

Competition for Altruism: Bone and Organ Procurement in the United States

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THERE IS A CHRONIC, INDEED GROWING, SHORTAGE of donors of human tissue in the United States. During the last three years, while the number of organ donations obtained in the nation has remained constant, the demand for organ transplantation in the last two years has increased by more than 30 percent (United Network for Organ Sharing 1990). This serious situation with regard to transplantation is only a small part of the larger problem of burgeoning medical demand for donated human tissue.

The medical demand for human bone and related soft tissue (fascia, tendons, ligaments, and so forth) and for heart valves is poorly quantified but immense. Although the actual number of procedures involving such body parts is not known, the scale is orders of magnitude higher than that of organ transplantation. In excess of 40,000 human corneas were implanted last year (Eye Bank Association of America 1990) and the number of "units" of bone employed during surgical procedures runs into the hundreds of thousands. (A single tissue donor can provide a large number of "units" of usable bone material in the form of bone chips, powder, and larger pieces. The actual number of human donors of bone, however, is in the range of 4,000 to 6,000.) There are no reliable estimates of the number of procedures done using tendons, ligaments, or fascia.

During the last several years musculoskeletal procurement agencies, which procure bone and soft tissue, have grown in size and aggressiveness. Bone banking (as we will call it for convenience) has become an important activity and bone banks actively seek donors. These donors come from essentially the same hospitals as organ donors and often are even the same individuals.

This overlap between the sources of organ and tissue donation has become a central issue, affecting the organization and supply of transplantable organs and tissue. It threatens to stifle the growth of American bone banking and has the potential for interfering with the supply of transplantable organs.

The convergence of two trends—the growth of musculoskeletal tissue banking and the stagnation of organ donation—creates new demands to be met by public policy. State and federal governments, although extensively involved in organ donation through laws, regulations, and reimbursement policies, not only take little cognizance of tissue procurement, but they may also exacerbate the competition of bone banks and organ banks for access to hospitals and donors.

Bone Banking System

Bone banks are not a recent phenomenon. For many years orthopedic surgeons have saved bone obtained during surgery for later use in other patients, usually processing it in minimal ways. It rarely left the surgical team, much less the hospital. The bone came from living patients and went to other patients of the surgeon. Many of these “surgical bone banks” still exist in the United States. Their actual number is not known because their activities are often sporadic and informal. Surgical bone banks tend to leave no records of their activities and provide tissue only to physicians who are directly involved with them. America’s organized bone-banking system tends to view these surgical banks as irrelevant to the nation’s tissue needs, believing the total amount of tissue that they obtain to be small. In fact, there are no trustworthy estimates of the volume of bone handled by surgical bone banks.

Between 75 and 120 organized musculoskeletal tissue banks exist in America. Each is a nonprofit organization and can be found in every part of the nation. (Some of the organizations that process bone, on the other hand, are for-profit businesses.) Little or no trustworthy quantita-

tive data are available on a national basis, a lacuna that is especially noticeable when we try to examine smaller tissue banks. The largest tissue banks employ as many as 20 employees and procure tissue from in excess of 300 donors each year. These banks generally have boards of directors on which physicians and full-time executive directors are heavily represented. Even our present incomplete knowledge of the system reveals considerable organizational variation. Some musculoskeletal banks are associated with universities, whereas others are free standing. Some are also organ procurement agencies and some are even associated with eye banks. However, the overall distribution of these variations will not be known until ongoing research is completed (Prottas 1990).

The system is clearly in the midst of substantial growth as indicated by the fact that, in 1988, the American Association of Tissue Banks had fewer than a dozen bone banks as institutional members, a number that by the spring of 1991 had grown to 30.

The tissue banking system, however, remains almost totally a local phenomenon with minimal regional or national structures in place. A professional association (American Association of Tissues Banks) has become more active and a number of small interagency organizations that deal with bone processing and distribution have sprung up. Interagency cooperation remains largely ad hoc, however, and most translocal activities are technical, as the tissue-banking "community" is only beginning to develop a self-awareness that extends beyond shared technical concerns. This development reflects its recent growth and increased involvement with the organ procurement system and with federal policy makers.

