

# The Point System for Organ Distribution

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WHEN congressional hearings on transplantation were held by Congressmen Gore and Waxman in the autumn of 1983, the full implications were not obvious to many who testified. Support for the proposed legislation was organized by Dr Oscar Salvatierra of San Francisco. Those who contributed to the Washington support of the legislation included officers of the American Society of Transplant Surgeons, Norman Shumway on behalf of the thoracic surgeons, many of the procurement coordinators, and myself (TES). There were three definable objectives. One was to increase the supply of organs with a small grants program that could strengthen procurement agencies already in existence or stimulate the development of new programs in underserved areas. An almost unnoticed proviso was the establishment of a national network for organ distribution. The second proposal was to pay for expensive medicines, such as the then new immunosuppressive agent cyclosporine, which had not yet been released by the FDA but which was predicted to be too costly for many patients to afford. The third issue was a prohibition on the buying and selling of organs. This was a specific response to an unpopular proposal by a Virginia physician that a kidney brokerage business be established through which recipients could negotiate with living donors on a commercial basis.

## THE POLITICIZATION OF TRANSPLANTATION

There was resistance to the proposed legislation, not only by the Republican-dominated executive branch of the government but also by powerful professional organizations, such as the American Medical Association (AMA) and the American College of Surgeons (ACS). To the conservative AMA and ACS, the Gore bill represented an incursion into the private practice of medicine and the imposition of controls that inevitably would permeate other aspects of medical care.

From the government's point of view, an important concern seemed to be avoidance of responsibility for payment of expensive transplantation services beyond those already committed in 1972 through the Social Security System for the End-Stage Renal Disease (ESRD) Program. Tactically, the battle lines were drawn over whether such operations as liver transplantation and heart transplantation were "experimental" or "service." The term "experimental" was an administrative convenience for the government bureaucracy, since it was used as a shield to deflect attempts to have the Social Security or other federal systems pay for extrarenal transplants. The undesirable consequence of this strategy was that many health insurance carriers cited the government position in excusing themselves from their obligation to their clients who were caught in the no man's land between service and experimental.

The 1984 Gore bill was passed, but the key issues so important to transplant surgeons were not resolved. Extrarenal transplant procedures remained classified as experimental. The key provision to fund medications was removed from the original bill, although it was restored subsequently in other legislation. The organ procurement and distribution network that already had developed unofficially to the point that it was an international model found itself under siege. A task force was called for to make recommendations in transplantation, including how to distribute organs equitably. Data collection was called for by a separate contract.

## THE JONASSON COMMITTEE

Implementation of the law was forestalled temporarily by deliberations of the task force, which was instructed to complete its work in 6 months. The reasonable and temperate White Paper eventually developed by this group (Chaired by Dr Olga Jonasson, now of Ohio State University) provided broad guidelines by which organ distribution should take place. The task force categorically rejected discrimination on the basis of sex, race, or economic class. It urged caution in giving any weight to such criteria as age, lifestyle, the presence of a social network, or other factors that merely could be judgments of social worth.

## THE UNOS CONTRACT AND THE POINT SYSTEM FOR KIDNEYS

In compliance with the Gore law, a contract was let in 1986 to establish a national organ procurement and distribution network. The contractor by law was the federal agency, The Health Care Financing Administration (HCFA). The contractee was the United Network for Organ Sharing (UNOS), a previously private and nonprofit organization. UNOS, in its turn, had been an offshoot of a regional network called the South Eastern Organ Procurement Foundation (SEOPF). UNOS committees that attempted to develop an organ distribution plan were unable to reach a consensus as the deadline of May 1987 for submission of the plan to HCFA approached.

Meanwhile, a point system for renal transplantation

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Supported by Research Grants from the Veterans Administration and Project Grant No. DK 29961 from the National Institutes of Health, Bethesda, Maryland.

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0041-1345/89/\$3.00/+0

already had been developed in Pittsburgh in the autumn of 1985 that gave credit points to aspiring kidney recipients. Credits were acquired for time waiting, quality of antigen match, degree of immunologic sensitization, medical urgency, and logistical considerations of getting the donor organ and the recipient together within the time limitations of safe organ preservation.

The system of kidney allocation had been in effect in western Pennsylvania since January 1, 1986. Because the results were encouraging,<sup>1</sup> the Pittsburgh plan was presented to the UNOS Board of Directors for national use to begin on November 1, 1987, and was accepted without change. At the same time, the Board of Directors of UNOS established a national kidney transplant registry on the framework of the old UCLA data registry that had been in existence for several years previously.

