Methods

Using a Standardized Donor Ratio to Assess the Performance of Organ Procurement Organizations

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Objective. To develop a Standardized Donor Ratio (SDR) as an outcome measure for evaluating the effectiveness of organ procurement organizations (OPOs).

Data Sources/Study Setting. All deaths by cause in the United States during 1993–1994 as reported in the Vital Mortality Statistics, Multiple Cause of Death files. The OPO-specific data were provided by the United Network for Organ Sharing (UNOS).

Study Design. Each OPO's expected number of donors was calculated by applying national donation rates to deaths with potential for donation in 24 age, sex, and race cells. The SDR was calculated by dividing the observed number of donors by the expected number. The X^2 tests of the hypothesis that the OPO's performance differed from the national norm of 1.0 were performed. The SDR was compared to the existing performance standard based on the unadjusted number of donors per million live population in the OPO's service area. An ordinary least squares (OLS) regression assessed predictors of the SDR.

Principal Findings. The SDRs ranged from 0.41 to 1.99. Twenty-nine of 64 OPOs had SDRs significantly different than 1.0. The SDRs were positively associated with the percent of white living population and the number of organ types transplanted per transplant center served by the OPO.

Conclusions. The SDRs can be used by Centers for Medicare and Medicaid Services (CMS), UNOS, and OPOs to target quality improvement initiatives, present more accurate comparisons of OPO performance, and develop public policy on the evaluation of the effectiveness of organ procurement efforts.

Key Words. Organ donation, organ procurement organization, effectiveness

Organ transplantation is one of the greatest modern medical achievements. Organ transplants give new life to more than twenty thousand Americans annually (United Network for Organ Sharing 1999). However, the organ procurement and distribution system faces great challenges. More than 64,000 patients are on transplant waitlists and median waiting time has risen substantially. About 4,000 waitlisted patients die annually before receiving a transplant (United Network for Organ Sharing 1999) and large regional variations exist in waiting times (Ojo et al. 1999; Institute of Medicine 1999).

The shortage and maldistribution of organs have led to controversial proposals, including monetary incentives for donation (DeJong et al. 1995), expanding donation criteria (Alexander and Vaughn 1991), and xenotransplantation (transplantation with nonhuman organs) (Soin, Vial, and Friend 2000). To address regional waiting time disparities, the Department of Health and Human Services proposed replacing the local/regional organ allocation system with a national approach. Although this might increase geographic equity, any gains enjoyed by one region are offset by losses in another region. Further, national sharing would increase the average time between procurement and transplant. Such delays have been shown to adversely impact transplant survival (Held et al. 1994). Facing opposition from parts of the transplant community, Congress delayed implementation of the new rules. Despite these concerns about the availability of organs, the organizations responsible for organ procurement have escaped any meaningful performance evaluation. In this paper, we develop a new tool to measure the performance of these organizations and discuss how such a tool could be implemented.

ORGAN PROCUREMENT IN THE UNITED STATES

The organizational framework for the U.S. organ procurement system was laid out by the 1984 National Organ Transplant Act. The organ and tissue recovery process is coordinated by organ procurement organizations (OPOs). The OPOs are nonprofit, federally designated agencies that facilitate organ recovery that face no competition within their specified service areas and receive cost-based reimbursement. Organ procurement organizations are divided into two organizational models, hospital-based OPOs (HOPOs) and

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independent OPOs (IOPOs). The HOPOs originally served as procurement entities exclusively for the transplant center hospitals where they were housed. Recently, some HOPOs have begun to serve other transplant centers in their locales. The IOPOs operate outside the hospital setting and usually provide services to a number of transplant centers. In 1993, there were 14 HOPOs and 52 IOPOs. An OPO's responsibilities include (United Network for Organ Sharing 1995b):