Several factors are fueling the growth of American bone banking, the most important being medical innovation and its diffusion. It is impossible to estimate accurately the medical demand for human bone, given present data. However, the demand can be characterized as, effectively, infinite. No bank in the United States appears able to maintain any meaningful reserve of bone products because bone is transplanted as fast as it is procured and processed. When interviewed, directors of the nation's most active bone banks stated that they could use any imaginable increase in the amount of bone procured without satiating the demand.

Medical uses of human bone are extensive, ranging from periodontic use of bone powder to spinal fusions to the replacement of large bones destroyed by tumor. Innovations in use are constant, as is the diffusion of new practices within the orthopedic and neurosurgical communities.

The growth of bone banking is essentially demand driven. Many physicians and dentists are capable of performing bone-based procedures that would greatly benefit their patients.

Bone banking also represents an organizational opportunity. All bone banks (and eye and organ banks as well) are nonprofit organizations as it is against federal law to buy or sell human tissue. Yet all agencies, however organized, must deal with financial and operational realities. Those realities are benign for bone banks. The insatiable demand for bone means that the scope of operation of any bone bank is limited only by its ability to locate donors. As the number of potentially suitable bone donors is far greater than the present supply, substantial growth is possible.

The fiscal environment is also encouraging. Although tissue banks do not sell human tissue, they do charge users in order to recover their costs. Bone banks have no trouble obtaining sufficient revenue and, in the view of some, are even particularly well situated to generate a substantial surplus of revenue over costs (allowing a margin of reserve, funding for growth or in order to subsidize other nonprofit activities, which are all legal and desirable from the point of view of nonprofit corporations). Among the reasons for this financial situation the excess of demand over supply is paramount. Another is that the medical system using the tissue is not very price sensitive. Most users are hospitals acting for surgeons. The cost of the bone is treated as a medical supply cost and is a small fraction of the cost of the procedures. The pricing of bone products is also complex. Every bone bank will offer hundreds of different bone products—powder, chips, dowels—in varying sizes and types. Inevitably, pricing policy is somewhat arbitrary and therefore the bank retains substantial flexibility. Each of these factors provides bone banks with the opportunity to manage their revenues so as to ensure comfortable operating surpluses.

Organ procurement organizations (OPOs) operate in a protected financial environment. Each of the nation's 67 OPOs is federally certified and obtains the bulk of its revenues from the federal government under the end-stage renal disease program, a subsection of Medicare. Under the rules of this program OPOs are reimbursed 100 percent of the actual costs they incur in kidney procurement. The costs of nonrenal organ procurement (primarily hearts and livers) are charged to the recipient's insurance carriers. Federal rules specify how an OPO's costs must be calculated and charged to different payers. In financial terms OPOs are

tightly regulated nonprofit utilities. Although they face no financial risks, their opportunities to achieve operating surpluses or fiscal innovation are constrained.

This difference between the finances of bone and organ banking causes many OPOs to be suspicious of bone banking (Prottas 1990). They believe that bone banks can generate a comfortable operating surplus and that some use this surplus to support nontransplant activities like research. Many OPOs hold the view that organizations are entering tissue banking in order to finance other activities. This perception applies especially to bone banks that explicitly perform other functions such as research or blood banking. This attitude affects the relationship between organ procurement agencies and bone banks in some areas of the country.

In addition to suspicion, there is a degree of envy. Some OPOs hoped that the increase in nonrenal organ procurement would result in increased financial freedom, but federal regulations have been interpreted to limit that flexibility. Revenue generated by nonrenal organs is deducted from federal reimbursements. A number of OPOs are therefore becoming involved in tissue procurement in part because it provides an attractive opportunity for organizational growth and increased financial flexibility. The exact number is not now known, but certainly two or three of the nation's largest OPOs are presently engaged in tissue procurement and a larger number plans to begin bone banks. Although financial considerations do not constitute the primary motivation for OPOs to enter tissue banking, they do play a role.

