

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**ORGAN PROCUREMENT ORGANIZATIONS
AND TISSUE RECOVERY**



JUNE GIBBS BROWN
Inspector General

MAY 1994
OEI-01-91-00250

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EXECUTIVE SUMMARY

PURPOSE

To describe and assess the role of organ procurement organizations in procuring tissue for transplantation, and to identify vulnerabilities associated with that involvement.

BACKGROUND

Human tissue grafts, from perhaps 10,000 donors, benefit as many as a half-million people annually. The great majority of these transplanted tissues are bones, bone products, or other parts of the musculo-skeletal system, such as tendons, fascia, and soft tissues. Consequently, we focus this inspection report on bone and musculo-skeletal tissue, and we use the term "tissue" to refer to these.

In December 1993, the Food and Drug Administration (FDA) regulated tissue banking for the first time by requiring testing for infectious disease, donor screening, and record keeping. New York, Florida, and California now regulate tissue banking at the State level.

Organ procurement organizations (OPOs) are responsible for recovering organs from donors. The National Organ Transplant Act requires that OPOs must also "have arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to assure that all useable tissues are obtained from potential donors." While OPOs see organ procurement as their primary function, to the extent that statutory expectations for tissue recovery are not met, opportunities for donating and using tissues are lost.

This inspection report focuses on the supply of tissues and the role of the OPOs in procuring tissue. The Public Health Service (PHS) estimates that 125 bone banks in the United States recover, process, and/or distribute bone for transplantation.

Federal law requires that OPOs have arrangements with tissue banks for tissue procurement. How well they perform this role can have a significant bearing on recovering a sufficient supply of high quality tissue for transplantation. The OPOs already are involved in tissue banking by virtue of their involvement in organ procurement. As much as 60 percent of bone tissue used for transplantation comes from donors of solid organs.

We conducted a mail survey of all Medicare-certified OPOs, with a response rate of 95 percent; interviewed staff from 15 OPOs by telephone; made site visits to four OPOs, as well as tissue banks and hospitals in their service areas; interviewed Federal officials from PHS and the Health Care Financing Administration (HCFA) and staff from relevant associations; conducted a focus group with directors of five tissue banks; and reviewed pertinent Federal reports, legislation, and literature.

FINDINGS

All 62 OPOs responding to our survey participate in tissue recovery to some degree.

- Thirty-four OPOs refer potential donors to tissue banks.
- Twenty-eight OPOs recover tissue themselves.

The OPOs' commitment to tissue recovery varies widely. Performance data show that they have not taken full advantage of opportunities to obtain tissue from potential donors.

As part of our review, we developed three performance indicators to measure the OPOs' involvement in tissue recovery:

Organ Donors Referred to Tissue Banks: For the 34 OPOs that refer potential tissue donors to tissue banks, we measured the percentage of organ donors who were referred for tissue donation. This performance indicator assesses the degree to which an OPO actually refers its organ donors for tissue donation.

- *Three of these OPOs reported that they referred all of their organ donors for tissue recovery. At the other extreme, 2 OPOs reported that they referred fewer than 20 percent of organ donors for tissue donation.*

Organ Donors Providing Tissues: For the 28 OPOs that recover tissue, we measured the percentage of organ donors from whom they recovered both organs and tissues. This performance indicator assesses the emphasis that an OPO gives to organ donors as a source of tissue.

- *The percentage of organ donors from whom these OPOs recovered both organs and tissue ranged from a high of 43 percent to a low of 6 percent.*

Ratio of Tissue Donors to Organ Donors: For the 28 OPOs that recover tissue, we measured the ratio of tissue donors to organ donors. This performance indicator assesses the attention that an OPO places on nonorgan donors as a source of tissue.

- *Three of these OPOs reported more than 150 tissue donors for every 100 organ donors. At the other extreme, 3 OPOs procured tissue from fewer than 20 tissue donors for every 100 organ donors.*

Tensions exist between organ procurement and tissue recovery. If these tensions intensify, they could have adverse consequences for the supply of tissues and of organs.

- Inherent differences between organ procurement and tissue recovery (in urgency, prestige, and organization) can limit OPOs' and tissue banks' willingness to work together.
- Competition for donors among multiple tissue banks could threaten hospitals' eagerness to work with OPOs and tissue banks.

Some OPOs and tissue banks have developed effective practices to improve organ and tissue donation.

- Some OPOs and tissue banks are working together to facilitate communication and cooperation. These efforts include a central telephone system to receive all donor referrals and written agreements specifying referral arrangements among OPOs and tissue banks.
- Some OPOs have established programs under which hospitals routinely refer all deaths to the OPO to increase the number of donor referrals.

RECOMMENDATIONS

Our recommendations arise from the statutory requirement that OPOs "have arrangements to cooperate with tissue banks for the retrieval of tissues to assure that all useable tissues are obtained from potential donors." Little national attention has focused on this mandate. The relationship between tissue banks and organ procurement organizations can have a significant impact on overall OPO performance.

The PHS should provide some general oversight and guidance for OPOs regarding their arrangements with tissue banks and their tissue recovery activity.

We encourage PHS to collect routine data about OPO involvement with tissue recovery. The agency could also disseminate information about effective OPO tissue banking practices to improve donation. In addition, we urge PHS to keep a watchful eye on tensions between OPOs and tissue banking to determine if these tensions are jeopardizing the supply of tissues and organs.

The HCFA should include an assessment of OPOs' performance in tissue recovery as part of the OPO recertification process.

The HCFA could utilize performance indicators to assess how well OPOs are meeting the requirement that they have arrangements to cooperate with tissue banks. We recognize that recertification focuses on an OPO's performance with respect to organ procurement and distribution. We believe that some measure of accountability for OPO performance in tissue recovery is also warranted.

COMMENTS

Within the Department of Health and Human Services, we received comments on the draft report from PHS, HCFA, and the Assistant Secretary for Planning and Evaluation (ASPE). We also received comments from the United Network for Organ Sharing (UNOS), the American Association of Tissue Banks (AATB), and the Association of Organ Procurement Organizations (AOPO). Overall, the comments share three major points:

Additional resources would be needed for PHS to provide general oversight and guidance.

The PHS concurs with our recommendation that the agency provide some general oversight and guidance for OPOs regarding their arrangements with tissue banks and their tissue recovery activity. That agency, AATB, and UNOS indicate, however, that additional resources would be needed to implement this recommendation, and ASPE calls it infeasible at this time. We are aware that funding for new initiatives is limited, but we believe that PHS could begin providing general oversight and guidance without incurring extensive new expenditures and without imposing a major reporting burden on agencies or tissue banks. Existing reporting systems can be revised incrementally to obtain these data with a minimum of expense and effort. We would be pleased to work with PHS toward this end.

The specific performance indicators we developed may not be adequate to evaluate OPOs' performance in tissue recovery.

The AATB finds our performance indicators to be reliable indicators of the strength of OPO commitment to tissue recovery from cadaveric donors, but HCFA, ASPE, and AOPO question their adequacy. We developed these indicators from readily available data, but we are confident that other indicators also would show wide variation in OPO performance. We are not wedded to these or other particular performance indicators. Rather, we offer them as a starting point in deliberations to develop performance indicators for OPOs and tissue banking. We encourage HCFA and PHS to collaborate either to modify these indicators or to develop other indicators that will begin to hold OPOs accountable for their activities with regard to tissue recovery.

Including an assessment of OPO performance in tissue recovery as part of the Medicare recertification process is not feasible at present.

Both HCFA and ASPE identify regulatory barriers to including an assessment of OPO performance in tissue recovery as part of OPO Medicare recertification processes. The HCFA notes that such an effort is a long-term initiative, which must be preceded by data collection and development of appropriate and valid performance indicators. We believe that the long lead time that HCFA requires makes a compelling case for initiating this activity soon. Collecting necessary data and developing more refined performance indicators are a precondition for this assessment. Consequently, we urge HCFA to establish an appropriate schedule to carry out such a proposal.

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INTRODUCTION

PURPOSE

To describe and assess the role of organ procurement organizations in procuring tissue for transplantation, and to identify vulnerabilities associated with that involvement.

BACKGROUND

Human tissue grafts, from perhaps 10,000 donors, benefit as many as a half-million people annually.¹ The great majority of these transplanted tissues are bones, bone products, or other parts of the musculo-skeletal system, such as tendons, fascia, and soft tissues. Consequently, we are focusing this inspection on bone and musculo-skeletal tissue, and we use the term "tissue" to refer to these. Tissues are used in procedures such as knee and hip replacements, spinal surgery, dental surgery, and strengthening ligaments and tendons.²

The Organ Procurement System

Organ procurement organizations (OPOs) are responsible for recovering organs from donors. The nation's 65 OPOs encourage organ donation, identify potential organ donors, obtain consent from next-of-kin, oversee the surgical excision of organs, coordinate the various laboratory tests associated with transplantation, arrange for transportation of organs, and operate a central register of transplant candidates in their service area.³

The National Organ Transplant Act requires that OPOs must also "have arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to assure that all useable tissues are obtained from potential donors."⁴ However, neither the Federal government nor the federally funded Organ Procurement and Transplantation Network (OPTN) provides guidance about these arrangements. Undoubtedly, OPOs see organ procurement as their primary function. At the same time, however, the National Organ Transplant Act clearly envisions an important role for OPOs in facilitating the recovery of tissues. To the extent that this expectation is not met, opportunities for donating and using tissues are lost.