- Providing clinical services to manage and coordinate organ and tissue recovery
- Providing educational and administrative services to hospitals to facilitate the appropriate referral of donors and recovery of organs and tissues
- Providing public and professional education to promote organ donation
- Working with donor families and hospital staff during the consent process
- Providing closure and bereavement support to donor families and communicating with all parties involved after the recovery to share information about outcomes
- Managing equitable sharing of recovered organs
- Maintaining required documentation, certifications, and performance measures

The oversight and regulation of the Organ Procurement and Transplant Network (OPTN) is administered by a private, nonprofit agency, the United Network for Organ Sharing (UNOS), through contracts with the Department of Health and Human Services (Health Care Financing Administration 1996). An OPO's primary objective is to obtain as many organ donations as possible from its service area. The procurement rate has been stable, at approximately 0.2 percent of deaths, over the last five years.

Determining how well OPOs perform is a controversial subject in the transplant community. The OPOs are currently judged using historical standards for the number of organ donors per million live population (Health Care Financing Administration 1996). Rates vary widely, ranging from 11.3 to 33.9 donors per million (United Network for Organ Sharing 1995a). There is no adjustment for demographics or other factors. Consequently, the crude number of donors per million live population could vary substantially even if OPOs' underlying performance does not vary. Likewise, if underlying

performance does vary, it is possible that some poorly performing OPOs may nonetheless have “acceptable” crude donation rates because they serve populations with above-average clinical donation potential or propensity to donate. These concerns have led to calls for improved performance measures (Wrone 1999; U.S. General Accounting Office 1997).

The goal of this research is to develop a new measure of OPOs’ effectiveness, the Standardized Donor Ratio (SDR). The SDR will measure each OPO’s donation rate relative to the national average, identifying potential donors by cause of death and standardizing for potential donors’ age, race, and sex. This new measure should represent a substantial improvement over the current standards based on unadjusted donation rates per million live population and extend other efforts to evaluate the organ procurement system (Ojo et al. 1999; Ozcan, Begun, and McKinney 1999; Prottas 1985).

DATA

National death data were derived from the 1993–1994 Vital Mortality Statistics Data, Multiple Cause of Death files. These data, based on death certificates, are compiled annually by the National Center for Health Statistics (NCHS) and include more than 99 percent of all deaths within the United States. Coding of underlying and contributing causes of death follows the International Classification of Disease, ninth revision (ICD-9).

The UNOS provided OPO-specific information on classification status (independent versus hospital-based), number of transplant center hospitals served, number and type of transplant programs (each type of organ transplanted constitutes a program), and the racial composition of each OPO’s service area. Because UNOS bylaws prohibit releasing information about individual OPOs, identifying information was not available and the SDR calculations were performed at UNOS following the researchers’ instructions. Puerto Rico was excluded due to lack of donor activity (less than three donors annually) and Oklahoma was excluded because death data were not reported in the required manner.

METHODS

The SDR was developed similarly to the standardized mortality ratio (SMR) (Wolfe et al. 1992) and the standardized hospitalization ratio (SHR)

(Strawderman et al. 1996). The SMR and SHR both compare an observed rate of mortality or hospitalization in a group of End Stage Renal Disease (ESRD) patients to a national ESRD average.

National Donor Rates

The first step was to evaluate the 4.6 million deaths in the United States during 1993–1994 for potential donation of at least one solid organ. A crucial criterion for identifying a death that may yield a potential donor is a medical record review indicating primary brain death. Since such reviews are not undertaken in the NCHS's compilation of death certificate data, our definition of potential donors is deaths clinically consistent with organ donor potential based on ICD-9 codes. The criteria are listed in Table 1. In addition, deaths older than age 75 (the highest age cutoff applied by any OPO) and deaths occurring outside a hospital were eliminated. Several studies have used variants of this methodology at the state level (e.g., Evans et al. 1992; Maximus 1985; Nathan et al. 1991). This process yields an estimate of the number of potential organ donors in the United States during 1993–1994. The actual (observed) number of organ donors from 1993–1994 is then divided by the potential number to determine the national donor rate. Organ donation rates vary substantially by age, sex, and race. Thus, we also calculated national donor rates for 24 specific age, sex, and race cells taking the ratio of actual to potential donors in each cell.