Second in importance to the supply-demand balance, technology is the factor that allows bone banks to operate with a surplus. Organ procurement is labor intensive and highly regulated, but bone banking has a substantial capital component. Procurement of the bone is analogous to procurement of human organs, but bone, unlike kidneys or livers, requires substantial processing before it is used. In the last several years, this processing has become more complex, technically sophisticated, and expensive. The sterile transformation of procured bones into bone products, such as dowels and chips, requires construction of specialized facilities so that it has come to resemble a pharmaceutical manufacturing process. As in any manufacturing process, there are economies of scale and other opportunities to control costs. Presently the processing stage of bone preparation represents between one-third and one-half of the cost of the transplantable product. Bone banks that are able to process

a large amount of bone efficiently, or that can contract advantageously with another organization, can therefore realize significant cost reductions. Such reductions are not possible when the bulk of costs come from donor procurement, so this is an alternative not open to OPOs or eye banks.

The capital-intensive aspect of bone banking not only makes it an attractive organizational activity when compared with other tissue organ procurement, but it also imposes an atypical structure on bone banking. When bone processing was simpler and less capital intensive, most bone banks did it themselves, but in recent years the trend appears to be toward the concentration of processing in a small number of organizations that contract with local bone banks and can benefit from the economics of scale. It is not yet clear how far that trend will go, but currently there are only three to five major processors of bone, and, at its present scale of operation, the bone-banking system probably cannot profitably support many more.

Structurally this implies a very different model from that obtaining in organ banking—and, for that matter, eye banking. OPOs are self-contained organizations with regard to processing and distribution of organs. Each OPO does its own organ evaluation and tissue typing and locally transplants the bulk of the organs it procures. The only translocal organization of importance in organ procurement is the federally mandated Organ Procurement and Transplantation Network (OPTN). This organization has regulatory and standard-setting powers and serves as a watchdog and facilitator for interagency organ sharing. OPO membership in the OPTN is mandatory. The organ procurement system, therefore, consists of a single, nonprofit regulatory unit and some three score of functionally identical organ procurement agencies. Although the OPOs differ in size, their identical functions are financed in the same way and they are accountable to similar boards of directors and the same federal agencies.

In contrast, bone banking contains a variegated organizational mix. Although there is no equivalent in organ procurement to the small and often informal surgical bones banks discussed above, the existence of a small number of specialized processing organizations constitutes a more important difference. In the first place, it means that some of the organizations critical to bone banking do not procure bone. As processing units these organizations have different interests, face other challenges, and operate in an environment unlike that of any tissue or bone pro-

curement agency. Are they to be understood as part of the tissue procurement system or simply as a technical adjunct to it?

The question is important for several reasons and is complicated by the fact that two of the largest bone-processing organizations are for-profit companies. The impact of their for-profit character and the fact that they have no analog in organ procurement affects the relationship between OPOs and bone banks.

The idea of profit is anathema among OPOs and eye banks and, indeed, among many in bone banking. OPOs played a major role in passing federal legislation that outlawed buying or selling human organs and has effectively excluded all for-profit organizations from the organ procurement world. Because all OPOs are directly involved in dealing with donor families they see tissue procurement as closely bound up with both human tragedy and human altruism. They see profit in any form as an exploitation of donor families and of the medical professionals whose work in donor identification and maintenance is uncompensated.

The fact that many bone banks employ for-profits to process their tissue colors the views of individuals involved in organ procurement. The issue is in fact a complex one. If a bone bank processed its own tissue and made a profit for shareholders, this certainly would be illegal as well as unacceptable to most organ and tissue procurement agencies. On the other hand, transplantable organs are preserved in special solutions and some kidneys are preserved with specialized equipment. The manufacturers of these medical supplies and equipment are for-profit agencies. In which category ought we to place bone-processing agencies? Are they to be seen as purveyors of a specialized sort of medical supply to bone banking, much like the manufacturers of pulsatile perfusion machines? Or have they simply carved out a profitable piece of the tissue procurement and preparation process that allows them to make money from tissue donation within the letter, but not the spirit, of the law? There are arguments on both sides, but OPOs tend toward the latter view, a natural result of the differences between organ and tissue procurement. In the organ procurement world, organ preparation and preservation are inevitably the responsibility of the procuring OPO; hence, they see this step in the process as embedded in the procurement system. The greater technical demands of bone processing make that step more complex and costly for bone banks, but does not alter its essential character. Justice aside, the important role of for-profit bone-processing

companies increases the distance between bone and organ banking and makes cooperation between them more difficult, particularly in localities where the local bone bank contracts with a for-profit. However, the issue colors relationships nationally as well.

