allocation scheme that addresses all (racial included) factors that affect organ distribution; and (c) Delineate standards to assess OPO activity and performance.

Among those commenting, most focused on our finding concerning the racial disparity and our recommendations addressing that finding. In that regard, many noted that human leukocyte antigen (HLA) matching was an important factor contributing to the disparity and that the report should have given more consideration to this factor. Others noted that once a donor organ becomes available to black candidates they may be less likely to receive it because of medical, financial, social, and/or personal considerations. In short, most of the respondents would have liked the report to have delved more thoroughly into the possible causes for the racial difference.

Two of those commenting expressed considerable concern that the report implied that racial prejudice might be contributing to the gap in black-white waiting times. A third (ASHI) added that a direct way to examine this matter would be "to examine the demographics of patients passed over for transplantation."

On our recommendation calling for each OPO to develop a single, unified list of patients and to allocate donated organs to those persons on a first come first served basis, PHS, NATCO, and ASHI expressed support; the latter's support of the concept, however, was clearly based on the associated use of allocation criteria that give some emphasis to good HLA matches. At the other end, ASTP, ASTS, and ASPE opposed the recommendation, arguing that it would not necessarily serve to reduce the racial disparity. The ASPE, which was critical of many of the report's findings and recommendations, added that a first come first served scheme was too simplistic and overlooked many important factors that must be considered in the organ allocation process.

Finally, three commenters (ASTP, ASTS, and ASHI) urged that more attention be given to the need to increase organ donation rates, especially among blacks. In fact, ASTP indicated that this was a bigger problem than organ distribution. Similar sentiment was expressed by some members of the National Kidney and Urologic Diseases Advisory Board during a briefing which we gave to that body.

In response to these comments, we offer the following information and considerations:

1. We revised our presentation on the factors that might contribute to the longer median waiting time for blacks. Compared with the draft report, the final report's discussion of these factors gives more emphasis to the possible influence of HLA matching, identifies a fuller range of other possible factors, and offers a more precise explanation of the possibility of racial bias. On the latter matter, we clearly state that we have no evidence of such bias, but that at least "subconscious bias" must be included on any list of possible causes.
2. We recognize that even with the revised text our finding concerning the racial disparity raises more questions than it answers. It is for that reason that we call for HCFA and PHS to support research efforts that could help reduce the disparity. Some such inquiry, we understand, is already being supported and may help provide some answers. We urge that it continue and that particular attention be given to research that seeks to add to the medical knowledge base on the immunogenetics of blacks (and other minorities).
3. On our first recommendation calling for each OPO service area to use a single waiting list and to allocate organs to patients on that list on a first come first serve basis, subject to medical criteria, we stress the following points:

We recognize the complexity of the considerations governing organ allocation. At the same time, we recognize the primacy of congressional expectations concerning allocation. Our review of legislative history makes it quite clear that Congress intends for organs to be distributed equitably among patients, not among transplant centers. Our discussions with staff closely involved with this history also suggest that the first come first served principle is at the core of what Congress means by equity and that medical factors provide the only legitimate basis for deviating from that principle.

We recognize, as the New England Organ Bank indicates, that there is not a national consensus on the medical criteria that should guide organ allocation and that there are legitimate scientific disagreements concerning these criteria. Our intent here is not to generate artificial national medical criteria, but to have the medical criteria being employed in each OPO service area clearly stated and to have those criteria be the only legitimate basis for deviating from the first come first served rule.

This approach would allow for the continued evolution of medical criteria. But it would not allow for the inclusion of criteria that are clearly not medical in nature. The "keep one, share one" criterion would seem to be one such criterion. It is directed to achieving equity among transplant centers more than among transplant patients and does not appear to be in concert with the authorizing legislation.

4. On the matter of organ donation, we certainly agree that it is a vital issue requiring serious attention throughout the country. But as long as we have a shortage of donor organs, it is also vital to address how to allocate that scarce resource most equitably. Indeed, as organ waiting lists grow, the matter of who receives donated organs and who does not becomes increasingly significant.
5. In this regard, it is pertinent to note that in a recent study of organ procurement conducted by ABT Associates, the authors urged that the Organ Procurement and Transplantation Network add a goal focusing on the equitable allocation of organs in place of one addressing improved access to organs. In view of the congressional concern about equity and the reality that the OPTN is not able to affect many of the most imposing barriers to access, they reasoned that such a shift would be timely.

# APPENDIX A

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## STATISTICAL METHODOLOGY AND NOTES

Potential recipients of cadaver kidneys, after registering for a transplant, typically wait for several months before they actually receive one. Some potential recipients wait for years. This appendix describes the statistical methods used for the analysis of median waiting times to transplantation of cadaver kidneys in the United States from October 1, 1987 through March 31, 1989. The analysis explored the relationship of median waiting time to demographic factors and biological factors.

### The Data

The analysis employs data routinely collected by the United Network for Organ Sharing (UNOS), an organization contracted to operate the national organ procurement and transplant network by the Public Health Service. Data were assembled from computer files which contain information on all people registered with UNOS for kidney transplants from October 1, 1987 through March 31, 1989. These data were then transmitted to the Office of Inspector General on a computer tape. The tape contains information on 23,632 people registered at either 202 transplant centers or 38 organ procurement organizations (we employ the term registration center in the future to refer to both groups).

The analysis focused on registrants awaiting their first transplant. As a result, the calculations exclude 4,770 people who received a transplant prior to October 1, 1987, and who were on the registry awaiting a second or third transplant during the time period covered by the analysis.

The analysis employed median waiting times to receive a first transplant. Because people can register at more than one center, it was necessary to define a unique "beginning date" and "beginning center" for each person in the analysis. The rules used to define the beginning date and beginning center were as follows:

1. If a person registered at only one center, that center and registration date were used.
2. If a person:
  - (a) *registered at more than one center, and*
  - (b) *had not yet received a transplant by March 31, 1989,*then the earliest registration date, and the associated center, were used.
3. If a person:
  - (a) *registered at more than one center, and*
  - (b) *received a transplant at a center other than the ones at which he or she had registered,*then the earliest registration date, and the associated center, were used.

4. If a person:
- (a) *registered at more than one center, and*
  - (b) *received a transplant at one of them,*
- then the transplanting center and the registration date at that center were used.

Analysis of waiting times requires both a valid beginning date and a valid transplant date. The data used in the analysis excluded those individuals that did not have valid dates. In 939 instances, no registration date appeared on the tape. In 134 instances, the transplant date preceded the registration date. Table A-1 summarizes the results of this first exclusion of records from UNOS data.

Reason for exclusion	Number excluded	Number remaining
Transplant prior to 10/1/87	4,770 (20%)	18,862 (80%)
No registration date	939 (4%)	17,923 (76%)
Transplant date precedes registration date	134 (1%)	17,789 (75%)

Only a case-by-case audit can determine that all dates in the data are valid. This analysis of waiting times assumes that all dates for people not explicitly excluded, as above, are valid. As fewer than one percent of the people in the data had clearly invalid dates, this assumption is probably reasonable.

Of the 17,789 people remaining in the data set, 8,048 (45 percent) received a first transplant from October 1, 1987 through March 31, 1989. The routes by which they obtained their transplants, according to the rules specified earlier, are shown in table A-2.

<b>TABLE A - 2</b>	
<b>The Relationship Between Registration Center And Transplant Center</b>	
<b>Transplantation Routes</b>	<b>Frequency</b>
Registered at only one center, received transplant at that center	5,974 (74%)
Registered at only one center, received transplant elsewhere	1,781 (22%)
Registered at more than one center, received transplant at center of earliest registration	125 ( 2%)
Registered at more than one center, received transplant at a center of later registration	132 ( 2%)
Registered at more than one center, received transplant elsewhere	36 ( 0%)

The relationship of waiting time to demographic and biological factors was included in this analysis. The demographic factors include age, race, sex, and location of registration (i.e., registration center). The biological factors include blood type and peak PRA, a measure of the likelihood of finding an organ which will not be rejected by the immune system of the recipient.

For some of the 17,789 people with valid waiting times to first transplant, information on demographic and biological factors was not in the UNOS data. Because the number of people missing values for these factors was small, these people were excluded from the analysis. Table A-3 summarizes the results of excluding these people.

<b>TABLE A - 3</b>		
<b>Construction Of Study Group Second Set Of Exclusions From Data</b>		
<b>Reason for exclusion</b>	<b>Number excluded</b>	<b>Number remaining</b>
Missing peak PRA	224 ( 1%)	17,565 (74%)
Missing race	8 ( 0%)	17,557 (74%)
Missing blood type	1 ( 0%)	17,556 (74%)

Unless otherwise stated, all results presented in this appendix will derive from analysis of the 17,556 people who appear to have complete information and valid dates. In appendix B, tables B1 and B2 summarize characteristics (age, race, sex, size of registration center, peak PRA, and blood type) of this group.<sup>65</sup>

## Median Waiting Times

The analysis of waiting times concentrates on estimation of the median waiting time to first transplant. The median waiting time is an appropriate statistic for summarizing the experience of different groups waiting for a kidney transplant. The median waiting time is the time by which 50 percent of registrants will have received a kidney. For example, analysis of first transplants from October 1, 1987 through March 31, 1989 indicates that the overall median waiting time is 8.6 months. That is, half of the people included in this analysis received a kidney within 8.6 months, and half waited longer. This result can be generalized to the current population assuming that (a) current registrants have demographic and biological characteristics similar to those of people in the analysis, and (b) the process of organ recovery and distribution remains the same.

We used survival analysis techniques to calculate the estimated median waiting times. The waiting time for each recipient was defined as the number of months from the beginning date of the period covered by the UNOS data, October 1, 1987, until the date of a first transplant. Those recipients not receiving a transplant during the study period are considered right censored. While the time to first transplant is unknown in these recipients, they still contribute data to estimate median waiting times. For these recipients, their censoring date is the ending date of the covered period, March 31, 1989. This date allows us to determine the total number of months contributed by censored recipients.

Kaplan-Meier survival curves<sup>66</sup> are used to calculate the estimated median waiting time to first transplant. This method correctly adjusts for right censoring and makes no assumptions about the underlying distribution of the individual waiting times. In the analysis, we also provide 95 percent confidence intervals for the median waiting times, using the methods of Brookmeyer and Crowley.<sup>67</sup>

A further adjustment is made in this analysis to account for what we define as prior registrants. Many of the recipients included in the UNOS data, among both those receiving a transplant and those still waiting at the end of the study period, registered at some point prior to the beginning of the study period. Adjustment for these recipients is accomplished using techniques described by Cnaan and Ryan.<sup>68</sup> The analysis provides estimated median waiting times by race, sex, blood group, and size of registration center as measured by the number of registrants.<sup>69</sup> The results of these analyses are presented in appendix B in tables B-3, B-4, and B-5.

Most of the apparent difference between the waiting times for men and women is due to the higher proportion of females with high PRA. When males and females are classified into two groups by PRA level, above and below .75, it is apparent that women, on average, are more likely to be highly sensitized than men (PRA =.75). Table A-5 shows the median waiting times by sex and peak PRA.

**TABLE A -5**  
**Median Time To Transplant By Average Peak**  
**Panel Reactive Antibody (PRA) And Sex**

SEX	Peak PRA < 75	Peak PRA > = 75
Women	20.8	92.6
Men	8.9	91.9

The longer waiting times for women in the K group largely reflect higher sensitivities than men—as measured by average peak PRA—within the group. However, the longer waiting times for women in the =75 group do not seem to relate to a similar disparity in average PRA level.

We also found that waiting times tend to be longer in the larger registration centers (see appendix B, table B-5), where size of center is measured by the number of registrants for a first transplant on the rolls at some time during the study period and classified into quartiles. For registrants with peak PRA less than 75, the estimated median waiting time in the top 25 percent of centers was 9.5 months, compared to 5.7 months in the bottom 25 percent.

### **Multivariate Survival Analysis**

While the estimated median waiting times can provide insight into the singular effects of variables, they do not make efficient use of all of the information available. Medians only take into account differences over the middle portion of the waiting time distribution and do not show the extent of these differences over the total length of follow-up. Also, one cannot fully adjust for the effects of continuously varying factors such as age and peak PRA.

To satisfy these concerns, we used the proportional hazards method of survival analysis.<sup>70</sup> This multivariate approach allows one to adjust simultaneously for multiple factors, whether continuous or discrete, over the length of the follow-up period. To adjust for the prior registrations, we stratified by registration date. This technique is referred to as blocking and is described by Cnaan.<sup>71</sup> The registration periods, or blocks, used are presented in table A-6.

**TABLE A -6**  
**Blocking Periods Employed In Multivariate Analysis**

Date of registration	Number of registrants
up to 09/30/84	433
10/01/84-03/31/85	142
04/01/85-09/30/85	221
10/01/85-03/31/86	404
04/01/86-09/30/86	644
10/01/86-12/31/86	421
01/01/87-03/31/87	629
04/01/87-06/30/87	796
07/01/87-09/30/87	1,573
10/01/87-03/31/89	12,293
Total in study:	17,556

In appendix B, table B-6 gives results of the proportional hazards analyses. The analyses are also stratified, or blocked, by age and blood type, so that these factors are held constant in assessing the effects of the other variables.

The table shows that a black has from 69 percent to 77 percent of an equivalent white registrant's chance of receiving a kidney at any point in time after the date of registration. The 77 percent figure refers to blood types B and AB, the 69 percent figure to blood types A and O. The probability of seeing a black-white disparity this great if kidneys were randomly allocated among equivalent blacks and whites is less than 1 in a billion. This result is statistically significant.

The proportional hazards analyses also examine the effect of different PRA levels on waiting times, holding constant other factors such as blood type. The table also shows that a person with a peak PRA of 75 has 40 percent of the chance of a person with a PRA of zero of receiving a kidney at any particular time after registering (blood type A or O) and 33 percent of a PRA zero person's chance for blood types B and AB.

Peak PRA appears to affect time to first transplant somewhat differently in the two different blood type subsets. For blood types A and O, the effect of increases in PRA becomes increasingly severe at higher PRA levels (the PRA-squared term in the proportional hazards model is negative). In other words, a PRA increase from 70 to 80 decreases one's chances for receiving a transplant more than an increase from 10 to 20.

model is negative). In other words, a PRA increase from 70 to 80 decreases one's chances for receiving a transplant more than an increase from 10 to 20.

For types B and AB, additional PRA increases at higher levels appear to have a diminishing effect. Of course, a person with blood type B and a high PRA level already has only a very distant possibility of getting a kidney. The diminishing marginal effect of PRA increases for such people basically restates that fact.

Finally, this analysis confirms the preliminary result that waiting times increase with the size of the registration center. A person registering at a center with 100 registrants during the study period has 90-93 percent of a person's chance of receiving a kidney at any point after registering at a center where the wait list is size 25.

The proportional hazards models reported here are just two of a number of models studied in the course of this analysis. Other models and assumptions did not give results markedly different from those reported above. In particular, excluding short waiting times (some people got a kidney the same day they registered), excluding long waiting times, restricting the analysis to registrants after 10/1/87, or incorporating "interactions" such as black and male, or different PRA effects for blacks and whites, did not alter the essential results regarding the significance of race, gender, peak PRA, and size of registration center.

However, proportional hazards models do assume proportionality of effect. That is, the effects of factors like race or PRA on the probability of receiving a kidney should be multiplicative over the entire follow-up period. Tests of proportionality show that the models used in this analysis fail to meet this requirement for center size (blood types B and AB) and for peak PRA and gender (blood types A and O).<sup>72</sup> It appears that these factors may have some time dependence in their effects. That is, the effect of an increase in PRA for a blood type A person who has been waiting a long time may differ somewhat from the effect of an equivalent increase in PRA for the same person with a short waiting time.

The investigation of such subtleties lies outside the scope of this analysis. There is no indication that such fluctuations from the proportional hazards assumption would alter the principal results regarding the significance of race, gender, blood type, PRA, and center size.

### Registration Center Specific Analysis

Additional analyses were conducted to examine the relationship between the median waiting time by characteristics of the registration center's waiting list. In these analyses, for each registration center, the median waiting time to transplants for white recipients and black recipients was calculated separately. It was also determined what percent of the registration centers' waiting lists consisted of black patients. We then calculated the ratio of the black recipients' median waiting time to that of the white recipients for each registration center. A ratio greater than one indicates that black recipients waited longer, on the average, than white recipients.

To determine the national applicability of the finding that black recipients wait longer for transplants than do white recipients, we categorized, where possible, each registration center into the appropriate region as defined by the Department of Health and Human Services (DHHS). We then calculated for each region the mean ratio of median waiting times. Table A-7 gives the results of this analysis.

**TABLE A - 7**  
**Mean Ratio Of Black Recipients' Waiting Time To That Of White Recipients,**  
**By DHHS Region**

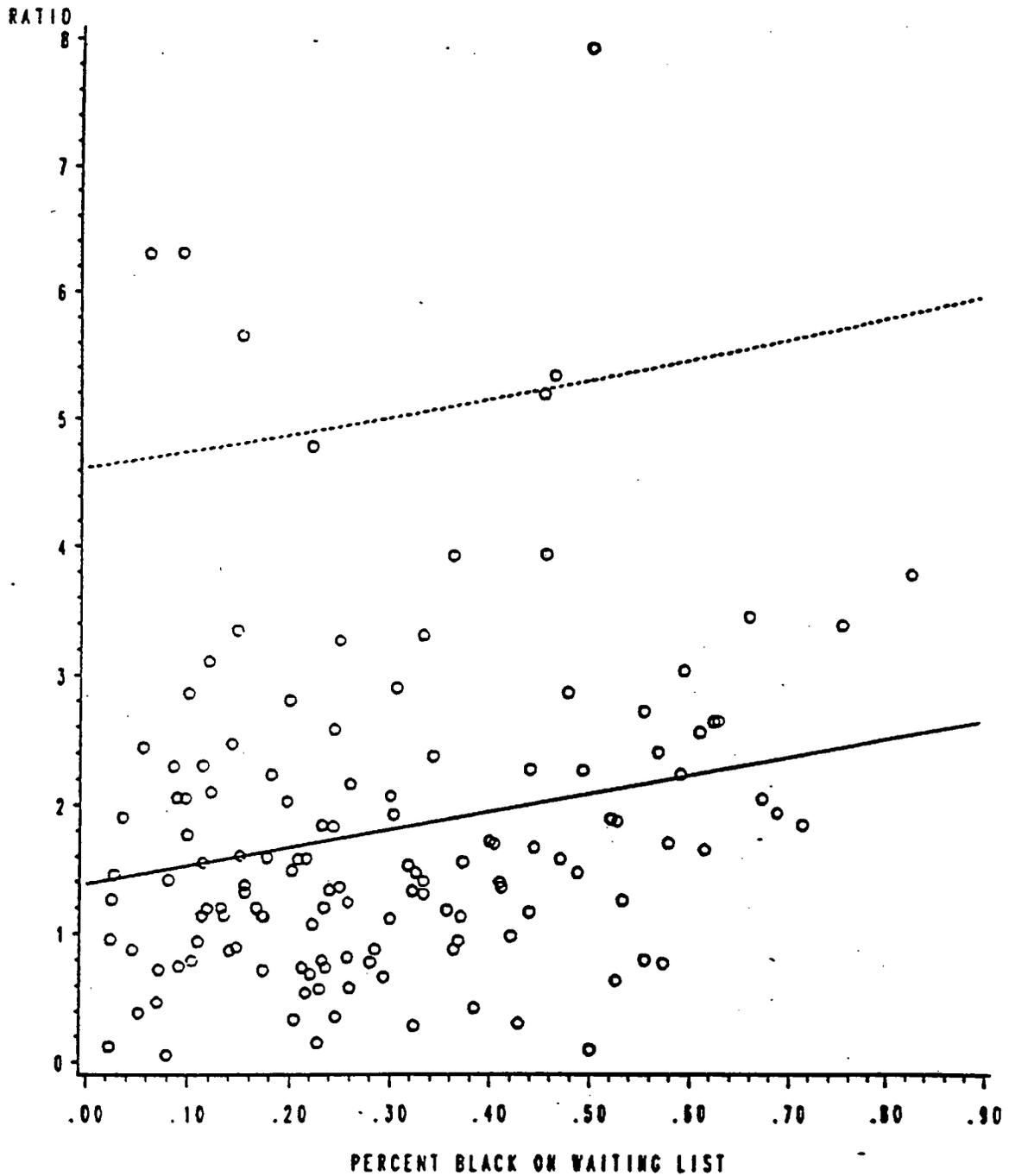
REGION	MEAN RATIO
I (CT, ME, MA, NH, RI, VT)	0.99
II (NY, NJ, PR, VI)	1.88
III (DE, MD, PA, VA, WV, DC)	1.82
IV (AL, FL, GA, KY, MS, NC, SC, TN)	2.34
V (IL, IN, MI, MN, OH, WI)	1.25
VI (AR, LA, NM, OK, TX)	1.89
VII (IA, KS, MO, NE)	1.94
VIII (CO, MT, ND, SD, UT, WY)	1.03
IX (AZ, CA, HI, NV, GU, Trust Territory of Pacific Islands, American Samoa)	1.85
X (AK, ID, OR, WA)	2.74
Unknown	1.64
<b>TOTAL</b>	<b>1.81</b>

The "unknown" category includes those registration centers, the identity of which is normally encrypted by UNOS, that refused to be identified. An Analysis of Variance showed that Regions I and VIII were lower than the other regions but that the other regions were not significantly different from each other when using Duncan's Multiple Range Test. These data suggest that the finding of longer waiting times to transplantation for blacks is a national problem and not confined to any specific geographic locality.

In a second analysis, we wished to determine the effect of the proportion of blacks on a registration center's waiting list on this ratio of median waiting times. We performed a regression of the percent of blacks in a registration center's waiting list against this ratio. We first used a linear model, where the ratio is assumed to have a linear relationship to the percent of blacks on the waiting list. The graph in figure A-1 shows the plot of this ratio with the percent of blacks on the waiting list. The  $R^2$  for this model was 0.03, which indicates that only 3 percent of the variation in the ratio can be explained by the variation in the percent of blacks on a transplant center's waiting list. The plot shows extremely wide confidence intervals (dashed line) around the expected value (solid line), also indicating a poor fit to the model.