Expected Number of Organ Donors by OPO

The mortality data are reported at the state and county levels, allowing for determination of potential organ donors by OPOs' service areas, which are defined by state or county borders. The number of potential organ donors in each age/sex/race cell is multiplied by the corresponding national donor rate, which yields the expected number of donors for that OPO in each cell, assuming the respective national rates apply to that particular OPO.

Standardized Donor Ratios

We compared national donor rates to actual donors procured by each OPO. Equation 1 defines the SDR for a particular OPO (i), which is the sum of actual donors (D) across the 24 age/sex/race cells (j) divided by the sum of the expected donors (E) across the cells. This adjusts for the unique demographic

mix among potential donors in each OPO’s service area.

$$SDR_i = \frac{\sum_{j=1}^{24} D_{ij}}{\sum_{j=1}^{24} E_{ij}} \tag{1}$$

An $SDR > 1$ denotes a donor rate that exceeds the national average, while $SDR < 1$ denotes performance below the national average. To determine if an OPO procured significantly more or less than the expected number of organs, we tested the null hypothesis that $SDR = 1$. The statistic $X^2 = (\text{observed} - \text{expected})^2 / \text{expected}$ has an approximate chi-squared distribution with one degree-of-freedom under the null hypothesis. $P < 0.05$ (equivalently, $X^2 > 3.84$) will be considered evidence of a significant difference between observed and expected number of donors.

Table 1: Criteria for Inclusion of Potential Organ Donors

Patients under the age of 75 in hospital death	
Indications for donation:	ICD9 CM
Malignant neoplasm of the brain	191–191.9
Bacterial meningitis	320–321
Intracranial abscess	324.0
Anoxic brain damage	348.1
Compression of the brain	348.4
Cerebral edema	348.5
Other conditions of the brain-brain death	348.8
Unspecified conditions of the brain	348.9
Subarachnoid hemorrhage	430
Intracerebral hemorrhage	431
Other/unspecified intracerebral hemorrhage	432
Occlusion and stenosis of precerebral arteries	433
Occlusion of cerebral arteries	434
Transient cerebral ischemia	435
Acute, ill-defined cerebrovascular diagnoses	436
Other and ill-defined cerebrovascular diagnoses	437
Respiratory arrest (cardiorespiratory failure)	799.1
Intracranial injury, excluding skull fracture	800–855
Other open wound of head	873
Injuries to the vessels of head/neck	900–901
Traumatic shock	958.4
Poisonings	960–990
CNS complications (includes anoxic brain damage)	977.0
Cardiopulmonary arrest (CPA)	977.1

To determine how closely the SDR tracks the existing performance measure (the crude donor rate per million live population), we calculated the correlation between the SDR and the crude donor rate. An ordinary least square (OLS) regression was estimated to assess the effects of characteristics of OPOs and their service areas on the SDR.

RESULTS

The estimated number of potential organ donors in the United States during 1993–1994 was 98,628. The actual number of organ donors from the same period, 9,830, was divided by the total potential donors, to arrive at the National Donor Rate (NDR) of 0.0997. This means that organs were procured from approximately 10 percent of potential donors. Analogous NDRs were calculated for age/race/sex subpopulations (Table 2). Many potential donors, though they meet cause of death inclusion criteria, would be ruled out due to other clinical factors. Thus, actual donation rates would be unlikely to ever approach 100 percent of potential donors, particularly among older donors.