Competition in Paradise

Many OPOs are involved in, or are considering involvement in, bone banking. The attractiveness of bone banking in terms of organizational growth and financial security is part of the motivation, but not the sole or even the primary one. Fear is the key.

Success in organ procurement depends on obtaining access to potential donors in a timely manner. The average organ donor spends between one and two days in the hospital before dying (Batten and Prottas 1989) and only the medical staff treating that patient is aware of his or her condition and prognosis. An OPO's key task is persuading those doctors and nurses to report on potential donors in time to make the necessary arrangements and to obtain permission from the potential donor's family. OPOs, especially effective OPOs, invest most of their time and resources in cultivating hospitals and their medical staffs. This is a demanding task for several reasons. The medical staff is being asked to assume an additional responsibility that differs from their primary one of caring for the sick; to do so they must both confront their failure to save a patient and be willing to explain brain death to distraught relatives. The OPO can offer no compensation beyond the opportunity to help strangers. For a hearteningly large number of doctors and nurses, this is sufficient.

However, OPOs are sensitive to the fragility of their relationships with hospitals and their staffs. They are at pains to minimize their demands on medical staffs and to maintain the trust of those doctors and nurses. They believe that success depends on prolonged and repeated proof that OPO staff is competent and sensitive and its actions will not offend families or cause the medical staff difficulties. Not surprisingly, they view with horror the prospect of strangers entering "their" hospitals and speaking with "their" doctors and nurses. Not only do they see it as adding an uncontrollable element into relationships that are the life blood of their organization, but they also perceive that it would confuse the staffs and complicate the donor referral process.

Whatever the validity of the OPOs' fears, the central fact of competition is indisputable. There are, it is true, potentially more musculoskeletal donors than organ donors, and they are to be found in more services in the hospital and, probably, in more hospitals. Nevertheless, many (some say most) organ donors are suitable bone donors and the hospitals and services that provide organ donors are prime locations for bone donors. The two activities overlap and the possibilities for serious mutual interference are significant. The average OPO obtains referrals about potential organ donors from about 50 hospitals (Prottas 1989). This despite the fact that the clinical criteria for organ donors are narrow; most are trauma victims and all must have been declared brain dead. Therefore, most organ donors will come from larger hospitals with the staff and equipment necessary to make brain-death determinations. Nevertheless, smaller and less sophisticated hospitals occasionally do see potential donors and most OPOs spend at least part of their resources maintaining relationships with these smaller institutions.

Bone donors can be found in a wider range of hospitals, but the best hospital sources for organ donors are also the best potential sources for bone donors. The overlap is size and acute-care orientation. Even if OPOs were very conservative and only worked with the hospitals that treat the largest numbers of potential organ donors—OPOs in fact cast their nets far more widely—they would still be dealing with hospitals that are the best sources of bone donors. This inevitably means that the most important hospitals are likely to face dealing with multiple agencies wanting to "harvest" human body parts.

Hospitals cooperate in organ and tissue procurement primarily out of a sense of an obligation to patients. (We will discuss legal requirements, but legal requirement is a long distance from effective cooperation.) They legitimately resent having to disentangle inconsistent demands for access and referral from different outside organizations. Hospitals are caught in the middle and, in some places, are already complaining to OPOs and state officials. Disgruntled hospitals, especially large ones, are threatening to all tissue procurement agencies.

Disgruntled doctors are an even more disturbing prospect. Busy doctors and nurses are even less inclined to speak with representatives of different procurement agencies, much less to make multiple referrals. Within a hospital almost all the organ donors will be found in intensive-care units (ICUs). Patients dying in the emergency room are not suitable because there is rarely time to place them on respirators or to

make a brain-death determination. Few patients in other services have the kind of acute insult to the central nervous system that is characteristic of suitable organ donors. Bone donors are to be found in many more services within the hospital and so, outside of the ICU staff, there is little danger of conflict. However, if ICUs are not the only place to locate bone donors, they offer the most promise. Here the risk is borne heavily by the OPO. If the ICU staff becomes disenchanted, bone donation suffers a serious setback and organ donation ceases. Moreover, the hospital administration tends to take its attitudes toward donation from the medical staff, multiplying the impact of unhappy doctors and nurses (Prottas and Batten 1986a).