An OPO also must have a working relationship with at least 75 percent of the Medicare hospitals in its service area. At the same time, Medicare participating hospitals must establish written protocols to identify potential organ donors. In most cases, these protocols utilize the OPO to carry out this function, giving them access to hospitals' actual and potential organ donors. Consequently, this access to hospitals places OPOs in a strong position to coordinate recovery of tissues from these or other hospital-based donors.

The Tissue Banking Industry

The Public Health Service (PHS) estimates that 125 bone banks operate in the United States, in addition to a number of small hospital facilities that retrieve and store bone from living donors. The American Association of Tissue Banks (AATB), a national professional organization, has accredited 50 tissue banks of all types that meet its voluntary standards, including bone banks.⁵

Tissue banking has three stages: (1) Recovery or procurement, the stage at which donors are identified and screened, consent is obtained from next-of-kin, and the bone is surgically recovered from a donor; (2) Processing and preservation, in which the bone is cleaned, treated, and preserved for future use; and (3) Distribution, in which the preserved bone is distributed to hospitals, surgeons, and dentists for implantation. (Appendix A provides a more detailed description of each of these stages.)

This report focuses on the procurement stage, during which tissue is recovered. This stage is the point at which the supply is established and is likely to be the most direct focus of OPO involvement.

Federal Interest in Tissue Procurement

In December 1993, the Food and Drug Administration (FDA) regulated tissue banking for the first time. The FDA issued an interim rule to require testing for certain infectious disease, donor screening, and record keeping in response to concerns that some human tissues were being offered for transplantation use without even minimum donor testing and screening.⁶

This report focuses on the supply of tissues and the role of the OPOs in procuring tissue. No other inquiry has been undertaken to assess their performance of this role. The National Organ Transplant Act requires that OPOs have arrangements with tissue banks for tissue procurement. How well they perform this role can have a significant bearing on recovering a sufficient supply of high quality tissue for transplantation. It is true that the shortage of tissue is not as critical a national problem as is the shortage of organs. Yet the demand for transplantable bone tissue is potentially unlimited, and could result in a shortfall. Indeed, for certain "specialty tissues," such as femurs and patellar tendons, shortages may already be occurring.

Few sources of data are available to accurately measure the increase in demand for bone tissue. According to one source, an investment firm, bone tissue transplants in the United States increased from 155,000 in 1981 to 375,000 in 1990. More importantly, in 1981, only 3 percent of all bone transplants--or 5,000 of the 155,000 procedures--used tissue from donors; the other 97 percent used the individual's own bone. By 1991, donor tissue was employed in 53 percent of these transplants. The investment firm cites a number of factors, such as aging of the general population and greater acceptance of donor tissue among surgeons, as indicators that the demand for tissue will continue to grow.⁷

The OPOs already are involved in tissue banking by virtue of their involvement in organ procurement. As much as 60 percent of bone tissue used for transplantation comes from donors of solid organs--kidneys, livers, hearts, lungs, and pancreata.⁸ One prominent researcher, Dr. Jeffrey Prottas of Brandeis University, has pointedly summarized the issues central to Federal concerns about tissue procurement and the role of the OPOs as follows:

Supplying bone cannot be a side-effect of the OPO referral system. . . . Insofar as the OPO system of hospital development and professional education is oriented solely to the needs of organ transplantation, it must miss innumerable opportunities to locate bone donors and to encourage bone donor referrals. The need for bone cannot be met as an afterthought of the need for organs. How to connect bone and organ banking is the basic question facing the tissue procurement community and government policy-makers.⁹

This study examines the interaction between OPOs and tissue banks at the recovery stage, where the supply of tissues for transplantation is established. Despite differences between organ and tissue transplantation, there are similarities in the critical stage of recovery. Procuring tissues and organs depends on access to and cooperation of hospitals and medical personnel to identify potential donors. Approval from family members must be obtained. Excising both organs and tissues requires the use of surgical techniques.

METHODOLOGY

In May 1993, we conducted a mail survey of each of the nation's 66 Medicare-certified OPOs; 63 OPOs (95 percent) responded, although we made the decision to exclude 1 OPO from our analysis. This left us with useable responses from 62 of the remaining 65 OPOs. During site visits to four OPOs, we interviewed staff from the OPO, local tissue banks, and local hospitals, and we reviewed documents related to their tissue banking activities.

In addition to the mail survey and site visits, we conducted telephone interviews with staff from 15 OPOs; Federal officials from the Food and Drug Administration and the Division on Transplantation in PHS, and from the Health Care Financing Administration (HCFA); and staff from relevant organizations, including the Association of Organ Procurement Organizations, the AATB, and the United Network for Organ Sharing (UNOS), which holds the Federal contract for the Organ Procurement and Transplantation Network. We also conducted a focus group with directors of five tissue banks during the August 1993 AATB scientific meeting.

Appendix B contains a detailed description of our methodology.

We conducted this study in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency.

FINDINGS

ALL 62 OPOs RESPONDING TO OUR SURVEY PARTICIPATE IN TISSUE RECOVERY TO SOME DEGREE.

The National Organ Transplant Act requires that OPOs have arrangements to participate in tissue banking. However, neither the Federal government nor the OPTN provides direction as to how this involvement should take place. The 62 OPOs that responded to our survey--95 percent of all OPOs--use two basic models for tissue recovery: They either refer donors to tissue banks, or they perform the actual recovery themselves. Within each of these basic models, there is substantial variation. Many OPOs are constantly evaluating their involvement, and it is important to recognize that the arrangements described here reflect only a point-in-time, the spring of 1993. In fact, the volatility of the arrangements is reflected by the fact that at least five OPOs had substantially changed their arrangements over the past year.

Thirty-four OPOs refer potential donors to tissue banks.

In 16 of these 34 OPO service areas, only 1 tissue bank operates. In these areas, a referral would typically be handled as follows: A staff member at an OPO or a tissue bank receives a call about all potential donors, both organ and tissue, through a central telephone number. The staff member asks one question: "Is the donor on a ventilator?" If the answer is yes, the donor is a candidate for organ donation, and the call is referred to the OPO; if the answer is no, there is no opportunity for organ recovery, and the call is referred to a tissue bank.

In 18 other OPO service areas, however, OPO staff and tissue bankers described to us situations in which multiple tissue banks operate and compete for available donors. The following two examples describe how referrals are made in such areas. In one city, a hospital calls the OPO first when it identifies a potential organ or tissue donor. If the hospital has an arrangement with any of the four tissue banks in its area, the OPO will inform that bank, which sends out a technician to handle the recovery. If the donor hospital has no such arrangement, the OPO calls one of the four banks on a rotating basis. In another city, dissatisfaction with service from two available tissue banks led the OPO to encourage a third bank to enter the service area and to receive all referrals from the OPO.

Some of these tissue-referral OPOs have little interest in being actively involved in tissue banking beyond referring donors. These OPOs define their mission to be *organ* procurement and distribution, not tissue recovery. Their primary motivation for participating in tissue banking, even to this limited extent, is to protect their organ relationships with hospitals, who may view them as the major procurement agency in the area.

In other places, independent tissue banks already were operating, so the OPO saw no need for further involvement, beyond cooperating with the existing tissue banks. These OPOs view coordinating with tissue banks as important for their own relationships with hospitals, because it gives them an opportunity to respond to donation referrals. They reason that even if the donor is inappropriate for organ donation, when a future opportunity for organ donation arises the hospital will be used to calling the OPO for donation. The OPOs view this as an opportunity to increase donation awareness and expand their hospital constituency beyond transplant surgeons.

Sixteen of these 34 OPOs reported that they charge tissue banks a fee for referring bone donors to them. These fees span a wide range. Five of these 16 OPOs charge a referral fee of \$100 or less, 5 charge between \$100 and \$500, 3 charge between \$500 and \$750, and 3 charge more than \$1,000. The differing fees do not always cover comparable costs. Some OPOs use the fees only to offset direct costs incurred in referring tissue donors. For example, one OPO reported that it charges a fee of \$35 per hour to cover the wages of an OPO procurement coordinator who assists the tissue bank. At the other extreme, the director of an OPO that charges \$1,200 indicated that its fee also covers operating room costs which are billed to the OPO, rather than directly to the tissue bank.

Eighteen of the referral OPOs, however, do not charge fees for tissue referral. Staff at these OPOs told us that they simply consider referral of any donor to be part of the donation process, and they do not expect to be compensated.

Twenty-eight OPOs recover tissue themselves.

The 28 tissue-recovery OPOs use three basic approaches. At the most comprehensive level, nine of these OPOs operate full-service tissue banks, either as part of the OPO or as a sister corporation within the overall OPO corporate structure. These comprehensive organ and tissue banks recover, process, and distribute tissue within their own service area. In addition, they may contract with OPOs in other areas to process their tissue and to distribute it back to that OPO's service area.

Twelve of the 28 OPOs recover and distribute tissue. After recovery, the OPO ships the tissue to a tissue processor. That processor might be one of the comprehensive OPO-based tissue banks described in the previous paragraph, or it might be an independent tissue bank or tissue processor. After being processed, the tissue is returned to the OPO, which distributes it to local practitioners.

