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ORGAN DONATION

Assessing Performance of Organ Procurement Organizations

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Organ Donation: Assessing Performance of Organ Procurement Organizations

Mr. Chairman and Members of the Subcommittee:

We are pleased to contribute this statement for the record as part of the Subcommittee's review of issues concerning organ donation. Our comments will focus on the current standard for assessing the effectiveness of organ procurement organizations and alternatives to this standard.

Advancements in organ transplant technology have increased the number of patients who could benefit from such transplants. The supply of organs, however, has not kept pace with the growing number of transplant candidates, continuing to widen the gap between transplant demand and organ supply. With the passage in 1984 of the National Organ Transplant Act, the Congress sought to increase the organ supply. To some extent, this has succeeded: the number of cadaveric[1] organ donors increased 33 percent between 1988 and 1996—from 4,083 to 5,416—and the number of organs transplanted from cadaveric donors rose from 10,964 to 16,802 in the same period. Nevertheless, the organ supply has not kept pace with demand, and over 54,000 patients are now on the waiting list for a transplant.

The Department of Health and Human Services (HHS) has just published a new regulation to change the allocation of organs from what is now a largely regional approach to a more national approach.[2] Under current policies, matching organs are usually made available to all listed patients in a local organ procurement area before they are made available to other patients. Today we will discuss a key element of the current system, the local organ procurement organizations (OPO), rather than the impact of the change in policy.

To help the Congress better understand the operation of the organ allocation and procurement system, we have issued several reports over the last few years examining the equity of organ allocation decisions, variations in patient waiting times, and the lack of adequate measures to assess organ procurement effectiveness.[3] Most recently, in November 1997, we reported on our examination of the approaches for

[1]Some patients receive organs, particularly kidneys, from living donors. In 1996, 3,524 people donated organs.

[2]63 Federal Register 16296 et seq., Apr. 2, 1998 (to be codified at 42 CFR Part 121).

[3]Organ Transplants: Increased Effort Needed to Boost Supply and Ensure Equitable Distribution of Organs (GAO/HRD-93-56, Apr. 22, 1993) and Impact of Organ Allocation Variances (GAO/HEHS-95-203R, July 31, 1995).

assessing the effectiveness of OPOs in increasing the organ supply.[4] Our statement will focus on this most recent work, in which we examined (1) whether the current standard for assessing OPOs' effectiveness appropriately measures the extent to which OPOs are maximizing their ability to identify, procure, and transplant organs and tissue and (2) alternatives to the current standard that could be more effective.

OPOs play a crucial role in procuring and allocating organs.[5] They provide all the services necessary in a geographical region for coordinating the identification of potential donors, requests for donation, and recovery and transport of organs. OPOs work with the medical community and the public through professional education and public awareness efforts to encourage cooperation in and acceptance of organ donation. Although they have similar responsibilities, OPOs vary widely in the geographic size and demographic composition of their service areas as well as in number of hospitals, transplant centers, and patients served. The Health Care Financing Administration (HCFA) administers section 1138 of the Social Security Act,[6] which requires, among other things, that the Secretary of HHS designate one OPO per service area and that OPOs meet standards and qualifications to receive payment from Medicare and Medicaid. Section 371(b)(3)(B) of the Public Health Service Act[7] provides that an OPO should "conduct and participate in systematic efforts, including professional education, to acquire all usable organs from potential donors."

HCFA regulations set performance standards for OPOs.[8] These standards assess OPOs according to their achieving numerical goals per million population in their service areas in five categories: (1) organ donors; (2) kidneys recovered; (3) kidneys transplanted; (4) extrarenal organs, that is, hearts, livers, pancreata, and lungs recovered; and (5) extrarenal organs transplanted. HCFA assesses OPOs' adherence to the standards and qualifications every 2 years. Each OPO must meet numerical goals in four of the five categories to be recertified by HCFA as the OPO for a particular area

[4]Organ Procurement Organizations: Alternatives Being Developed to More Accurately Assess Performance (GAO/HEHS-98-26, Nov. 26, 1997).