Finally, there is the issue of families. Everyone understands that families ought never to be subjected to multiple donor requests. Avoiding this requires both coordination and trust. The coordination is itself not easy because it is clearly desirable for those who speak to the family to know the patient's condition and the medical staff caring for him or her. This means that the decision to assign primary responsibility for the procurement process must occur at its initiation and cannot begin when the family is to be contacted. The issue of trust is even more central. Asking permission from a family for organ and tissue donation is a sensitive matter; a judgment regarding how to ask and *for what* is subjective and not easily evaluated in retrospect. Until recently, many organ procurement coordinators hesitated to ask for hearts or livers for fear of losing permission to excise kidneys. Bone banks must wonder if they can be "trusted" to ask for bone or soft tissue and, conversely, OPOs might fear the loss of permission for some organ donation in the pursuit of bone donation.

In 1991 there have been complaints from hospitals, OPOs, and bone banks about conflicts and each other's practices. These complaints have taken the form of letters written to the secretary of the Department of Health and Human Services, representations to congressional representatives, and, in the Washington, D.C., area, letters to hospital administrators. This is not to suggest that all or even many of these potential difficulties are occurring everywhere or frequently. Until now there have been limited complaints by a few hospitals and bone banks, but their impact on the transplantation communities has been out of proportion to their present scale, exaggerating as much as confirming fears. Complaints have also begun to draw public officials into the issue because they have often been directed to state and federal policy makers.

Government Role

It is traditional in the health care field (as well as in other sectors of the economy) for those dissatisfied with outcomes to turn to the government for relief. The history of organ transplantation is composed of efforts to engage the government in the resolution of difficulties that have emerged over matters of financing, organization, and policy. In the early 1980s several elements of the organ transplantation community turned to the federal government to solve their problems. Nonrenal transplant surgeons lobbied vigorously to have heart and liver transplantation declared an acceptable clinical procedure. The goal was not so much to obtain Medicare reimbursement (few Medicare beneficiaries are suitable candidates), but rather to induce private insurers and states to cover nonrenal transplantation. Renal transplanters who were committed to the efficacy of tissue matching among OPOs, along with other dissatisfied segments of the transplant community, sought federal assistance in regularizing the criteria for sharing kidneys. Finally, the entire community joined in the effort to persuade the federal government to outlaw the buying and selling of organs.

During the last two years a similar process has begun to emerge in tissue banking. The particular forms of dissatisfaction differ, but the essence has been consistent regardless of who is complaining: "My competitors are unfairly excluding me from access to donors and hospitals. They are refusing to inform me of potential donors and/or pressuring hospitals to refer donors to others in lieu of my organization." Most commonly these complaints would be from bone banks about OPOs. Bone banks have alleged that the local OPO did not inform them of potentially suitable donors, either because the OPO itself intended to procure tissue or because the OPO had given preferential treatment to another bone bank. Another common complaint has been that the local OPO discouraged hospitals from directly contacting the bone bank, asking them to make all potential donor referral through the OPO itself. At the same time, some OPOs have alleged that several bone banks associated with blood banks have tried to pressure hospitals into dealing solely with them on matters involving tissue donors or face the loss of access to blood supplies. The accuracy of these complaints aside, they have three striking features. The first is that they were widely discussed in the organ and tissue procurement community and influenced attitudes far beyond their local significance. Second, each involved a call to public officials

for redress. Finally, most of these complaints have come from bone banks and are directed to federal and state officials because, the bone banks allege, it is the actions of these officials that have allowed OPOs to exclude them.