Finally, seven OPOs just recover tissue. These OPOs have a contractual relationship with a tissue bank, which then processes and distributes the tissue. Many observers may not consider these OPOs to be extensively involved in tissue banking. They are, however, clearly involved in recovering tissue, including obtaining consent, screening donors, and performing the surgical excision.

We identified four major reasons for OPO involvement in tissue recovery and, for some OPOs, processing and distribution. First, some OPOs see an opportunity to fill a void, by being able to provide a service (and a product) that local surgeons can use. In fact, in many of the arrangements in which an OPO only recovers tissue, the processed tissue is distributed back to that OPO's local area.

Second, by coordinating organ and tissue recovery more effectively, OPOs expect to provide better service to hospitals, making it easier for them; we heard the term "one-stop shopping" to describe this goal. For other OPOs, tissue recovery is just a logical extension of their organ procurement activities.

A third reason for OPO involvement in tissue recovery is to keep some control over donation in general, and to guard their access to hospitals. In areas where they feel that other tissue banks may be performing poorly, the OPOs cited a need to protect their reputation in order to protect their source of donors for organs.

Finally, those OPOs involved in recovery have a substantial financial interest. We did not undertake a comprehensive financial analysis of tissue banking and OPOs; however, the following examples illustrate the monetary side of such a business. The director of one OPO told us that this year his OPO expects to realize gross revenues of about \$1 million from recovering and distributing tissues; this would yield a net operating surplus, or profit, of between \$50,000 and \$100,000. At another OPO, the staff informed us that tissue banks typically pay OPOs between \$5,000 and \$6,000 per donor for performing recovery services; this amount is sufficient to cover their direct recovery costs--staff, operating room time, supplies, transportation--as well as a portion of their allocated overhead costs.

THE OPOs' COMMITMENT TO TISSUE RECOVERY VARIES WIDELY. PERFORMANCE DATA SHOW THAT THEY HAVE NOT TAKEN FULL ADVANTAGE OF OPPORTUNITIES TO OBTAIN TISSUE FROM POTENTIAL DONORS.

The OPOs show a wide range of success in referring donors or recovering their tissue. The range may not be surprising, given the lack of guidelines or standards for performance in this area. Nevertheless, it raises questions about why some OPOs are recovering more tissue or referring more donors than others. Are those that recover more tissue performing more effectively or efficiently? Are those at the lower performance levels simply not paying attention to tissue donation as they carry out their organ procurement activities? Are they missing opportunities to identify donors and recover tissues?

As part of our review, we developed three performance indicators to measure OPOs' involvement in tissue recovery. One of these performance indicators applies to OPOs that refer potential tissue donors to tissue banks, and two of these performance indicators are relevant for OPOs that recover tissue themselves. For each of these, we

first describe the performance indicators; we then examine the range of OPO performance, utilizing 1992 data that the OPOs reported to us. Importantly, these data are for one year only; an OPO's performance could change substantially from year to year.

- **Organ Donors Referred to Tissue Banks:** For the 34 OPOs that refer potential tissue donors to tissue banks, we measured the percentage of organ donors who were referred for tissue donation. Theoretically, at least, every organ donor is a *potential* tissue donor; this performance indicator assesses the degree to which an OPO actually refers its organ donors for tissue donation.

Three of these OPOs reported that they referred all of their organ donors for tissue recovery. At the other extreme, 2 OPOs reported that they referred fewer than 20 percent of organ donors for tissue donation.

TABLE 1 Percentage of Organ Donors Referred for Tissue Donation in OPOs that Refer Tissue Donors, 1992	
Percentage of Organ Donors Referred for Tissue Donation	Number of OPOs
fewer than 20 %	2
21 % - 40 %	4
41 % - 60 %	10
61 % - 80 %	9
81 % - 100 %	4
n = 29 (of 34) OPOs that refer tissue donors and that supplied sufficient data for analysis. source: OIG survey of OPOs, May 1993 mean = 58.4 %	

Clearly, for the 4 OPOs in the highest category, referral for tissue donation is routine; 3 of these OPOs actually referred all of their organ donors, and the fourth referred 90 percent of its donors. These data also show that some OPOs may not be giving full consideration to tissue donation. Certainly, those OPOs that fall at the low end on this performance indicator--for example, the 6 OPOs that refer fewer than 40 percent of their organ donors for tissue donation--appear to give little attention to tissue referral.

This performance indicator raises questions about whether and how the number of tissue donors could be increased. Do the OPO staff have incentives to refer donors to tissue banks? Are the OPO staff adequately trained to discuss tissue donation and

recovery with donor families? Would better marketing and outreach by tissue banks alleviate this shortfall? Would more cooperation between tissue banks and OPOs generate more referrals?

- **Organ Donors Providing Tissues:** For the 28 OPOs that recover tissue, we measured the percentage of organ donors from whom they recovered both organs and tissues. This performance indicator assesses the emphasis that an OPO gives to organ donors as a source of tissue.

The percentage of organ donors from whom these OPOs recovered both organs and tissue ranged from a high of 43 percent to a low of 6 percent.

TABLE 2 Percentage of Organ and Tissue Donors in OPOs that Recover Tissues, 1992	
Percentage of Organ Donors from whom OPO also Recovered Tissues	Number of OPOs
fewer than 10 %	2
11 % - 20 %	9
21 % - 30 %	7
31 % - 40 %	5
41 % - 50 %	2
n = 25 (of 28) OPOs that recover tissue and that supplied sufficient data for analysis. source: OIG survey of OPOs, May 1993 mean = 22.8 %	

Even in those OPOs at the highest level on this indicator, fewer than one-half of all organ donors also donate tissue. An organ donor's family may not consent to tissue donation. The nature of the consent process, the length of the forms, the nature of the surgical recovery of tissues, and the publicity given to organ donation may mean that some families are less likely to give consent for tissues. At one OPO, for example, the staff informed us that only about 50 percent of organ donor families also consent to bone donation.

Further analysis of these data, however, reveal that those OPOs that are most involved with tissue banking tend to fall towards the higher end on this performance indicator. Four of the 6 "comprehensive OPOs"--those that recover, process, and distribute tissue--procured tissue from more than 25 percent of their organ donors. This number compares with 4 of the 11 OPOs that recover and distribute tissue, and 2 of 8 OPOs that only recover tissue. The implication, not surprisingly, is that those OPOs that are

more involved with tissue banking are likely to put greater effort into tissue recovery. This emphasis may result from factors such as a greater financial interest, or it may result from an organizational culture that encourages and supports tissue procurement.

- **Ratio of Tissue Donors to Organ Donors:** For the 28 OPOs that recover tissue, we measured the ratio of tissue donors to organ donors. This indicator assesses the attention that an OPO gives to nonorgan donors as a source of tissue.

Three of these OPOs reported more than 150 tissue donors for every 100 organ donors. At the other extreme, 3 OPOs procured tissue from fewer than 20 tissue donors for every 100 organ donors.

TABLE 3 Ratio of Bone Donors to Organ Donors in OPOs that Recover Tissues, 1992	
Number of Bone Donors per 100 Organ Donors	Number of OPOs
fewer than 50	12
51 - 100	5
101 - 150	5
more than 150	3
n = 25 (of 28) OPOs that recover tissue and that supplied sufficient data for analysis. source: OIG survey of OPOs, May 1993	
mean = 77.0	

This measure addresses OPOs' performance in looking for tissue donors outside of their traditional pool of organ donors. The data presented in table 3 are based on donors who provided tissues only. We also analyzed data on tissue donors from whom the OPO also recovered organs and found a similar distribution.

These data are consistent with the data presented in table 2. Those OPOs that provide the most comprehensive tissue banking services--recovery, processing, and distribution--tend to have higher rates of tissue procurement than do other OPOs; OPOs that both recover and distribute tissue have higher rates than those that recover tissue only. Three of the 6 comprehensive tissue banks procure tissue from more tissue than organ donors, as do 4 of the 12 OPOs that both recover and distribute tissue. Just one OPO that only recovers tissue is above that level.

TENSIONS EXIST BETWEEN ORGAN PROCUREMENT AND TISSUE RECOVERY. IF THESE TENSIONS INTENSIFY, THEY COULD HAVE ADVERSE CONSEQUENCES FOR THE SUPPLY OF TISSUES AND OF ORGANS.

Inherent differences between organ procurement and tissue recovery can limit OPOs' and tissue banks' willingness to work together.

Although organ procurement and tissue recovery are intertwined in many aspects, they remain quite different. To some degree, these differences reflect higher prestige generally accorded to organ procurement and transplantation than to tissue recovery and transplantation. Organ transplantation is considered to be a life saving procedure, while tissue transplantation is viewed as life enhancing. Renowned surgeons perform organ transplantation in a limited number of federally approved transplant centers, while tissue transplantation is part of routine surgery performed at most community hospitals.

The Federal government has designated organ procurement organizations, which operate with virtual monopoly powers in a defined territory, and has set up a special program within Medicare to pay for organ recovery and transplantation. On the other hand, no Federal regulation governs how tissue banking is organized, multiple tissue banks compete with each other in many areas of the country, and payment is no different than for any other hospital supply.