[5]OPOs are nonprofit private entities that facilitate the acquisition and distribution of organs.

[6]42 U.S.C. 1320b-8.

[7]42 U.S.C. 273(b)(3)(B).

[8]42 CFR Part 486, Subpart G.

and to receive Medicare and Medicaid payments.[9,10] Without HCFA certification, an OPO may not continue to operate. In 1996, HCFA assessed OPOs for the first time using the population-based standard with 1994 and 1995 procurement and transplant data.

Whether the HCFA population-based standard appropriately measures the extent to which OPOs are maximizing their ability to identify, procure, and transplant organs and tissue was the subject of our recent report. We determined the strengths and weaknesses of the current standard and identified and assessed alternatives to that standard.

In brief, HCFA's current performance standard does not accurately assess OPOs' ability to meet the goal of acquiring all usable organs because it is based on the total population, not the number of potential donors, within the OPOs' service areas. We identified two alternative performance measures that would better estimate the number of potential organ donors: measuring the rates of organ procurement and transplantation compared with either the number of deaths or the number of deaths adjusted for cause of death and age. Both these approaches have limitations, however, in data availability and accuracy. Two other methods for assessing OPO performance—medical records reviews and modeling—show promise because they could more accurately determine the number of potential donors. Because OPOs must meet the performance goals to continue to operate, approaches that more accurately differentiate between OPOs that achieve greater or lesser proportions of all possible donations in their service areas can help increase donations.

Background

Although the number of donors is growing more slowly than the demand for organs, the number of donors has steadily increased since 1988. The major reason for this increase is because many more older people are becoming organ donors than in the past. Nearly two-thirds of cadaveric donors were between the ages of 18 and 49 in 1988, but by 1996 only about one-half of donors were in this age group. The proportion of donors aged 50 and older doubled from about 12 percent in 1988 to about 26 percent in 1996. Another reason for the increase in donors is because more minorities are consenting to donate organs. Between 1988 and 1996, the

[9]During the 1996 designation period only, HCFA redesignated OPOs that met numerical goals in three of the five categories and submitted an acceptable corrective action plan.

[10]According to HCFA regulations, certification or recertification refers to HCFA's determination that an entity meets the standards for a qualified OPO; designation or redesignation refers to HCFA's approval of an OPO to receive Medicare and Medicaid payments. These terms are usually used interchangeably.

percentage of organ donors who belonged to racial and ethnic minority groups increased from about 16 to 23 percent.

The organ donation process usually begins at a hospital when a patient is identified as a potential organ donor. Only those patients pronounced brain dead are considered for organ donation.[11,12] Most organ donors either die from nonaccidental injuries, such as a brain hemorrhage, or accidental injuries, such as a motor vehicle accident. Other causes of death that can result in organ donation include drowning, gunshot or stab wound, or asphyxiation.

Once a potential organ donor has been identified, a staff member of either the hospital or the OPO typically contacts the deceased's family, which then has the opportunity to donate the organs. If the family consents to donation, OPO staff coordinate the rest of the organ procurement activities, including recovering and preserving the organs and arranging for their transport to the hospital where the transplant will be performed.

One donor may provide organs to several different patients. Each cadaveric donor provides an average of three organs. In 1996, OPOs procured kidneys from 93 percent of organ donors and livers from 82 percent of them; other organs were procured at lower rates.

Role of OPOs

The national system of 63 OPOs currently in operation coordinates the retrieval, preservation, transportation, and placement of organs. For Medicare and Medicaid payment purposes, HCFA certifies that an OPO meets certain criteria and designates it as the only OPO for a particular geographic area. OPOs must meet service area and other requirements. As of January 1, 1996, each OPO had to meet at least one of the following service area requirements:

1. It must include an entire state or official U.S. territory.

2. It must either procure organs from an average of at least 24 donors per calendar year in the 2 years before the year of redesignation, or it must request and receive an exception to this requirement.

[11]States set the legal standard for determining death. "Brain death" is defined as the irreversible cessation of all functions of the entire brain, including the brain stem.