Federal law and state "required request" laws give OPOs significant advantages over other procurement agencies. Federal required request law makes all hospitals that receive Medicare reimbursement cooperate with a certified OPO in organ procurement.¹ All hospitals must have organ procurement protocols and an arrangement for donor referrals with a specified OPO. Individual physicians are expected to refer potential donors and to enter into medical records the outcomes of those referrals or the reasons a referral was not made. The effectiveness of required request laws is open to dispute, but the special status they confer on OPOs is not (Caplan and Wilrang 1989). As a result of these laws thousands of hospitals have governmentally mandated relationships with organ procurement agencies. In 1986 these relationships generated in excess of 15,000 donor referrals (Prottas 1989). From the hospital's point of view a relationship with a bone bank must be *in addition* to one with an OPO. In this sense government action has tilted the playing field strongly in favor of the OPO. Whether this tilting is good or bad, indeed whether it is intentional or not, the relationship between organ and tissue procurement becomes a public matter, making it inevitable that dissatisfaction will be brought to the attention of policy makers. Therefore, unless the government were to retreat from its involvement in organ procurement, it cannot avoid dealing with the implications of its actions for tissue procurement.

Retreat is not a practical alternative. Renal transplantation depends totally on federal funding and it saves the end-stage renal disease (ESRD) program a considerable amount of money by removing 8,000 people a year from dialysis dependence (Eggers 1984). Moreover, as a matter of public policy, state and federal governments have made a strong, and probably irreversible, commitment to overseeing the equity of human organ distribution. Ever since the Task Force on Organ Transplantation Report in 1986, it has been the official policy of the federal government to consider human organs a national resource whose use must adhere to public standards of fairness. At base this perspective is

¹ P.L.99-509.50. National Transplantation Act of 1986. Sixth Omnibus Reconciliation Act, October 1986.

rooted in the fact that donated organs are considered to be unique—to be gifts from the families of the dead. This conception of the public interest in organs underlies the public funding of the Organ Procurement and Transplantation Network (OPTN), federal regulations requiring public representation on the boards of directors of the OPTN and local OPOs, and a host of other financial and regulatory interventions into organ transplantation.

This line of thinking applies as readily to bones, tendons, heart valves, and, for that matter, eyes, as it does to kidneys and livers. All are non-replaceable parts of the human body (unlike blood or bone marrow, which the donor's body replaces, leaving the body essentially unchanged). All are obtained by permission of the family of a deceased donor. Whatever ethical obligations uncompensated, altruistic donation imposes on the distribution of kidneys applies to bone and other tissue. If there is a public interest in how one is used, that interest extends to all others. This is implicitly recognized in the National Transplantation Act of 1984, which makes it illegal either to buy or to sell human organs *or* tissue.

Both because of the overarching principles that affect organ and tissue donation and the practical relationship that exists between the two, the foundation for government involvement in the emerging challenges already exists. The only issues are the timing and character of that involvement.

Similarities and Differences

Public action would be easier if organ procurement activities were either wholly like or wholly unlike tissue procurement activities. To the extent that the process of tissue procurement is almost indistinguishable from organ procurement, the argument for the OPOs being involved with or coordinating the process is greatly strengthened. After all, OPOs exist in every part of the nation; state and federal laws require that hospitals associate with and refer patients to them. Nationally OPOs receive over 15,000 such referrals each year. However, if the two areas of procurement are considered to be fundamentally distinct, then there is no compelling argument for imposing a solution that excludes specialized tissue banks. The procurement of corneas is a case in point. This is technically

and operationally so different from organ procurement that there is no serious movement to merge eye banking and organ banking.

Eye banking is an activity an order of magnitude larger than organ or tissue banking. Over 40,000 eye donations were obtained last year (Eye Bank Association of America 1990). Because the medical requirements for a suitable corneal donor are so broad and because there is a large potential supply of donors, the fact that eye banks have traditionally experienced difficulties in obtaining access to organ donors is not a matter of great concern.

At first glance the similarities between organ and tissue procurement are more striking than their differences. Bone and organ procurement involves the same core activities: developing working relationships with hospitals and health professionals and interacting effectively and compassionately with families. This is the "core technology" of both activities. The two share a clientele found in the same hospitals and composed of many of the same professionals and families. OPOs have spent almost two decades perfecting the interpersonal skills necessary to obtain referrals. Finally, no policy change could diminish the OPOs' need to continue working with hospitals and families: they are a permanent reality in hospitals.