To determine if there may be some curvilinear relationship, we also fit a quadratic model to the data. The plot of this model is shown in figure A-2. The  $R^2$  for this model was increased to only 0.05; that is, only 5 percent of the variation in the value of the ratio is explained by the variation in the percent of blacks on a registration center's waiting list. The results of both of these attempts at model fitting would indicate that the ratio of blacks' median waiting time to transplant to that of whites is not affected by the percent of black recipients, or potential recipients, residing on a registration center's waiting list.

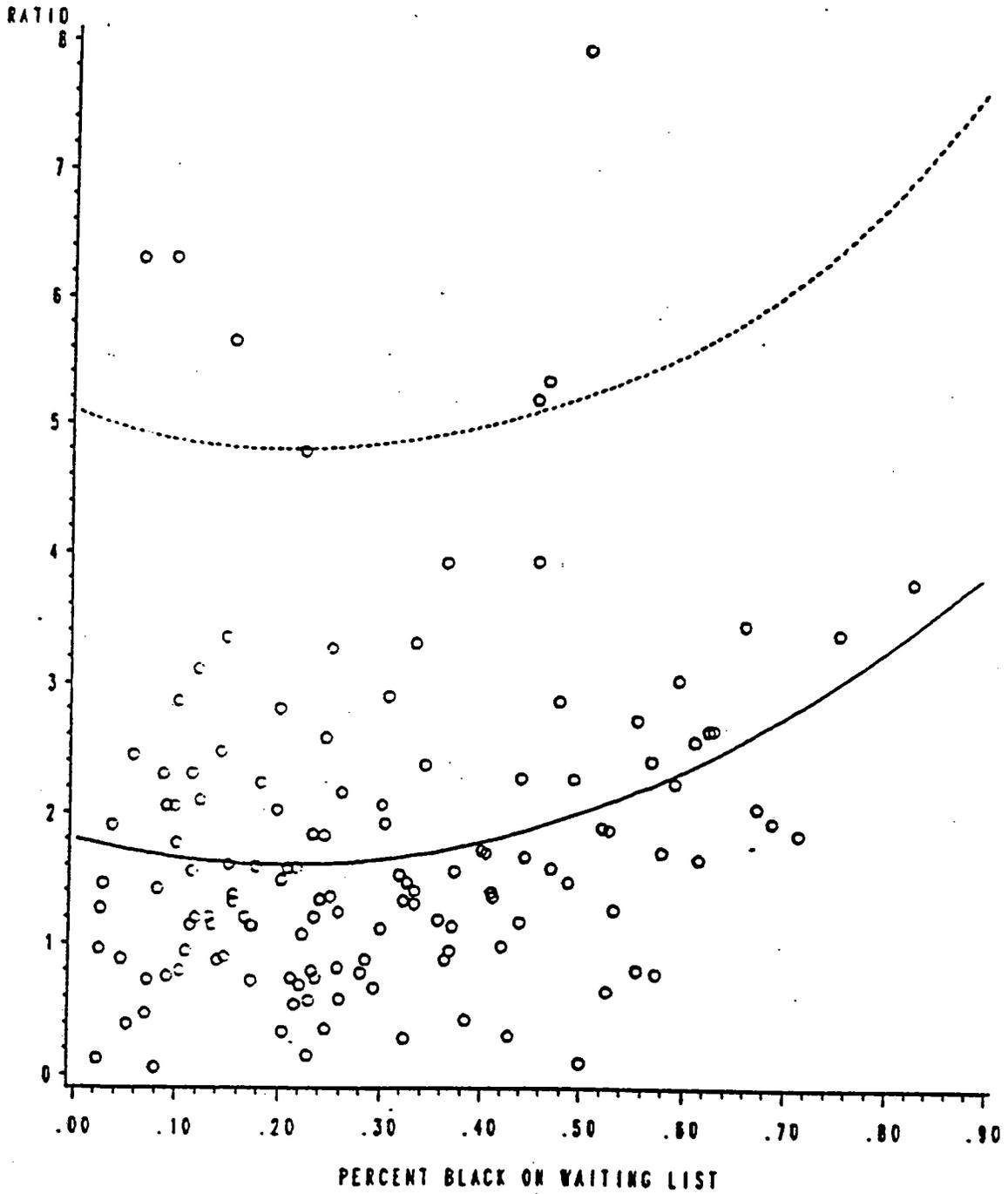
**FIGURE A-1**  
**RATIO OF MEDIAN WAITING TIMES**  
**BY PERCENT BLACK ON TRANSPLANT CENTER WAITING LIST**  
**BLACK TO WHITE RATIO**



**LINEAR MODEL  $Y = B_1 + B_2 * X$**   
**SOLID LINE IS EXPECTED, DASHED LINE IS 95 % C.I.**

# FIGURE A-2

RATIO OF MEDIAN WAITING TIMES  
BY PERCENT BLACK ON TRANSPLANT CENTER WAITING LIST  
BLACK TO WHITE RATIO



QUADRATIC MODEL  $Y=B_1+B_2*X+B_3*X^2$   
SOLID LINE IS EXPECTED, DASHED LINE IS 95 % C.I.

# APPENDIX B

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## *TABLES DERIVED FROM THE ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK DATA BASE*

Following are six tables presenting data that are relevant to our findings and that are based on our primary data base of 17,556 individuals in the United States who between October 1, 1987, and March 31, 1989, were waiting for or actually received a first kidney transplant.

**TABLE B-1**  
**Demographics Of Those Receiving And Waiting For Their First Kidney Transplant**  
**October 1, 1987 - March 31, 1989**

AGE	TRANSPLANTED		WAITING		TOTAL	
	NUMBER	PERCENT	NUMBER	PERCENT	NUMBER	PERCENT
1-5	71	0.9	44	0.5	115	0.7
6-18	379	4.8	360	3.7	739	4.2
19-45	4,551	57.3	5,521	57.4	10,072	57.4
46-65	2,775	34.9	3,478	36.2	6,253	35.6
65+	164	2.1	213	2.2	377	2.1
<b>TOTAL</b>	<b>7,940</b>	<b>100.0</b>	<b>9,616</b>	<b>100.0</b>	<b>17,556</b>	<b>100.0</b>

AGE	TRANSPLANTED		WAITING		TOTAL	
	NUMBER	PERCENT	NUMBER	PERCENT	NUMBER	PERCENT
Black	1,792	22.6	2,965	30.8	4,757	27.1
White	5,205	65.6	5,237	54.5	10,442	59.5
Other	943	11.9	1,414	14.7	2,357	13.4
<b>TOTAL</b>	<b>7,940</b>	<b>100.0</b>	<b>9,616</b>	<b>100.0</b>	<b>17,556</b>	<b>100.0</b>

SEX	TRANSPLANTED		WAITING		TOTAL	
	NUMBER	PERCENT	NUMBER	PERCENT	NUMBER	PERCENT
Female	3,079	38.8	4,424	46.0	7,503	42.7
Male	4,861	61.2	5,192	54.0	10,053	57.3
<b>TOTAL</b>	<b>7,940</b>	<b>100.0</b>	<b>9,616</b>	<b>100.0</b>	<b>17,556</b>	<b>100.0</b>

QUARTILE	TRANSPLANTED		WAITING		TOTAL	
	NUMBER	PERCENT	NUMBER	PERCENT	NUMBER	PERCENT
First	208	2.8	232	2.6	440	2.7
Second	994	12.9	945	10.5	1,889	11.6
Third	1,860	25.4	1,968	21.9	3,828	23.5
Fourth	4,309	58.9	5,848	65.0	10,157	62.3
<b>TOTAL</b>	<b>7,321</b>	<b>100.0</b>	<b>8,993</b>	<b>100.0</b>	<b>16,314</b>	<b>100.0</b>

**TABLE B-2**  
**Blood Type And Peak PRA Of Those Receiving And Waiting For Their First Kidney Transplant**  
**October 1, 1987 - March 31, 1989**

BLOOD TYPE	TRANSPLANTED		WAITING		TOTAL	
	NUMBER	PERCENT	NUMBER	PERCENT	NUMBER	PERCENT
A	2,943	37.1	2,383	24.8	5,326	30.3
AB	318	4.0	197	2.0	515	2.9
B	963	12.1	1,621	16.9	2,584	14.7
O	3,716	46.8	5,415	56.3	9,131	52.0
<b>TOTAL</b>	<b>7,940</b>	<b>100.0</b>	<b>9,616</b>	<b>100.0</b>	<b>17,556</b>	<b>100.0</b>

PEAK PRA	TRANSPLANTED		WAITING		TOTAL	
	NUMBER	PERCENT	NUMBER	PERCENT	NUMBER	PERCENT
0 - 24	6,303	79.4	6,330	65.8	12,633	72.0
25 - 49	621	7.8	792	8.2	1,413	8.0
50 - 74	420	5.3	678	7.1	1,098	6.3
75 - 100	596	7.5	1,816	18.9	2,412	13.7
<b>TOTAL</b>	<b>7,940</b>	<b>100.0</b>	<b>9,616</b>	<b>100.0</b>	<b>17,556</b>	<b>100.0</b>

**TABLE B-3**  
**Estimated Median Waiting Times In Months To First Transplant By Race**  
**Controlling For Blood Type And Peak PRA**  
**Ages 18-64**

<b>PEAK PRA LESS THAN 75</b>			
<b>RACE</b>			
<b>BLOOD TYPE</b>	<b>BLACK</b>	<b>WHITE</b>	<b>OTHER</b>
A	7.2	4.2	5.9
AB	6.1	4.0	3.1
B	17.4	10.9	11.8
O	15.2	9.7	14.4
OVERALL	12.6	6.9	9.7
<b>PEAK PRA GREATER THAN 75</b>			
<b>RACE</b>			
<b>BLOOD TYPE</b>	<b>BLACK</b>	<b>WHITE</b>	<b>OTHER</b>
A	--	21.2	61.9
AB	10.0	20.4	3.8
B	35.5	--	19.5
O	48.7	31.3	28.5
OVERALL	48.7	26.7	43.7
<b>ALL BLOOD TYPES AND ALL PRA LEVELS</b>	<b>13.9</b>	<b>7.6</b>	<b>12.0</b>

**TABLE B-4**  
**Estimated Median Waiting Times In Months To First Transplant**  
**By Sex**  
*Controlling For Blood Type And Peak PRA*  
**Ages 18-64**

<b>PEAK PRA LESS THAN 75</b>		
<b>SEX</b>		
<b>BLOOD TYPE</b>	<b>FEMALE</b>	<b>MALE</b>
A	5.1	4.6
AB	4.4	4.0
B	14.3	12.3
O	12.1	11.3
OVERALL	8.9	8.4
<b>PEAK PRA GREATER THAN 75</b>		
<b>SEX</b>		
<b>BLOOD TYPE</b>	<b>FEMALE</b>	<b>MALE</b>
A	31.3	23.0
AB	20.4	2.5
B	—	21.1
O	38.9	25.7
OVERALL	36.6	22.7
<b>ALL BLOOD TYPES AND ALL PRA LEVELS</b>	<b>10.7</b>	<b>8.5</b>

<b>TABLE B-5</b>				
<b>Estimated Median Waiting Times In Months To First Transplant By Quartile</b>				
<b>Controlling For Blood Type And Peak PRA</b>				
<b>Ages 18-64</b>				
<b>PEAK PRA LESS THAN 75</b>				
<b>QUARTILE</b>				
<b>BLOOD TYPE</b>	<b>FIRST</b>	<b>SECOND</b>	<b>THIRD</b>	<b>FOURTH</b>
A	4.3	4.5	4.1	5.4
AB	5.1	4.1	6.1	3.6
B	7.8	9.7	12.3	15.5
O	8.6	9.7	10.1	12.8
OVERALL	5.7	7.2	7.7	9.5
<b>PEAK PRA GREATER THAN 75</b>				
<b>QUARTILE</b>				
<b>BLOOD TYPE</b>	<b>FIRST</b>	<b>SECOND</b>	<b>THIRD</b>	<b>FOURTH</b>
A	17.5	21.2	19.0	39.1
AB	--	--	8.2	27.9
B	43.9	22.9	21.8	--
O	34.6	30.3	32.4	34.3
OVERALL	23.4	27.7	24.7	38.6

\* For an explanation of the quartiles, see appendix A, section on "median waiting times."

**TABLE B-6**  
**Results Of Proportional Hazards Analysis Time In Months To First Transplant<sup>1</sup>**  
**Relative Risks and 95 Percent Confidence Intervals (CI)\***

FACTOR	BLOOD TYPES A AND O		BLOOD TYPES B AND AB	
	Relative Risks	95% CI	Relative Risks	95% CI
Male	1.05	(1.00-1.11)	1.08	(.96-1.22)
Black	.69	(.64-.73)***	.77	(.68-.87)***
Peak PRA (75 vs 0)	.40	(.26-.63)***	.33	(.11-.98)***
Center Waiting List Size (100 vs 25)	.93	(.90-.96)***	.90	(.84-.97)**
	6,659 Transplants 7,798 Still Waiting		1,281 Transplants 1,818 Still Waiting	

\* p <0.05

\*\* p <0.01

\*\*\* p <0.001

<sup>1</sup> Age and blood type held constant by blocking and adjusting for all other variables in the models. Results derived from the models presented in table A-5.

**TABLE B-7**  
**Date Of Registration Of Study Population**

DATE OF REGISTRATION	NUMBER	+
		PERCENT
Before 1986	967	5.4
1/86 - 6/86	506	2.8
7/86 - 12/86	798	4.5
1/87 - 6/87	1,432	8.0
7/87 - 12/87	3,649	20.5
1/88 - 6/88	3,952	22.2
7/88 - 12/88	4,180	23.5
1/89 - 3/89	2,305	13.0
<b>TOTAL</b>	<b>17,789</b>	<b>99.9</b>

# APPENDIX C

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## ENDNOTES

1. On April 2, 1990, the United Network for Organ Sharing reports that there were 20,171 individuals on the organ Procurement and Transplantation Network's national waiting list. This included 16,939 awaiting a transplant for a kidney, 1,572 for a heart, 936 for a liver, 328 for a pancreas, 260 for a heart/lung, and 136 for a lung.
2. In much of the literature in the organ transplantation field, this process is referred to as the "allocation" process rather than the "distribution" process. We use the latter term with the understanding that it is a broader one that addresses not only the factors used in allocating the limited supply of organs to individuals on waiting lists, but also the actual results of that process—that is, the individuals who actually received the donated organs. Given the broad sense in which medical criteria are used to guide the final selection of patients, the distinction between allocation criteria and final results is an important one.
3. Our inquiry focuses on those already on transplant waiting lists, not on those who may be candidates for such lists.

This report follows-up on earlier Office of Inspector General reports concerning the access to organ transplantation and the costs of organ acquisition. These are: (1) "The Access of Foreign Nationals to U.S. Cadaver Organs," August 1986; (2) "The Access of Dialysis Patients to Kidney Transplantation," March 1987; "Organ Acquisition Costs: An Overview," September 1987; and (4) "Kidney Acquisition Costs: A Management Advisory Report," November 1988.

4. Although the data are not available, kidney transplants almost certainly account for an even higher proportion of Federal expenditures for organ acquisition and transplantations. While the Medicare program provides a near universal entitlement for those with kidney failure, it covers expenditures for heart and even more so liver transplants under more restricted conditions. Other types of transplants are still regarded as experimental.
5. In the early 1980s, when heart and liver transplants were still experimental, organ procurement organizations (OPOs) were developing protocols for the various activities associated with kidney donation, procurement (a term which in this report we use interchangeably with "retrieval"), and distribution. As heart and liver transplants have become more common, the OPOs have been increasingly involved in multiple organ recoveries. While the established practices governing kidneys provided the framework for the donation, procurement, and distribution practices governing these other organs, there are, of course, some differences. This is most especially the case with respect to allocation decisions, since the receipt of non-renal organs is more likely to be a life-saving development for the individuals involved (those with kidney failure have access to dialysis and an alternative treatment) and since the allowable preservation time for excised hearts and livers is much less than that for kidneys.

6. The data were made available to us by the United Network for Organ Sharing, the contractor selected by the Public Health Service to help operate the Organ Procurement and Transplantation Network.
7. The four OPOs selected were the Regional Organ Procurement Agency of Southern California, the Shands Hospital at the University of Florida, the University of Wisconsin Hospital, and the Delaware Valley Transplant Program. They account for 13.2 percent of all cadaver kidneys procured in the United States in 1988.
8. Individuals (primarily presidents, but including some executive directors and designated vice-presidents) from the following organizations were interviewed: American Council on Transplantation, Association of Organ Procurement Organizations, North American Transplant Coordinators' Organization, American Society of Transplant Physicians, American Society of Transplant Surgeons, American Society for Histocompatibility and Immunogenetics, American Medical Association, American Hospital Association, United Network for Organ Sharing, American Nurses Association, South-Eastern Organ Procurement Foundation, and the American Association of Kidney Patients. Others interviewed included individuals from PHS and HCFA, congressional staffs, the Institute of Medicine, private consulting firms, and various OPOs, immunological laboratories, transplant centers, and universities.
9. These included published research; newspaper and magazine articles; the Report of the Task Force on Organ Transplantation; testimony from hearings conducted by the House Committee on Science and Technology; legislation and committee reports; reports issued or commissioned by American Council on Transplantation, Government Accounting Office, Congressional Research Service, and the National Institute of Digestive, Diabetes and Kidney Diseases; UNOS articles of incorporation, bylaws, policies, board minutes, publications, committee reports, proposed policies, and letters of comment on current and proposed policies; several OPO distribution protocols; and PHS and HCFA regulations, including the OPTN contract.
10. See U.S. Congress, House of Representatives, Committee on Science and Technology, Hearings before the Subcommittee on Investigations and Oversight, *Organ Transplants*, 98th Congress, 1st Session, April 13, 14, and 27, 1983 and November 7 and 9, 1983.
11. National Organ Transplant Act P.L. No. 98-504, 1984. The Act had five major components: (1) establishment of a national Task Force on Organ Transplantation to examine and report to Congress on the array of issues facing the transplant community; (2) establishment of the Organ Procurement and Transplantation Network (OPTN) to coordinate and regulate the procurement, matching, quality assurance, distribution and transplantation functions of the transplant community; (3) provision for a national scientific registry to collect transplantation data and facilitate evaluation research; (4) authorization of funding for the creation or upgrading of qualified organ procurement organizations; and, (5) prohibition on the sale of human organs.

12. Report of the Task Force on Organ Transplantation, *Organ Transplantation: Issues and Recommendations*, April 1986.
13. The UNOS emerged from the South-Eastern Organ Procurement Foundation (SEOPF). Composed of numerous transplant centers in southeastern and other States, SEOPF was established in the 1970s to facilitate the computerized matching of donors and recipients among the member institutions. In 1976, SEOPF made its computerized matching program available, for a fee, to all transplant centers in the United States that wished to register their patients. This program was called UNOS. In 1984, UNOS was incorporated as an organization separate from SEOPF. See John McDonald, "UNOS and ASHI," *American Society for Histocompatibility and Immunogenetics Quarterly*, Winter 1989, Vol. 13, No. 1, pp. 18-20.
14. The contract requires UNOS to provide the PHS with statistics and reports on the composition of the waiting list and on-transplantation activity.
15. The 1986 legislation was part of the Sixth Omnibus Budget Reconciliation Act of 1986 (P.L. 99-509).

Congress also passed legislation concerning organ transplantation, procurement, and distribution in 1988. That legislation included a number of amendments bearing on the PHS grant program, level of OPO procurement activity, and the workings of the OPTN. In regard to the latter were requirements that the OPTN "establish membership criteria and medical criteria for allocating organs" and carry out studies and demonstration projects "for the purpose of improving procedures for organ procurement and allocation." See the Health Omnibus Program Extension Act of 1988, P.L. 100-607.

16. Under the Social Security amendments of 1972, Congress extended near universal Medicare coverage for dialysis and transplantation services for individuals with end stage renal disease.
17. The authorizing regulations stipulate criteria for covered transplant centers and guidelines for patient selection.
18. Here, too, the proposed regulations stipulate criteria for covered transplant centers and guidelines for patient selection. Medicare already covers liver transplants for Medicare eligible children with biliary atresia. Medicaid, at State government option, also covers liver transplants and thus far has been the major Federal source of funding for liver transplants.
19. UNOS/OPTN, *Facts About Transplantation in the United States*, April 1990.
20. Among the 72 OPOs, 50 are independent and 22 are hospital based. The OPOs perform some or all of the following functions: encouraging organ donation; identifying potential organ donors; obtaining consent from next-of-kin; and overseeing or coordinating the surgical excision of organs, the various laboratory tests associated with transplantation, the

transportation and storage of organs, and, where applicable, the operation of a central register of transplant candidates in the service area.

21. Early estimates, based on HCFA data, suggest that the number of cadaver and living-related kidney transplants for 1989 may actually be lower than in 1986, 1987, or 1988: 8,759 transplants in 1989, compared with 8,931 in 1988, 8,967 in 1987, and 8,976 in 1986. See Alan Hull, "U.S. Donor Procurement in 1989: Same Song, Third Verse," *Nephrology News and Issues*, Vol. 4, No. 3, pp. 32 and 34.
22. Throughout the report, our focus is on organs procured from cadaver rather than living-related donors. The latter accounted for about 20 percent of all kidney transplants in 1988. Such donations are, of course, made with a particular relative designated as the recipient. Donations of cadaver organs by the family of the deceased person cannot be targeted to specific individuals or places.
23. Throughout the report, we often use the term "professional leaders." In so doing, we draw heavily on the views expressed by the individuals we interviewed (see endnote 8) and on the expressions of the Task Force on Organ Transplantation. While the latter, as noted, involved more than professional leaders in the organ transplantation field, it was strongly weighted with and influenced by such leaders.

Further, the expectations we address are basic ones involving general principles. We deliberately focus on them rather than on the more detailed issues about which there are more varied expectations.

