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ORGAN TRANSPLANTS

Increased Effort Needed to
Boost Supply and Ensure
Equitable Distribution of
Organs

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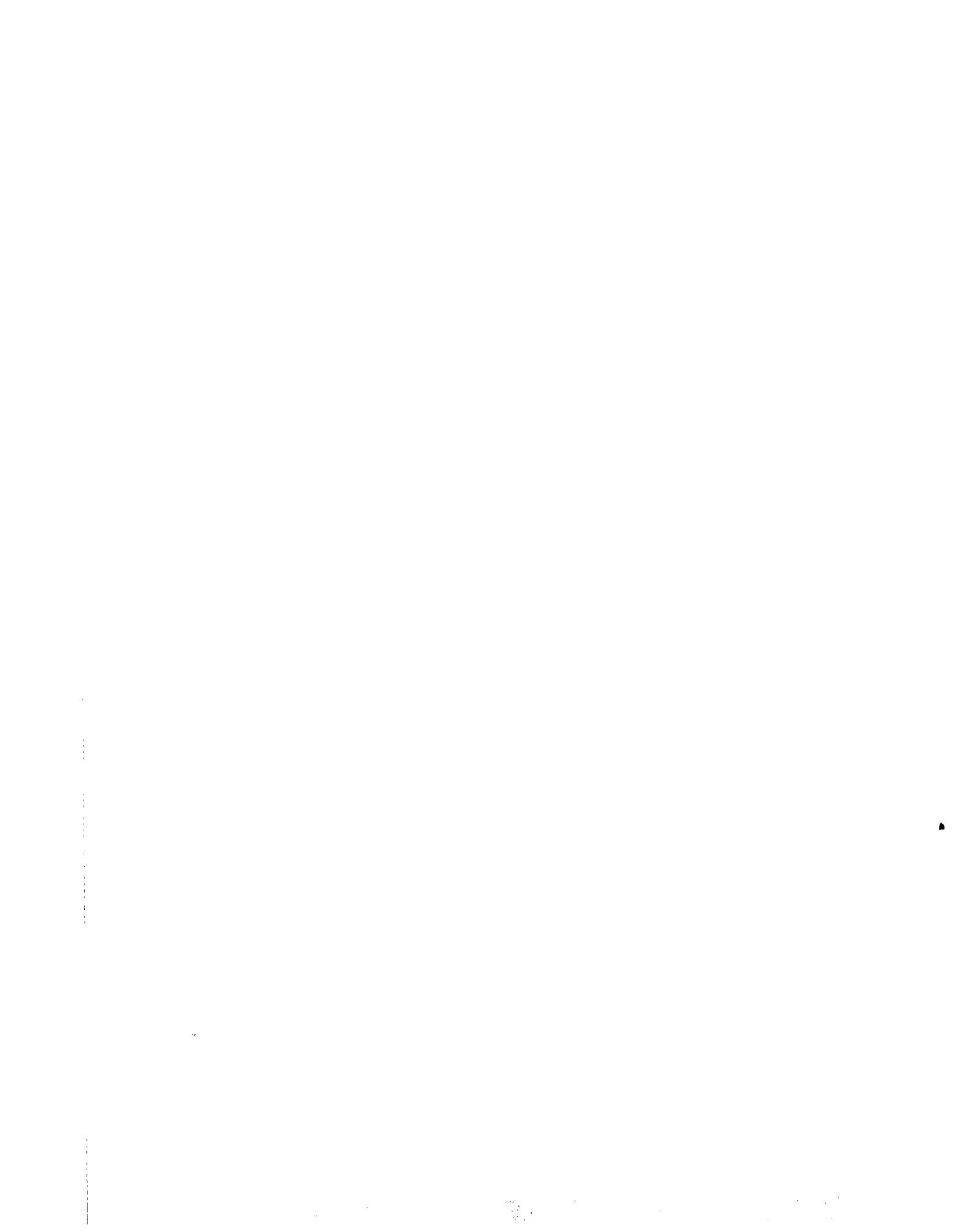
SUMMARY

The gap between the demand for organ transplants and the supply of organs continues to widen. This increases the need to assure that all available organs are obtained and then allocated to patients on an equitable basis.