The number of potential donors (98,628) exceeds earlier estimates (Evans et al. 1992; Nathan et al. 1991; Taskforce on Organ Transplantation 1986). Increasing the age limit from 65 to 75 years added 61,396 potential donors. This accounted for 62 percent of the total number of potential donors but only 4.4 percent (436) of actual donors. A second factor contributing to the high number of potential donors is that the NCHS, in some cases, does not list the clinical cause of death for persons who died from injuries and poisonings (ICD-9-CM codes 800–999). The NCHS recoded the cause of death in some cases to be the mechanism of death. The total of 98,628 potential donors included those deaths coded with the ICD-9-CM codes of 800–999 (Injuries and Poisonings). Deaths may be coded either on the basis of the mechanism by which the death occurred (e.g., motor vehicle accidents) or by clinical cause of death (e.g., blunt trauma to the head) or both. This makes it difficult to tabulate potential donors by mechanism of death unless clinical cause-of-death codes are listed in the record. Previous inclusion criteria did not have this problem because coding was for clinical causes of death.

Figure 1 illustrates the distribution of SDRs. The mean SDR was 1.04, with a median of 1.0 and a standard deviation of 0.3. Observed SDRs ranged from 0.41 to 1.99. The 95 percent confidence intervals for nearly half (29/64) of OPOs' excluded the national norm of 1.0 (16 performed better than expected; 13 performed worse than expected).

Table 2: National Donor Rates (NDRs) by Age, Sex, and Race

<i>Population Descriptors</i>	<i>Actual</i>	<i>National Donor Rate Potential</i>	<i>NDR</i>
Overall NDR	9,830	98,628	0.0997
White			
Female			
0-17	557	1,481	0.3761
18-49	1,507	6,298	0.2393
50-74	980	21,774	0.045
Male			
0-17	1,086	2,237	0.4855
18-49	2,598	12,075	0.2152
50-74	925	25,206	0.0367
Black			
Female			
0-17	94	361	0.2604
18-49	193	2,391	0.0807
50-74	75	5,530	0.0136
Male			
0-17	249	615	0.4049
18-49	452	3,877	0.1166
50-74	71	6,000	0.0118
Hispanic			
Female			
0-17	68	249	0.2731
18-49	149	874	0.1705
50-74	55	1,511	0.0364
Male			
0-17	152	469	0.3241
18-49	350	2,626	0.1333
50-74	56	1,927	0.0291
Other			
Female			
0-17	21	79	0.2658
18-49	42	386	0.1088
50-74	27	946	0.0285
Male			
0-17	31	119	0.2605
18-49	66	570	0.1158
50-74	26	1,027	0.0253
Other Major Groups			
Sex			
Female, all	3,768	41,880	0.09
Male, all	6,062	56,748	0.11
Age Groups			
0-17	2,258	5,610	0.402
18-49	5,357	29,097	0.184
50-74	2,215	63,921	0.035
Race			
White	7,653	69,071	0.11
Black	1,134	18,774	0.063
Hispanic	830	7,656	0.11
Other	213	3,127	0.068

Figure 1: Distribution of SDRs

To determine if the standardization process developed here results in similar performance assessments as those derived from the simpler, crude donor rates per million live population currently used to assess OPOs' performance, we calculated the correlation between SDRs and crude rates. The correlation was moderately strong (0.636, $p < 0.001$). Nonetheless, the SDR differed substantially from the crude rate for many OPOs. After standardizing the crude rate to have a mean of 1.0 (to create a readily interpretable comparison for the SDR), the absolute value of the difference between the SDR and crude rate exceeded 0.1 for 43 of the 64 OPOs (see Figure 2). Some of the differences were very large. For example, one OPO had a crude donation rate of 1.45 (indicating performance substantially better than the national norm), but a standardized donor ratio of only 0.67 (indicating substantially worse than expected performance).

A simple multivariate model of OPOs' performance was developed. Due to the relatively small number of OPOs (64), we selected a limited set of explanatory variables. The model, reported in Table 3, included classification status (HOPO versus IOPO), number of transplant centers served, the

Figure 2: Scatter Plot of Crude Donation Rates versus Standardized Donor Ratios

number of transplant programs per center served, and percent of the service area's living population that was nonwhite or older than 50 years of age.