24. It should be noted that some individuals might add the expectation that the distribution system enhance the procurement of organs. This certainly is an important goal in relationship to organ transplantation and is often used as a rationale to support particular configurations of the distribution system. We address this issue further in our discussion of the finding concerning the cooperative relationships among transplant professionals.
25. See National Organ Transplant Act, P.L. 98-507, Title II.
26. Senate Report 98-382, p. 13, Labor and Human Resources Committee, April 6, 1984, accompanies Senate bill 2048 which was passed in lieu of House bill 5580. The House Conference Report 98-1127, p. 16, October 2, 1984, accompanies the Senate bill 2048 and reiterates that: "The conferees are particularly concerned that OPOs adopt medical criteria for the equitable allocation of donated organs among transplant centers and patients."
27. See Task Force, p. 89.
28. See the Health Omnibus Program Extension Act of 1988, P.L. 100-607.
29. See Committee on Energy and Commerce, *House Report 100-383*, October 20, 1987, p. 6.
30. See National Organ Transplant Act, P.L. 98-507, Title II.

31. More specifically, those patients who are “highly sensitized” have developed antibodies to many different human leukocyte antigens (HLAs), which are genetically predetermined proteins located on body tissues. The presence of the antibodies increases the chances that the body will reject a transplanted organ. Patients develop antibodies and thus become highly sensitized in a variety of ways—most especially through blood transfusions, through the transplantation and rejection of an organ, and through pregnancies. See Task Force, pp. 66-7, 71.
32. Among participating institutions in the South-Eastern Organ Procurement Foundation, there was a more pronounced operative commitment to formal, collaborative efforts involving many transplant centers.
33. See Task Force, p. 69.
34. Ibid., p. 68.
35. A commonly used measure of sensitivity is a patient’s Panel Reactive Antibody (PRA) level. It is determined by mixing a sample of a transplant candidate’s serum with that of a panel of sera representing the population as a whole. On the basis of that mixing of sera, a candidate is given a PRA number which represents an estimate of percentage of the population against which he/she possesses antibodies and from whom he/she cannot receive a transplanted organ. The higher the PRA number of a candidate, the less likely a donated organ will be an acceptable biological match for that candidate. Thus, a candidate with a PRA of 90 would likely reject 90 of each 100 organs that became available. On the basis of advice from several immunologists, we use a PRA level of 75 or over to define “highly sensitized” and less than 75 as “non-highly sensitized.”
36. HCFA, ESRD Program Management and Medical Information System: November 1989 update. The 23 percent cited is for 1988. Through the 1980s, the annual percentage has remained between 22 and 24. In 1989, with the data 60-70 percent complete, black recipients accounted for 22 percent of all cadaver kidney transplants.
37. UNOS/OPTN, as reported by PHS. The percentage is for 1989.
38. Through this statistical technique we also examined the independent effects of PRA level and transplant center waiting list size, while holding age and blood type constant. Through proportional hazards analysis, we determined that when age and blood type were held constant, blacks on the waiting list were 23 to 31 percent less likely than whites to receive a kidney at any point in time (see appendix B, table B-6).
39. As explained in appendix A, we use the term “registration center” because the OPTN data base we draw upon contains information on individuals registered at either transplant centers or organ procurement organizations.

40. See S. M. Greenstein, et al., "Does Kidney Distribution Based upon HLA Matching Discriminate Against Blacks?", *Transplantation Proceedings*, 21, December 1989, pp. 3874-75. This issue of the journal presents the proceedings of the Second International Samuel L. Kountz Symposium on Renal Disease and Transplantation in Blacks, held on March 28-31, 1989, in Washington, D.C.
41. Council on Ethical and Judicial Affairs, "Black-White Disparities in Health Care," *Journal of the American Medical Association*, 263, No. 17, May 2, 1990, p. 2345. For other articles that address, at least in part, the racial differentials in access to kidney transplantation waiting lists, see Philip J. Held et al., "Access to Kidney Transplantation: Has the United States Eliminated Income and Racial Differences?", *Archives of Internal Medicine*, 148, December 1988, pp. 2594-2600; and Paul Eggers, "Effect of Transplantation on the Medicare End-Stage Renal Disease Program," *New England Journal of Medicine*, 318, pp. 223-229.
42. Council on Ethical and Judicial Affairs, p. 2346.
43. *Ibid.*, p. 2346.
44. U.S. Census Bureau Estimates, July 1, 1988.
45. HCFA, Program Management and Medical Information System: May 1989 update.
46. HCFA, ESRD Program Management and Medical Information System: November 1989 update.
47. For a discussion of factors contributing to the lower rates of donations among blacks, see Callender, C.O., "The Results of Transplantation in Blacks: Just the Tip of the Iceberg," *Transplantation Proceedings*, Vol. 21, No.3, 1989, pp. 3407-10; and McDonald, J.C., "Comment: Issues Related to Race in Transplantation," *Transplantation Proceedings*, Vol. 21, No. 3, 1989, pp. 3411-12.
48. The Division of Organ Transplantation in the Public Health Service indicates that it has received information from an OPO official that there are only about 14 black procurement coordinators working for OPOs.
49. Among non-highly sensitized candidates, we found no significant difference between the median waiting time of males and females (see appendix B, table B-4).
50. Every person in the United States that is on a transplant center waiting list is supposed to be included on the national list. However, as explained later, the great majority of donated organs that become available are not distributed on the basis of this national list.
51. This policy of the OPTN ("mandatory sharing of phenotypically identically matched kidneys") can be found in Section 3.3 of the OPTN by-laws.

52. See UNOS Articles of Incorporation, Policy 3.5.1, May 31, 1988.
53. The proportion of kidneys leaving the OPO service area in which they are procured is somewhat higher than 22 percent because of the distribution arrangements that some transplant centers have with donor hospitals outside the OPO services area in which they (the transplant centers) are located.
54. For further elaboration on these arguments, see Starzl, T., et al., "A Multifactorial System for Equitable Selection of Cadaver Kidney Recipients," *Journal of American Medical Association*, 257, 1984, pp. 3073-5; Congressional Research Service, "Organ Transplantation in the United States: Analysis of Selected Ethical Issues," February 1989; and "Patient Selection Criteria in Organ Transplantation: The Critical Question," *Transplantation Proceedings*, Vol. 21, No. 3, 1989, pp. 3377-3445.
55. There is a wide range in the rate of organ procurement from one OPO to another. In 1988, for 44 of 52 reporting OPOs, the Association of Organ Procurement Organizations (AOPO) found the rate to range from a low of 24 organs per million population to a high of 73. For kidneys alone, the range was from 17 to 49. See Committee Report, "AOPO Data Acquisition: June 1989," pp. 13 and 15.
56. See Report of the Organ Procurement and Distribution Committee to the Board of Directors," Washington, D.C., June 20, 1989.
57. See OPTN, "Statements of Policy: Inter-Organ Procurement Sharing Agreements, Definition of Resident Alien, Exportation of Organs, and Payback System for Shared Kidneys," Undated, p. 8.
58. The letter is from Dr. Robert Kirkman, medical director of the New England Organ Bank.
59. See Evans, R. and Manninen, D., "Public Opinion Concerning Organ Donation, Procurement, and Distribution: Results of a National Probability Sample Survey," *Transplantation Studies*, Battelle Human Affairs Research Centers, Undated. The survey was conducted in January 1987.
60. See *Transplantation Proceedings*, December 1989, particularly the article by Greenstein, et al. In this report, we use the term "medical criteria" in a broad sense that would also encompass biologic criteria. This would appear to be consistent with the National Organ Transplant Act, which does not specifically refer to biologic criteria.
61. A recertification decision is not, of course, simply a matter of whether or not to recertify an OPO. It can involve a decision to grant a conditional recertification, whereby the OPO must develop and have approved a corrective action plan addressing specific concerns raised by HCFA.

62. In 1988, the 42 OPOs responding to the AOPO's survey had an average procurement rate of 34 per million; 4 had a rate below HCFA's minimum of 23 per million. See Committee Report, p. 16.
63. For a useful overview of performance measures and standards, see *MAXIMUS*, "Final Report: Development of Organ Procurement Organization Descriptors, Performance Measures, and Criteria," Prepared for Office of Transplantation, Health Resources and Services Administration, Department of Health and Human Services, May 15, 1986, pp. III-1 to III-13.
64. Council on Ethical and Judicial Affairs, p. 2346.
65. The study data are not clear as to what date "age" of a registrant is correct. Obviously, age changes with waiting time. However, since the range of ages in the study is an order of magnitude greater than the range of waiting times, the ambiguity of age was not deemed important.
66. The original reference is Kaplan, E.L., and P. Meier, "Nonparametric Estimation from Incomplete Observations," *Journal of the American Statistical Association*, 53, 1958, pp. 457-481. A good current summary of the method and subsequent modifications appears in Kalbfleisch, J.D., and R.L. Prentice, *The Statistical Analysis of Failure Time Data*, John Wiley, 1980, pp. 10-16.
67. Brookmeyer, R., and J. Crowley, "A Confidence Interval for the Median Survival Time," *Biometrics*, 38, 1982, pp. 29-41.
68. See Cnaan, A., and L. Ryan, "Survival Analysis in Natural History Studies of Disease," *Statistics in Medicine*, 8, 1989, pp. 1255-1268. The authors also cite some earlier references regarding the adjustment of risk groups. Some of the adjustment methods have their origin in the study of AIDS, "...where the onset time of infection is...frequently unobservable."
69. Note that estimated medians do not behave like arithmetic averages. It is perfectly possible for a group to have an estimated median waiting time of 6 months (for example), and to divide into two subgroups with median waiting times of 3 months and 6 months, respectively.
70. The original reference to proportional hazards is Cox, D.R., "Regression Models and Life Tables," *JRSS-B*, 34, 1972, pp. 187-220. A more recent summary again can be found in Kalbfleisch and Prentice, referenced above. We use the PHGLM computer program written by Frank Harrell for the SAS(TM) system described in F. Harrell, "The PHGLM Procedure," *SUGI Supplemental Library User's Guide*, Version 5, 1986, pp. 437-466.
71. See Cnaan and Ryan.

72. Deviation from strict proportionality was determined by examining "partial residuals" tests as described by F. Harrell (1986), cited above, and Schoenfeld, D., "Partial Residuals for the Proportional Hazards Regression Model," *Biometrika*, 69, 1980, pp. 239-241.

# APPENDIX D

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## ***DETAILED COMMENTS ON THE DRAFT REPORT AND OIG RESPONSE TO THE COMMENTS***

In this appendix we present the full comments of all the parties that responded to the draft report and our brief response to each set of comments. Our response supplements that offered in the final section of the text.

The comments offer a wide range of views and much pertinent information bearing on the issues addressed in our report. We urge the reader to review them carefully. In order, the comments presented in this appendix are from the following:

- The Public Health Service
- The Health Care Financing Administration
- The Assistant Secretary for Planning and Evaluation
- The United Network for Organ Sharing
- The American Society of Transplant Surgeons
- The American Society of Transplant Physicians
- The American Society for Histocompatibility and Immunogenetics
- The Association of Organ Procurement Organizations
- The North American Transplant Coordinators Organization
- The New England Organ Bank
- The South-Eastern Organ Procurement Foundation



# Memorandum

Date . DEC 10 1990

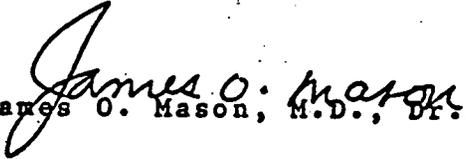
From Assistant Secretary for Health

Subject PHS Comments on OIG Draft Report "The Distribution of Organs for Transplantation: Expectations and Practices" *DEI-01-89-00550*

To Inspector General, OS

Attached are the PHS comments on the subject draft report's findings and recommendations. We concur with all recommendations directed to PHS and have taken or plan to take actions to implement them. Regarding the recommendations whereby PHS is to collaborate with the Health Care Financing Administration (HCFA) in its Medicare recertification of organ procurement organizations, we are prepared to provide information or assistance to HCFA upon request.

In the "general comments" section of the attachment, we express our concern that this report did not sufficiently consider human leukocyte antigen (HLA) matching as a factor contributing to racial disparity in estimated median waiting times for a first kidney transplant. Additionally, we state that the concept of a single, national list of patients awaiting transplantation needs additional study before conclusions can be reached about its utility and comparable effectiveness.

  
James O. Mason, M.D., Dr.P.H.

Attachment

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COMMENTS OF THE PUBLIC HEALTH SERVICE (PHS) ON THE OFFICE  
OF INSPECTOR GENERAL (OIG) DRAFT REPORT "THE DISTRIBUTION OF  
ORGANS FOR TRANSPLANTATION: EXPECTATIONS AND PRACTICES,"  
OEI-01-89-00550, AUGUST 1990.

GENERAL COMMENTS

The OIG draft report states that access of patients to donated organs remains unequal in some important respects. Under the Health Resources and Services Administration's (HRSA) Organ Procurement Transplantation Network (OPTN) contract, the United Network for Organ Sharing (UNOS) is conducting a study of the organ allocation systems. Where disparities are found, the study will explain those differences and, where appropriate, propose measures to eliminate them. This study is scheduled to be completed in July 1991. Additionally, a study of OPTN and Scientific Registry data is currently underway. The study will evaluate the factors that affect waiting time for renal transplantation. This particular study evaluates data for all patients added to the national kidney waiting list since the inception of OPTN to identify the biologic, demographic and Organ Procurement Organization (OPO) related factors that impact time waiting for kidney transplantation. This study will be submitted to the New England Journal of Medicine in early 1991. Further, the Department is developing a Notice of Proposed Rulemaking (NPRM) that will address the waiting list issue and will be subject to public comment.

A concern PHS has with the OIG report is that it appears that the OIG did not sufficiently consider human leukocyte antigen (HLA) matching as a factor contributing to the racial disparity in estimated median waiting times for the first kidney transplant. PHS believes it is a significant variable that should be considered when looking at the black versus white waiting times. Although the degree of antigen matching that positively affects the outcome of a transplant continues to be a matter of much controversy, current UNOS policy requires that the highest priority be given to six antigen matched or phenotypically identical recipients. This policy may place blacks at a disadvantage because in many cases antigens in blacks cannot be identified. Therefore, if one holds the belief that a six antigen match should be given the highest priority for transplantation, then by definition, blacks are at a disadvantage in terms of organ allocation.

A preliminary finding of the study entitled "Factors Affecting Waiting Periods for Renal Transplantations in the United States" (See chart below), is that when ABO blood type, panel reactive antibody sensitization, HLA antigen profiles and recovery rate of organ procurement organizations are controlled for, much of the difference between white and black males disappears. For reasons not yet clear, the difference between white and black females remains about the same.

Median Waiting Times, Per UNOS  
(Months to Transplant)

Black		White	
Male	Female	Male	Female
13.3	16.0+	7.9	9.0

Waiting Times, Adjusted by Variables

Black		White	
Male	Female	Male	Female
12.1	15.1	11.1	9.2

The OIG advocates the use of a single, unified waiting list of patients awaiting transplantation for each OPO. PHS supports this position. The concept of a single national list needs additional study before any conclusions can be reached about its utility and comparable effectiveness. Those who favor local lists suggest several drawbacks to a national list. For example, seeking recipients and transporting organs nationwide results in greater time expenditures which may have an effect on the quality of the organ that is ultimately transplanted.

Specifically, preservation time becomes a critical issue and success rates may be affected with the length of time that elapses before transplantation can occur. Secondly, transporting organs long distances leads to increased costs because in some cases a transplant team has to fly to the site of the donation to procure the organ and then fly back to the site of the recipient to do the transplant. For OPOs, knowing that an organ would not be used locally, but shipped off to some other location in the United States may provide a disincentive to procurement for the benefit of one's patients. This might discourage those OPOs that are high producers because potential recipients in their area may or may not have access to the organs they procured. Similarly, national sharing provides minimal incentive for less successful OPOs to try to step up their efforts as their own procurement rate will have little effect on the allocation of organs to individuals on the waiting list in their service areas. While PHS is concerned about the deviations from the approved allocation system and believes they should be reduced, we are not yet

convinced that implementing a national system is the appropriate solution to this problem.

Finally, the OIG states that blacks are less inclined to donate organs than other groups and points out that in 1988, only about eight percent of all cadaver kidney transplants involved the use of a kidney from a black donor. It further states that of an estimated 300 organ procurement specialists working in the 72 organ procurement organizations, only about 14 are black. PHS believes that any efforts to reduce racial disparities in organ allocation, should include education for potential donors, recruitment of black organ procurement specialists, and training of organ procurement coordinators on how to approach families of differing cultural and ethnic background.

#### OIG RECOMMENDATION

PHS, in collaboration with OPTN, should issue regulations to require that each OPO: (1) establish a single, unified list of patients awaiting transplantation, and (2) distribute donated organs to those patients on a first-come first-served basis, subject to established medical criteria.

#### PHS RESPONSE

We concur.

(1) DHHS is developing regulations for governing OPTN that will address these issues. The proposed regulations will be issued by means of a NPRM. The date of issuance is unknown at this time. Additionally, the OPTN contract requires that a study be conducted of the feasibility of establishing a national waiting list. This study is to be completed in July 1991.

(2) DHHS is exploring including organ distribution and allocation policies as part of the regulations package implementing P.L. 99-509, which requires transplant hospitals to be members of OPTN. The Office of the General Counsel has advised that the Department cannot share the draft proposed regulations with OPTN until they are issued. However, before undertaking revisions to the organ distribution allocation system, PHS will ascertain the effect of HLA matching and other biological factors on waiting times for blacks and whites. Additional qualitative studies will be undertaken if actual disparities are identified.

OIG RECOMMENDATION

PHS, in collaboration with OPTN, should issue regulations to require that each transplant center and donor hospital in an OPO service area adhere to the centralized organ distribution policies of the OPO governing that area.

PHS RESPONSE

We concur. The proposed regulations will address this issue.

OIG RECOMMENDATION

PHS, in collaboration with OPTN, should support the development of medical practice guidelines addressing organ transplantation.

PHS RESPONSE

We concur. Following the development and issuance of the above-referenced regulations, HRSA will initiate discussions with the Agency for Health Care Policy and Research (AHCPR) and the National Institutes of Health (NIH) to determine the feasibility of establishing medical practice guidelines addressing organ transplantation. We expect that OPTN will play an active role in the development of the medical practice guidelines.

AHCPR has awarded a grant for a 3-year research study which will commence during the first quarter of fiscal year 1991. The study will examine the legal, organizational, and health care professional factors which affect the donation process of organs and tissue for transplantation. Characteristics of the donor and donor family that will be studied include age, sex, race, and insurance status. This study should provide useful information that may address some of the questions raised in the OIG report and be of assistance in future guidelines development. It will be conducted in two geographical areas in which there are established "required request laws." The draft report does not comment on the fact that 44 States have now passed a "required request law," which, among other things requires hospitals in those States to develop protocols related to organ and tissue procurement. The study will also provide for structured interviews with health care providers and administrators and will assess various aspects of the donation process of organ and tissue transplantation, including the required request laws, hospital policies, and provider knowledge and attitudes.

OIG RECOMMENDATION

PHS should fund a demonstration effort incorporating the following two features: (1) the establishment of a single, unified waiting list including all patients awaiting an organ transplant in a number of OPO service areas, and (2) the mandatory distribution of donated organs to those patients on a first-come, first-served basis, subject to established medical criteria.

PHS RESPONSE

We concur in principle. HRSA supports the concept of a single, unified waiting list per OPO and an equitable organ transplantation allocation system, and will be proposing these as part of the NPRM.

OIG RECOMMENDATION

HCFA and PHS should support research efforts that could help reduce racial disparities in organ allocation.

PHS RESPONSE

We concur. The OPTN contract has been modified to include the following:

1. A specific monitoring requirement to identify and explain significant variations in waiting times among racial and ethnic groups and to promote measures to eliminate differences that exist.
2. A specific requirement to examine current policies and practices regarding organ recipient selection. Where disparities are found to result from those policies and practices, the contractor is to explain those differences and, where appropriate, propose measures to eliminate them.

Additionally, HCFA is undertaking a study of patient access to transplantation. The study, being conducted by the RAND Corporation will examine how patients are selected for transplantation and why organs are frequently transplanted into patients other than those identified by the UNOS computer as the best matched recipient.

**OIG RECOMMENDATION**

Before granting Medicare recertification to an OPO, HCFA, in collaboration with PHS, should assure that the OPO is:

1. distributing organs equitably among patients, according to established medical criteria, and
2. conducting a rigorous, soundly based organ procurement effort.

**PHS RESPONSE**

We concur. We will provide information or assistance requested by HCFA to support their Medicare recertification decisions regarding OPOs. PHS, through HRSA's Division of Organ Transplantation, periodically meets with UNOS to review the activities and performance of the OPOs. The information and data obtained through this and other means will continue to be made available to HCFA.

Also, HCFA surveyors periodically visit OPOs to evaluate their performance and compliance with OPTN and/or HCFA standards. The proposed regulations that were discussed above will strengthen OPTN's standards especially regarding equitable distribution of organs among patients awaiting transplantation.

TECHNICAL COMMENTS

## 1. Page 6, 3rd paragraph

Include the footnote no. 31 in text to offer an explanation of highly sensitized patients.

## 2. Page 9, last paragraph

Change "registration center" to "transplant hospital" each place it occurs, since "registration center" is not a commonly used term in transplantation discussions.

## 3. Page 13, 1st paragraph

Insert "regional lists, then" after individuals.

## 4. Page 15, 3rd paragraph

Change "keep one-donate one" to "keep one-share one."

## 5. Page 18, Recommendation

Change "donor hospital" to "transplant hospital." It is the transplant hospital and the OPO that make decisions about organ distribution. If the intention here is to get the transplant center or surgeons out of the process of making organ distribution policies, this recommendation may fall short of reaching that goal. Many OPOs are either directed by a transplant surgeon or have a medical/advisory board that sets organ distribution policies. The recommendation that OPOs serve as the "engine of the organ distribution system" will be applauded by the OPO community. Conversely, transplant surgeons/physicians who believe that OPOs have too much control already, will strongly oppose this recommendation.