The GAO report, ORGAN TRANSPLANTS: Increased Effort Needed to Boost Supply and Ensure Equitable Distribution of Organs (GAO/HRD-93-56, April 22, 1993), assesses the effectiveness of the organ allocation and procurement system. We found that existing practices raise questions as to equity of organ allocation decisions, and the lack of an adequate measure of organ procurement effectiveness hinders efforts to monitor and improve organ procurement. More specifically, we found:

- Many organ procurement organizations have altered the Organ Procurement and Transplantation Network criteria for ranking patients. However, the Department of Health and Human Services (HHS) has not assessed the impact of these changes.
- Some organ procurement organizations may inappropriately limit the pool of patients considered for an organ transplant to a single transplant center when organs become available for allocation, thereby passing up higher ranked patients of other centers.
- When allocating organs, some organ procurement organizations do not document why patients on waiting lists who were potentially well-suited to receive an organ were skipped over.
- The organ procurement organizations' adherence to Network organ allocation policies is voluntary because federal regulations have not been promulgated by HHS.
- HHS cannot target assistance to organ procurement organizations falling short of their potential for obtaining organ donors because procurement effectiveness is not monitored or evaluated.

Although the National Organ Procurement and Transplantation Network has improved the procurement and allocation of organs for transplant, further improvements are needed. First, organ procurement organizations should be required to use national allocation criteria and a single area-wide list unless they can demonstrate a benefit to patients by allocating organs in a different manner. Second, all allocation decisions should be documented. Finally, HHS should establish criteria for evaluating organ procurement organizations' effectiveness in increasing the supply of organs, and should provide technical assistance to those organizations identified as least effective.



Mr. Chairman and Members of the Committee:

I appreciate the opportunity to be here today to discuss our report on the effectiveness of the nation's organ procurement and allocation system.¹

Because of concerns of unfair organ allocation practices and an inadequate organ supply, Congress passed the 1984 National Organ Transplant Act. The Act provided for the establishment of the Organ Procurement and Transplantation Network. Prior to the establishment of the Network, there were no national policies regarding transplantation and organ distribution was done on an ad hoc basis. Network membership includes 67 organ procurement organizations, responsible for procuring and allocating organs in specified geographic areas, and over 250 transplant centers spread throughout the U.S. The Department of Health and Human Services (HHS) is responsible for overseeing the Network.

In 1990, the Transplant Amendments Act mandated that GAO study the effectiveness of the organ procurement and allocation system. We found that existing allocation practices raise questions about the equity of organ allocation decisions, and that the lack of an appropriate measure of the effectiveness of organ procurement

¹ORGAN TRANSPLANTS: Increased Effort Needed to Boost Supply and Ensure Equitable Distribution of Organs, (GAO-HRD-93-56, April 22, 1993).

organizations in procuring organs may hinder efforts to increase the supply of organs.

BACKGROUND

In 1986, HHS awarded a contract to establish the National Procurement and Transplantation Network to the United Network for Organ Sharing (UNOS). The contract requires UNOS to maintain a national computerized list of patients awaiting an organ transplant, set criteria for allocating organs to these patients, and help organ procurement organizations make the allocations.

The National Organ Transplant Act requires that organs be distributed equitably among patients on the basis of medical criteria. UNOS has developed medical criteria for determining which patients should be selected to receive organs. These criteria emphasize transplant effectiveness and patient fairness. Patients are ranked according to such factors as organ compatibility, medical urgency, and length of time waiting for an organ. Organ procurement organizations have the primary responsibility--working with hospitals in their area--for identifying potential donors and obtaining family consent to donate.

PRINCIPAL FINDINGS

HHS Does Not Assess Impact of Changes to UNOS Allocation Criteria

The transplant community faces difficult decisions on how best to allocate the limited supply of organs. Because of the organ shortage, not all waiting patients will be selected to receive an organ. Therefore, factors such as the likelihood of a successful transplant outcome, how urgently a transplant is needed, and length of time on the waiting list need to be considered. However, there are differences of opinion among transplant surgeons and others about the emphasis that should be placed on various criteria when ranking potential recipients.

In GAO's survey of organ procurement organizations, 25 out of 68 reported altering the weight assigned to the UNOS criteria for ranking patients. For example, some organizations changed the weight given to those patients waiting the longest for organs or to those whose conditions are most urgent. However, neither HHS, UNOS, nor the organ procurement organizations have evaluated these changes to determine their impact on the equitable distribution of organs or to assess the need for UNOS to incorporate these changes into its allocation criteria.