At the same time tissue procurement does differ significantly from organ procurement. In the first instance, the clientele for organ procurement is only a subset of that for tissue procurement. The potential supply of tissue donors is larger, for technical reasons, and is more widely distributed in the medical system.

The economics of the two endeavors differ. Although all bone and tissue banks are nonprofit organizations, they differ significantly in amount of revenue a given donor can generate. A multiorgan donor may easily generate \$40,000 of revenue to an OPO. This reflects, of course, the costs incurred in the procurement, but it also indicates the level of effort and resource allocation justified in donor location. On the other hand, a tissue donor can generate between \$9,000 and \$20,000. A tissue bank clearly cannot invest as much time and energy as an OPO in locating a donor.

This difference implies important differences in strategy, staffing, and operations between the two endeavors. An OPO can, and on average does, invest 35 percent of its staff time in professional education: talking to doctors and administrators, doing in-service training programs at hospitals, and so forth (Prottas and Batten 1986b). This is a ratio that a

tissue bank cannot easily afford and, as bone banks must approach a far larger range of medical professionals, the professional education strategies of the two organizations must differ.

Staffing needs differ as well. Technically, procurement of bone is unlike that of organs. OPO staff skills are different, as is the role played by the staff. Organ procurement is always carried out by physicians, generally by the transplant surgeons themselves. Bone procurement can be done by bone bank technicians alone or in conjunction with local residents or other physicians not directly associated with the bone bank or transplantation.

The role of bone processing has already been alluded to as a difference between bone and organ banking. Organizationally, the relationship between the processing organization and the bone banks has no OPO equivalent. It involves the management of financial transactions and inventory control unique to bone banking. In addition, the processed nature of graftable bone has an impact on distribution. The distribution of organs is both relatively simple and subject to severe time constraints. In contrast, the typical bone bank may process and distribute bone—to say nothing of soft tissues—in hundreds of different forms. The bone “units” can be stored indefinitely. Bone distribution is several orders of magnitude larger than organ distribution: there are 25 to 40 times as many bone graft procedures as organ transplants. Thus, the organizational structures of bone and organ distribution are completely different, even to the level of who receives the tissue. Whereas organs are given to specific surgeons to be transplanted into identified patients, more often than not it is the hospital purchasing department that orders bone, often to maintain the hospital’s reserve stock of graft material.

Finally, the relationship between the OPO and the transplant surgeons does not resemble what exists between bone banks and its “customers.” This is most clearly seen in the dual role transplant surgeons play for OPOs. On one hand, transplant surgeons function as an OPO’s customers, which is roughly the relationship between bone banks and surgeons. However, transplant surgeons also run OPOs; in many cases surgeons are the directors of OPOs and in all cases they dominate their boards of directors. OPOs therefore have a very different relationship with the medical community they serve than do other kinds of tissue banks.

Sorting out these similarities and differences and crafting responsive policy is the challenge that now faces public decision makers.

Grounds of Resolution

Conflict over bone and soft tissue procurement is destructive to all public goals in the transplant field. It impedes supply, imposes burdens on hospitals, increases costs, and has the potential to generate public controversy and so to undermine public trust. All this is quite apart from the impact on doctors and families! The range of possible solutions is wide. The entire system might be centralized by giving to a single organization in each locality overall responsibility for procurement of all human body parts. As a practical matter this would almost certainly mean that OPOs would become the sole harvester of organs and tissue. Less radically, a single organization might become the coordinating center of a structured local system. Such an agency would handle all hospital and family contacts, but would refer donors to the appropriate organ or tissue bank. Many variations on this coordination role can be imagined, ranging from the central agency acting as the sole contact point with the medical system to its being nothing more than an information agency. Finally, parallel tissue and organ procurement systems are possible, whereby referrals are handled by interagency agreements.

It is also necessary to resolve the question of whether the relationship between OPOs and tissue banks ought to be uniform in all locations or whether local variations are acceptable. At the operational level, there are wide intercity differences in how tissue and organ banks interact.

None of these questions is easily answered, nor ought we to expect a definite answer until the criteria for an acceptable tissue and organ procurement system are carefully considered.