## 6. Page C-5, Footnote 24

The footnote related to the underlying legitimacy and continued advancement of organ transplantation is vague and should specifically refer to the keep-one share-one concept and the idea that local use encourages procurement efforts. Additionally, the last sentence which refers to variations in the distribution system is incorrect. It is possible to do a computer study to determine whether OPOs with variances (especially a variance that permits keep-one share-one) have better procurement rates. As part of the OPTN contract, UNOS will conduct such study.

7. Page C-7, Footnote 41

The articles in the footnote deal with access to the waiting list, not access to transplantation after getting on the list.

## OIG Response To PHS Comments

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We appreciate PHS' positive response to the report. We particularly appreciate its concurrence with the first two recommendations concerning the single OPO waiting lists. We look forward to the implementing regulations.

On two of the recommendations, we are unclear about the scope of the PHS concurrence. One of these is the recommendation calling for PHS to fund a demonstration effort that applies the single list and first come first served concept to a number of OPO service areas. In response, PHS indicated that it agreed in principle but did not indicate if it would proceed with such a demonstration. Although the NEOB in its comments makes a good point about how the diversity of medical criteria being used may limit the practical effects of such a demonstration, we continue to think, for the reasons put forth in the text, that such a demonstration could provide data quite useful to the further development of organ distribution systems.

The other recommendation is the one to PHS and HCFA calling for research efforts that could help reduce racial disparities in organ allocation. In this sphere, PHS makes no mention of one of the two types of research efforts we called for: those addressing the immunogenetics of blacks. In this regard, we continue to urge, as the American Society Histocompatibility and Immunogenetics noted in its response, that funding be directed "toward improving definition of HLA antigens unique or nearly unique to blacks."

In view of PHS' introductory comments concerning waiting lists, we wish to emphasize that we do not advocate the use of a single national waiting list as the basis for organ allocation. We recognize, as PHS states, that this concept "needs additional study before conclusions can be reached about its utility and comparable effectiveness." Our recommendations focus on the establishment of a single list within each OPO service area that would serve as the basis for organ allocation within that area.

It is in that context that we make our second recommendation calling for donor hospitals and transplant centers to abide by the policies of the OPO. Its intent is not, as PHS suggests in its Technical Comment #5, "to get the transplant center or surgeons out of the process of making organ distribution policies," but rather to assure that the OPO's policies are adhered to by all transplant centers and donor hospitals in its service area. As NEOB notes in its response: "It seems strange to establish OPO territories and OPO/OPTN rules and then allow individual hospitals to act outside of them."

A further clarification, in response to PHS' Technical Comment #2, concerns the term "registration center." We use that term deliberately, in accord with the methodological discussion on pp. A-1 and A-2. As noted there, when a transplant candidate is registered at more than one center, we use the transplant center having the earliest registration date as the focus of analysis.

Finally, with respect to PHS' comment on the importance of HLA matching as a factor contributing to black-white racial disparities, we recognize, as noted in the comments portion of the text, that this is an important consideration and that further inquiry concerning it is needed.



# Memorandum

Date DEC 3 1990

From Gail R. Wilensky, Ph.D. *gw*  
Administrator

Subject OIG Draft Report - "The Distribution of Organs for Transplantation:  
Expectations and Practices", OEI-01-89-00550

To The Inspector General  
Office of the Secretary

We have reviewed the subject report which concerns the distribution of organs, primarily kidneys, from the point of procurement to the point of transplantation.

The report found that there has been improvement in organ distribution practices. However, current practices fall short of providing patients equal access to donated organs. Organ distribution remains heavily controlled by local Organ Procurement Organizations (OPOs), and OPOs and transplant centers impede the national system for distributing organs by acting with a sense of local ownership of organs they have procured. The findings are consistent with those reported in the professional literature on the subject.

In the report, OIG makes the following recommendations:

- o HCFA and PHS should support research efforts that could help reduce racial disparities in organ allocation;
- o HCFA, in collaboration with PHS, should assure that the OPOs are distributing organs equitably among patients, according to established medical criteria; and
- o HCFA, in collaboration with PHS, should assure that the OPO is conducting a rigorous, soundly based organ procurement effort.

HCFA is concerned about the inequity of the current allocation system, and has taken steps within this Agency's purview to remedy the situation. We concur with all of OIG's recommendations. Our specific comments on the report's recommendations are attached for your consideration.

Thank you for the opportunity to review and comment on this draft report. We found the methodology and statistical analyses used in the report to be very reasonable, and the findings to be consistent with HCFA's knowledge of this subject. Please advise us whether you agree with our comments on the report's recommendations at your earliest convenience.

Attachment

Comments of the Health Care Financing Administration (HCFA)  
on the OIG Draft Report - The Distribution of Organs for  
Transplantation: Expectations and Practices  
OEI-01-89-00550

HCFA and PHS Recommendation 1

HCFA and PHS should support research efforts that could help reduce racial disparities in organ allocation.

Response

HCFA concurs with OIG's recommendation. In response to this audit report, HCFA has contracted with the Rand Corporation to complete a study which will address racial disparities in organ allocation. The study was started September 30, 1990 and completion is expected by September 30, 1991.

HCFA and PHS Recommendation 2

Before granting Medicare recertification to an OPO, HCFA, in collaboration with PHS, should assure that the OPO is distributing organs equitably among patients, according to established medical criteria.

Response

HCFA concurs with OIG's recommendation. We plan to publish manual instructions that will require HCFA surveyors of OPOs to determine if organs are distributed equitably among patients. It is anticipated that the revised manual instructions will be issued in early December 1990. The first certification reviews using these manual instructions are scheduled for January 1991.

However, it should be noted that HCFA does not have the authority to set the standards by which organs are distributed. This authority rests with the Organ Procurement and Transplantation Network (OPTN), under the auspices of the Public Health Service. HCFA will enforce the rules regarding the allocation of organs that are established by the OPTN.

HCFA and PHS Recommendation 3

Before granting Medicare recertification to an OPO, HCFA, in collaboration with PHS, should assure that the OPO is conducting a rigorous, soundly based organ procurement effort.

Response

HCFA concurs with this recommendation. Regulations at 42 CFR 485.306 outline the standards by which HCFA surveyors evaluate the procurement efforts of OPOs. If an OPO does not meet the procurement performance standards, HCFA will not recertify the OPO. HCFA believes the standards for procurement currently in effect, are for the most part, appropriate, but will strengthen the enforcement of those requirements. HCFA has received data on organ transplantation from the Public Health Service, and will continue to use this information to make decisions regarding procurement performance standards.

## OIG Response To HCFA Comments

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We are pleased with HCFA's support of our methodological and statistical analysis and of our recommendations. In response, we make two brief points.

First, concerning the recommendation that OPOs distribute organs equitably among patients, we continue to urge that as a part of the process of determining the equity of an OPO's organ allocation processes, HCFA examine the median waiting time in the OPO service area of those on transplant waiting lists and compare the characteristics of those on the lists with those receiving transplants. Although such data alone will not indicate the equity of an OPO's organ allocation efforts, it will contribute to more precise and effective inquiry along that line.

Second, in regard to the recommendation that OPOs conduct rigorous procurement efforts, we understand that various types of performance indicators are now being considered by HCFA. This is a constructive development. It would also be constructive to keep a close look at the number of black transplant coordinators working for OPOs. If the numbers of such coordinators do not increase significantly, the prospects of increasing donations among blacks may be hampered.



RECEIVED  
REGION 1 - OIG/OEI

OCT 12 1990

Washington, D.C. 20201

OCT 19 1990

TO: Richard P. Kusserow  
Inspector General

FROM: Assistant Secretary for  
Planning and Evaluation

SUBJECT: OIG Draft Report: "The Distribution of Organs for  
Transplantation: Expectations and Practices,"  
OEI-01089-00550

I appreciate the opportunity to review this draft report. Because of its sensitive nature, my staff and I have examined it with particular care. Based on that review, while I believe that the report raises substantial numbers of important issues, I am concerned that some of its findings, and the recommendations which flow from them, may be premature.

For example, one of the recommendations is "to require that each OPO (1) establish a single, unified list of patients awaiting transplantation, and (2) distribute donated organs to those patients on a first come first served basis, . . . ." In addition, there is a finding that "While there has been progress, current organ distribution practices fall short of congressional and professional expectations in each of the three areas." The discussion of this shortfall focuses on waiting lists and waiting time.

The inherent difficulty with these conclusions is that, while perhaps appearing eminently equitable on its face, a focus on waiting time with emphasis on "first come, first served" as an allocation principle belies the complexity of the factors that are considered, and should be considered, in the organ allocation process.

Further, there appears to be an underlying assumption in the report that the principle of "first come, first served" as an organ allocation methodology was intended by the Congress. While there is statutory language and legislative history to the effect that transplant patients should be protected by assuring equitable allocation of the limited supply of organs, no specific allocation methodology has been delineated in statute or legislative history.

In fact, the Organ Transplant Amendments of 1988 deleted the statutory requirement that the Organ Procurement and Transplantation Network (OPTN) assist organ procurement organizations (OPO) in the distribution of organs "which cannot

be placed within the service area of the organizations." The stated purpose of the deletion was "to remove any statutory bias respecting the important question of criteria for the proper distribution of organs among patients." (See House Report 100-383, page 7.) The report also states that "The Committee does not wish the statute to be read as establishing a preference [sic] for, or against, distribution within the service area of the OPO." This reflects what I believe Congress' intent to be: first, that there be equitable allocation of organs; second, that extensive work be done to develop appropriate mechanisms to meet the desired goal.

I am also concerned with statements (see, for example, pages 5, 13, 15 and 18) to the effect that the OPTN imposes various requirements on OPOs governing the distribution of organs. This is not the case. Currently, policies developed by the OPTN are being followed voluntarily by OPOs and transplant hospitals. Further, regulations governing organ distribution have not as yet been promulgated by the Secretary. HRSA has, however, convened a workgroup to develop an NPRM on several operational aspects of the OPTN, possibly including regulations directed at organ distribution.

Additional concerns are addressed in the following comments.

1. Equity Issues

- o Disparate Waiting Times: As previously noted, the report places great emphasis on "first come, first served" as a primary criterion for kidney allocation. However, medical criteria are primary. Thus, a finding that disparate waiting times based solely on a "first come, first served" principle are inappropriate or inequitable appears somewhat arbitrary, in light of other considerations which enter the decision to transplant. Many of these are identified in the report. See, for example page 10, where factors such as level of sensitization are discussed.

- o Lower donation rates among blacks have also been associated with lower transplant rates of black-ESRD patients. But it is important to note that blacks seek transplant at a lower rate than do whites (Callender, 1987).

Other waiting time issues are raised for your consideration in the attachment. I urge that these be explored more fully in the report.

- o Single List Per OPO. I agree that the distribution system should provide for equitable allocation of donated organs, and that a single list per OPO may have the potential to improve organ sharing. However, as noted above, the focus on "waiting time" as a primary criterion for transplantation in two of the recommendations and much of the text is inappropriate and premature.

- o Socio-economic Considerations

A number of socio-economic factors may influence the decision to transplant, including an assessment of a patient's ability to comply with rigid post-transplant regimens. This is an area which further exploration should be recommended. "Findings from the National Kidney Dialysis and Kidney Transplantation Study" might be consulted for data in these areas.

Also, there is no discussion of the weight given to age in the transplant decision, and the age at which different racial groups are diagnosed, i.e., as juveniles, young adults, or the elderly. Are younger persons expected to have better outcomes -- longer graft survival -- or less likely to have co-morbid conditions that may contraindicate transplantation, etc.? If younger persons are otherwise not better candidates than older persons, doesn't an organ placed in a younger person nonetheless maximize the benefit derived from that organ simply because it will (statistically) provide many more years of use? Inclusion of data from Eggers' (1988) findings on graft survival would be informative.

Such issues point to the need for additional research to determine the causes of disparities rather than for flatly stated recommendations for particular allocation policies.

- o Medical Criteria. As noted above, medical criteria governing organ allocation have not yet been promulgated by the Secretary, although the OPTN has developed consensus guidelines giving preference to six-antigen matches. Additionally, the brief discussion of level of sensitization (page 12) fails to present the extent to which patients who are highly sensitized are more likely to reject organs. It is our understanding that this is a significant problem and that transplants for highly sensitized patients are

likely not only to subject them to major trauma (initial operation, rejection episodes and medication with major adverse side effects, and operation to remove the rejected organ), but also to lead to wastage (i.e., non-productive use) of scarce organs.

This latter aspect is particularly significant as an equity issue since an organ wasted is an organ unavailable to another patient for whom it might have proven more long lived. (It also eliminates the savings to the Treasury which an earlier IG report documented.) I recommend that the report discuss these matters explicitly and that the finding on sensitized patients be modified to acknowledge prominently the problem of non-productive organ use. An organ not wasted is effectively the same as an additional organ procured.

2. The draft recommends that the PHS require, by regulations, that transplant centers and donor hospitals adhere to distribution policies. The accompanying discussion fails to point out that allocation rules have been under development for several months and they will be published in the near term. Although compliance will be monitored by PHS, the rules will be implemented by HCFA under section 1138 of the Social Security Act. However, until these rules are published, there are no binding distribution policies.
3. In several places (pages 13 and 18) the draft criticizes the right of a transplant center to make arrangements with an OPO in a service area other than the one in which it is located. And, the report recommends that PHS "require that each transplant center . . . in an OPO service area adhere to the centralized organ distribution policies of the OPO governing that area."

The arrangement criticized, however, is specifically allowed in HCFA regulations governing hospital/OPO interactions. Therefore, if any recommendation is to be made it should be couched in terms of HCFA modifying its present policy and regulation.

Such a recommendation, however, is inappropriate because the IG staff have neither recognized, nor balanced, the considerations which led to current HHS policy. The policy implemented in the current HCFA regulations prevents a hospital from being forced to deal exclusively with an inefficient or uncooperative OPO. Further, the policy gives

leverage on OPOs and was specifically designed to make clear that OPOs do not "govern" any areas.

As the draft report elsewhere acknowledges, there are many OPOs whose performance in procuring organs could be improved, and the literature on monopolization makes abundantly clear that airtight monopolies almost without exception have worse performance than systems allowing competition. These facts suggest the strong possibility that the recommendation, if implemented, could have the perverse consequence of reducing organ procurement.

I certainly have no objection to a discussion of this issue provided that the competing considerations are presented fairly. Nonetheless, I do not see how existing evidence could support a strong recommendation to overturn current policy by establishing OPO monopolies.

4. The discussion of the "local ownership" sentiment as it relates to procurement incentives on pages 14 to 16 is generally well balanced. However, my staff is unaware of any statistical analysis of the incentives question having been performed. If none has been, there seems no basis for any conclusion other than that more research should be done to determine whether organ procurement would be weakened if local preferences were reduced (or strengthened if local preferences were increased).

Again, thank you for the opportunity to comment.

  
\_\_\_\_\_  
Martin H. Gerry

Attachments: Editorial Comments  
Waiting List Issues

## Editorial Comments

The "background" should be expanded (at page 3, after the bullets) to state that, per F.R. 51802, Volume 54, No. 241, to date, no rules or requirements binding upon transplant hospitals and organ procurement organizations have been approved or implemented by the Secretary. With that background, care should be taken to describe any forthcoming issuances as "rules and requirements approved by the Secretary." In no instance should the terms "mandatory OPTN policies and/or regulations" be used. This applies to endnotes as well, e.g., "regulate" in note 11 should be changed to "facilitate." See also pages 13 and 15.

Thus, at this time (and throughout the time covered by the IG study), all OPTN policies are voluntary. Whether the transplant community was aware of this HHS distinction or not, the OPTN did no monitoring or compliance activities to assure that members were following the policies. Therefore, the report should be careful to couch references to the OPTN policies and compliance with them in terms that reflect the voluntary nature of compliance.

Page 3, bullets 2 and 4: "regulations" should be changed to "requirements" to conform to statutory and regulatory language. Also, in the penultimate paragraph, next to the last line: "coverage of" should be inserted after "proposing."

Page 4, line one, first word: change "certified" to "designated."

Page 5, under "Expectations," paragraph one, line one: the word "congressional" preceding statutes is redundant. Also, documents developed by the OPTN should be characterized as "policies," not as "regulations."

Page 10, penultimate paragraph: Antigen frequency differences between blacks and whites are often cited as a possible explanation of the differences in transplantation rates. The IG should analyze this variable (which we understand was to be done) to determine whether it is explanatory. Possible explanations of the differential may also include date of entry on list. For instance, do physicians tend to list blacks earlier than whites? Another explanation may be that blacks may have multiple complex medical conditions which tend to militate against receipt of a transplant.

Page 12: The discussion of the common "pool" arrangement should be followed by a sentence pointing out that this may serve important purposes in maintaining high donation rates and that the IG did not explore these in this study.

Page 13: Care should be taken not to link the OPTN's "local use" philosophy with HCFA's OPO designations. To overcome this appearance, the last sentence (after endnote 52) of the penultimate paragraph on page 13 should be deleted. The last sentence on the page (after endnote 53) also should be deleted. The database is only about three years old.

Also, on page 13, two sentences in the second full paragraph should be modified as follows:

"That is no longer the norm. Centers and OPOs have formally stated criteria governing the distribution of organs. OPOs use the national organ center for distributing any organs that they cannot use within their individual service areas."

Pages 13-14: The balanced discussion of tissue matching vs. drug regimens is inconsistent with the recommendation to move to a "single, unified list" per OPO (see Recommendation 1).

Page 14: Omitted from the discussion on organ sharing are State laws that establish priority for intrastate matching.

Page 15, fifth paragraph, line five: insert "excerpt from a" after the word "following."

Page 17: Rewrite the end of paragraph two to state that the OPTN was established "to facilitate organ procurement and transplantation nationally," not as a policy-making and oversight body.

Page A.5: The description of the "quartile" differentiator is not clear. Is the first quartile comprised of the centers with the largest list or the smallest?

Appendices A and B: "Size of Cells." Some tables include the n of the cells. All tables should include this information.

## Waiting List Issues

There are many reasons why reliance on "waiting lists" and/or "first come, first served" as organ allocation principles are unsupportable.

First, there is no definition of "waiting time" which would allow comparison among individuals on the transplant candidate lists, i.e., there is no agreed-upon point in the patient's course of disease when that patient can be entered on the list. Patients may be listed at any time, regardless of health status. Newly diagnosed patients, never dialyzed, and patients who are in extremis may be listed on the same date. The recently concluded Abt study found that over one-third of those on lists for whom a perfectly matched organ was found were medically unsuitable for transplantation, which may imply many people should be removed from current lists. Therefore, currently, "waiting time" is a meaningless measure.

Second, the repeated insistence on "first come, first served" as an ethical principle fails if waiting lists can be "gamed" by physicians and patients. For example, the statistical analysis used in this report found that one percent of all transplants occurred at an earlier date than registration on the waiting list. If length of time on list became a more important allocation factor, thousands of additional unsuitable or premature candidates might be added to preserve a space. This would not only make such lists meaningless, but would also impede organ matching by creating many "false positives" in the very short period of time allowed to match organs. Potentially, if the persons longest on the lists were in fact unsuitable candidates (and the unsuitable would naturally gravitate to the top of the list), almost all of the names at the top of a computer "hit list" would be unsuitable.

Third, "waiting time" is not a surrogate for any medical condition and "first come, first served" is not a compelling ethical principle. Neither should be unduly emphasized as an organ distribution criterion if there are any potential alternatives.

Fourth, in the event that "waiting time" became a significant criterion for organ allocation, ESRD program costs would likely increase significantly. Such an increase would be due to the perceived advantage of being placed on the list early, regardless of health status, and the subsequent need for frequent, relatively expensive, PRA testing.

Therefore, I recommend that consideration be given to developing both a finding and a recommendation on the need to conduct research on lists of potential recipients and on improving their appropriateness for use in allocating organs.

I also recommend that the term "waiting list" be avoided wherever possible and replaced with more neutral and technically correct terms. It is noteworthy in this regard that the law carefully refrains from using the term "waiting list" and instead refers to a "national list of individuals who need organs."

Finally, if the recommendations regarding waiting time are retained in any form, at the least they should be reworded along the following lines:

"Require that each OPO. . . (2) distribute all donated organs to patients based on criteria which maximize productive use of organs and consider arbitrary non-medical factors such as waiting time (if at all) only as tie-breakers between equally qualified potential recipients."

# OIG Response To ASPE Comments

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The ASPE's critical assessment of the report is obviously a fundamental one encompassing many aspects of the study's methodology, findings, and recommendations. Below, we respond to three of the major points.

1. On the first come first served recommendation, we believe, as noted in the comments section of the report, that as expressed, it is fully in accord with congressional expectations. Further, as explained in the text, we do not view it as a straightjacket on OPTN/OPO organ allocation policies. The "medical criteria" provision allows for the specification of exceptions to first come first served, as long as they are formally stated, in accord with HHS/OPTN policies, and based on medical considerations. Such an approach would still allow for much innovation. However, it would not, in our view, allow for "keep one, share one" arrangements and other such exceptions not rooted in medical considerations.
2. We recognize the point of ASPE's comments about the voluntary nature of OPTN policies. After much review, the Department has determined that all OPTN rules lack the force of Federal law because they have not been issued through the Department's formal rule making process. Efforts are now underway to correct this situation. As ASPE notes, regulations will soon be issued that will encompass "several operational aspects of the OPTN."

Accordingly, we have edited the text to minimize any implication that OPTN policies are tantamount to Departmental regulations. At the same time, we recognize that since the establishment of the OPTN, the operational reality among OPTN members has been that OPTN policies are not merely suggestions but rather authoritative expressions of national policy.

3. In its supporting comments on waiting list issues, ASPE indicates that if "'waiting time' became a significant criterion for organ allocation, ESRD program costs would likely increase significantly." This is an important point, one reinforced by ASTP's expressed concerns that some of those on waiting lists might not be "bona fide" transplant candidates, be it for medical, financial, social or other reasons.