Despite UNOS policy that organ procurement organizations should obtain UNOS approval for modifying patient ranking criteria, until recently UNOS did not have specific guidelines for granting approval. In addition, we found that some of the organ procurement organizations had not obtained UNOS approval before altering the organ allocation criteria.

Failure to Use Areawide List May
Result in Inequitable Organ Allocation

In selecting organ recipients, some organ procurement organizations narrowed their pool of potential recipients to a given transplant center, rather than using areawide lists and considering potential recipients from all transplant centers in the organization's area. This practice, unless based on medical criteria, is inconsistent with federal law requiring equitable distribution of organs. Unless the use of transplant specific waiting lists can be justified based on medical criteria, it may violate federal law.

Inadequate Documentation Raises
Questions on Equity of Allocations

UNOS policy stipulates that organ procurement organizations document their patient selection decisions. Such documentation helps assure fairness by demonstrating an organization's adherence to criteria for selecting organ recipients. At 10 organ

procurement organizations, GAO found great variation in the documentation of cases in which the highest ranked patients were not selected for the organ being allocated. These organ procurement organizations could not justify, through documentation, the organ allocation decision making process for every organ they allocated. The lack of adequate documentation hampers the ability to determine if established allocation guidelines were followed or if abuses to the system are occurring.

UNOS Policies are Not Binding

Upon Its Members

In November 1992, UNOS adopted policies which would have addressed some of the concerns we raised. Specifically UNOS asked that organ procurement organizations (1) use a single patient list that encompasses an organization's entire service area, (2) submit justifications for deviating from UNOS allocation criteria, and (3) provide UNOS with assessment data on the impact of modified allocation criteria. However, HHS had ruled in 1989, that the policies of UNOS, a private contractor, are advisory. To establish requirements with which organ procurement organizations and transplant centers must comply, HHS must develop these policies as federal regulations.

Success of Organ Procurement Organizations'

Efforts to Increase Organ Supply Unknown

HHS's Health Resources and Services Administration and UNOS are responsible for overseeing the effectiveness of the organ procurement organizations in increasing the organ supply. Neither, however, monitor the organizations' procurement efforts, nor have they adopted an appropriate measure for assessing procurement effectiveness. Donor procurement rates--consisting of the number of donors procured per million population within a geographic area--varied among the 68 procurement organizations GAO surveyed. Because this rate is not based on the number of potential organ donors, the procurement rate is not an adequate measure of procurement success.

Targeted Technical Assistance Needed

to Increase Organ Procurement

Neither UNOS or HRSA systematically targets technical assistance to organ procurement organizations that may need help obtaining donors. In the absence of an effective measure of procurement performance, the agencies cannot identify which organ procurement organizations would benefit the most from technical assistance. However, UNOS and HRSA have taken some outreach actions, including efforts to educate the general public about the need for donations

and efforts to improve the solicitation of organ donations at hospitals.

CONCLUSIONS

In summary, the growing gap between organ supply and demand has increased the importance of assuring equitable organ allocation. Because of the continuing debate on how best to allocate organs, the modifications to the Network's allocation criteria need to be evaluated to determine their impact on the equitable distribution of organs and whether they should be adopted by the Network. Limiting consideration for an organ to a specific transplant center's patients may deprive equally or better suited patients within the same area the chance for a transplant. Furthermore, this practice, unless for medical reasons, is contrary to federal legislation.

Increasing the donation of organs is matter of life and death to many patients on the UNOS waiting list. Although HRSA, UNOS and organ procurement organizations have made efforts to increase organ donation, they have not evaluated the effectiveness of these efforts has not been done. Until a measure of organ procurement effectiveness is implemented it will be difficult to target assistance to those organ procurement organizations in the most need of assistance.

RECOMMENDATIONS

GAO makes several recommendations to HHS regarding the allocation and procurement practices of organ procurement organizations. These include requiring organ procurement organizations and transplant centers to

- use Network criteria for selecting patients to receive organs, or an approved change to that criteria,
- use a single organ procurement organization-wide list when allocating organs unless the organization can document compelling medical reason for doing otherwise, and
- document their allocation decisions.

In addition, GAO recommends that HHS (1) evaluate the outcome of modifications made to established patient selection criteria and (2) establish criteria for determining the success of organ procurement organizations in increasing the supply of organs for

transplant and target technical assistance to procurement organizations identified as least effective.

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Mr. Chairman, this concludes my statement. I would be happy to answer any questions you might have.



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