Even at our present level of uncertainty, we can enunciate some fundamental requirements. A developed and reasonably sophisticated organ procurement system already serves the nation. Building a parallel tissue procurement system that does not benefit from the public investment of money, time, and expertise that OPOs represent would be an unjustifiable waste. At the same time, if tissue procurement is performed only at the convenience of organ procurement agencies it will never adequately meet public need. Bone procurement is different enough and important enough to merit the priority attention of dedicated professionals.

The organ procurement system generates over 15,000 referral calls each year. No system that fails to screen these referrals for suitable tissue

donors is acceptable. About 4,000 of these calls lead to an organ donation and the medical indications for suitable bone and soft tissue donors are, in most ways, less restrictive than those for organ donors. What percentage of these referrals leads to tissue donation is unknown; the potential percentage is also unknown. However, even by pessimistic estimates, this pool of referrals represents an indispensable resource for identifying tissue donors. Whatever the final relationship between tissue and organ procurement, it must ensure routine access to the existing referral base.

Policy Directions

It is unlikely that policy makers, especially at the federal level, can avoid involvement in structuring the bone bank-organ bank relationship. Conflict and confusion at the local level will continue to draw public attention to the problems.

There is no reason to expect that satisfactory arrangements between organ and tissue procurement systems will develop in the natural course of events. They may in some areas where historical arrangements are satisfactory to all; in others, exceptional people may step in with original solutions. Nationwide, however, conflict and confusion are likely to be more typical. Nor is it likely that the leadership of the bone- and organ-banking communities will be able to resolve their own problems. Although many in these communities are aware of the problems and are willing to address them, they lack the ability to enforce resolutions. Grounds for public intervention are therefore unlikely to diminish over time.

Moreover, the different substantive views about how to maximize tissue supply are honestly held, but cannot be separated from organizational self-interest. Many bone banks are just now coming into organizational maturity. The scale of bone banking is growing, the medical role of human tissue expanding, and, for the first time, there is some public appreciation of the contributions human tissue (beyond organs) can make to medical treatment. Tissue banks see themselves coming out of the shadow of organ procurement for the first time. The belief of bone bankers that their expertise is necessary to the future growth of the tissue supply is inextricably intertwined with their organizational interest in

maintaining an identity distinct from organ procurement. On the other hand, OPOs believe that their extensive infrastructures constitute the firmest foundation for tissue banking and this too is bound up in their organizational concerns: fear that their relationships with hospitals will have to be shared and the desire to gain entrée into the "growth market" of tissue procurement.

One of the first questions policy makers will confront is the level of required national consistency. There may be no need for each locality to develop the same mechanism for coordinating organ and bone procurement, but certainly some arrangements that may be locally acceptable would not be acceptable from a national point of view. There exists a strong public interest in developing the supply of transplantable tissue and ensuring the equitable distribution of that supply. How policy makers choose to ensure the acceptability of local practices within national standards will depend on how "bad" the worst of local practices seem to be, on the effectiveness of the communities in dealing with their own problems, and on the adequacy of the tissue supply.

The supply of tissue is and will continue to be grossly inadequate. This is not necessarily the "fault" of bone banks, but it is certain that the bone banks in some localities will be seen as ineffective and, in many instances, as not meeting public standards for procedural or substantive equity in their distribution practices. Questions of effective procurement and equitable distribution will come increasingly under public scrutiny.

Leadership is required and policy must be developed now. Bone banking is still in its early years, but it is growing rapidly. Reform of an entrenched system is politically difficult and often expensive; guidance now is the proverbial "ounce of prevention." At present, tissue policy is like tissue procurement—too often an afterthought of organ policy. A comprehensive approach to the need for transplantable human organs *and* tissue is essential. Public policy must become what it calls itself: transplantation policy. Delay will be costly. The supply of tissue will be impeded and conflicts will become more difficult and costly to resolve. While policy marks time, technology develops. This time next year or the following year, there will be more uses for human tissue and more kinds of tissue in use; there will be more procurement systems, more competition in hospitals, more replication of programs, and resistance to changing needs. We will soon need more than a pound of cure.

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