Different risk-benefit calculations also apply for transplanting organs and tissues. Because vital organs are life-saving and scarce, potential recipients are likely to take greater risks with the absolute safety of an organ than would be the case for tissue transplantation. The person who is facing death unless he receives a kidney or liver may be more willing to risk using a donated organ than someone who needs a transplanted tendon to gain full function of the knee joint. Both organ and tissue donors are subject to extensive screening and testing to minimize the risk of transmitting infectious disease.¹⁰ However, the short time frame in which organs must be recovered, transported, and transplanted means that lengthy testing--such as blood and tissue cultures--is not possible if the organs are to remain viable. Tissue banks, on the other hand, can take advantage of the nonurgent nature of tissue transplantation to conduct a comprehensive testing of a tissue donor.

As part of their testing and screening, tissue banks also may conduct extensive interviewing of the donor's family in an effort to rule out behaviors associated with HIV or other infectious diseases. In fact, this more extensive interviewing of family members and acquaintances was cited to us by several OPO staff as being insensitive to a grieving family, and not meeting their needs for support; tissue bankers, however, cite an obligation to do everything possible to protect the recipient of the tissue from transmission of infectious disease.

In some instances, according to OPO staff, tissue banks fail to understand hospitals' concerns and needs. As a result, the OPO simply may not refer a donor out of fear that the tissue bank may harm its relationships with hospitals. An OPO director told us about a recent event that illustrates this concern. Nurses at a local hospital that previously had referred organ donors called the tissue bank about a potential donor, but no one returned their call. An hour later they called the OPO to complain. The OPO director eventually tracked down the tissue bank recovery team in the operating room at another hospital. But the team never called the hospital. The director noted that, "The donor was lost, plus the hospital is less likely to want to hassle with this in the future. The hospital had given us six organ donors per year, but we haven't had one from it in 6 months."

Despite the concerns cited here, in many areas the relationship between tissue banks and OPOs appears to be working well. In these areas, OPO and tissue bank staff report that they focus efforts on encouraging donation in general terms--not in separating organs and tissues in their work with hospitals.

Competition for donors among multiple tissue banks could threaten hospitals' eagerness to work with OPOs and tissue banks.

Unlike OPOs, tissue banks have no defined service area in which they operate. According to our survey, one-half of the OPOs reported that more than one tissue bank operates in their service area. Where multiple tissue banks operate, the competition for donors can become intense. The fear, from the OPO perspective, is that competition among multiple tissue banks can damage the OPO's relationships with hospitals, which many OPO staff believe are already tenuous.

Tissue banks may compete for referral contracts with hospitals that will guarantee they will be contacted when potential donors are identified. For example, the director of one OPO told us that in the past year three new tissue banks have solicited hospitals' support for their services; but she raised concerns that these contacts are very time-consuming and create confusion for the hospitals. In another part of the country, nurses at one hospital told us that a new tissue bank approached the hospital administration about using its services, claiming that if the hospital failed to comply, it would bring suit on the basis of restraint of trade.

The competition for donors also may focus on providers of care. An example relayed to us by staff nurses on the intensive care unit in one hospital illustrates how this competition takes place. An orthopedic surgeon on the hospital staff had used tissues from one of the local tissue banks. The tissue bank convinced the surgeon that the nurses must now refer donors to it, presumably to pay back the tissue bank for supplying the original tissue.

Seeking hospital cooperation in organ donation entails constant education by the OPO. Even large medical centers yield few organ donors. In order to obtain organs from as many potential donors as possible, OPOs have a tremendous vested interest in

keeping their referral relationship with hospitals working well. Tissue banks, on the other hand, report that obtaining donors is the bottleneck in ensuring an adequate supply of tissue, just as it is for organs. Tissue bankers cite the privileged position that OPOs have with respect to access to hospitals. This OPO access means that tissue banks are, at least to some degree, dependent upon the OPOs for tissue donor referrals.

For some--but by no means all--OPO directors, the solution to problems caused by multiple tissue banks lies in designating a single tissue bank for each service area, along the lines of the OPO service area designation. For other OPO directors, as well as tissue bankers, such a solution would do little to solve the donor supply problem. Instead, they support tissue bank competition, so long as it is based on meeting the service needs of hospitals. One OPO director typified the comments of others when he told us that, "selection of a tissue bank still boils down to who serves the hospital best."

SOME OPOs AND TISSUE BANKS HAVE DEVELOPED EFFECTIVE PRACTICES TO IMPROVE ORGAN AND TISSUE DONATION.

During our mail survey, interviews, and site visits we sought information from OPOs and tissue banks about what they considered to be effective practices to improve donation and coordination between organ and tissue donation. Based on the descriptions and results reported by these officials, the following practices appear to be worth further consideration by other OPOs and tissue banks.

Some OPOs and tissue banks are working together to facilitate communication and cooperation. These efforts include a central telephone system to receive all donor referrals and written agreements specifying referral arrangements among OPOs and tissue banks.

Identification of potential organ and tissue donors is a relatively rare event in most hospitals.¹¹ As a result, when a potential organ or tissue donor is identified, hospital staff may not be clear about which organization to call, how to proceed, and what organs or tissues a donor might provide. Because of this confusion, potential donors may be lost to the system. The OPO and tissue banks in some areas are working together to address this problem and to improve service to hospitals.

In several areas, OPOs and tissue banks use a central telephone number to coordinate donor referral for both organs and tissue. One OPO reported to us that "we have had only one phone number for referrals in our area for 10 years. This is essential to achieve best support from donor hospitals." The goal of this arrangement is to save hospitals from having to make calls to several agencies for a multiple tissue donor. Instead, the OPO can then make the referrals to the appropriate agencies. Another OPO, operating in an area with two tissue banks, reports that both tissue banks have agreed to utilize the OPO's donor hotline for tissue referrals within the OPO service area. This single number is included in each tissue bank's hospital development

materials, as well as the OPO's materials. The OPO coordinators screen all calls and exclude unacceptable tissue donors on the basis of screening criteria that were jointly established and agreed to by the tissue banks and OPO.

Some OPOs and tissue banks also have developed written referral arrangements to clarify their respective roles. An example of such an arrangement is the Transplant Council of the Rockies, which consists of Colorado Organ Recovery System (OPO), Mile High Transplant Bank (tissue bank), the Colorado Eye Bank, and the Rocky Mountain Lions Eye Bank. The Council agreement specifies the manner in which the OPO, tissue bank, and eye banks share referrals. Council members have agreed to guidelines and standards intended to maintain high quality service to the area hospitals. For example, each organization must be certified or accredited by the appropriate national body, such as HCFA for the OPO, the AATB for the tissue bank, and the Eye Bank Association of America for the eye banks. The organizations have agreed to participate in a neutral arbitration system to resolve disputes. They collect regional referral and recovery data on a quarterly basis to provide information on outcome of referrals, recovery by donor, and disposition of recovered organs and tissues. The organizations also share expenses for professional education and hospital development.

Some OPOs have established programs under which hospitals routinely refer all deaths to the OPO to increase the number of donor referrals.

Hospital staff may not refer a potential donor because they assume--perhaps incorrectly--that a particular patient was inappropriate for donation. Rather than rely solely on the hospital staff's judgment, OPO or tissue bank staff believe themselves to be more knowledgeable about donor appropriateness. They prefer to make judgments about donor suitability on the basis of the OPO's or tissue bank's own screening criteria.

Six OPOs informed us about their programs under which hospitals routinely refer all deaths to the OPO for consideration of organ and tissue donation. The decision on whether the deceased individual is appropriate for donation then rests with the OPO. The OPOs reported that they implement this practice on a hospital-by-hospital basis, beginning with larger hospitals that have higher numbers of donors. One OPO which has implemented this approach notes that it is difficult to get this system started, because it requires changes in hospital routines. But the OPO estimates that routine referral has led to a three-fold increase in calls to their office, and has been of particular benefit to tissue referrals (although less so to organ referrals). Routine referral may, however, add some cost. One OPO reported that it had to hire a nurse to be on duty all night in order to receive these calls and make judgments about whether the potential donor is acceptable.

RECOMMENDATIONS

Our recommendations arise from the statutory requirement that OPOs "have arrangements to cooperate with tissue banks for the retrieval of tissue." While activity is taking place at the local OPO level, little national attention has focused on this mandate. Over the last decade, there has been tremendous growth in the use of bone tissue in surgical procedures, and the procurement of that tissue is closely intertwined with the procurement of organs. Because it can have a significant impact on overall OPO performance, the relationship between tissue banks and organ procurement organizations can no longer be relegated to secondary status.

Both PHS and HCFA have important roles to play in this respect, and we direct recommendations to each of these agencies. We believe that the Department needs to provide some national guidance to establish accountability for the requirement regarding OPOs and tissue banks. We have developed our recommendations to further that objective.

The PHS should provide some general oversight and guidance for OPOs regarding their arrangements with tissue banks and their tissue recovery activity.

The Division on Transplantation within PHS provides general oversight of the nation's organ procurement system and administers the contract for the Organ Procurement and Transplantation Network. Our recommendation means that PHS would extend its oversight of OPOs to include some guidance on their involvement with tissue banking, in light of the requirement in the National Organ Transplant Act. This oversight and guidance could take several forms.