[12]Organs are recovered from a small number of donors declared dead by traditional cardiac death criteria. Some have termed these donors as "non-heartbeating."

3. If it operates exclusively in a noncontiguous U.S. state, territory, or commonwealth, the OPO must procure organs at the rate of 50 percent of the national average of all OPOs for both kidneys procured and transplanted per million population.

4. If it is a new entity, the OPO must demonstrate that it can procure organs from at least 50 potential donors per calendar year.

In addition, an OPO must be a nonprofit entity and meet other requirements for the composition of its board, its accounting, its staff, and its procedures. To ensure the fair distribution and safety of organs, OPOs must have a system to equitably allocate organs to transplant patients. In addition, OPOs must arrange for appropriate tissue typing of organs and ensure that donor screening and testing for infectious diseases, including the human immunodeficiency virus, are performed.

OPOs use a variety of methods for increasing donation such as raising public awareness of organ donation and developing relationships with hospitals. The goal of public education is to promote the consent process, giving people the information they need to make decisions about organ and tissue donation and encouraging them to share their decisions with their families. Such public education campaigns include mass media advertising; presentations to schools, churches, civic organizations, and businesses; and informational displays in motor vehicle offices, city and town halls, public libraries, pharmacies, and physician and attorney offices.

In addition, education efforts help hospital staff clarify organ and tissue recovery policies to ensure that potential donors are consistently recognized and referred. OPOs also conduct hospital development activities to build strong relationships with service area hospitals to promote organ donation.

Problems With the Current Standard

HCFA chose a population-based standard to assess OPO performance after considering the availability and cost to the OPOs of obtaining and analyzing various types of data. When HCFA first applied this standard in 1996, five OPOs were subject to action for failing to meet the standard. This resulted in two OPOs' service areas being taken over by adjacent OPOs, a portion of one OPO's service area being taken over by an adjacent OPO, and the merger of one OPO with another. The fifth OPO that failed the standard was

determined to be a new entity and not subject to meeting the performance standard.

A population-based standard, however, does not accurately assess OPO performance because OPO service areas consist of varying populations. Although potential organ donors share certain characteristics, including causes of death, absence of certain diseases, and being in a certain age group, OPO service area populations can differ greatly in these characteristics.

For example, motor vehicle accidents, the cause of death for about one-quarter of organ donors in 1994 and 1995, ranged from about 4.4 to about 17.9 per 100,000 population among the states and the District of Columbia. In addition, the rates of acquired immunodeficiency syndrome, a disease that eliminates someone for consideration as an organ donor, differ among the states and the District of Columbia—from 2.8 to 246.9 cases per 100,000 people in 1994. Furthermore, although most organ donors were between 18 and 64 years of age in 1994 and 1995, this age group constitutes from 56 to 66 percent of the population in different states. Thus, the number of potential organ donors can vary greatly for OPOs serving equally sized populations.

Alternative Standards Could More Accurately Assess OPO Performance

We identified several performance measures as alternatives to the current population-based standard. The alternatives we examined included measuring organ procurement and transplantation compared with (1) the number of deaths, (2) the number of deaths adjusted for cause of death and age, (3) the number of potential donors based on medical records reviews, and (4) the number of potential donors based on modeling estimates in an OPO service area.

In developing its current OPO performance standard, HCFA considered using the number of service area deaths as the basis for assessing performance. Although some organs, typically kidneys, are obtained from living donors, OPOs recover organs from cadaveric donors. Therefore, the number of deaths in an OPO's service area more accurately reflects the number of an OPO's potential donors. In 1994, the United States had about 2.3 million deaths out of a population of about 260 million. Although using total deaths fails to consider other factors about and characteristics of potential donors, it would eliminate considering a portion of the population that an OPO clearly could not consider for organ donation.