#### Administrative Features

The point system accepted by the UNOS Board of Directors contained three important principles. The first was that of regional primacy, which gave the right of first usage of a kidney to the procurement area where the organ was obtained, with secondary refusal rights to anyone else in the same UNOS region. After passing through these checkpoints, the organ was released to the national pool. The only exception to regional primacy was in the event of a 6-antigen (perfect) match elsewhere in the country.

The second principle was the primacy of physician judgment in rejecting a kidney offer if proceeding with its use was thought to be inappropriate. The third principle was that patients had a right to select transplantation centers locally or at a distance in a "sunshine" atmosphere in which all matters of transplant policy were completely open to the public.

#### A Lightning Rod Effect

Far from settling disputes about kidney allocation, the point system has created a battleground for vested interests and viewpoints of great range and complexity. Even before the point system was given a preliminary national trial, regional and local variances were submitted to the procurement and distribution committee of UNOS. These variances, which were accepted for the most part, made the overall system fragmented and heterogeneous. Analyses were thereby inhibited that might have shown if any of the factors used to compute points for the recipient scores would affect graft or patient life survival curves either favorably or adversely. In discussing the unanswered questions, including the value of typing among other considerations, we fall back on our own use of the original point system, since this experience preceded by almost 2 years the implementation of the system by other centers.

#### Antigen Matching

The chance to discuss unanswered questions is particularly timely, since the point system has survived conceptually.

However, at the meeting last month (February, 1989) of the Board of Directors of UNOS, broad changes were made that increased the weight given to antigen matching and minimized the importance of time waiting. Were these changes justified? During the last year, a number of large centers or regional consortia have reported the results of typing versus outcome. In practically all of these trials, matching had no influence on the results. Reports that have claimed a significant effect of typing have come from such data pools as those compiled by Opelz<sup>2</sup> and Cook and Terasaki.<sup>3</sup> In June 1988, Opelz's report in the *New England Journal of Medicine* provoked an editorial by Salvatierra, who cited evidence from most of the largest US centers that typing was irrelevant.<sup>4</sup> Cook and Terasaki's report, published in the same month,<sup>3</sup> had been presented at an international cyclosporine conference at which none of the centers or regional centers (two United States and two European) that reported from the same podium could see a matching effect.

At our own center in the first 418 bellwether cases in which the point system was used in 1986 and 1987, there was no significant difference at any level of matching, from perfect to poorest.<sup>5</sup>

The original point system conceded that typing could have a subtle but important influence on early or late outcome. Some upgrading in the frequency of less than perfect matches was assured by awarding 2 points for each of the 6 antigens of the class I and class II systems. In addition, all 6-antigen-matched kidneys were placed immediately in a national pool. From this experience, had it been completed, a comparison would have been available between the ideal conditions of a 6-antigen match and all other levels of matching. Such data already have been compiled, but the publication in January in the UNOS newsletter of preliminary results sent shock waves through the typing community when the perfectly matched organs enjoyed no advantage.<sup>6</sup>

What if the sweeping changes passed by the Board of Directors of UNOS in February 1989 were unjustified? If so, the directorship may have institutionalized a prejudice ("typing counts") as passionately held as some of the others that have been overthrown or inadequately supported. These shibboleths include a major influence of race ("blacks do badly"), age, diabetes, lupus erythematosus, and sex. If typing is not a valid and practical instrument of donor-recipient matching, think of the consequences that a small group of determined lobbyists will have imposed on society. First, the fairness of giving high value for waiting will be undermined for specious reasons. Second, the principle of regional primacy and the incentive for organ procurement that this brings to local programs will be eroded by greatly increasing the number of kidneys that must be exported. Third, the nightmare envisioned by Rapaport<sup>7</sup> of organs compiling ischemia time while being rushed around from city to city at great expense but with no biologic advantage will become reality. Finally, the typing itself, while perpetuating the dreams and ambitions of a few hundred or a few thousand typers or transplant surgeons and physicians, will

become an instrument of social injustice to the extent that the distribution patterns are distorted. The first question to be asked is if ethnic minorities, specifically blacks, will be placed at a disadvantage by the new emphasis on matching.

For those who disapprove of such expressions of concern, let us state that we do not believe it possible or wise to turn the clock back to before the February Board of Directors meeting. This time, we must do the experiment. We must look at the results of the new point system pitilessly, critically, and under audit. Within a relatively short time and on the basis of the results, we must make whatever course adjustments are required. There has never been this kind of opportunity to have a clean answer about typing. The use of variances, gerrymandering of regions, and other devices to avoid doing the experiment should be resisted. At the end of the observation period, the cottage industry of typing may be strengthened, or it may be made into a shadow of its present prominence and influence. It does not really matter what the result is, since special interests in this field have become an inconsequential drop in the sea of humanity that we are expected to serve.