First, we encourage PHS to collect routine data about OPO involvement with tissue recovery. Data to be collected might include information on what arrangements an OPO has in place for tissue recovery or referral of potential donors. These data might also include statistics on performance indicators such as the number of potential tissue donors referred, number of donors from whom tissue was recovered, and number of donors providing both organs and tissue. The PHS could use UNOS, the OPTN contractor, to gather this information through the current OPO reporting structure.

Second, PHS could play a useful role by disseminating information about effective practices that OPOs have undertaken to work with tissue banks. We have described two such practices in this report--steps to facilitate communication and routine referral of all deaths. We expect that other practices also merit consideration. An evaluation of these efforts and distribution of the findings to OPOs and tissue banks could complement ongoing PHS efforts to encourage organ donation.

Third, we urge PHS to keep a watchful eye on the types of tensions between OPOs and tissue banking that we describe in this report. It is important that PHS monitor

these tensions and determine if they are intensifying to a degree that jeopardizes the supply not only of tissues, but of organs as well. We also encourage PHS to consider ways in which it can help OPOs and tissue banks overcome these tensions.

The HCFA should include an assessment of OPOs' performance in tissue recovery as part of the OPO recertification process.

This recommendation would require that an OPO must meet certain performance expectations with respect to its involvement in tissue banking in order to maintain its certification for Medicare and Medicaid.

In light of the statutory requirement, we believe that some measure of accountability for OPO performance in tissue recovery is warranted. At present, HCFA responds to this requirement by asking OPOs to "document your affiliation with tissue banks for the retrieval, processing, preservation, storage and distribution of tissues to assure that all useable tissues from potential donors are obtained."¹²

Based on our findings in this report that wide variation exists in OPO performance in tissue recovery, we have reason to question whether all useable tissues are indeed being obtained from potential donors. We believe that HCFA could improve OPOs' accountability and performance in tissue recovery by examining data that substantiate these organizations' participation in this activity.

We recognize that recertification focuses primarily on an OPO's performance with respect to organ procurement and distribution. However, the law explicitly requires that OPOs also participate in tissue recovery. Establishing accountability for this requirement is not inconsistent with reviewing organ procurement efforts, and it would help meet expectations that all useable tissues are obtained from donors.

The HCFA could utilize performance indicators to assess how well OPOs are meeting the requirement that they have arrangements to cooperate with tissue banks. In this report, we identify three such performance indicators that offer a starting point for this examination. One of these performance indicators can be applied to OPOs that refer potential tissue donors to tissue banks, and two can be applied to OPOs that recover tissue themselves. These three indicators revealed wide variation in the performance of OPOs with respect to their tissue recovery and referral activities. The HCFA could use indicators such as these to measure that performance, or it could develop its own tools to assess an OPO's performance in recovering tissues.

COMMENTS ON THE DRAFT REPORT

Within the Department of Health and Human Services, we received comments on this report from the Public Health Service, the Health Care Financing Administration, and the Assistant Secretary for Planning and Evaluation. We also received comments from the United Network for Organ Sharing, the American Association of Tissue Banks, and the Association of Organ Procurement Organizations. Appendix C contains the full text of each set of comments.

We are encouraged that the respondents agree that we raise legitimate questions about an important issue. It is clear that organ procurement organizations are intricately involved in tissue recovery by the very nature of the anatomical donation system. We also are compelled to note that the National Organ Transplant Act includes a role for OPOs in tissue recovery. As we indicate in this report, obtaining and allocating vascular organs is the primary task facing OPOs; while we also view tissue procurement as important, we do not imply that tissue recovery should take precedence over OPOs' efforts to improve their organ procurement practices.

Our interest is in ensuring that OPOs and tissue banks do not operate in a fashion that could be detrimental to the recovery and allocation of a scarce and valuable resource that relies on a voluntary system of donation. We are concerned about competition that could have a deleterious impact on organ procurement, about duplication of effort, and about organizations operating at cross purposes in their procurement activities. As a result, we believe that the Department has an important role to play in encouraging the coordination of organ procurement and tissue recovery, as was envisioned by Congress in legislation establishing the national organ transplant system.

Overall, the comments share three major points. Below, we identify these points and offer our response to them.

Additional resources would be needed for PHS to provide general oversight and guidance.

The PHS concurs with our recommendation that the agency provide some general oversight and guidance for OPOs regarding their arrangements with tissue banks and their tissue recovery activity. That agency, AATB, and UNOS indicate, however, that additional resources would be needed to implement this recommendation, and ASPE calls it infeasible at this time.

We are keenly aware that funding for new initiatives is limited. In this instance, however, we believe PHS could begin providing general oversight and guidance without incurring extensive new expenditures. Our intent in making this recommendation is not to create a new reporting structure; nor do we wish to impose a major reporting or data processing burden on agencies within the Department, on

the OPTN, nor on the OPO or tissue banking community. We would be pleased to work with PHS toward this end.

We believe that existing reporting systems can be revised incrementally to obtain these data with a minimum of expense and effort. As we note in our recommendation, we envision the collection of *routine* data. We anticipate that few data elements beyond those currently submitted for monitoring and guiding organ procurement would be needed. These elements could be incorporated easily with data that OPOs and tissue banks gather in their current business practices, and that OPOs report to HCFA, PHS, and UNOS. Our experience in conducting this study reinforces the availability of this information, as we found that OPOs had little problem in providing the data we used in this inspection.

The specific performance indicators we developed may not be adequate to evaluate OPOs' performance in tissue recovery.

Although AATB finds our performance indicators to be reliable indicators of the strength of OPO commitment to tissue recovery from cadaveric donors, HCFA, ASPE, and AOPO question the adequacy of our indicators. We believe that the indicators we present are quite sufficient to draw attention to questions that the Department and the organ and tissue transplant community should begin to address. We developed these indicators based on readily available data, and we are confident that other indicators would also show wide variation in OPO performance.

At the same time, however, we are not wedded to these or any other particular performance indicators. Rather, we offer them as a starting point in deliberations around performance indicators for OPOs and tissue banking. We encourage HCFA and PHS to collaborate either to modify these indicators or to develop other indicators that will meet our intended purpose: to begin to hold OPOs accountable for their activities with regard to tissue recovery. We also believe that PHS and HCFA would find it useful to include representatives from professional groups, such as AOPO, AATB, and UNOS in developing any indicators, because of the expertise of these organizations and their constituencies.

Including an assessment of OPO performance in tissue recovery as part of the Medicare recertification process is not feasible at present.

Both HCFA and ASPE identify regulatory barriers to including an assessment of OPO performance with regard to tissue recovery as part of OPO Medicare recertification processes. We recognize that regulations needed to implement this recommendation have not yet been proposed, and that the Secretary has not expanded the list of organs to include tissues.

The HCFA notes that any such effort is a long term initiative, which must be preceded by data collection and development of appropriate and valid performance indicators. We believe that the long lead time that HCFA requires for such an effort makes its own compelling case for initiating this activity sooner rather than later. Collecting necessary data and developing more refined performance indicators are preconditions for this assessment. Consequently, we urge HCFA to establish an appropriate schedule to carry out such a proposal.

Technical Comments

- FDA Interim Rule on Human Tissue Intended for Transplantation

Subsequent to the preparation of our draft report, the Food and Drug Administration issued an interim rule to require testing for infectious disease, donor screening, and recordkeeping to help prevent the transmission of AIDS and hepatitis through human tissue used in transplantation. We have modified the text of this report to provide note of this interim rule, published at 58 Fed. Reg. 65,514, December 14, 1993.

- Number of OPOs

The HCFA comments note that the correct number of OPOs is 66, rather than 65 as we report in the text. The larger number includes the OPO of Puerto Rico which we excluded from our analysis due to its low level of procurement activity, as we note in our methodological appendix. We also reference this exclusion in endnote 3 to the text.

APPENDIX A

AN OVERVIEW OF TISSUE BANKING: RECOVERY, PROCESSING, AND DISTRIBUTION

RECOVERY

Recovery is the first stage in the tissue banking process. It involves four steps: identification and referral of the potential donor, consent to donation from the donor family, donor screening, and surgical recovery of the tissues from the donor.

Identification and Referral of Donors

Unlike organ donation, which requires that the donor be ventilator dependent, virtually any death can be considered for tissue donation. Most tissue donors are referred by hospitals, although medical examiners also are an important source. Upon identifying a potential donor, hospitals may notify a tissue bank directly about the possibility of donation, or it may call the OPO, which passes on the referral to the appropriate tissue bank.

Consent

Hospitals are required, as a condition of participation in Medicare, to ensure that families of potential donors are made aware of the option to donate organs and tissues. In addition to offering the option of donation, the hospital, OPO, or tissue bank must obtain consent from the donor's next-of-kin.

According to OPO staff with whom we spoke, the preferred approach to obtaining consent is a face-to-face conversation with the donor's family. In the case of tissue donation, however, consent is often requested over the telephone.

The form in which staff obtain consent can vary widely. For example, in some cases, the OPO will obtain consent using a blanket statement that authorizes donation of all organs and tissues. In other cases, the form will spell out specifically which organs and tissues the family wishes to donate.

Screening

If the family consents to donation, the tissue bank or OPO will screen the donor based on its own criteria for acceptance. The Centers for Disease Control (CDC) has published draft guidelines for donor screening, but the guidelines are voluntary. According to literature we reviewed¹³ and the staff from tissue banks and OPOs with whom we spoke, donor screening is considered to be a very important step in ensuring the safety and quality of tissue.