We agree that this is an important issue warranting further inquiry. It is an issue we raised in a September 1987 report entitled "Organ Allocation Costs: An Overview." It could help explain the racial inequity we have documented in this report and, because of the ongoing tests conducted on the sera of those on waiting lists, could be adding unnecessarily to program costs.

Finally, we have made a number of edits in response to minor technical points raised by ASPE.

# UNOS

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Richard P. Kusserow  
Inspector General  
Department of Health and Human Services  
Washington, DC 20201

Dear Mr. Kusserow:

OEI-01-89-00550

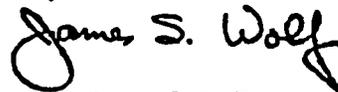
We would like to take the opportunity to comment on the draft report entitled "The Distribution of Organs for Transplantation: Expectations and Practices." UNOS is gratified that your report found "the development of the organ procurement and transplantation network is a significant cooperative achievement of transplant professionals and others. Just as the OPTN has been a constructive factor in the development of a national organ distribution system, so too has it been an important reflection of the readiness of many diverse interests to work together cooperatively."

UNOS, too, is concerned about the difference in waiting times among minority groups and has been conducting an independent study of factors affecting time waiting for kidney patients. The donation rate among blacks was 8% in 1989, but despite that low donation rate, blacks received 21% of all kidney transplants in 1989. We have found that at over a third of the U.S. transplant centers, blacks wait less time than whites to receive a kidney. Thus, the problem described in your report is not universal.

One aspect of your report which we strongly urge you to personally review and change regards statements that lead the reader to believe that your office has found that the difference in waiting time are as a result of racial prejudice. It is unfortunate that the popular press focused on that aspect of the report and even quoted the American Medical Association's Council on Ethical and Judicial Affairs out of context. (The Council's comments about a "subconscious bias" and "racial prejudice" were about medicine in general and were not directed at transplantation as the press seemed to infer from the report.) No evidence supporting a finding of racial bias was presented in the report and indeed we are unaware that any such evidence has been forthcoming. Thus, the inclusion of even a collateral discussion of such a speculative issue may have the unwanted effect of further dampening the enthusiasm of minorities to donate organs. This would be particularly tragic since increased donation among minorities is universally agreed to be greatly needed.

If we can provide your office with any further information to assist you in your study, please do not hesitate to contact our office.

Very truly yours,



James S. Wolf, M.D.  
President

GAP:gm

## OIG Response To UNOS Comments

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As noted in the comments section of the report, we have amended the text to make it clear that we are not claiming that the black-white discrepancies documented are the result of racial prejudice. At the same time, we feel compelled to include at least “subconscious bias” in the inventory of possibly contributing factors. The comments of the AMA’s Council on Ethical and Judicial Affairs would seem to support this decision.

We recognize, as UNOS notes, that the disparity in black-white waiting time is not universal throughout the country and that the degree of the disparity varies across the country. Appendix A provides some data to support these observations.

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September 28, 1990

The Honorable Richard P. Kusserow  
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Dear Mr. Kusserow:

The American Society of Transplant Surgeons (ASTS), welcomes the opportunity to comment on the Draft Document: "The Distribution of Organs for Transplantation: Expectations and Practices". The Draft has been distributed to the Members of the ASTS Council, its elected governing body. The Draft Document will also be the topic of discussion and for active measures at the Annual Fall Meeting of the Council (October, 1990). The following comments represent a consensus opinion of the ASTS Council on the Draft circulated:

The 450 Members of the ASTS perform the majority of solid organ transplants in the United States, and the Society's mission is the advancement of scientific knowledge for the benefit of patients. The Society has been active in providing information to Congress, and several of its Members served on the Organ Transplantation Task Force. Thus, on the one hand, several of the points made in the Document have already been endorsed by the ASTS and its Members, since they coincide with the major goals of the National Transplantation Act of 1984, namely that:

- 1) Each person have equal opportunity to transplantation subject to "established" medical criteria.
- 2) There be uniform policies and standards for organ distribution.
- 3) National cooperative mechanisms be established.

On the other hand, the ASTS decries the implication in the Draft Document that the two-fold longer average waiting time for black versus white renal transplant recipients is due to "subconscious prejudice" by transplant centers and transplant surgeons in particular. The ASTS and its Ethics Committee regard discriminatory practices as cause for expulsion of a Member.

The Draft Document explores possible causes of the differences in racial proportion of patients listed as waiting for a transplant and the patients who actually receive a transplant. The findings that the disparities exist within all blood groups, as well as the subgroups with pre-formed antibodies to less than and greater than 75% of the population, indicates a need to examine demographic and non-demographic factors that could be responsible for imbalance in organ distribution. The ASTS believes that examination of other recognized components of the recipient selection process probably will show the cause for the difference between the demography of the patients listed as waiting, versus the demography of the patients that actually receive transplants. We also contend that prejudice will not be a factor. No conclusions should be drawn until investigations are completed.

We note that the Document compares patients on the waiting list only with those who are "transplanted". Each Transplant Center or Organ Procurement Organization (OPO) has priority criteria approved by the Organ Procurement and Transplantation Network (OPTN) for selecting recipients for a given organ. No comparison was made of the racial demographics of the individuals who are first offered an organ and who accept the offer, versus those who are first offered the transplant and exercise an individual decision to refuse the offer. There also was no information on the racial demographics of the "back-up" patients who are offered an organ after there was either a primary refusal, or the patient initially identified as the prospective recipient could not be given the organ for reasons such as a positive crossmatch or detection of a medical contraindication at the time the offer was made.

Social and economic factors that may prevent patients from accepting offered organs must be examined. It needs to be determined whether there are differences in the racial prevalence of the factors that lead potential recipients to reject the opportunity to receive a transplant.

If the priority distribution schemes approved by the OPTN are being followed, the differences in the demography of the patients initially offered a transplant and the demography of those who are waiting for the transplant would reflect a bias that is not prejudicial in origin, but inherent in algorithms designed to be objective. Most algorithms for priority of organ distribution are at least partially based on HLA matching. Since most donors are white, whites are more likely to have better HLA matches than blacks with a given donor; thus, among potential recipients the proportion of whites first offered a kidney could be greater than the proportion of whites waiting because of the increased probability of having a "good match". Conversely, the proportion of blacks offered a kidney could be less than the proportion of blacks waiting because of the lower likelihood of having a good match. However, no data was given in the Draft Document on the HLA type of the recipients, nor on the racial and HLA demographics of those first offered an organ. Such data is needed. Access in terms of being "offered" a transplant as well as actual "distribution" need to be examined.

Some patients listed as waiting for a kidney, upon receiving an offer, reassess whether to accept the travel and other costs incumbent upon acquiring and maintaining a transplant. Individual differences in trust of the health care system, as well as differences in the perceived difficulty of complying with a medical regimen, may also influence the decision to accept the offered transplant. There may be dissimilarities in the percentage of blacks and whites who decide to accept an organ. Disparities in education and in perception of the transplant process could lead to a higher rate of refusal of the proposed transplant for patients from certain socioeconomic groups, and the proportion of such patients could be higher in the black than in the white population. This hypothesis needs to be critically examined. When a perishable organ is being allocated, such factors as telephone access of the patient, or ability to rapidly come to the Transplant Center, are not trivial considerations.

Although the Draft implies that these factors may not be sufficient to explain the data, the ASTS recommends that the Office of the Inspector General examine the OPTN documentation (Forms A and B) by Transplant Centers, in order to ascertain the proportions of blacks, whites and other races that are first offered the kidneys procured. The frequencies by which the initial patient identified does not receive the transplant should also be determined, as well as the reason (e.g., illness disclosed at time of offer, positive crossmatch, refusal of the offer). The frequency by which patients of different races accept or refuse offered organs, have medical contraindications, or positive crossmatches should be tabulated. Such documentation should be possible, since the information on Forms A and B includes a compilation of telephone calls by organ procurement personnel and the patients' responses to these calls.

The ASTS also points out that existent legislation contains financial disincentives for patients to undergo transplantation, and the impact could be greater in the black than in the white population. The disincentives include:

- 1) Automatic cessation of disability payments three years after successful transplantation. In contrast, payments for dialysis patients continue indefinitely without question and without need to file for special dispensation. The ASTS recommends that the Office of the Inspector General divide the recipients, and the patients on waiting lists, according to a) whether or not they are receiving ongoing disability payments, and b) whether they reside in a state that provides long-term reimbursement for immunosuppressive drugs. The racial proportions in each of these subgroups should be determined.
- 2) Failure of Medicare to provide financial coverage for immunosuppressive drugs after the first posttransplant year. Previous ASTS surveys have documented that most transplant patients have serious problems paying for medications. The ASTS has continuously urged Congress to authorize funds for reimbursement of patients for the costs of anti-rejection therapy.
- 3) Lack of mechanisms to reimburse for multiple miscellaneous expenses incurred by transplantation. For example, expenses for travel back to the Transplant Center for rejection episodes, procedures or routine follow-up visits are not reimbursable. Is there a difference between black and white recipients in regard to the distances that must be traveled, or the ability to pay for travel as well as other expenses, such as baby-sitters, etc.?

The considerations listed above underscore the need to examine transplant waiting lists to ensure that those listed are "*bona fide*" transplant candidates. It is presumed that patients listed are not only medically, but also financially and socially, able to meet the commitments inherent to the transplant process. Documentation that this is so is missing. When a patient (or the dialysis physician) repetitively refuses offered organs, steps should be taken to rectify the situation leading to the refusals, and if this is not possible the patient should be removed from the list. Such a measure would remove imbalances in the first tier of the recipient selection process. The perceived inequities in organ distribution may not be from deficiency in the distribution process *per se*, but related to other factors, medical, financial, or social, that need our attention.

There are also several other issues which require further examination. The study notes that Regions I and VIII (a total of 12 States, a fair number of which

have only small minority populations) do not show any significant waiting time differential between black and white recipients. Unfortunately, the study did not focus on OPOs from either region and does not offer any explanation for this lack of a waiting time differential. Furthermore, the report does not analyze white male : female versus black male : female ratios as accounting for the higher average panel reactive antibody (PRA).

The Document's findings may also be flawed by its use of only a few broad, heterogeneous PRA and age categories for comparison purposes. For example, the Document itself shows (at Table B-2), that some individuals with PRA levels less than 75% (i.e. those with 0-24%) have much higher transplantation rates than other individuals with PRA values less than 75% (i.e. those with 25-49% and 50-74%). If blacks are disproportionately represented in the latter categories, the Document's comparisons of whites and blacks with a PRA less than 75% may be misleading. The Document does not permit the reader to determine whether this might provide a partial explanation of waiting time differences. However, the failure of the statistical proportional hazard model on this data set suggests the parameter is flawed.

The Office of the Inspector General proposes that the second tier of allocation be designed to ensure that the ratio of whites and blacks receiving transplants be the same as those waiting ("racial equity") by having single waiting lists for each OPO. The data in the Draft Document was not analyzed to determine whether there are significant differences in waiting times for the blacks and whites registered at the 30 OPOs serving multiple Transplant Centers with single lists, versus the 13 with multiple, transplant center-based lists. Certainly this already existent data would fulfill the requirement for the "demonstration effort" proposed, and such an analysis should be incorporated into the final Document.

It is also important to point out that single lists *per se* will not ensure racial balance in organ distribution unless other factors believed to improve transplant outcome, such as HLA matching, are ignored. If HLA is to be used as part of the selection criteria, balance in allocation will be achieved only if the proportion of black donors (currently 8%) is increased to approach that of the proportion of blacks waiting for kidneys (currently 31%). The final version of the Inspector General's Document should advise the Secretary of Health and Human Services to initiate programs to increase organ donation rates, particularly in blacks. The ASTS also plans to reintensify efforts to increase the organ donation rates nation-wide.

Programs for organ distribution should be designed to improve the long-term function of transplants in blacks, and not to simply increase the black : white

ratio of recipients over that presently achieved. Specifically, allocation schemes that might decrease the success rate should be avoided. Virtually every paper presented at the "Second International Samuel L. Kountz Symposium on Renal Disease and Blacks" (published in Transplantation Proceedings 21:December, 1989), document an inferior transplant success rate (up to 20% difference), increased mortality, and higher incidence of non-compliance in the black versus other racial groups. The general transplant literature is in accordance with the papers presented at the Symposium. It is essential that the Final Document of the Inspector Generals Report not ignore the biological and other factors that affect transplant outcome. A first-come, first-served organ distribution scheme could produce a result just the opposite of that intended. Furthermore, although perhaps secondary, economics should not be ignored. Medicare, and more specifically, the End Stage Renal Disease (ESRD) program, are an important component of the federal dollar expenditure. Congressman Stark has estimated that a successful transplant saves \$19,000 per year. All schemes designed to ensure equity must include outcome in the equation.

Most current organ allocation algorithms use a combination of matching and waiting time on the list. Any scheme that uses one criterion is just as likely to lead to inequities as one which uses multiple factors. Using waiting time alone as a sole criteria is not without medical concern. For example, a patient on dialysis for several years probably has less chance of rehabilitation than a patient who has never been dialyzed, is entering renal failure, and has only been on the list for one month hoping for a preemptive transplant without dialysis. Similarly, should children who do not grow on dialysis wait for as long as a stable adult dialysis patient? Data is available showing poor neurologic development as well as poor growth for children on dialysis. Finally, there is the difficult situation of a "sensitized" patient who may have received multiple prior transplants and is at increased risk to lose a subsequent graft. There is an equity issue about how many transplants should be given to a single patient when there is such a limited pool of donors. While abandoning allocations based upon HLA tissue matching would improve the access of black patients to organs, a simple mandate to distribute organs based upon time on the waiting list is not equitable to all patients.

Concerns can also be raised about distribution schemes that would result in excessive "shipping" of organs across the United States. Donor and recipient pools are large enough such that allocation of organs within a single OPO should be equitable. Shipping adds to the costs and may reduce organ viability, impairing short-term function and long-term transplant success. Initial transplant nonfunction prolongs hospital stay, thus compromising ability to hospitals to meet financial restrictions of the stipulated payment plan through diagnosis-related groups. The Draft Document brings up the topic of ownership in a way that implies the procurement and transplant processes can be

divorced. It is difficult to see how this can be achieved, or how it would be helpful. In the opinion of the ASTS it would be better for the Final Document to focus on such issues as the impact of prolonged ischemia and transplant dysfunction on the overall success rates of transplantation.

The Document emphasizes the importance of evaluating OPO performance relating to organ procurement activities. The ASTS supports this recommendation. In particular, if OPOs could achieve higher levels of organ retrieval from minority donors, this would improve the chances of obtaining better matched organs for minority transplant candidates. The ASTS believes there is a need to improve local OPO activities, and proposes that review/recertification procedures be strengthened through the following measures:

- 1) Individual OPOs should establish medical criteria for listing patients, as well as review/punishment procedures for violations.
- 2) Each OPO should follow guidelines for distribution of organs based upon racial, matching, time on the list, as well as exceptional medical situations (pediatric, preemptive recipients). The guidelines should be designed so that variances between OPOs are allowed, so as not to stifle innovation while maintaining fairness.
- 3) Quality parameters, in terms of low rates of acute graft dysfunction and/or primary non-function, should be set for each OPO to achieve.
- 4) The Department of Health and Human Services should not only establish performance goals (number of transplantable kidneys retrieved) for local OPOs, but also use them as a basis (together with the above items), for a formal biannual review of OPO activities. Organizations that fail to meet performance or distribution goals should have well-defined, short timeframe plans to correct deficiencies. Procedures must be established to create new OPO structures in regions demonstrating poor OPO function.

**Concluding Statement:**

The ASTS is committed, professionally and ethically, to efficient and equitable use of the national resource of cadaveric donor organs. Indeed, the Society's Ethics Committee is prepared to investigate dereliction in this area. However, we are concerned that the Draft Document did not include other readily available data that could have shown the causes of the apparent racial imbalance in organ distribution. The ASTS recommends that such data be added to the Document and be thoroughly analyzed before conclusions are drawn and before recommendations on organ allocation are formulated. The ASTS also recommends that the Document address the need to alleviate systemic defects in the Medicare and National Transplantation Acts that discourage some patients from accepting transplants for economic reasons, inadvertently resulting in inequitable distribution of organs. The ASTS has and continues to lobby Congress to make changes in both of the Acts that we feel will encourage patients from the lower economic strata to undergo transplantation. In addition, the ASTS is willing to: a) Define medical indices of patient suitability for being placed on transplant waiting lists; b) Develop an allocation scheme that addresses all (racial included) factors that affect organ distribution; and c) Delineate standards to assess OPO activity and performance.

Finally, the ASTS is willing to work with the Office of the Inspector General in both the collection and analysis of the transplant data relative to organ allocation and outcome.

Again, the ASTS appreciates the opportunity to comment on the Draft Document.

Sincerely yours,

David E.R. Sutherland, M.D.  
President, ASTS

## OIG Response To ASTS Comments

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The ASTS makes a number of good points concerning the factors that might contribute to black-white discrepancy in waiting time. Our revised text reflects most of these points. In fact, on the matter of HLA matching and its possible contribution to the discrepancy, our text now includes a direct quotation from the ASTS response.

On page 4 of its response, ASTS raises an extremely important consideration about the suitability of some candidates on transplant waiting lists. As we noted in response to ASPE's comments, we concur that this is an issue warranting further inquiry.

Finally, the ASTS raises important issues concerning the inclusion of expected graft survival time as a factor in allocating organs. Allocation approaches, such as first come first served, that might decrease the success rate should be avoided, it says.

We recognize that factor and accommodate it in our recommendation. The "medical criteria" exclusion provides an opportunity for the OPTN and OPOs to address the factor. In this regard, ASHI's suggestion (page 5 of its response) for a threshold level of matching within a region would seem to warrant careful consideration.

At the same time, we must all recognize that there is a point where reliance on HLA matching in allocating organs could necessitate policy guidance that goes beyond medical considerations, however much matching may extend the graft survival time for the transplant recipients. If such reliance increases and is not accompanied by increasing rates of donations among blacks, the racial disparities noted in this report could increase significantly. Whether an increasing disparity of this kind could or should be accepted would appear to be a societal consideration, calling for guidance from governmental policymakers.

**President:**

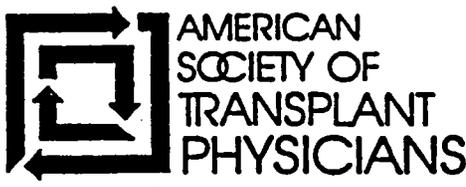
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September 27, 1990

Richard P. Kusserow  
Inspector General  
Department of Health & Human Services  
Washington, DC 20201

Dear Sir:

*OEI-01-89-00550*

I would like to thank you for sending me the draft report entitled "The Distribution of Organs for Transplantation: Expectations and Practices" for my review. I wish to compliment you and your staff for the thoroughness of this report, and to thank you for asking for input from the American Society of Transplant Physicians (ASTP).

The ASTP is in complete agreement with the expectations outlined in your report regarding "the development of organ distribution practices that are equitable to those in need." There are a number of areas in your report which I wish to address, and I would also like to respond to your recommendations to the ASTP, and to inform you of the report which the Patient Care and Education Committee of the ASTP has recently completed. In May of 1988, the Executive Council of the ASTP asked the Patient Care and Education Committee to examine the issue of racial inequality in transplantation. This Committee is chaired by Martin G. White, M.D. of Dallas. Other members of the Committee are Betram L. Kasiske, M.D. (Minneapolis), John F. Neylan, M.D. (Atlanta), Robert R. Riggio, M.D. (New York), Gabriel M. Danovitch, M.D. (Los Angeles), and Lawrence Kahana, M.D. (Tampa). Their 39 page report, titled "The Effect of Race on Access and Outcome in Transplantation", was completed in July of this year and submitted to the New England Journal of Medicine (NEJM) for consideration for publication. The initial review from the NEJM was highly favorable and the reviewers have suggested certain changes in the manuscript. A revised paper has now been resubmitted to the NEJM. The editorial policy of the NEJM prevents me from submitting their report to you until a final decision has been made regarding publication. As soon as an editorial decision has been made by the NEJM, I shall forward the entire manuscript. Essentially, the findings of the Patient Care and Education Committee are in agreement with your report.

The ASTP Executive Committee is in agreement with the finding of the Patient Care and Education Committee on the potential benefits of matching on transplant outcome. For this reason we do not agree with the recommendation to "distribute donated organs to those patients on a first come first served basis" (page 18). This might well have an unfortunate and unintended negative impact on allograft survival in black recipients.

Overall, it would appear that a bigger problem than organ distribution is organ donation. As your report points out, cadaver kidney transplant numbers are levelling off, or even decreasing slightly, while the number of patients waiting on transplant lists continues to grow. If there was no organ shortage, there would be little discussion of distribution. The first priority of all of us concerned about the equitable distribution of this scarce commodity should be to increase organ donation. This could have a major impact in correcting the unequal access of black patients to donated organs, even using the current criteria for distribution. As your report shows, blacks make up 30.8% of those waiting for a first kidney transplant, and only 22.6% of those transplanted. However, "in 1988 only about 8% of all cadaver kidney transplants involved the use of a kidney from a black donor" (page 11). A disconcerting aspect of the report is the fact that "of an estimated 300 organ procurement coordinators working in the 72 organ procurement organizations, only about 14 are black" (page 11). Some years ago we hired a black social worker in our ESRD program. Related donor transplantation, which had previously been negligible in blacks in our program, rose substantially soon after he took on the position. I strongly believe that cadaver organ donation in blacks would increase significantly if black families were approached by black organ procurement coordinators. Therefore, I would like to suggest that the OPO be strongly encouraged to train and hire black transplant coordinators. This effort could be coordinated through NATCO and AOPO.

I trust that my remarks have been of some value to you. I would appreciate hearing your thoughts about this letter and would be very interested in a copy of the final report. Hopefully, in the relatively near future we shall be looking at a far higher rate of organ donation with equitable organ distribution for all concerned; patients awaiting transplants do not have forever and ultimately they are the ones most affected by what we do!