#### Immunosuppression and Race

The point system in its previous life and also today not only is colorblind but also has no way of avoiding old, frail, immunologically difficult, or otherwise bad-risk recipients. Between January 1, 1986, and June 1988, 505 patients were treated with cadaveric kidney transplantation at the University of Pittsburgh after being selected by the point system. All but 42 were adults, who averaged  $42.4 \pm 12.8$  (SD) years; 22% of these were diabetic. Fifteen percent of the 505 patients had panel reactive antibodies (PRA) greater than 40% and were considered highly sensitized.

The results with all 505 recipients are reported elsewhere.<sup>5</sup> The mortality after 9 months to 3 1/4 years is 7.9%, and 75% of those who started are dialysis free. OKT3 for steroid-resistant rejection was available throughout the study period.<sup>8</sup> A 10 to 15% better graft survival at 1 year was obtained with triple-drug therapy (cyclosporine, prednisone, and azathioprine) than with cyclosporine and prednisone alone.<sup>5</sup> Using triple-drug therapy, the 1-year graft survival after primary cadaveric transplantation was 88%, and after retransplantation it was 75%. The retransplantation group had a large proportion of sensitized patients.

In this 30-month time period, 75 (14.2%) of the kidneys used were given to black recipients, and 1% were used for other minorities.<sup>9</sup> The percentage of black patients was somewhat higher than the black constituency of Pittsburgh and its surrounding areas, probably because of a higher incidence of renal disease in this ethnic group. Graft and patient survival in the black population was equivalent to that in the other patients,<sup>9</sup> contrary to popular belief and a number of published reports from other centers.<sup>10-15</sup>

The effect of the point system was to diminish judgmental factors in case selection, which in the past probably had operated to the disadvantage of "undesirable" potential

recipients, including older ones and possibly ethnic minorities.<sup>16,17</sup> The consequences of ad hoc selection have been particularly well documented in the University of Minnesota-Mayo Clinic experience, in which an unmistakable bias against older, female, and black recipients was revealed.<sup>16</sup> Although the Minnesota approach has been defended by Fryd<sup>18</sup> on the basis that it ensures optimal use of kidneys, the results and observations with the Pittsburgh point system have provided assurance that the concepts of equitable access and efficient use of a scarce resource are not mutually exclusive.

#### EXTRARENAL ORGANS

During the congressional hearings of 1983, kidney sharing did not make headlines. Far more dramatic was the appearance of pitiful, jaundiced children who were brought with their anguished parents to the witness table. Until then, there had been little effort or pressure to support patients financially who needed new livers and hearts or to find organs in a procurement network run by kidney transplant surgeons with understandable proprietary interests and attitudes. The obvious need to look after indigent patients who had no catastrophic health insurance activated alarm buttons in a Washington bureaucracy that had perceived for the first time in history (or at least in recent years) the need for frugality and a balanced budget at exactly the same time as the expensive new technology of liver and heart transplantation arrived.

How to pay for extrarenal transplantation has not yet been resolved satisfactorily. In order to be on a waiting list for a liver or heart, it is necessary to have a financial commitment from someone. Angel candidates could be a health insurance carrier, a state government or other agency, a private benefactor, or a fund-raising organization. How many people cannot find an angel and do not make it to the list is not known, but each example becomes a source of shame and sorrow. Suffice it to say that many transplantation centers have surreptitiously underwritten the cost of liver or heart transplantation, fearful that their good deeds will be discovered and make their hospital an indigency capital to which other patients with a similar plight will flock.

For liver candidates who make it to the list, a point system that also was developed in Pittsburgh<sup>19</sup> and applied nationally has served remarkably well. The concept of the point system for liver allocation is the same as that for kidneys, but with far greater emphasis on medical urgency and logistic factors. The principles of regional primacy, physician judgment as a final arbiter, and the patient right of center selection were retained.

The principle of regional primacy may have been unusually important because without it new centers attempting to get started with so-called elective patients could find it difficult or impossible to obtain organs in spite of the most effective local organ procurement efforts. Under the present system, organs can be used preferentially by the procuring center and within a region before being entered into the

remaining national pool, which is composed of the other nine regions and Canada.

When the point system was installed for livers in Pittsburgh in June 1987, the limits of hepatic cold ischemia were still in the 6 to 8 hour range. Consequently, points were awarded for proximity of donor and recipient to the transplant center that was providing care. Now that the new UW preservation solution has made possible the safe preservation of livers for up to a day,<sup>20</sup> the logistic factor has lost its biologic importance,<sup>21</sup> and some day it may be eliminated.

Whether a liver is used locally, regionally, or nationally, the overriding point totals given for the various stages of urgency ensure that the sickest patient will be given the liver at any of the local, regional, and national checkpoints. Originally, there were 6 stages.<sup>19</sup> A recent change to a 4-tier urgency classification will not really change the pattern of distribution very much. A 4-tier urgency system is used in many parts of Europe.