Screening generally includes assessing the potential donor's social and medical history. To identify any risk factors associated with transmitting diseases, the tissue bank assesses social history through interviews with family members, spouses, and/or sexual partners. The medical history includes blood tests, cultures, cause of death, and previous illnesses. Some, but not all, tissue banks require autopsies in their screening.

Generally, a tissue bank reserves its final determination about the acceptability of the donor's tissue until blood tests and culture results, and in some cases, autopsy results, are available, which could take several weeks. During this waiting time, the bank keeps the tissue in quarantine.

Surgical Recovery

If the donor passes the initial screens, tissue bank or OPO staff will surgically remove the tissue. Approaches to recovery vary among tissue banks. Some tissue banks recover tissue only in a hospital operating room under aseptic conditions; other tissue banks will recover tissue in the morgue or in a funeral home under clean--but not aseptic--conditions. If organs are also being donated, tissue recovery would follow the organ recovery, which takes place in the operating room. The time allowed to pass between death and recovery also varies among tissue banks. Although there are no definitive standards, those tissue banks we met with require recovery of tissues within 12 hours of death if the body is not refrigerated, or 24 hours if the body is refrigerated within 12 hours of death.

The qualifications of staff performing the surgical excision of tissues vary. The AATB has a certification program for tissue specialists. At some tissue banks the staff are nurses, physician assistants, or medical residents. At other tissue banks, however, staff with little or no medical training learn to do surgical recovery through on-the-job training.

Once the tissues are surgically removed, the tissue bank reconstructs the donor's body to allow for an open casket, should the family desire it. The tissue generally is wrapped and sent to a processing facility, where it is stored until final results of screening tests are available.

PROCESSING

Processing comprises three stages: processing, preservation, and labeling. We have seen estimates that between 30 and 40 organizations process bone, with 4 large processors dominating the field. Processors may process bone from several different tissue banks.

Processing

During this stage, any remaining soft tissue is removed from the whole bone. The bone is processed into the different sizes, shapes, or products required for eventual use. Generally, bone recovered under clean (i.e., nonsterile) conditions is subjected to some type of secondary sterilization, while bone recovered under aseptic conditions is not.

Several approaches to secondary sterilization are used. Some banks process the bone using chemical treatment, such as ethylene oxide (ETO); research has linked ETO with carcinogenic properties, however, and it apparently has fallen from favor. Nevertheless, it is still used by some banks and the AATB has accreditation standards covering its use. Other banks sterilize bone, using either low-dose or high-dose gamma radiation; while those we spoke with indicate that high-dose radiation assures that the bone does not carry HIV, others maintain that such treatment reduces the osteogenic (bone regenerating) characteristics of the bone. Individual surgeons and bone processors prefer different methods, out of legitimate disagreements over which approach is best for their needs.

Preservation

Several basic approaches exist to preserve processed bone until it is transplanted. Simple hypothermia is used for short term preservation (usually less than 10 days). Deep freezing, at temperatures of -80°C , is used for longer-term preservation. Cryopreservation, deep freezing at a controlled rate of temperature decrease, also is used for longer-term preservation. Tissue may also be freeze-dried (lyophilized). This process involves the removal of virtually all water from the bone. Freeze-dried tissue can be maintained at room temperature, but must be rehydrated prior to use.

Labeling

Once tissue has been processed and preserved, it is packaged for use. Each unit of tissue receives a label. Typically, the label will contain an identifying number for the donor, information on how it was processed and treated, and instructions for storage and use (e.g., thawing or rehydrating).

DISTRIBUTION

Distribution

Tissue processors may distribute bone directly to hospitals, surgeons, and dentists for their use. In other cases, the processor may return the tissue to the originating OPO or tissue bank, which then distributes the tissue. In still other situations, a processor may send the tissue to another tissue bank for distribution. Often, procurers negotiate with processors and/or distributors for distribution back to the donor's area or donor

hospital--even if the procurer is not the one distributing the bone. During the course of our inspection, we also heard about "tissue brokers," individuals who buy and sell surplus bone tissue to meet the needs of individual surgeons or hospitals. We also heard that some companies distribute tissue procured outside the United States.

Recordkeeping

Tissue banks include a response card with each unit of bone. That card includes the identifier number. The tissue banks rely on cards being completed and returned by the surgeon, hospital, or dentist implanting the bone. Tissue banks informed us that the response rate on these cards varies widely. We heard figures that ranged from 13 percent at one tissue bank to 90 percent at another.

This record-keeping system, at least theoretically, would allow the tissue to be traced back to its donor. We heard examples, however, of cases in which the tissue could not be traced. For example, a surgeon may have privileges at more than one hospital; if that hospital lacks the tissue that he or she needs, the surgeon may simply "borrow" the tissue from the other hospital, with no notice in the medical record. In a recent incident reported by the AATB, the presence of Hepatitis C was discovered in tissue, but "tracking of the remaining grafts was complicated by incomplete hospital records and, in one case, by the repackaging of a single graft for multiple patients."¹⁴

APPENDIX B

METHODOLOGY

Mail Survey of Organ Procurement Organizations

In May 1993, we mailed a survey to directors of each of the nation's Medicare-certified OPOs to assess their involvement in tissue banking. This survey included questions about the numbers of organs and tissues procured in 1992, OPO arrangements for tissue recovery, effective practices for tissue recovery, and vulnerabilities associated with tissue banking. We received responses from 63 OPOs. We decided to exclude the OPO of Puerto Rico from the study universe because of its low level of organ procurement activity (two donors in 1992). This left us with responses from 62 OPOs, out of a universe of 65--a response rate of 95 percent.

Telephone Survey of Sample of OPOs

Following the mail survey, we conducted more extensive telephone interviews with staff from 15 OPOs. We selected these OPOs based on the results of the mail survey. We stratified the OPOs according to whether they recover tissue themselves or refer donors to a tissue bank. We selected OPOs from each strata in proportion to the size of the strata relative to the total number of OPOs responding to the survey. In deciding which OPOs in each strata to interview, we also gave attention to geographic distribution and to sponsorship (*i.e.*, whether the OPO was hospital-based or independent). In addition to the 15 telephone interviews, we gathered similar information during a meeting with staff from one additional OPO.

Site Visits to OPOs

We conducted visits to four OPOs:

Regional Organ Procurement Agency of Southern California, Los Angeles, CA;
OPO of the University of Wisconsin, Madison, WI;
LifeNet Transplant Services, Virginia Beach, VA; and
Tennessee Donor Services, Nashville, TN.

During these visits, we interviewed staff of the OPO, local tissue banks, and local hospitals. Our visits also included a review of forms and procedures the OPOs utilize in their tissue-banking activities.

Interviews with Federal Officials and National Associations

We interviewed staff from PHS and HCFA who deal with organ transplantation to obtain information on federal policies addressing the OPO role in tissue recovery. Our PHS interviews included officials from the Division on Transplantation and the Food and Drug Administration. We also interviewed staff from UNOS, which holds the Federal contract for the Organ Procurement and Transplantation Network.

We interviewed staff from national associations, including the Association of Organ Procurement Organizations, and AATB. During the August 1993 AATB annual scientific meeting we convened a focus group of staff from five tissue banks to obtain their views on issues related to OPO involvement in tissue banking.

Review of Literature and Legislation

Our literature review included an examination of Federal reports on tissue banking, in particular "Tissue and Organ Transplantation Assessment Report," (PHS WorkGroup on Organ and Tissue Transplantation, July 18, 1991). We examined legislation introduced in the U.S. Senate in 1992 (S. 2908) by Senator Paul Simon, and 1993 legislation introduced by Congressman Ron Wyden (H.R. 3547) and Senator Simon (S. 1702). We reviewed testimony presented at hearings before the Senate Committee on Labor and Human Resources, September 29, 1992, and the House Committee on Small Business, Subcommittee on Regulation, Business Opportunities and Technology, October 15, 1993.

Our study also included a review of medical and scientific literature on tissue banking.

APPENDIX C

COMMENTS ON THE DRAFT REPORT

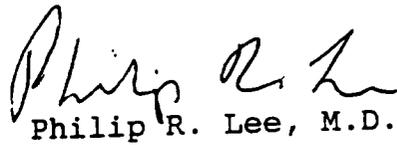
AGENCY/ORGANIZATION	PAGE
Public Health Service	C-2
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Association of Organ Procurement Organizations	C-12



Memorandum

Date APR 20 1994
From Assistant Secretary for Health
Subject Office of Inspector General Draft Report "Organ Procurement Organizations and Tissue Recovery," OEI-01-91-00250
To Inspector General, OS

Attached are the Public Health Service (PHS) comments on the subject draft report. Though we agree with the recommendation directed to PHS, we note that to undertake the steps encouraged in the report would require additional programmatic resources.


Philip R. Lee, M.D.

Attachment

PUBLIC HEALTH SERVICE (PHS) COMMENTS ON THE OFFICE OF INSPECTOR
GENERAL (OIG) DRAFT REPORT "ORGAN PROCUREMENT ORGANIZATIONS AND
TISSUE RECOVERY," OEI-01-91-00250

OIG Recommendation

The PHS should provide some general oversight and guidance for organ procurement organizations (OPO) regarding their arrangements with tissue banks and their tissue recovery activity.