Sincerely yours,



M. Roy First, M.D.

Professor of Internal Medicine

President, American Society of Transplant Physicians

MRF:mcm

## OIG Comments To ASTP Comments

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*The New England Journal of Medicine* article mentioned in the ASTP response was published in the January 31, 1991 issue under the title "The Effect of Race on Access and Outcome in Transplantation." It is an informative piece that as ASTP notes is largely in accord with our findings. However, in our view, it does not incorporate the information presented in our report about the relative lack of influence of blood type on the black-white discrepancy.

We welcomed Dr. First's comments concerning his own experience and views on the hiring of black transplant coordinators and have incorporated his comments into our text, in the section addressing black-white disparities.

Our response to the matters concerning the first come first served rule and the significance of organ donation has already been made—both in the comments section of the text and in prior responses.



# AMERICAN SOCIETY FOR HISTOCOMPATIBILITY AND IMMUNOGENETICS

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September 19, 1990

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Dear Sir:

We have reviewed the draft report "The Distribution of Organs for Transplantation: Expectations and Practices" (referred to hereafter as the report) and appreciate the opportunity to comment on this important document. Organ transplantation, like many areas of medicine, is undergoing a rapid evolution which demands the interaction of experts in multiple disciplines, reflecting different approaches to achieving a common goal. Unlike any other field of medicine, organ transplantation is encumbered with an insufficient supply of the therapeutic agent, donor organs. Before commenting on the content of the OIG report, we believe it is important and appropriate to note the achievements of the OPTN in its four year existence. The most notable of these achievements are:

- establishment of policies and criteria governing professional credentials and medical practices;
- establishment of geographic regions as a basis for interaction among transplant programs;
- achievement of a uniform, high level of quality, nationally, in histocompatibility testing (we are pleased to note that this was achieved through a contractual agreement for ASHI to perform laboratory evaluation for the OPTN);
- establishment of an objective system for distribution of organs which assigns points for waiting time, presensitization and HLA match.

Despite these achievements, several problems persist and have been identified in the report. While we agree with the overall findings of the report, we comment on additional or alternative explanations for and solutions to certain problems.

## **Equitable Access**

If equity in access is defined as distribution of organs to each group of patients according to the proportion of the waiting list they represent, it is clear that equitable access does not exist for several groups examined: Blacks, women patients of blood types O and B, sensitized patients, and children 1-5 years old (as noted in Appendix B of the report). We question the use of median waiting

time as the only statistic to evaluate access of Blacks to transplantation. We note that this statistic leads to a curious anomaly. If one examines the ration of median waiting times for Blacks vs. Whites (as presented in Figure 2, on page 9 of the report) the ratio is greater for all blood types combined than for any single blood type as follows:

<u>Blood Type</u>	<u>Ratio of median waiting time Blacks vs. Whites</u>
A	1.71
B	1.60
AB	1.53
O	1.57
all blood types	1.83

This is difficult to interpret.

In addition, waiting time does not take into account several factors.

1. Organs from a donor who is (HLA) phenotypically identical to a recipient, must be offered to that recipient. The medical benefit, in terms of extended graft survival, has been accepted widely enough that this is a mandatory policy of the OPTN. It is not surprising that when 92% of the donor pool is White, the majority of patients with such matches are also White and that since these matches involve the most common HLA types, these patients would be transplanted more rapidly than others on the waiting list, on the average. Therefore, any analysis of median waiting time should exclude the phenotypically identical matches.
2. As stated in the report, waiting time is proportional to the size of the waiting list. An evaluation of waiting time should investigate the distribution of Blacks according to list size. It is possible that a majority of Blacks are listed with programs at large, urban medical centers with large waiting lists.
3. The report has not investigated the effect of multiple listing. Patients who are listed with multiple programs have access to a larger donor pool than those listed with a single program. Multiply listed patients are those who are aware of the advantage provided by multiple listing and who have the financial resources which permit travel to several institutions. Patient representatives to the OPTN support multiple listing, quite possibly because they are capable of taking this advantage. Nonetheless, an analysis of median waiting time should examine the proportion of Blacks among multiply listed patients.
4. Waiting time is affected by the availability of the patient at the time of donor recovery. Patients who for medical or other reasons are not immediately available for transplantation have their status listed as "inactive" in the computer registry. It should be determined whether there is a difference between Blacks and Whites in the length of time which patients have "inactive" status.

On the other hand, we know that less than the proportion waiting for transplantation. We have noted in testimony to the Institute of Medicine that this disparity can be accounted for, in large part, by the fact that the donor pool, which is predominantly (93%, 1988 UNOS data) White, consists of 39% blood type A donors and 45% blood type O donors while the frequency of A and O blood types among Black patients are 27% and 49% respectively. Furthermore, sensitization to Lewis antigens, which can lead to a positive crossmatch which, in turn, prohibits transplantation, is almost limited to Blacks. Thus, while both median waiting time (MWT) and proportion of transplants reveal diminished access of Blacks, MWT does not provide insight into the causes of the diminished access. We address the issue of HLA matching later. However, we note here that:

1. during the first half of the time period covered in the report, organs were distributed using a point system which gave the highest value to waiting time and that even under the present point system, patients are ranked most often by waiting time, except when extremely good matches occur; and
2. data being prepared for publication by one of our members show that in the experience of one large institution, the percentage of Blacks receiving transplants did not change when kidneys were distributed by waiting time versus under the current UNOS point system which gives more weight to HLA match; more importantly when 6 antigen matches were eliminated, the percentage of Blacks receiving transplants was the same as the percentage of Blacks on the waiting list.

The report raises the possibility of social bias as the cause of inequity in access of Blacks. A more direct way to examine this question is to examine the demographics of patients passed over for transplantation. For each donor, a list is generated in which patients are ranked in descending numerical order according to points assigned for waiting time, sensitization and HLA match. Patients with a positive crossmatch are routinely eliminated from this list and organs are to be offered to the remaining patients according to reasons which are primarily medical. While this system provides an opportunity for abuse, we have no data or anecdotal information which suggests that racial bias affects organ distribution.

With respect to recommendations, we submit that the major factors producing racial disparity in access are known: differences in distribution of ABO and Lewis blood types. Other contributing factors have been noted above and can be readily investigated from existing data. Based on this information, it seems apparent that efforts and funding should be directed primarily toward increasing organ donation among Blacks and secondarily toward improving definition of HLA antigens unique or nearly unique to Blacks.

### **A Single National System**

Although the OPTN has adopted a point system for distribution of kidneys, we believe that it has been a mistake to permit the many variances requested by individual programs. We further support the concept of a single regional list which increases the likelihood of good HLA matches and of finding donors compatible with highly sensitized patients. Regarding concerns about cost of transplantation and increased ischemia time, we note that transportation is a one time cost while the benefits derived from matching extend throughout the life of the graft. Since graft survival time reflects the quality of match it may be reasonable to establish a

matching threshold which predicts a certain level of graft survival. Regional sharing should be mandated for all situations in which the match exceeds that threshold. Increases in ischemia times are avoidable by obtaining and testing donor specimens prior to recovery of organs. We share the dismay of those who believe that organ sharing should be practiced for the benefit of the patients and should not require a payback system. It is true that such a system reflects a sense of ownership on the part of the transplant team or OPO. This is evident from the fact that although there was universal acknowledgement of the benefit, as measured by graft survival, of phenotypically identical transplants, it was not possible to establish a policy of mandatory sharing for these transplants without also establishing the payback system. We note that while there may be no mandate to accord preference to the highly sensitized patient, special protocols and practices must be implemented in order for these patients to be transplanted. To do otherwise would be to condemn these patients to spending years on waiting lists at an appreciable cost to the public.

Finally, we are concerned with the OIG's perception of the role of the OPO. Specifically, we note the statement found on page iii that the OPO should "shape" and oversee distribution policies. We interpret the intent of Congress to be to make the OPTN the organization responsible for developing distribution policies, while the OPO is responsible for assuring adherence to those policies.

It is important to recognize that the unwillingness of many centers to share organs results from many factors, some of which are discussed in the next section. However, one factor has been the lack of fair play on the part of a few centers in which sharing is interpreted as "receiving" only.

### **Cooperation**

We strongly agree with the report's observation that a large, and perhaps inappropriate, level of control lies with the transplant surgeons. In addition to the proportion of the OPTN board of directors which they occupy, transplant surgeons dominate the medical boards of most OPO's; as UNOS regional councillors, surgeons have the opportunity to often, unilaterally, determine regional policies and representation on UNOS committees; and, as directors of transplant programs, surgeons have the opportunity to determine the choices for the single vote afforded to transplant centers for UNOS elections and by-laws/policies approval. This level of authority and/or influence combined with measurement of "success" according to the number of transplant performed, a misconception of many, has resulted in strong opposition to organ sharing. SEOPF has clearly demonstrated that organ sharing is the single most effective way to provide a realistic chance for sensitized patients to be transplanted. Further, because of the extensive diversity of HLA types, organ sharing is the only way to improve the degree of HLA matching. Since the overwhelming majority of phenotypically identical transplants occurred at centers other than that at which the donor was recovered, it is clear that, in the absence of the mandatory sharing policy, these transplants which have far and away the longest average graft survival among cadaveric donor transplants, would not have occurred. It is in establishing and maintaining true cooperation in organ sharing that OPTN has its most serious shortcoming.

## **HLA Matching**

We note that twice in the report, HLA matching is cited as a possible, significant factor contributing to differences in access between Blacks and Whites. Further, the report also notes the current controversy regarding the benefit of HLA matching. We believe it is of utmost importance to clarify this issue. HLA matching is the single major factor affecting graft success that can be manipulated prior to transplantation, unlike immunosuppression, has no major adverse effects, and also unlike immunosuppression, involves a one time cost. The benefits of HLA matching are well documented. Analysis of the UNOS data base, the UCLA Transplant Registry Data base and the International Collaborative Transplant Study data base all clearly show a stepwise increment in graft survival as the degree of HLA matching improves. However, although HLA match is one of the current allocation criteria, at an operational level, patients are effectively ranked almost exclusively by waiting time, with only very well matched patients superseding that. The few hundred HLA phenotypically identical transplants that have been performed certainly cannot account for the disparity in waiting times between Blacks and Caucasians. Nevertheless, an important goal of the transplant community should be to extend the benefits of HLA matching to more individuals. This will require regionalization and specifically, for Black patients will require further elucidation of those HLA antigens found predominately in the Black population. It will also be important to encourage increased organ donation from the Black community.

Many of our members believe that the current controversy is not really about the benefits of HLA matching but rather about sharing. As noted earlier, because of the diversity of the HLA system, it is necessary to share organs, at least at the regional level, to achieve any appreciable numbers of good HLA matches. It is evident that there is a strong reluctance, on the part of many surgeons, to share organs. As we have noted above, the increased benefit of some lesser matches may be insufficient to warrant the cost involved (transportation, etc.). A reasonable compromise is to establish a threshold level of match and to mandate sharing, within a region, for all organs for which a match better than the threshold level is found within the region. The concept of regional sharing has several important benefits. First, it provides the opportunity of multiple listing to all patients. Second, for some patients to have a realistic opportunity for transplantation, they must have an increased access. That is, they must have a larger donor pool available. This is particularly true of the sensitized patient. Regional sharing, when combined with the use of regional crossmatch trays, provides the best opportunity for transplantation of the sensitized patient.

## **Patient Choice**

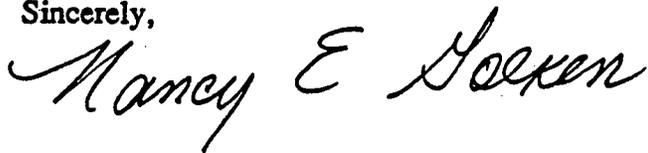
It is of concern that the issue of patient choice is not addressed in any legislation nor in any policies of the OPTN. Implicit in the right choice, is the requirement for patient education. Under the present system, patients do not have a choice about donor selection. The report's analysis of equity in access utilizes waiting time which implies a disadvantage associated with waiting time. However, some patients who are aware of the benefits of HLA matching and of their likelihood of finding a well-matched donor, may elect to wait for such a donor. Others may not. The factors which determine selection of a transplant center are unknown. It is not unreasonable to expect that at least some sensitized patients would choose to be

treated at a center which participates in regional sharing, if they were aware of the increased likelihood of transplantation.

In summary, we find that:

- we agree with the conclusions of the report that
  - some groups of patients have diminished opportunity for transplantation
  - a program of mandated regional sharing should be investigated
  - governance of the transplantation network should involve greater participation by those in non-surgical areas
  
- the basis for the reduced access of Blacks has not been adequately investigated; because median waiting time can be affected by so many variables, we recommend alternative approaches, specifically proportion of transplants
  
- since ABO disparity clearly represents a major barrier to transplantation of Blacks, efforts should be directed at increasing organ donation by Blacks
  
- regional sharing should be mandated for certain HLA matches which extend beyond the present level of mandatory sharing.

Sincerely,

A handwritten signature in cursive script that reads "Nancy E. Goeken". The signature is written in black ink and is positioned below the word "Sincerely,".

Nancy E. Goeken, Ph.D.  
President, ASHI

## OIG Response To ASHI Comments

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The ASHI response is a thoughtful review of many important issues bearing on organ allocation. We have reflected some of their comments in our revised text concerning the black-white disparities and have addressed many of the points in prior responses. We have also referenced some of their comments in some of our previous responses.

One point that we have not addressed is the one that ASHI raises concerning figure 2. It notes that in that figure, which provides the median waiting time for blacks and whites on the basis of blood type, "the ratio is greater for all blood types combined than for any single blood type." It then notes that this result is difficult to interpret.

The explanation is that our data address the median waiting time, not the average waiting time. In converting that data to ratios, as ASHI has done, it is taking a parametric model (averages) and applying it to a nonparametric statistic (medians).

An additional clarification concerns the role of the OPO. In urging that the OPOs "shape and oversee distribution policies in their service areas," we do not intend to imply that they do that independent of OPTN and HHS policies, rules, and guidelines. What we urge is that they, rather than individual transplant centers be the primary, authoritative vehicles for allocating organs in accord with those policies, rules, and guidelines.



November 7, 1990

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*Association*

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*of Organ*

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*Procurement*

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*Organizations*

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President

Ken Richardson  
President

Mary Anne House  
President

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Brian Broznick  
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Regina Workman  
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REGION 1-OIG/OEI

NOV 16 1990

Dear Mr. Kusserow,

On behalf of the Executive Committee of the Association of Organ Procurement Organizations (AOPO), I am pleased to be able to respond to the Draft Document: "The Distribution of Organs for Transplantation: Expectations and Practices." This response represents the consensus of the AOPO's Executive Committee.

The AOPO represents sixty-two of the sixty-nine recognized Organ Procurement Organizations (OPO) in the United States, both independent and hospital based, who are collectively involved in over ninety percent of the solid organ procurements that occur each year. The AOPO's purpose is to expand the public's awareness of, and receptiveness to organ donation. We are committed to promulgating the distribution of transplantable organs in an equitable and expeditious manner as determined by the designated Organ Procurement and Transplantation Network. Lastly, its purpose is to study and evaluate the organizational, administrative and educational methodologies which will lead to the attainment of the above purposes.

First, let me say that AOPO does not at all disagree with the basic findings of the draft document your office has produced. We do agree that there is a significant disparity between the percentage of Black Americans on the transplant waiting lists and the percentage transplanted each year. Secondly, it certainly appears that a Black American waits significantly longer than a White

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Mr. Kusserow  
November 7, 1990  
Page Two

American for a kidney transplant. And, AOPO would concur that these disparities do not seem to be related to either recipient age or blood type. Nonetheless, AOPO feels that this report is far too limited to identify the causes of these very real disparities.

It would seem to us that there are three broad areas that should be studied in much greater detail. First, are there medical-scientific biases - either justified or unjustified - that account for these disparities? Secondly, what part do socio-economic and cultural factors play in the equitable distribution of transplantable organs? Thirdly, AOPO would question whether or not some of the seeming inequity in current practice might arise from local organizational structure rather than from the system as a whole? Certainly Organ Procurement Organizations differ just as regions differ.

AOPO would point out, however, that neither the AOPO nor its members make distribution policy. They carry it out. Policy is determined by the Organ Procurement Transplant Network (OPTN) and the local medical and scientific oversight committees. And, in the final analysis, whether or not a given patient is transplantable with a given donor organ is initially decided by that patient's physician and/or surgeon and eventually in conjunction with the patient. The common thread throughout the algorithm is the transplant physician or surgeon - both at the donor and recipient selection and evaluation, and at the transplantation event.

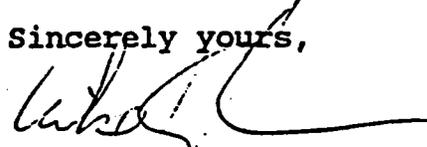
AOPO and its member Organ Procurement Organizations are ready to assist your office in the design and/or performance of any studies deemed appropriate. When root causes for the racial disparity in the distribution of transplantable organs are determined, the AOPO and its members will be happy to assist in the design and implementation of appropriate solutions.

Mr. Kusserow  
November 7, 1990  
Page Three

The AOPPO thanks you for the opportunity to comment on the draft report and would be most happy to provide your office with any further information you require. Our ongoing dedication is to the donor and recipient public and we stand ready to help you assure that they are equitably served.

Thank you.

Sincerely yours,



Mike P. Kaplan, M.D.  
President  
Association of Organ  
Procurement Organizations

MPK/krk

## OIG Response To AOPO Comments

We agree that the report does not identify the causes of the black-white disparity. We have shown that some factors thought to contribute to that disparity (such as blood type) have little or no effect. Beyond that we have simply identified a number of possibly contributing causes and called for more research to examine such causes. Some such research, such as the Rand study mentioned by HCFA, is already underway.

We regret that AOPO was not more supportive of our observation that the OPOs rather than individual transplant centers should be regarded as the engines of the organ distribution system. We recognize, as we noted in our response to ASHI, that allocation policies must be made in accord with OPTN (and HHS) policies. Yet, within that context, OPOs still have a very important role to play in developing and overseeing the particular approaches in their service areas. Indeed, many OPOs and transplant centers have already been quite active and successful in obtaining variances from OPTN policies.

October 1, 1990

**NATCO**  
North  
American  
Transplant  
Coordinators  
Organization

**Richard Kusserow**  
Inspector General  
Office of the Inspector General  
Department of Health and Human Services  
Washington, D.C. 20201

RE: IG Draft Report OEI-01-89-00550

Dear Mr. Kusserow:

Enclosed for your consideration is the response of the North American Transplant Coordinators Organization (NATCO) to the draft report titled, "The Distribution of Organs for Transplantation: Expectations and Practices".

NATCO is the professional society representing organ procurement and clinical transplant coordinators. Our membership totaling 1200 is composed of practitioners from over 300 transplant centers and organ procurement agencies in the United States. Our organization has positively influenced the specialty of organ procurement and transplantation by assuring quality care for organ donors and their families as well as recipients of organ transplants.

We have developed and promoted the recognition of standards of practice, provided professional and public education, encouraged certification (by the American Board of Transplant Coordinators) for practitioners in this specialty and participated in ongoing research to advance immunosuppressive therapies and histocompatibility techniques.

Our proactive involvement in Federal and State government has enabled us to work with professional staff and elected officials to further support our goals. These are defined in our organizational legislative policy statement, which I have enclosed for your review.

In responding to each of the issues addressed in your report, I will follow the format of the report commenting first on the Executive Summary and concluding with the recommendation section.

1) THE REPORT CITES THAT BLACK PATIENTS ARE WAITING TWICE AS LONG AS WHITE PATIENTS FOR FIRST KIDNEY TRANSPLANTATION.

It appears that even when factors such as blood type and age were taken into account, a disparity was still found between the waiting time for black patients and white patients.

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**Immediate Past President**  
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Louisiana Organ Procurement Agency  
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Metairie, LA 70001

**Executive Director**  
Deirdre Gish Panjeda  
Box 15384  
Lenexa, KS 66215

However, we are concerned that histocompatibility factors, specifically HLA matching, were not adequately addressed in your report. 1989 data from the United Network for Organ Sharing (UNOS) indicates that only 8% of U.S. kidney donors were black. This is in sharp contrast with the fact that blacks constituted 22.4% of the kidney transplant recipient population for that same year. It is well known that the HLA antigen pool for blacks differs from that of whites. One reason for the disparity between black and white patients is that it is more difficult to locate HLA compatible kidneys that match black recipients when available kidneys are primarily from white donors. It is our opinion that the issue of antigen matching and donor/recipient pool requires specific analysis and strongly recommend that research in this area be identified as a priority if the disparity between black and white patients is based on purely histocompatibility factors.

## 2) VARIATION IN TIME AWAITING TRANSPLANTATION

The time on a waiting list varies dependent on the transplant center. This occurs for many reasons. Some transplant centers and/or organ procurement organizations (OPO's) simply have longer waiting lists. Thus a patient's chances are reduced as the waiting list increases unless there is an equal ratio of donor kidneys procured in the local area. Herein lies the real issue - the balance between the number of locally procured kidneys, the number of imported kidneys, and the number of patients awaiting transplantation. Clearly, this balance differs from center to center and OPO to OPO and subsequently patient waiting times vary accordingly.

A comparison between waiting times to transplant and the actual transplant does not take into account patients who have declined the transplant or who have not been transplanted because of medical or technical reasons. NATCO recommends closer analysis of existing data to identify accurate information on which to base an assumption.

## 3) IMPACT OF ANTIGEN MATCHING ON WAITING TIME

The rate of locally procured kidneys is higher in some areas than in other areas. Certain transplant centers are able to import more kidneys through regional and national sharing because they have patients listed who have been waiting greater than three (or more) years and thus have a high number of accumulated waiting points giving them priority according to the current UNOS kidney sharing system.

At some centers, both HLA-DR antigens cannot be identified in all patients due to a number of technical and/or medical reasons. Subsequently, patients without complete DR identification will not have the opportunity to receive a specific antigen or phenotypically matched kidney on a national sharing basis. All of these factors influence why patients at some transplant centers wait longer than at other centers for kidney transplantation.

