

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

Informed Consent in Tissue Donation

Expectations and Realities



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EXECUTIVE SUMMARY

PURPOSE

To assess expectations for and limitations of informed consent for tissue donation.

BACKGROUND

Human tissue is an important source of medical treatment. The specific number of tissue donors in this country is unknown. It is clear, though, that the numbers are growing. In 1999, more than 20,000 donors provided cadaveric tissue, up from perhaps 6,000 donors in 1994. Tissue banks distributed over 750,000 allografts for transplantation in 1999.

A first step in tissue donation is obtaining consent from a deceased individual's family. Even if the individual had indicated willingness to donate organs (*e.g.*, on the driver's license), it is practice in this country to obtain consent from the next-of-kin.

Tissue banking is subject to more limited regulation than is the nation's organ procurement system, even though both organ procurement organizations (OPOs) and tissue banks are involved in approaching families to request consent for donation. For example, the National Organ Transplant Act requires OPOs to meet certain organizational and staffing requirements; the Act also requires OPOs to assist hospitals in establishing and implementing protocols for making routine inquiries about organ donation by potential donors. No similar requirements exist for tissue banks.

This report responds to a request from the Secretary of Health and Human Services, asking the Office of Inspector General to examine issues related to informed consent for tissue donation. We base our report on interviews with 30 organizations involved in tissue recovery and processing; responses from more than 50 donor families to questions posted on an Internet web site; interviews with officials of associations representing sectors of the tissue banking industry; and a review of laws, regulations, and association standards for tissue banking.

In this report, we use the term "tissue banks" to refer to entities involved in procuring, processing, storing, and distributing tissue. We use the term "tissue" to refer to skin, heart valves, and musculoskeletal tissue such as bone, cartilage, ligaments, and tendons.

FINDINGS

The expectations and altruistic motives of donor families are the foundation of tissue banking. Donor families and tissue bank staff told us that in agreeing to donation, families make some basic assumptions:

- **Enhancing the lives of others.** Tissue will be used to meet important medical needs.
- **Respect for the donor and the family.** The donor's body will be respected during tissue recovery, the gift will be recognized as coming from donated human tissue, and

the donor family's emotional needs will be respected.

- **Trust in the tissue banking community.** Organizations involved in procuring and using the donation will act as stewards of the gift.

However, the reality of tissue banking raises some underlying tension with families' assumptions.

- **Commercialization of tissue banking.** Large scale financial operations may overshadow the underlying altruistic nature of tissue donation.
- **Tissue viewed as a commodity.** After processing, tissue and products containing tissue often are marketed and sold as a medical supply, rather than as a donation.
- **Cosmetic uses of tissue.** Some tissue, particularly skin, may be processed into products that are used for cosmetic purposes that may not be medically indicated.

Fundamental factors limit the amount of information that is given to families.

- Families are asked to give their consent at a point in time when they are extremely vulnerable.
- Families may not wish to receive detailed information about tissue banking.
- Obtaining consent and documenting a donor's medical suitability require time-consuming and invasive questioning about a recently deceased loved one.

Current practices in requesting consent raise concerns about how and what information is provided to families.

- Tissue banks often request consent over the telephone, rather than in person.
- Many tissue banks rely on staff from other organizations to obtain consent. There may be little training and accountability of external tissue requestors.
- Tissue banks provide donor families with little written material at the time of donation.

Until recently, standards governing how families are approached and what they are told about tissue donation have been nonexistent. However, some advice and guidance have emerged.

- Federal laws and regulations do not address the manner in which tissue banks obtain consent.
- States' Uniform Anatomical Gift Acts do not address what information tissue banks should provide in obtaining consent.
- The National Donor Family Council has proposed key elements of an informed consent policy for tissue donation.
- Organizations representing the tissue banking industry have issued a statement that addresses elements of informed consent. These organizations include the American Association of Tissue Banks (AATB), the Association of Organ Procurement Organizations, and the Eye Bank Association of America. The AATB is incorporating this statement into its accreditation standards for tissue banks.

CONCLUSION

Tissue banking and processing practices have gradually diverged from donor families' expectations in recent years. The tissue banking industry has expanded and become more complex and costly. New ways of using tissue for medical treatment have been developed. Processed tissue often is marketed and sold like any other medical product. For some people, these practices call into question the non-profit basis of the tissue banking community. Despite these changes, the industry's foundation remains that of human tissue altruistically donated by individuals and their families at an extraordinarily sensitive time. The special nature of this product, and the circumstances under which it is made available, call for steps to be taken above and beyond those that would apply to most other business or philanthropic enterprises.