PHS Comment

We concur with this recommendation, but note that it cannot be implemented as OIG envisions and encourages without additional staffing resources or funds. As additional resources become available, the Health Resources and Services Administration's Division of Organ Transplantation would foresee taking the following specific actions in response to this recommendation:

- o Collect information regarding the arrangements that OPOs have made for tissue recovery and donor referral. Statistical data on the performance indicators suggested by OIG would be collected.
- o Disseminate information about effective arrangements between OPOs and tissue banks in order to facilitate the efforts of other OPOs in this area. A part of this activity could be the development of protocols for coordinating tissue recovery between OPOs and independent tissue banks.
- o Serve as a liaison between OPOs and tissue banks and monitor points of conflict between these two groups. This would include the development of performance standards for OPOs concerning tissue recovery activities.

Activities envisioned under the first two bullets could be performed under contract. The third activity, which requires program liaison between OPOs and tissue banks, can only be performed using Federal staff. However, as noted above, staffing resources and contract funds are not currently available to perform these activities.



The Administrator
Washington, D.C. 20201

DATE MAR 21 1994

FROM Bruce C. Vladeck
 Administrator *Bruce Vladeck*

SUBJECT Office of Inspector General (OIG) Draft Report: Organ Procurement
 Organizations and Tissue Recovery (OEI-01-91-00250)

TO June Gibbs Brown
 Inspector General

We reviewed the above subject draft OIG report which examines the role of organ procurement organizations (OPOs) in procuring tissues for transplantation.

The study's findings, taken as a whole, raise legitimate concerns about the efficacy of OPOs and tissue bank relationships and OPOs' performance in assisting in the recovery of tissues. Clearly, OPOs can play a key role in supporting and encouraging the recovery of tissues; however, we disagree with OIG's recommendation that the Health Care Financing Administration take a more active role in the monitoring of OPOs' involvement with tissue recovery. We have provided our detailed comments on the report's recommendations for your consideration in the attached.

Thank you for the opportunity to review and comment on this draft report. Please advise us if you would like to discuss our comments at your earliest convenience.

Attachment

Health Care Financing Administration's (HCFA) Comments
on Office of Inspector General (OIG) Draft Report:
"Organ Procurement Organizations (OPOs) and Tissue Recovery"
OEI-01-91-00250

Recommendation

HCFA should include an assessment of OPOs' performance in tissue recovery as part of the OPO recertification process.

Response

The study's findings, taken as a whole, raise legitimate concerns about the efficacy of OPOs and tissue bank relationships and OPOs' performance in assisting in the recovery of tissues. However, we do not concur with the recommendation for two reasons. First, performance indicators must be published in regulations before we can incorporate them into the OPOs' survey and certification requirements. Neither current regulations nor proposed regulations (BPD-646-FC, Conditions of Coverage for OPOs) include any performance indicators for tissue recovery. Secondly, we do not believe the three performance indicators used in the report are adequate for HCFA to use in evaluating OPOs' performance and, potentially, denying certification. Our specific concerns are as follows:

- The first indicator (Organ Donors Referred to Tissue Banks) does not account for the inherent variability in referral methods. No definition of "referral" is provided and we suspect the term may be applied differently.
- The second indicator (Donors Providing Organ and Tissue) is used by OIG to capture the "emphasis that an OPO gives to organ donors as a source of tissue." However, the report also notes that "fewer than half of all organ donors also donate tissue" and suggests a number of reasons for this phenomenon which have no bearing on OPO "emphasis" or commitment or the nature of OPO-tissue bank relationships. No benchmark for acceptable or exemplary performance is provided for this measure.
- The third study indicator (Ratio of Tissue Donors to Organ Donors) is not the appropriate measure of tissue recovery as a whole. We believe the real issue is the lack of availability of tissue donors throughout the community, rather than the level of tissue recovery by OPOs alone.

If the Public Health Service (PHS) agrees to OIG's recommendation to begin routine collection of data regarding OPOs' involvement with tissue recovery, we would suggest further collaboration between PHS and HCFA to assure the data to be collected can be used by HCFA to develop performance indicators. Based upon our analysis of such data, HCFA may then determine the appropriateness of developing valid indicators and implementing a monitoring process using these indicators. We see the data collection, analysis, and possible development of performance indicators as a long-term initiative.

Technical Comment

The total number of OPOs referred to in the report (65) is incorrect. The correct number of OPOs is 66 nationwide.



MAR 1 1994

TO: June Gibbs Brown
Inspector General

FROM: Assistant Secretary for
Planning and Evaluation

SUBJECT: OIG Draft Report, "Organ Procurement Organizations
(OPOs) and Tissue Recovery," OEI-01-91-00250 --
COMMENTS

Thank you for the opportunity to review the draft report in which you recommend that:

- o the Public Health Service provide some general oversight and guidance for OPOs regarding their arrangements with tissue banks; and
- o the Health Care Financing Administration include an assessment of OPOs' performance in tissue recovery as part of the OPO recertification process.

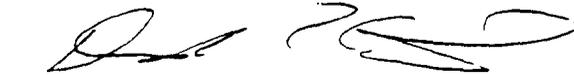
The report bases its recommendations on the requirement in the Public Health Service Act that OPOs "have arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to assure that all usable tissues are obtained from potential donors" (section 371b).

While I fully agree with the purpose of your recommendations, I must disagree with the specifics of both. Although OPOs are required to have cooperative arrangements with tissue banks, the primary charge to OPOs under section 1138 of the Social Security Act is to coordinate procurement of solid organs (human kidney, liver, heart, lung, pancreas, and any other human organ or tissue specified by the Secretary). To date, the Secretary has not expanded the statutory list to include tissue. Thus, requiring HCFA to evaluate OPOs' performance in tissue recovery would exceed statutory authority. Also, additional PHS oversight and guidance to OPOs appears infeasible at this time.

The finding that OPOs' commitment to tissue recovery varies widely is not particularly revealing since nearly half of the OPOs also recover tissue; they would be expected to devote greater efforts to tissue recovery. In addition, evaluating tissue and organ recovery on the same scale is not practical because of disparate consent rates of next of kin regarding donation of both organs and tissue.

Again, I appreciate your objective to enhance procurement of both solid organs and tissues. For some medical conditions, tissues may serve to enhance life. However, as the report acknowledges, the critical shortage remains in life-saving organs. Also, some tissues may be procured autologously, they should not be compared with scarce cadaver organs.

In addition, please note that the recently proposed FDA regulation implements testing requirements to "detect infectious diseases" in tissue donors. "Safety and quality" regulations have not yet been promulgated.

A handwritten signature in black ink, appearing to read 'David T. Ellwood', written in a cursive style. The signature is positioned above a horizontal line.

David T. Ellwood

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February 3, 1994

June Gibbs Brown
Inspector General
Department of Health & Human Services
Office of Inspector General
Washington, D.C. 20201

Re: Draft Report on "Organ Procurement Organizations and Tissue Recovery" (OEI-01-91-00250)

Dear Ms. Brown:

Thank you for providing us with the opportunity to comment on the Office of Inspector General's draft inspection report entitled, "Organ Procurement Organizations and Tissue Recovery."

As you know, the United Network for Organ Sharing (UNOS) is a Virginia non-profit corporation that operates the National Organ Procurement and Transplantation Network (OPTN) under contract with the federal government and pursuant to the National Organ Transplant Act of 1984, as amended (NOTA). Among the duties assigned to the OPTN contractor under NOTA are responsibilities for developing and operating a national computer system for matching patients in need of organ transplants with available donor organs, establishing the medical criteria by which these donor organs are allocated among all patients who are registered with the national matching system and establishing membership criteria for transplant centers and organ procurement organizations (OPOs) that participate in the organ transplantation process.

The draft report (at pages 1 and 4) states that the OPTN does not provide guidance about the arrangements for participation in tissue banking that OPOs are required to have under NOTA. Included in the draft report's recommendations (at page 14) is the following recommendation:

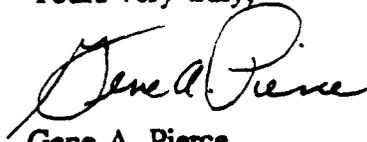
June Gibbs Brown
Inspector General
February 3, 1994
Page 2

The PHS could use UNOS, the OPTN contractor, to gather this information [*i.e.*, data about OPO involvement with tissue recovery] through the current OPO reporting structure.

The draft report's statements regarding the involvement of UNOS, as operator of the OPTN, in guiding OPO tissue retrieval, processing, preservation, storage and distribution efforts is correct. We simply note that UNOS is not presently authorized under NOTA or pursuant to our contract with the federal government to participate in such activity. While we would be pleased to gather the information described in the draft report's recommendation, there currently are no funds available for this task under the OPTN contract. Also, UNOS has no private funding available for this task. Therefore, implementation of this recommendation would require additional funding from the federal government.

Again, we appreciate the opportunity to comment on the Office of Inspector General's draft report on "Organ Procurement Organizations and Tissue Recovery." If you have any questions regarding our comments, please do not hesitate to contact me.