#### 4) HIGHLY SENSITIZED PATIENTS AWAITING TRANSPLANTATION

NATCO agrees that the highly sensitized patient waits much longer for a kidney transplant than other patients. There is no question that this patient is placed at a disadvantage because of their immunological status and thus, may wait for a number of years before a suitably matched donor is found. It is important to note that a large percentage of highly sensitized patients are those who have received a prior kidney transplant and have become "sensitized"; although many patients are sensitized due to pregnancy and blood transfusions.

All sensitized patients experience great difficulty in finding a suitably matched kidney but have a better chance for transplant if their sera is crossmatched with a large pool of donors. Therefore, NATCO supports a system to offer kidneys to these patients from a large pool which affords them the best tissue match.

Also, the issue of equity must be addressed to answer the question of how many kidney transplants should one have access to with such a severe shortage of donor organs.

#### 5) ORGAN PROCUREMENT TRANSPLANT NETWORK (OPTN)

NATCO is committed to furthering the development of the OPTN and a national system for organ sharing. We agree that much work has been done and progress has been made in establishing a national system with uniform policies for the distribution of organs since the creation of the OPTN. The OPTN has increased organ sharing in an orderly manner resulting in more equitable distribution than prior to their formation. It is also true however, that organ distribution is still somewhat controlled on the local level and within the region.

of each OPO. There are some acceptable reasons to maintain limited control at this level:

- a) assuring viable organs because of time constraints with preservation
- b) limiting travel time to prevent wastage of the organ, and
- c) exercising efficient and cost effective processing of transplantable organs

We believe however, that these factors can be taken into account in a consolidated recipient waiting list per designated OPO.

#### 6) ORGAN DISTRIBUTION

There appear to be documented evidence that variances in distribution are based on local scientific studies. Such practices foster community involvement in the organ procurement and transplant process and increase organ donor referral and eventual consent to donate. As there exists differences in opinions as to histocompatibility matching for transplantation, local variances play an important part in selecting patients for transplantation. We support ongoing research to effectively analyze the benefits and risks of histocompatibility matching but realize the importance of a system which takes into account accumulated waiting time.

#### 7) SINGLE UNIFIED WAITING LIST

NATCO endorses the recommendation that there should be movement toward a single unified list for patients awaiting transplantation per each designated OPO service area. In addition to using the criteria of first-come first-served, is important that objective medical criteria be employed to address the urgency of the recipient's need for transplantation as well as histocompatibility factors such as HLA matching and sensitization rates (reactive antibody level).

A point system which includes objective medical criteria as well as the recipients waiting time is important to assure optimum results of the kidney transplant with reasonable expectations of success.

#### 8) RELATIONS WITH DONOR HOSPITALS

NATCO has concerns relating to the recommendation that the Public Health Service should issue regulations requiring each OPO and donor hospital to adhere to required organ distribution arrangements within the designated OPO service area. It is a shared responsibility of the Organ Procurement Organization (OPO), related tissue and eye banks, and the donor hospital to create an open working relationship that fosters organ and tissue donation and distribution.

As critical as this working relationship is, NATCO cautions against the development of any regulations which have the potential to negatively impact on the relationship of the OPOs, related tissue and eye banks and the donor hospitals.

#### 9) RELATIONS WITH TRANSPLANT CENTERS

In the same spirit of fairness, NATCO supports a consistent system which assures equitable distribution following objective medical criteria. As responsibility for organ donation lies with the OPO, tissue and eye banks and donor hospital, responsibility for the transplant opportunity for each patient is shared by the transplant center and OPO and fostered by a similar open working relationship.

#### 10) MEDICAL PRACTICE GUIDELINES

NATCO endorses the development of medical practice guidelines which address organ transplantation. Additional studies and more conclusive findings are needed to assure that policies governing organ sharing are scientifically based and that we continue to provide optimum patient care to those seeking transplantation.

#### 11) DEMONSTRATION PROJECT EVALUATION A REGIONAL DISTRIBUTION SYSTEM

NATCO also supports funding for a demonstration effort which would establish a single, unified waiting list for all patients in a specified number of combined OPO service areas and mandates sharing of organs to those patients on a first-come first-served basis subject to objective medical criteria. Such a project would evaluate the potential of a regional patient driven distribution system as well as assess the cost effectiveness of such a system. Before undertaking an attempt at a national distribution system, a regional system demands further evaluation.

Richard Kusserow  
October 1, 1990  
Page 6

## 12) ORGAN PROCUREMENT ORGANIZATION RESPONSIBILITIES

NATCO recognizes that it is the responsibility of the Organ Procurement Organization to assure equitable distribution of organs and thus supports that this responsibility be a criteria for Medicare recertification. In addition, rigorous and soundly based organ procurement criteria should be designed to measure the procurement efforts of the OPO as well as measure other performance beyond actual recovery of organs which has a direct impact on organ donation (i.e., the development of community outreach programs).

As organ donation and transplantation is a responsibility shared by the medical community, we encourage the professional associations, in particular the American Society of Transplant Surgeons (ASTS) and the American Society of Transplant Physicians (ASTP) to conduct their own analysis of those factors which may lead to longer median waiting times for black patients versus white patients. NATCO would welcome the opportunity to work with these groups in studying these issues.

As NATCO is committed to assuring optimum standards of practice, we appreciate the opportunity to comment on this draft report and look forward to providing additional information to your office as the need arises.

Thank you.

Sincerely,



Barbara A. Ellick, R.N., CCTC/CPTC  
President

## OIG Response To NATCO Comments

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The NATCO's response to our recommendations was generally supportive. We agree that more attention must be given to the influence of HLA matching on the black-white differential and, as previously noted, have modified the text accordingly. We also recognize, as NATCO notes, that there are numerous other factors that might contribute to the situation.

We welcome NATCO's support on our recommendation calling for a single waiting list per OPO service area as the basis for allocation. We fully agree that in accord with the first come first served principle, it is important to use "objective medical criteria" to indicate "the urgency of the recipient's need for transplantation" and to use "histocompatibility factors such as HLA matching and sensitization rates . . ."

On the matter of relationships with donor hospitals, we accept NATCO's caution about issuing regulations that would have a negative impact "on the relationship of the OPOs, related tissue and eye banks and the donor hospitals." Indeed, the intent of our proposed regulation is to foster and protect good working relationships by calling for transplant centers and donor hospitals in an OPO service area to abide by the policies developed by the OPO.



# New England Organ Bank, Inc.

Renew a life

December 27, 1990

Richard P. Kusserow  
Inspector General  
Department of Health and Human Services  
HHS North Building  
330 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Mr. Kusserow:

The New England Organ Bank (NEOB) appreciates the opportunity to comment on the draft report issued by your office, "The Distribution of Organs for Transplantation: Expectations and Practices." 01-89-00550

NEOB is the oldest and largest organ procurement organization in the United States. Founded in 1968, NEOB now serves 11.5 million people, more than 200 hospitals, and 14 transplant centers in the six New England states. Given the number and diversity of institutions we serve, NEOB has had extensive experience dealing with many of the logistical, political and scientific issues analyzed in the report. While we are generally supportive of the intent of the recommendations, equitable access for all in need of a transplant, we do not agree with some of the methods proposed to achieve this. Our concerns are based around three general issues:

- Although, (as quoted on page 7 of the report) the 1986 Task Force on Organ Transplantation noted that transplantation had developed sufficiently to "allow for the establishment of certain standards of practice," we believe their conclusion was somewhat premature. Transplantation continues to be a rapidly evolving clinical field which is still categorized by diverse protocols and practices. Within limits, it is essential to encourage this diversity if we are to continue to progress. However, legitimate scientific disagreements should not be allowed to obscure the issue of equal access.

- While an absolutely uniform national system is appealing, it is more realistic and practical to organize at a regional level. This provides sufficient scale of activity while minimizing logistical problems.

- Any system of organ distribution should focus on the outcome, i.e., equal access. There will be more than one legitimate way of achieving that end. A national system should encourage multiple models in order to assess which proves to be most effective.

More specifically, we would offer the following thoughts on the report's recommendations.

Recommendation # 1 - "The PHS, in collaboration with the OPTN, should issue regulations to require that each OPO (1) establish a single, unified list of patients awaiting transplantation and (2) distribute organs to these patients on a first come first served basis, subject to established medical criteria."

Comments:

- It is not reasonable to assume that "established medical criteria" have been agreed upon by the transplant community or that they could be in the immediate future. There are legitimate scientific disagreements on issues such as HLA matching, prioritization of highly sensitized patients, etc. While it is inappropriate to allow any surgeon or transplant center to decide these issues unilaterally, it is equally unreasonable to suggest that there is only one correct answer for all the nation. Instead we would suggest that equal access can best be assured by requiring that each region of the country establish an objective process for distribution, which is evenly applied to all waiting in the region. This system would have to be prospectively justified and should then be under the scrutiny of all the transplant centers in the region, the OPO(s), and a national body such as UNOS. In addition, complete and timely sharing of data should be required so that periodic retrospective analysis may be performed. This would allow comparisons among the regions.

- Some proposals suggest the establishment of OPO-wide lists rather than region-wide lists. This is acceptable if the OPO encompasses a sufficient number of transplant centers to assure patient equity. If this option is adopted, it must be accompanied by rules preventing the proliferation of OPOs and encouraging consolidation of existing ones. The alternative will be the creation of new, one or two transplant center OPO's to avoid impact of a shared list.

Recommendation # 2 - "The PHS, in collaboration with the OPTN, should issue regulations to require that each transplant center and donor hospital in an OPO service area adhere to the centralized organ distribution policies of the OPO governing that area."

Comments:

- Such regulations are appropriate. It seems strange to establish OPO territories and OPO/OPTN rules and then allow individual hospitals to act outside of them.
- Such regulations will need to be accompanied by compliance monitoring and reasonable penalties for violations. Current sanctions, (e.g., denial of all Medicare and Medicaid payments), are so severe that they are never invoked.

Recommendation # 3 - " The PHS, in collaboration with the OPTN, should support the development of medical practice guidelines addressing organ transplantation."

Comment:

It will be difficult to develop guidelines given the disagreements within the transplant community on appropriate methods of selecting potential recipients, matching organs to recipients, and protocols for post-transplant patient care. It may be possible for all transplant centers within a regional OPO to agree on a general set of medical criteria, but national consensus is unlikely. Whatever is developed must have sufficient flexibility to allow for the uniqueness of each patient. Unfortunately, guidelines which are developed in a regulatory framework frequently become absolute rules when implemented.

Recommendation # 4 - " The PHS should fund a demonstration effort incorporating the following two features: (1) the establishment of a single, unified waiting list including all patients awaiting an organ transplant in a number of OPO service areas and (2) mandatory distribution of donated organs to those patients on a first come first served basis, subject to established medical criteria."

Comment:

Such a study, while desirable, is likely to be impractical given the lack of agreement on what constitutes "established medical criteria." (See comments above), and political concerns of adjacent OPO's. However, it might be more practical to study organ allocation at those larger OPO's which already have unified lists and include a large number of transplant centers. This would also allow examination of different sets of "established medical criteria" which have been implemented in different regions of the country. Given the existing

Richard P. Kusserow

December 27, 1990

Page 4

diversity of approaches to organ distribution, it would seem the structure is already in place to determine which methods have proven effective in achieving the goal of equal access. Once again, we stress the plural nature of the answer based on our belief that there will be more than one "right" way.

Recommendation # 5 - " The HCFA and the PHS should support research efforts that could help reduce racial disparities in organ allocation."

Comment:

We strongly support this recommendation. It is critical to determine if the apparent disparities in waiting times are truly related to inherent clinical issues, discriminatory behavior (intentional or unintentional), or a combination of factors. Given the apparent disparity among regions (e.g. no difference in waiting time NEOB's region but varying levels of difference in most others) this is obvious a complex issue. For example, is there a significant difference between the experience at single-transplant center OPO's versus those that serve many transplant centers? Is there a difference between those OPO's that already have a single unified list and those that still allocate among each individual center's list? These data already exist, could be analyzed further now, and the results included in the final version of the report.

Finally, NEOB would be pleased to work with the Office of the Inspector General in collecting and analyzing data, as well as the testing of any proposals.

We look forward to conversations with you and/or members of your staff concerning these important issues.

Sincerely yours,

  
Richard S. Luskin  
Executive Director

## OIG Response To NEOB Comments

We recognize the importance of NEOB's caution on the danger of seeking premature consensus on medical practice guidelines concerning organ transplantation. Yet, there is an extensive body of information which has been developed which, it appears, could be drawn upon to provide some authoritative framework for guiding (not prescribing) medical practice in this area. If the medical criteria exception serves as the only legitimate basis for deviating from the first come first served rule, such a framework would seem to be especially important. The matter of determining a threshold level of match, as suggested by ASHI, might be one particular to focus on in this regard.

We also recognize the limitation that NEOB notes concerning the relevance of a demonstration project concerning the use of the first come first served concept. Yet, as we note in the text, such an effort can provide some useful data and can help us gain a better understanding of the costs and benefits of allocating organs from larger donor pools. If two or more adjacent OPOs are ready to participate, we think such a demonstration warrants the effort.



# South-Eastern Organ Procurement Foundation

January 22, 1991

*R. Randal Bollinger, M.D., President*  
*Patricia Adams, M.D., Vice President*  
*Michael Rehr, M.D., Treasurer*  
*James J. Wynn, M.D., Secretary*  
*William LeFor, Ph.D., Past President*

*Thomas A. Armata, Executive Director*

The Honorable Richard P. Kusserow  
Inspector General  
Department of Health and Human Services  
HHS North Building  
330 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Mr. Kusserow:

The South-Eastern Organ Procurement Foundation (SEOPF) wishes to comment on the Draft Document: "The Distribution of Organs for Transplantation: Expectations and Practices". SEOPF has been an important contributor for more than 20 years to the science of transplantation including the use of histocompatibility matching as a basis for organ distribution (bibliography attached). Several issues concerning the equitable distribution of organs for transplantation raised in your Draft can be addressed by scientific organizations such as SEOPF. These issues have sparked some controversy and a considerable debate within our organization. The observation that blacks wait longer than whites, the finding that women wait longer than men, the focus upon short-term rather than long-term results, the role of histocompatibility testing and the availability of particular patients for transplantation when an organ comes available are examples of important questions discussed with the committees of SEOPF. Data from a SEOPF Member Organ Procurement Agency indicate that black patients are more often unavailable for an identified donor organ than whites ( $p < 0.01$ ). SEOPF believes that additional data collection and analysis will be important to a correct interpretation of the findings in your Draft Document. The SEOPF Scientific Projects and Publications Committee is undertaking studies of center effects and the access of minorities to cadaver donor kidneys for transplantation. We expect that the results of these SEOPF research studies will be helpful to you and the entire transplant community in our effort to understand the reasons for differential access of particular patient groups to cadaver organs for transplantation. SEOPF appreciates the opportunity to comment on the Draft Document and looks forward to sharing the results of its research with you later this year.

Sincerely yours,



R. Randal Bollinger, M.D., Ph.D.  
President, SEOPF

RRB:lc

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## OIG Response To SEOPF Comments

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We are pleased that SEPOF has been examining many of the issues raised in our report and that its Scientific Projects and Publications Committee is devoting particular attention to the access of minorities to cadaver kidney transplantation. SEOPF and its member institutions bring much expertise to such inquiry. We look forward to the results.



## **HLA Matching**

We note that twice in the report, HLA matching is cited as a possible, significant factor contributing to differences in access between Blacks and Whites. Further, the report also notes the current controversy regarding the benefit of HLA matching. We believe it is of utmost importance to clarify this issue. HLA matching is the single major factor affecting graft success that can be manipulated prior to transplantation, unlike immunosuppression, has no major adverse effects, and also unlike immunosuppression, involves a one time cost. The benefits of HLA matching are well documented. Analysis of the UNOS data base, the UCLA Transplant Registry Data base and the International Collaborative Transplant Study data base all clearly show a stepwise increment in graft survival as the degree of HLA matching improves. However, although HLA match is one of the current allocation criteria, at an operational level, patients are effectively ranked almost exclusively by waiting time, with only very well matched patients superseding that. The few hundred HLA phenotypically identical transplants that have been performed certainly cannot account for the disparity in waiting times between Blacks and Caucasians. Nevertheless, an important goal of the transplant community should be to extend the benefits of HLA matching to more individuals. This will require regionalization and specifically, for Black patients will require further elucidation of those HLA antigens found predominately in the Black population. It will also be important to encourage increased organ donation from the Black community.

Many of our members believe that the current controversy is not really about the benefits of HLA matching but rather about sharing. As noted earlier, because of the diversity of the HLA system, it is necessary to share organs, at least at the regional level, to achieve any appreciable numbers of good HLA matches. It is evident that there is a strong reluctance, on the part of many surgeons, to share organs. As we have noted above, the increased benefit of some lesser matches may be insufficient to warrant the cost involved (transportation, etc.). A reasonable compromise is to establish a threshold level of match and to mandate sharing, within a region, for all organs for which a match better than the threshold level is found within the region. The concept of regional sharing has several important benefits. First, it provides the opportunity of multiple listing to all patients. Second, for some patients to have a realistic opportunity for transplantation, they must have an increased access. That is, they must have a larger donor pool available. This is particularly true of the sensitized patient. Regional sharing, when combined with the use of regional crossmatch trays, provides the best opportunity for transplantation of the sensitized patient.

## **Patient Choice**

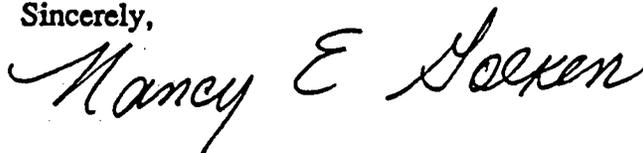
It is of concern that the issue of patient choice is not addressed in any legislation nor in any policies of the OPTN. Implicit in the right choice, is the requirement for patient education. Under the present system, patients do not have a choice about donor selection. The report's analysis of equity in access utilizes waiting time which implies a disadvantage associated with waiting time. However, some patients who are aware of the benefits of HLA matching and of their likelihood of finding a well-matched donor, may elect to wait for such a donor. Others may not. The factors which determine selection of a transplant center are unknown. It is not unreasonable to expect that at least some sensitized patients would choose to be

treated at a center which participates in regional sharing, if they were aware of the increased likelihood of transplantation.

In summary, we find that:

- we agree with the conclusions of the report that
  - some groups of patients have diminished opportunity for transplantation
  - a program of mandated regional sharing should be investigated
  - governance of the transplantation network should involve greater participation by those in non-surgical areas
  
- the basis for the reduced access of Blacks has not been adequately investigated; because median waiting time can be affected by so many variables, we recommend alternative approaches, specifically proportion of transplants
  
- since ABO disparity clearly represents a major barrier to transplantation of Blacks, efforts should be directed at increasing organ donation by Blacks
  
- regional sharing should be mandated for certain HLA matches which extend beyond the present level of mandatory sharing.

Sincerely,

A handwritten signature in cursive script that reads "Nancy E Goeken".

Nancy E. Goeken, Ph.D.  
President, ASHI

## OIG Response To ASHI Comments

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The ASHI response is a thoughtful review of many important issues bearing on organ allocation. We have reflected some of their comments in our revised text concerning the black-white disparities and have addressed many of the points in prior responses. We have also referenced some of their comments in some of our previous responses.

One point that we have not addressed is the one that ASHI raises concerning figure 2. It notes that in that figure, which provides the median waiting time for blacks and whites on the basis of blood type, “the ratio is greater for all blood types combined than for any single blood type.” It then notes that this result is difficult to interpret.

The explanation is that our data address the median waiting time, not the average waiting time. In converting that data to ratios, as ASHI has done, it is taking a parametric model (averages) and applying it to a nonparametric statistic (medians).

An additional clarification concerns the role of the OPO. In urging that the OPOs “shape and oversee distribution policies in their service areas,” we do not intend to imply that they do that independent of OPTN and HHS policies, rules, and guidelines. What we urge is that they, rather than individual transplant centers be the primary, authoritative vehicles for allocating organs in accord with those policies, rules, and guidelines.



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## Association

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## of Organ

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## Procurement

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## Organizations

Mike Kaplan, M.D.  
President

Ken Richardson  
President

Mary Anne House  
President

James Nolan  
President

Brian Broznick  
President

Regina Workman  
President

November 7, 1990

The Honorable Richard P. Kusserow  
Inspector General  
Department of Health and Human Services  
HHS North Building  
330 Independence Avenue, S.W.  
Washington, D.C. 20201

RECEIVED  
REGION 1 - OIG/OEI  
NOV 16 1990

Dear Mr. Kusserow,

On behalf of the Executive Committee of the Association of Organ Procurement Organizations (AOPO), I am pleased to be able to respond to the Draft Document: "The Distribution of Organs for Transplantation: Expectations and Practices." This response represents the consensus of the AOPO's Executive Committee.

The AOPO represents sixty-two of the sixty-nine recognized Organ Procurement Organizations (OPO) in the United States, both independent and hospital based, who are collectively involved in over ninety percent of the solid organ procurements that occur each year. The AOPO's purpose is to expand the public's awareness of, and receptiveness to organ donation. We are committed to promulgating the distribution of transplantable organs in an equitable and expeditious manner as determined by the designated Organ Procurement and Transplantation Network. Lastly, its purpose is to study and evaluate the organizational, administrative and educational methodologies which will lead to the attainment of the above purposes.

First, let me say that AOPO does not at all disagree with the basic findings of the draft document your office has produced. We do agree that there is a significant disparity between the percentage of Black Americans on the transplant waiting lists and the percentage transplanted each year. Secondly, it certainly appears that a Black American waits significantly longer than a White

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1714 Hayes Street  
Nashville, TN 37203  
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(615) 329-2513 (Fax)

Mr. Kusserow  
November 7, 1990  
Page Two

American for a kidney transplant. And, AOPO would concur that these disparities do not seem to be related to either recipient age or blood type. Nonetheless, AOPO feels that this report is far too limited to identify the causes of these very real disparities.