#### The Effect of the Point System on Liver Transplantation

The point system for liver recipient selection went into effect in January 1987. Since then, the actuarial 1-year survival has been no different than it was from 1980 through 1986,<sup>22</sup> although the number of older patients has increased substantially. The reason is that the point system does not recognize age as a necessary exclusion factor any more than it recognizes sex.

The point system is also color-blind for liver recipients, for which reason it was interesting to see the percentage of black recipients before and after adoption of the point system. The black contribution to the recipient population has not varied much from year to year and was not really changed by use of the point system.<sup>22</sup> In the total case collection of 1458 patients treated from 1981 to 1988, 8.4% were black and 6.5% were other minorities, for a total of 14.9%. The global life survival in the pooled 1981 to 1988 cases was the same in the black recipients as with the other minorities or white recipients.<sup>22</sup>

#### The Thoracic Organs

At the beginning of November 1987, the same allocation plan used for livers was adapted by UNOS for heart programs, the only difference being in the details of medical urgency. The system was promptly dismantled by subcommittees of dissatisfied heart surgeons who believed that only the categories of (1) catastrophic urgency and (2) elective should be used. The opening of more than 100 new heart transplant centers has enormously complicated the problem of cardiac procurement and distribution, has reduced the activity of the larger centers to a suboptimal level, and has engendered serious dissatisfaction at many levels of these activities.

#### INTERCONTINENTAL SHARING OF LIVERS

The medical and cultural relationships with Canada are so close that our northern neighbors are considered for adminis-

trative purposes to constitute Region 11. Conversations have been authorized and encouraged between European and American centers under the aegis of UNOS. A meeting for this purpose was held in Paris on March 6, 1989, at which representatives were present from Eurotransplant (Pichlmayr and Persijn), the French network (Bismuth), the United Kingdom (Calne), and Scandiatransplant (Groth). Mr Brian Broznick (procurement chief, Pittsburgh), Dr Andreas Tzakis, and I [TES] came from the United States. The consensus of the group was that livers were being wasted in both Europe and the United States and that to transport these organs effectively would require very personal communications between specific centers in a pilot project and only after making sure that the organs were not needed on the originating side of the Atlantic. What was surprising was the very limited sharing that is going at present among the European networks. For example, the Eurotransplant group (German-speaking countries and Holland) sent only 18 livers to other European regions in 1988 while using 345. Apparently, Eurotransplant was the largest importer, having obtained 51 livers from outside the region. The present Eurotransplant waiting list is 124 patients, of whom 17 are urgent, 81 elective, and 26 inactive.

If intercontinental sharing can be developed, it will be by the trial and error pathway by which sharing between the United States and Canada was done only a few years ago. It was agreed by the participants that there would have to be center-to-center communication in the pilot project.

#### HAS UNOS FAILED?

Where UNOS fits into these efforts remains to be clarified. UNOS seems to have become a political punching bag, caught between the expectations of the liberal and the conservative political philosophies. Its policies have been further molded by the maneuvering and lobbying of some of its members, often those who are least knowledgeable about and involved in clinical services. Unfortunately, these struggles have obscured the role of the UNOS directorship, many of whose members are not expert in the specifics of the field that they now govern.

At a recent meeting of the American Council of Transplantation (ACT), an important member of the staff of a United States Senator pronounced UNOS to be a failure in spite of its prodigious accomplishments. A highly public power struggle has developed between UNOS and its contractor (HCFA) about many issues, including who is really responsible for the setting of standards and the enforcement of these standards. At the heart of this conflict is control over financial payments.

Meanwhile, efforts go on to gerrymander and redefine the regions of UNOS, frequently at the initiative of tissue typers with a strong interest in maintaining previously established regional networks and collaborations (SEOPF, for example) that are inimical to central UNOS objectives. The avalanche of paper that is sent from UNOS has become almost too voluminous to read and too bulky to file. However, it may be

hoped that these are growing pains in view of what has been accomplished. After all, there is in place a national system that may be stronger than ever in its most essential ingredient—communication. After analyzing the US transplant practices, Singer, a Canadian physician and Robert Wood Johnson Foundation Fellow wrote<sup>23</sup>:

... renal transplant policy (through UNOS) has become a model of political fairness and empowerment that could inform other aspects of the health care system in the United States. . . . The language of justice, access, fairness, equity, and political empowerment should not remain restricted to the area of renal transplantation. Rather, renal transplantation could serve as the ideological springboard for a system of national health care to ensure equitable access to medical care for all citizens of the United States.

Whether this accolade will continue to be deserved remains to be seen.

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