Yours very truly,



Gene A. Pierce
Executive Director



American Association of Tissue Banks

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February 8, 1994

June Gibbs Brown
Inspector General, Office of the Inspector General
Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

Dear Mrs. Brown:

Thank you for affording us the opportunity to review the Inspector General's draft report entitled Organ Procurement Organizations and Tissue Recovery. We have reviewed the report and offer the following comments:

The report describes a research effort that appears to be both thorough and well constructed for its intended purpose. The three performance indicators you selected are reliable indicators of the strength of the commitment made by OPOs to the overall recovery of tissue from cadaveric donors. Your findings are consistent with the anecdotal reports and complaints that members of American Association of Tissue Banks have presented to us in recent years. The report accurately identifies a persistent problem.

Although the wide variance in the contribution of OPOs to tissue recovery is already being recognized by those in the field of transplantation, it is not likely that correction of current inequities will occur as the result of voluntary efforts. Rather, such corrections would require the imposition of well designed changes in current procedures. Unfortunately, neither HRSA nor HCFA could undertake such a daunting task without substantial increases in resources. Even monitoring by UNOS would entail additional costs.

We sincerely hope that widespread distribution of your perceptive, well-written report will prompt self-examination by those OPOs that have been least effective in supporting tissue donation,

Cordially yours,

[Handwritten signature]
Jeanne C. Mowe, Executive Director
AMERICAN ASSOCIATION OF TISSUE BANKS

Executive Director Jeanne C. Mowe, 1350 Beverly Rd., Suite 220-A, McLean, VA 22101, Phone: 703-827-9582, Fax: 703-356-2198

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April 14, 1994

June Gibbs Brown
Inspector General
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330 Independence Avenue, S.W.
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Washington, D.C. 20201

RE: DRAFT Inspection Report "Organ Procurement Organizations and Tissue Recovery"

Dear Mrs. Brown:

Thank you for the opportunity to respond to the above. I understand the purpose is to describe and assess the role of organ procurement organizations (OPOs) in procuring tissue for transplantation.

I apologize for my significant delayed response.

Executive Summary: In your background statement it is stated, "While OPOs see organ procurement as their primary function, to the extent that statutory expectations for tissue recovery are not met, opportunities for donating and using tissues are not met." From the content in this report it assumes this conclusion was drawn from the various survey methods used. Loosely interpreted, OPOs do not see tissue donation as a priority, given whatever the OPO does in collaboration with tissue recovery, processing and distribution? Is that correct?

How well each OPO performs its role with tissue banks will, in fact, vary significantly. How this is evaluated and concluded is problematic because of a wide variety of confounding issues. A few examples are:

- o an absence of standards for performance expectations of the OPO and the tissue bank/s
- o an absence of tissue bank leadership communication with OPO leadership and visa versa
- o inter-relationships for OPOs and tissue banks
- o inter-relationships of tissue banks in the same or close service areas

These examples are not inclusive, but each will create problems in OPO and tissue bank relationships.

"The OPOs' commitment to tissue recovery varies widely." This statement is as accurate as the detailed obtained in your survey methods. Your survey data reports 3 OPOs refer all organ donors for tissue recovery and 2 OPOs reported they refer fewer than 20% of their organ donors for tissue donation.

***Be an organ donor.
it's the chance of a lifetime!™***

For example the 2 OPOs reporting less than 20%:

- o Is this before or after the consent process?
- o Who asked for consent?
- o What was the consent process like?

Similar, more introspective questions would need to be asked of the same data summarized on page ii.

In the Recommendations section it is reiterated that the statutory requirements for OPOs is to "have arrangements to cooperate with tissue banks for the retrieval of tissues to assure that all useable tissues are obtained from potential donors." In addition, having the same expectation of tissue banks should assist in this process and must be a component of the process. One way communication will not bring about the desired change. This is a two-way street.

If the PHS is to provide general oversight and guidance, there must first be some standards for expectations for OPOs and tissue banks. Those standards should be developed in a collaborative manner to create buy in. Once standards are developed and implemented then a reasonable system for oversight would be more effective.

Findings: In the analysis beginning on page 8 the report focuses on the per cent outcome for tissue donors from organ donors. The report brings to light important confounding concerns in adequately evaluating the data, ie the impact of the consent process, the publicity given to organ donation. Further analysis concludes "that OPOs more involved in tissue banking are likely to put greater effort into tissue recovery." The report goes on to comment that this may be the result of a greater financial interest or an organizational culture that encourages and supports tissue procurement. While both are feasible, perhaps the enhanced outcomes in these OPOs has to do with investment and control over the actions that OPOs have learned over time will enhance the commitments of the public served and the professionals involved.

Recommendations: It is not fruitful to not support the general recommendations. It is imperative that we track together, keeping our goals focused on the public we each serve.

The PHS should provide some general oversight and guidance for OPOs regarding their arrangements with tissue banks and their tissue recovery activity.

Recommendation #1: The stated perspective tends to be one-sided, focusing primarily on what OPOs must do to "defend" themselves based on perceived expectations. In addition, the questions that may be asked to ascertain useful data are not going to get at the real problems. Pull together the leadership in organ donation and tissue donation and assist them in developing standards that hold up expectations of performance for each that result in the outcomes desired.

Recommendation #2: The effective dissemination of "what works" will be useful. The actual determinants for "what works" is more complex than examining numbers. Again, there are so many confounding factors to consider. A similar approach as noted above could be useful in this process.

Recommendation #3: It is unclear how you monitor tensions, evaluate the reality of these and then proactively problem-solve.

The HCFA should include an assessment of OPOs' performance in tissue recovery as a part of the OPO recertification process.

Page 3
Mrs. Brown

It is not unreasonable for OPOs to be held to a standard of performance that will provide organs and tissues to the public we serve. It is a known fact that OPOs have sought measurements of performance in organ donation since the late 1980's. It is much simpler to know what standards you are being held to rather than guessing whether you "measure up." As a result of this need, currently, there is a multidisciplinary OPO Performance Standards Task Force in place. This is a collaborative effort between UNOS and AOPO.

The key to developing performance standards is to involve the parties that will be affected. This creates ownership and a buy in for the outcome/s.

Again, AOPO appreciates the opportunity to respond. AOPO supports the efforts of the Inspector General to hold each of us to a high standard, especially in our service to the public. This has been and continues to be demonstrated by AOPO's relationship with the Division of Transplantation, under Ms. Braslow's adept leadership. AOPO offers its membership and leadership to assist in the process.

Sincerely,



Diana Clark
President

cc: Inspector General File

APPENDIX D

ENDNOTES

1. DHHS, PHS WorkGroup on Organ and Tissue Transplantation, *Tissue and Organ Transplantation: Assessment Report*, July 18, 1991; Staff Memorandum for Senate Committee on Labor and Human Resources, September 29, 1992. The exact level of tissue donation and transplantation activity is unknown. We have seen estimates range as high as 600,000 tissue grafts annually. The PHS report states that "OPOs and tissue banks recovered tissues from an estimated 7,500-10,000 donors last year. These tissues were used in approximately 250,000 to 300,000 (mostly bone) allografts." The Senate Staff Memorandum reports that "more than 10,000 tissue donors annually supply more than 500,000 pieces of tissue for transplantation."

2. Other tissues used in transplantation include human heart valves and arteries, skin, bone marrow, and corneas.

3. HHS Office of Inspector General (OIG), *The Distribution of Organs for Transplantation: Expectations and Practices*, (OEI-01-89-00550), March 1991.

There are actually 66 Medicare-certified OPOs, including the OPO of Puerto Rico. We limited our universe for this study to the 65 OPOs operating in the 50 States and the District of Columbia. A further consideration in this decision was the low level of organ procurement activity in that OPO, two donors in 1992. (Appendix B describes our methodology in more detail.)

4. Public Health Service Act, Section 371(b)(2)(I), 42 U.S.C. §273.

5. *American Association of Tissue Banks Newsletter*, 16 (Oct 1993) 5:10.

6. 58 Fed. Reg. 65,514, Dec. 14, 1993 (to be codified at 21 CFR Parts 16 and 1270). Representative Ron Wyden and Senator Paul Simon have introduced legislation in Congress to regulate tissue banking (H.R. 3547, S. 1702). In addition, New York, Florida, and California have passed legislation that regulates tissue banking to differing degrees.

7. Bear, Stearns & Co., Inc., Investment Research, "Osteotech, Inc.," December 30, 1991.

8. Jeffrey Prottas, "Issues in Tissue Banking," (unpublished paper, Brandeis University), January 1990.

9. *Ibid.*

10. PHS, "Draft USPHS Guidelines for Prevention of Transmission of HIV through Transplantation of Human Organs and Tissues," March 17, 1993. When finalized, these guidelines will update recommendations on organ and tissue transplantation published in 1988.
11. According to data from the Division of Transplantation in HRSA, 1,137 hospitals provided at least one organ donor in 1992, out of more than 5,000 hospitals in the country. 481 hospitals provided only one donor, and 656 hospitals provided more than one donor.
12. HCFA Form-576, "Organ Procurement Organization (OPO) Request for Designation as an OPO under §1138 of the Social Security Act," question IV-7.
13. See, for example, Helen W. Leslie and Scott Bottenfield, "Donation, Banking, and Transplantation of Allograft Tissues," *Nursing Clinics of North America* 24 (December 1989): 891-905.
14. E.U. Conrad, D.M. Strong, K.R. Obermeyer, and M.S. Moogk, "Tissue Donor Testing and Recipient Tracking for Hepatitis C," *AATB Information Alert*, 3 (April 1993) 2.