HCFA also considered using an adjusted measure of deaths for the performance standard. Measuring OPO performance according to the number of service area deaths adjusted for cause of death and age more accurately reflects the number of potential donors than measuring performance according to the number of all service area deaths. The number of service area deaths adjusted for cause of death and age better estimates the number of potential donors because it accounts for the small subset of the deceased that may be suitable organ donation candidates. Adjusting for cause of death and limiting consideration to deaths of those under age 75, we found that in 1994 about 147,000, or 6 percent, of the 2.3 million U.S. deaths involved these causes of death or were of people in this age group. This estimate, however, is much larger than the estimates some have made of a national donor pool of from 5,000 to 29,000 people per year.

We found that both the death and adjusted-death measures have drawbacks that limit their usefulness, however, including lack of timely data and inability to identify those deaths suitable for use in organ donation. We ranked the OPOs, using 1994-95 OPO procurement and transplant data, according to the current population-based measure and these two alternative measures—number of deaths and adjusted deaths. Although three OPOs would not qualify for recertification under any of these measures, according to our review, the number of and which OPOs would not qualify vary depending on the measure used. More OPOs would have been subject to termination under either of these alternative measures.

HCFA did not consider two other methods for determining the number of potential donors—medical records reviews and modeling—that show promise for determining OPOs' ability to acquire all usable organs. Reviewing hospital medical records is the most accurate method of estimating the number of potential donors in an OPO's service area. A medical records review involves reviewing all deaths at a hospital with an in-depth examination of those meeting certain criteria. Reviewing the records of these patients reveals the patients' suitability for organ donation based on several factors, including cause of death, evidence of brain death, and contraindications for donation such as age and disease. Such reviews can identify that subset of deaths in which patients could have become organ donors—the true number of potential donors for an OPO service area.

Most OPOs do conduct medical records reviews but at varying levels of sophistication. For records reviews to be useful for assessing OPO performance, the reviews would have to be conducted consistently among OPOs and the results would need to be available for validation. Such reviews, however, are labor intensive and therefore expensive. Although most OPOs are conducting some form of medical records reviews and therefore already incurring the costs of these reviews, HCFA must consider its own and the OPOs' additional expense involved in standardizing such reviews. Other considerations include the extent to which the reviews would add to the cost of organs and whether these costs would outweigh the benefit of more accurately measuring the number of potential donors.

Another alternative, modeling, shows promise and would be less expensive than medical records reviews. At least one group is developing a modeling method using substitute measures to provide a valid measure for estimating the number of potential donors. The goal of this effort is to design an estimating procedure that will be relatively simple to execute, inexpensive, and valid. This approach uses information from hospitals in the OPO's service area on variables, such as total number of deaths, total staffed beds, Medicare case mix, medical school affiliation, and trauma center certification, to predict the number of potential donors. Using existing data would make this alternative less costly than medical records reviews; however, the accuracy of such a model has yet to be established. If the number of potential donors for an OPO can be reasonably predicted using a set of variables, this could eliminate concerns about the cost of implementing medical records reviews.

Recommended Future Steps

HCFA believes its current standard identifies OPOs that are poor performers. When publishing its final rule, however, the agency stated that it was interested in any empirical research that would merit consideration for further refining its standard. The approaches we identified in our report merit HCFA's consideration.

More specifically, our report recommended that to better ensure that HCFA accurately assesses OPOs' organ procurement performance and that OPOs are maximizing the number of organs procured and transplanted, the Secretary of Health and Human Services direct HCFA to evaluate the ongoing development of methods for determining the number of potential donors for an OPO. These methods include medical records reviews and a model to estimate the number of potential donors. If HCFA determines that one or both of these methods can accurately estimate the number of

potential donors at a reasonable cost, it should choose one and begin assessing OPO performance accordingly.

HCFA has concurred with our recommendation. It has indicated that when the ongoing research on medical records reviews and modeling are complete and it receives the studies, it will review the results to determine if it can support a better performance standard.

HCFA's continuous monitoring of the developments in approaches to identifying potential organ donors is important. Because the demand for organs surpasses the supply, OPOs are required by law to conduct and participate in systematic efforts to acquire all usable organs from potential donors. As we have reported, unless HCFA measures OPO performance according to the number of potential donors, the agency cannot determine OPOs' effectiveness in acquiring organs.

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