It would seem to us that there are three broad areas that should be studied in much greater detail. First, are there medical-scientific biases - either justified or unjustified - that account for these disparities? Secondly, what part do socio-economic and cultural factors play in the equitable distribution of transplantable organs? Thirdly, AOPO would question whether or not some of the seeming inequity in current practice might arise from local organizational structure rather than from the system as a whole? Certainly Organ Procurement Organizations differ just as regions differ.

AOPO would point out, however, that neither the AOPO nor its members make distribution policy. They carry it out. Policy is determined by the Organ Procurement Transplant Network (OPTN) and the local medical and scientific oversight committees. And, in the final analysis, whether or not a given patient is transplantable with a given donor organ is initially decided by that patient's physician and/or surgeon and eventually in conjunction with the patient. The common thread throughout the algorithm is the transplant physician or surgeon - both at the donor and recipient selection and evaluation, and at the transplantation event.

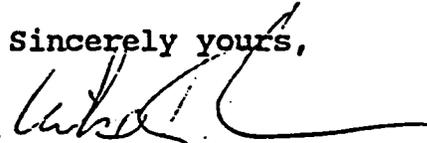
AOPO and its member Organ Procurement Organizations are ready to assist your office in the design and/or performance of any studies deemed appropriate. When root causes for the racial disparity in the distribution of transplantable organs are determined, the AOPO and its members will be happy to assist in the design and implementation of appropriate solutions.

Mr. Kusserow  
November 7, 1990  
Page Three

The AOPO thanks you for the opportunity to comment on the draft report and would be most happy to provide your office with any further information you require. Our ongoing dedication is to the donor and recipient public and we stand ready to help you assure that they are equitably served.

Thank you.

Sincerely yours,



Mike P. Kaplan, M.D.  
President  
Association of Organ  
Procurement Organizations

MPK/krk

## OIG Response To AOPO Comments

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We agree that the report does not identify the causes of the black-white disparity. We have shown that some factors thought to contribute to that disparity (such as blood type) have little or no effect. Beyond that we have simply identified a number of possibly contributing causes and called for more research to examine such causes. Some such research, such as the Rand study mentioned by HCFA, is already underway.

We regret that AOPO was not more supportive of our observation that the OPOs rather than individual transplant centers should be regarded as the engines of the organ distribution system. We recognize, as we noted in our response to ASHI, that allocation policies must be made in accord with OPTN (and HHS) policies. Yet, within that context, OPOs still have a very important role to play in developing and overseeing the particular approaches in their service areas. Indeed, many OPOs and transplant centers have already been quite active and successful in obtaining variances from OPTN policies.

October 1, 1990

**NATCO**  
North  
American  
Transplant  
Coordinators  
Organization

**Richard Kusserow**  
Inspector General  
Office of the Inspector General  
Department of Health and Human Services  
Washington, D.C. 20201

RE: IG Draft Report OEI-01-89-00550

Dear Mr. Kusserow:

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Barbara A. Etck  
University of Minnesota Hospitals  
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**Executive Director**  
Deidre Gish Panjeda  
Box 15384  
Lenexa, KS 66215

Enclosed for your consideration is the response of the North American Transplant Coordinators Organization (NATCO) to the draft report titled, "The Distribution of Organs for Transplantation: Expectations and Practices".

NATCO is the professional society representing organ procurement and clinical transplant coordinators. Our membership totaling 1200 is composed of practitioners from over 300 transplant centers and organ procurement agencies in the United States. Our organization has positively influenced the specialty of organ procurement and transplantation by assuring quality care for organ donors and their families as well as recipients of organ transplants.

We have developed and promoted the recognition of standards of practice, provided professional and public education, encouraged certification (by the American Board of Transplant Coordinators) for practitioners in this specialty and participated in ongoing research to advance immunosuppressive therapies and histocompatibility techniques.

Our proactive involvement in Federal and State government has enabled us to work with professional staff and elected officials to further support our goals. These are defined in our organizational legislative policy statement, which I have enclosed for your review.

In responding to each of the issues addressed in your report, I will follow the format of the report commenting first on the Executive Summary and concluding with the recommendation section.

1) THE REPORT CITES THAT BLACK PATIENTS ARE WAITING TWICE AS LONG AS WHITE PATIENTS FOR FIRST KIDNEY TRANSPLANTATION.

It appears that even when factors such as blood type and age were taken into account, a disparity was still found between the waiting time for black patients and white patients.

P.O. Box 15384 • Lenexa, KS 66215 • 913/492-3600

However, we are concerned that histocompatibility factors, specifically HLA matching, were not adequately addressed in your report. 1989 data from the United Network for Organ Sharing (UNOS) indicates that only 8% of U.S. kidney donors were black. This is in sharp contrast with the fact that blacks constituted 22.4% of the kidney transplant recipient population for that same year. It is well known that the HLA antigen pool for blacks differs from that of whites. One reason for the disparity between black and white patients is that it is more difficult to locate HLA compatible kidneys that match black recipients when available kidneys are primarily from white donors. It is our opinion that the issue of antigen matching and donor/recipient pool requires specific analysis and strongly recommend that research in this area be identified as a priority if the disparity between black and white patients is based on purely histocompatibility factors.

## 2) VARIATION IN TIME AWAITING TRANSPLANTATION

The time on a waiting list varies dependent on the transplant center. This occurs for many reasons. Some transplant centers and/or organ procurement organizations (OPO's) simply have longer waiting lists. Thus a patient's chances are reduced as the waiting list increases unless there is an equal ratio of donor kidneys procured in the local area. Herein lies the real issue - the balance between the number of locally procured kidneys, the number of imported kidneys, and the number of patients awaiting transplantation. Clearly, this balance differs from center to center and OPO to OPO and subsequently patient waiting times vary accordingly.

A comparison between waiting times to transplant and the actual transplant does not take into account patients who have declined the transplant or who have not been transplanted because of medical or technical reasons. NATCO recommends closer analysis of existing data to identify accurate information on which to base an assumption.

## 3) IMPACT OF ANTIGEN MATCHING ON WAITING TIME

The rate of locally procured kidneys is higher in some areas than in other areas. Certain transplant centers are able to import more kidneys through regional and national sharing because they have patients listed who have been waiting greater than three (or more) years and thus have a high number of accumulated waiting points giving them priority according to the current UNOS kidney sharing system.

At some centers, both HLA-DR antigens cannot be identified in all patients due to a number of technical and/or medical reasons. Subsequently, patients without complete DR identification will not have the opportunity to receive a sensitized antigen or phenotypically matched kidney on a national sharing basis. All of these factors influence why patients at some transplant centers wait longer than at other centers for kidney transplantation.

#### 4) HIGHLY SENSITIZED PATIENTS AWAITING TRANSPLANTATION

NATCO agrees that the highly sensitized patient waits much longer for a kidney transplant than other patients. There is no question that this patient is placed at a disadvantage because of their immunological status and thus, may wait for a number of years before a suitably matched donor is found. It is important to note that a large percentage of highly sensitized patients are those who have received a prior kidney transplant and have become "sensitized"; although many patients are sensitized due to pregnancy and blood transfusions.

All sensitized patients experience great difficulty in finding a suitably matched kidney but have a better chance for transplant if their sera is crossmatched with a large pool of donors. Therefore, NATCO supports a system to offer kidneys to these patients from a large pool which affords them the best tissue match.

Also, the issue of equity must be addressed to answer the question of how many kidney transplants should one have access to with such a severe shortage of donor organs.

#### 5) ORGAN PROCUREMENT TRANSPLANT NETWORK (OPTN)

NATCO is committed to furthering the development of the OPTN and a national system for organ sharing. We agree that much work has been done and progress has been made in establishing a national system with uniform policies for the distribution of organs since the creation of the OPTN. The OPTN has increased organ sharing in an orderly manner resulting in more equitable distribution than prior to their formation. It is also true however, that organ distribution is still somewhat controlled on the local level and within the region.

of each OPO. There are some acceptable reasons to maintain limited control at this level:

- a) assuring viable organs because of time constraints with preservation
- b) limiting travel time to prevent wastage of the organ, and
- c) exercising efficient and cost effective processing of transplantable organs

We believe however, that these factors can be taken into account in a consolidated recipient waiting list per designated OPO.

#### 6) ORGAN DISTRIBUTION

There appear to be documented evidence that variances in distribution are based on local scientific studies. Such practices foster community involvement in the organ procurement and transplant process and increase organ donor referral and eventual consent to donate. As there exists differences in opinions as to histocompatibility matching for transplantation, local variances play an important part in selecting patients for transplantation. We support ongoing research to effectively analyze the benefits and risks of histocompatibility matching but realize the importance of a system which takes into account accumulated waiting time.

#### 7) SINGLE UNIFIED WAITING LIST

NATCO endorses the recommendation that there should be movement toward a single unified list for patients awaiting transplantation per each designated OPO service area. In addition to using the criteria of first-come first-served, it is important that objective medical criteria be employed to address the urgency of the recipient's need for transplantation as well as histocompatibility factors such as HLA matching and sensitization rates (reactive antibody level).

A point system which includes objective medical criteria as well as the recipients waiting time is important to assure optimum results of the kidney transplant with reasonable expectations of success.

#### 8) RELATIONS WITH DONOR HOSPITALS

NATCO has concerns relating to the recommendation that the Public Health Service should issue regulations requiring each OPO and donor hospital to adhere to required organ distribution arrangements within the designated OPO service area. It is a shared responsibility of the Organ Procurement Organization (OPO), related tissue and eye banks, and the donor hospital to create an open working relationship that fosters organ and tissue donation and distribution.

As critical as this working relationship is, NATCO cautions against the development of any regulations which have the potential to negatively impact on the relationship of the OPOs, related tissue and eye banks and the donor hospitals.

#### 9) RELATIONS WITH TRANSPLANT CENTERS

In the same spirit of fairness, NATCO supports a consistent system which assures equitable distribution following objective medical criteria. As responsibility for organ donation lies with the OPO, tissue and eye banks and donor hospital, responsibility for the transplant opportunity for each patient is shared by the transplant center and OPO and fostered by a similar open working relationship.

#### 10) MEDICAL PRACTICE GUIDELINES

NATCO endorses the development of medical practice guidelines which address organ transplantation. Additional studies and more conclusive findings are needed to assure that policies governing organ sharing are scientifically based and that we continue to provide optimum patient care to those seeking transplantation.

#### 11) DEMONSTRATION PROJECT EVALUATION A REGIONAL DISTRIBUTION SYSTEM

NATCO also supports funding for a demonstration effort which would establish a single, unified waiting list for all patients in a specified number of combined OPO service areas and mandates sharing of organs to those patients on a first-come first-served basis subject to objective medical criteria. Such a project would evaluate the potential of a regional patient driven distribution system as well as assess the cost effectiveness of such a system. Before undertaking an attempt at a national distribution system, a regional system demands further evaluation.

Richard Kusserow  
October 1, 1990  
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## 12) ORGAN PROCUREMENT ORGANIZATION RESPONSIBILITIES

NATCO recognizes that it is the responsibility of the Organ Procurement Organization to assure equitable distribution of organs and thus supports that this responsibility be a criteria for Medicare recertification. In addition, rigorous and soundly based organ procurement criteria should be designed to measure the procurement efforts of the OPO as well as measure other performance beyond actual recovery of organs which has a direct impact on organ donation (i.e., the development of community outreach programs).

As organ donation and transplantation is a responsibility shared by the medical community, we encourage the professional associations, in particular the American Society of Transplant Surgeons (ASTS) and the American Society of Transplant Physicians (ASTP) to conduct their own analysis of those factors which may lead to longer median waiting times for black patients versus white patients. NATCO would welcome the opportunity to work with these groups in studying these issues.

As NATCO is committed to assuring optimum standards of practice, we appreciate the opportunity to comment on this draft report and look forward to providing additional information to your office as the need arises.

Thank you.

Sincerely,



Barbara A. Ellick, R.N., CCTC/CPTC  
President

## OIG Response To NATCO Comments

The NATCO's response to our recommendations was generally supportive. We agree that more attention must be given to the influence of HLA matching on the black-white differential and, as previously noted, have modified the text accordingly. We also recognize, as NATCO notes, that there are numerous other factors that might contribute to the situation.

We welcome NATCO's support on our recommendation calling for a single waiting list per OPO service area as the basis for allocation. We fully agree that in accord with the first come first served principle, it is important to use "objective medical criteria" to indicate "the urgency of the recipient's need for transplantation" and to use "histocompatibility factors such as HLA matching and sensitization rates . . ."

On the matter of relationships with donor hospitals, we accept NATCO's caution about issuing regulations that would have a negative impact "on the relationship of the OPOs, related tissue and eye banks and the donor hospitals." Indeed, the intent of our proposed regulation is to foster and protect good working relationships by calling for transplant centers and donor hospitals in an OPO service area to abide by the policies developed by the OPO.



# New England Organ Bank, Inc.

Renew a life

December 27, 1990

Richard P. Kusserow  
Inspector General  
Department of Health and Human Services  
HHS North Building  
330 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Mr. Kusserow:

The New England Organ Bank (NEOB) appreciates the opportunity to comment on the draft report issued by your office, "The Distribution of Organs for Transplantation: Expectations and Practices." *01-89-00550*

NEOB is the oldest and largest organ procurement organization in the United States. Founded in 1968, NEOB now serves 11.5 million people, more than 200 hospitals, and 14 transplant centers in the six New England states. Given the number and diversity of institutions we serve, NEOB has had extensive experience dealing with many of the logistical, political and scientific issues analyzed in the report. While we are generally supportive of the intent of the recommendations, equitable access for all in need of a transplant, we do not agree with some of the methods proposed to achieve this. Our concerns are based around three general issues:

- Although, (as quoted on page 7 of the report) the 1986 Task Force on Organ Transplantation noted that transplantation had developed sufficiently to "allow for the establishment of certain standards of practice," we believe their conclusion was somewhat premature. Transplantation continues to be a rapidly evolving clinical field which is still categorized by diverse protocols and practices. Within limits, it is essential to encourage this diversity if we are to continue to progress. However, legitimate scientific disagreements should not be allowed to obscure the issue of equal access.

- While an absolutely uniform national system is appealing, it is more realistic and practical to organize at a regional level. This provides sufficient scale of activity while minimizing logistical problems.

- Any system of organ distribution should focus on the outcome, i.e., equal access. There will be more than one legitimate way of achieving that end. A national system should encourage multiple models in order to assess which proves to be most effective.

More specifically, we would offer the following thoughts on the report's recommendations.

Recommendation # 1 - "The PHS, in collaboration with the OPTN, should issue regulations to require that each OPO (1) establish a single, unified list of patients awaiting transplantation and (2) distribute organs to these patients on a first come first served basis, subject to established medical criteria."

**Comments:**

- It is not reasonable to assume that "established medical criteria" have been agreed upon by the transplant community or that they could be in the immediate future. There are legitimate scientific disagreements on issues such as HLA matching, prioritization of highly sensitized patients, etc. While it is inappropriate to allow any surgeon or transplant center to decide these issues unilaterally, it is equally unreasonable to suggest that there is only one correct answer for all the nation. Instead we would suggest that equal access can best be assured by requiring that each region of the country establish an objective process for distribution, which is evenly applied to all waiting in the region. This system would have to be prospectively justified and should then be under the scrutiny of all the transplant centers in the region, the OPO(s), and a national body such as UNOS. In addition, complete and timely sharing of data should be required so that periodic retrospective analysis may be performed. This would allow comparisons among the regions.

- Some proposals suggest the establishment of OPO-wide lists rather than region-wide lists. This is acceptable if the OPO encompasses a sufficient number of transplant centers to assure patient equity. If this option is adopted, it must be accompanied by rules preventing the proliferation of OPOs and encouraging consolidation of existing ones. The alternative will be the creation of new, one or two transplant center OPO's to avoid impact of a shared list.

Recommendation # 2 - "The PHS, in collaboration with the OPTN, should issue regulations to require that each transplant center and donor hospital in an OPO service area adhere to the centralized organ distribution policies of the OPO governing that area."

Comments:

- Such regulations are appropriate. It seems strange to establish OPO territories and OPO/OPTN rules and then allow individual hospitals to act outside of them.
- Such regulations will need to be accompanied by compliance monitoring and reasonable penalties for violations. Current sanctions, (e.g., denial of all Medicare and Medicaid payments), are so severe that they are never invoked.

Recommendation # 3 - " The PHS, in collaboration with the OPTN, should support the development of medical practice guidelines addressing organ transplantation."

Comment:

It will be difficult to develop guidelines given the disagreements within the transplant community on appropriate methods of selecting potential recipients, matching organs to recipients, and protocols for post-transplant patient care. It may be possible for all transplant centers within a regional OPO to agree on a general set of medical criteria, but national consensus is unlikely. Whatever is developed must have sufficient flexibility to allow for the uniqueness of each patient. Unfortunately, guidelines which are developed in a regulatory framework frequently become absolute rules when implemented.

Recommendation # 4 - " The PHS should fund a demonstration effort incorporating the following two features: (1) the establishment of a single, unified waiting list including all patients awaiting an organ transplant in a number of OPO service areas and (2) mandatory distribution of donated organs to those patients on a first come first served basis, subject to established medical criteria."

Comment:

Such a study, while desirable, is likely to be impractical given the lack of agreement on what constitutes "established medical criteria." (See comments above), and political concerns of adjacent OPO's. However, it might be more practical to study organ allocation at those larger OPO's which already have unified lists and include a large number of transplant centers. This would also allow examination of different sets of "established medical criteria" which have been implemented in different regions of the country. Given the existing

Richard P. Kusserow

December 27, 1990

Page 4

diversity of approaches to organ distribution, it would seem the structure is already in place to determine which methods have proven effective in achieving the goal of equal access. Once again, we stress the plural nature of the answer based on our belief that there will be more than one "right" way.

Recommendation # 5 - " The HCFA and the PHS should support research efforts that could help reduce racial disparities in organ allocation."

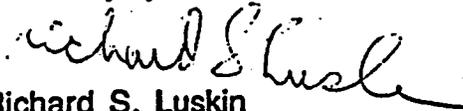
Comment:

We strongly support this recommendation. It is critical to determine if the apparent disparities in waiting times are truly related to inherent clinical issues, discriminatory behavior (intentional or unintentional), or a combination of factors. Given the apparent disparity among regions (e.g. no difference in waiting time NEOB's region but varying levels of difference in most others) this is obvious a complex issue. For example, is there a significant difference between the experience at single-transplant center OPO's versus those that serve many transplant centers? Is there a difference between those OPO's that already have a single unified list and those that still allocate among each individual center's list? These data already exist, could be analyzed further now, and the results included in the final version of the report.

Finally, NEOB would be pleased to work with the Office of the Inspector General in collecting and analyzing data, as well as the testing of any proposals.

We look forward to conversations with you and/or members of your staff concerning these important issues.

Sincerely yours,



Richard S. Luskin  
Executive Director

## OIG Response To NEOB Comments

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We recognize the importance of NEOB's caution on the danger of seeking premature consensus on medical practice guidelines concerning organ transplantation. Yet, there is an extensive body of information which has been developed which, it appears, could be drawn upon to provide some authoritative framework for guiding (not prescribing) medical practice in this area. If the medical criteria exception serves as the only legitimate basis for deviating from the first come first served rule, such a framework would seem to be especially important. The matter of determining a threshold level of match, as suggested by ASHI, might be one particular to focus on in this regard.

We also recognize the limitation that NEOB notes concerning the relevance of a demonstration project concerning the use of the first come first served concept. Yet, as we note in the text, such an effort can provide some useful data and can help us gain a better understanding of the costs and benefits of allocating organs from larger donor pools. If two or more adjacent OPOs are ready to participate, we think such a demonstration warrants the effort.



South-Eastern organ procurement foundation

January 22, 1991

R. Randal Bollinger, M.D., President  
Patricia Adams, M.D., Vice President  
Michael Rohr, M.D., Treasurer  
James J. Wynn, M.D., Secretary  
William LeFer, Ph.D., Past President

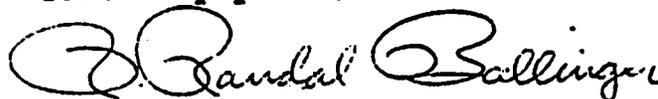
Thomas A. Armata, Executive Director

The Honorable Richard P. Kusserow  
Inspector General  
Department of Health and Human Services  
HHS North Building  
330 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Mr. Kusserow:

The South-Eastern Organ Procurement Foundation (SEOPF) wishes to comment on the Draft Document: "The Distribution of Organs for Transplantation: Expectations and Practices". SEOPF has been an important contributor for more than 20 years to the science of transplantation including the use of histocompatibility matching as a basis for organ distribution (bibliography attached). Several issues concerning the equitable distribution of organs for transplantation raised in your Draft can be addressed by scientific organizations such as SEOPF. These issues have sparked some controversy and a considerable debate within our organization. The observation that blacks wait longer than whites, the finding that women wait longer than men, the focus upon short-term rather than long-term results, the role of histocompatibility testing and the availability of particular patients for transplantation when an organ comes available are examples of important questions discussed with the committees of SEOPF. Data from a SEOPF Member Organ Procurement Agency indicate that black patients are more often unavailable for an identified donor organ than whites ( $p < 0.01$ ). SEOPF believes that additional data collection and analysis will be important to a correct interpretation of these findings in your Draft Document. The SEOPF Scientific Projects and Publications Committee is undertaking studies of center effects and the access of minorities to cadaver donor kidneys for transplantation. We expect that the results of these SEOPF research studies will be helpful to you and the entire transplant community in our effort to understand the reasons for differential access of particular patient groups to cadaver organs for transplantation. SEOPF appreciates the opportunity to comment on the Draft Document and looks forward to sharing the results of its research with you later this year.

Sincerely yours,



R. Randal Bollinger, M.D., Ph.D.  
President, SEOPF

RRB:lc

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## OIG Response To SEOPF Comments

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We are pleased that SEPOF has been examining many of the issues raised in our report and that its Scientific Projects and Publications Committee is devoting particular attention to the access of minorities to cadaver kidney transplantation. SEOPF and its member institutions bring much expertise to such inquiry. We look forward to the results.