RECOMMENDATIONS

Importance of increasing donation. The Office of Inspector General has examined issues related to organ, tissue, and bone marrow donation, allocation, and transplantation for more than a decade. The principles underlying our work have focused consistently on enhancing equity for patients, improving access to transplantation, and encouraging donation.

Encouraging donation was of paramount importance to us as we developed our recommendations. It is our hope that these recommendations will encourage donation. Our recommendations encourage joint action among groups representing the tissue banking industry, donor families, and the government.

RECOMMENDATIONS TO THE DEPARTMENT

The Health Resources and Services Administration should work with groups representing donor families and the tissue banking industry to develop guidelines for conveying information to families about tissue donation.

HRSA's Division of Transplantation supports the development of programs to increase donation. In that role, HRSA has gained considerable expertise about effective practices in requesting consent. The agency could act as a resource to tissue banks and families.

HRSA's efforts could focus on such areas as:

- Identifying principles and guidelines that should underpin consent requests, such as those outlined recently by the National Donor Family Council and by industry groups;
- Making suggestions as to the type, format, and content of written information about donation that tissue banks could share with families.
- Making recommendations on information that would be useful for training tissue bank staff and external requestors; and
- Making recommendations on assessment tools that would be useful in evaluating the effectiveness of requestors.

The Health Care Financing Administration should address informed consent for tissue donation through the Medicare conditions of participation.

HCFA requires hospitals to assure that the family of each potential donor is aware of its options to donate tissues, organs, and eyes. Elsewhere in this report, we call upon donor family groups, the tissue banking industry, and HRSA to develop guidelines for conveying information to families about tissue donation. HCFA could use these guidelines as it provides information about the conditions of participation for organ, tissue, and eye donation. The agency could publicize these principles through the HCFA Internet site.

In the longer term, the agency may wish to examine the Medicare conditions of coverage governing organ procurement organizations. In that examination, the agency could consider additional requirements to strengthen working relationships between OPOs and tissue banks. Such requirements might include:

- Holding OPOs responsible for informed consent for tissue donor families when they request consent on behalf of tissue banks; and
- Requiring OPOs to include tissue banks in the training that they conduct for designated requestors.

RECOMMENDATIONS TO THE INDUSTRY

At the time of obtaining consent, tissue banks should provide families with written materials that provide fuller disclosure about the uses of tissue and the nature of the gift.

Tissue banks should give written material to families at the time the banks ask for consent to donation, or in the days immediately following the request. The material should be appropriately thorough. It would serve as one way to supplement the information that requestors provide to the family during their conversation about donation, while providing requestors with flexibility to adapt that conversation to the unique needs and responses of each donor family. At a minimum, this material should include:

- A copy of the signed consent form;
- Written material on how to follow up with the tissue bank if concerns arise;
- A full description of the uses to which donated tissue may be put; and
- A list and description of other companies and entities with which the bank has relationships for processing and distributing tissue.

Tissue processors and distributors should ensure that information accompanying their product clearly indicates it is derived from *donated* human tissue.

Such a step would require only minor changes in packaging and marketing materials. But it would go a long way towards showing ongoing respect for the donor, the family, and the gift of donation. Tissue banks should:

- Indicate clearly on all tissue packaging that the contents derive from donated human tissue; and

- Indicate clearly on all marketing and informational material that these products derive from donated human tissue.

Tissue banks should foster greater accountability for the performance of those who request consent for donation.

Responsibility for ensuring that requestors are providing accurate, sensitive, and appropriate information rests with tissue banks and the processors with which they work. These organizations should:

- Ensure that requestors — both from their own organizations and from hospitals — are fully and appropriately trained;
- Provide continuing education for requestors; and
- Conduct an ongoing assessment of requestor performance as a means of ensuring that they are providing full and accurate information to families approached for donation.

The tissue banking industry should work with groups representing donor families to explore a process for periodic public disclosure about tissue banks' financing.

The purpose of the examination we recommend here is to respond to family and general public concerns about knowing the sources of funding for tissue banks and other entities with which the bank has financial arrangements. The examination would consider whether financial information would be useful as part of a package of information provided to donor families. The examination would consider:

- What types and how much financial information would be useful for families and individuals in making decisions about donation;
- The advantages and disadvantages of disclosure, including the potential impact of financial disclosure on donation;
- Whether the information should be provided in all cases, or only if requested by a family; and
- The content, style, and format of disclosure.

COMMENTS ON THE REPORT

We received comments on a draft of this report from the Department of Health and Human Services. They are supportive of our findings and recommendations. The full text is included in Appendix C.

Our work in tissue banking continues. We will maintain an active watch on how the tissue banking community responds to the concerns we have raised.