Even though the SDR adjusts for the demographics of potential donors, OPOs with a higher percentage of whites living in their service areas performed better than expected. This suggests the existence of some factor beyond differences in mortality rates by cause that increases actual donations relative to expected donations for OPOs serving more whites. The only other significant predictor was the number of transplant programs per center served by the OPO. This suggests that the more types of organ transplants performed by the centers served by an OPO, the better its performance. This might reflect the greater ability to make use of multiple organs within the OPO's area or greater pressure to procure organs when more programs rely on the OPO, suggesting that OPO performance may respond positively to some degree of competitive pressure.

DISCUSSION

Health policy debates have increasingly focused on accountability and performance measurement. Public and private efforts have been undertaken

Table 3: OLS Regression Model for SDR ($n = 64$)

<i>Predictor</i>	<i>Coefficient</i>	<i>t-statistic</i>
Intercept	0.857	6.33
HOPO (vs. IOPO)	0.065	0.67
# of transplant centers served	0.013	1.04
# of transplant programs per center served	0.069	2.23
% of population non-white	-0.004	1.87
% of population over 50 years of age	0.007	0.98
R²	0.142	

to systematically evaluate health plans, hospitals, renal dialysis centers, transplant surgery programs, and other health care organizations. To date, OPOs have been evaluated only on the basis of the crude measure of donors procured per million live population. This research demonstrates the feasibility of a more sophisticated measure, the standardized donor ratio, and shows that variation in SDRs is substantially greater than would be expected from chance alone.

The SDR can improve the ability of the Centers for Medicare and Medicaid Services (CMS), UNOS, and the OPTN to assess OPOs' effectiveness, yielding readily interpretable results and bringing more consistency to the evaluation of OPO performance. A measure standardized for characteristics of potential donors could help determine which observed differences in performance represent variation in OPO effectiveness versus variation in the donor pool. Using SDRs as outcome measures for evaluating the procurement system and for targeting particular OPOs for further investigation and quality improvement initiatives is likely to yield better decisions than those based on the existing standard. More appropriate and effective targeting of OPOs could result in increases in organ availability. The SDRs for specific age/race/sex cells could identify demographic groups where an OPO is not procuring the expected number of organs and where the opportunity for improvement may be greatest.

A variety of factors that influence organ donation remain outside an OPO's control. The regression model indicates that the race distribution of the living population and the number of programs per center might be two such factors. Similarly, observed OPO performance may be influenced by state laws (e.g., motorcycle helmet laws, donor registration at motor vehicle departments), variation in donor characteristics for which the SDRs are not adjusted, or even publicized, individual cases such as the wait listing and death

of Chicago football legend Walter Payton. To the extent that such factors can be identified and measured, they could be used to improve the standardization process.

Two issues dominate the organ donation and transplantation policy debate: the national shortage of transplantable organs and geographic disparities in access to transplants. To the extent that the SDR can more accurately identify underperforming OPOs and be used in targeted quality improvement initiatives, simultaneous increases in the overall organ supply and reductions in geographic access variation could be achieved.

Better information will provide a quantitative basis for improvement in OPOs' structures, processes, and outcomes. Recent work by Ozcan, Begun, and McKinney (1999), using the unadjusted number of organs procured as the dependent variable, found that larger OPOs appeared to be more efficient at acquiring organs. Our results suggest that OPOs with greater local outlets for multiple organs (i.e., OPOs serving transplant centers with larger numbers of programs) perform better. Likewise, our findings suggest that performance suffers for OPOs whose service areas include larger proportions of racial and ethnic minorities (even after standardization for the racial and ethnic mix of potential donors). Several factors may explain this finding. First, race in the general population may proxy for unadjusted variables, such as income and education, which leads to success in acquiring donations. Second, OPOs may strategically pursue the "easy" organ donations from demographic groups with higher success rates. Exploration of OPOs' procedures and operations with respect to minority outreach appears warranted.

This study found that organs were procured from only 10 percent of potential donors. Of course, not all of the potential donors identified using the national mortality database would be viable donors, particularly given our inclusion of older donors among whom donation rates are, and undoubtedly will remain, low. However, there is clearly room to improve the national donor rate. Even if OPOs with SDRs less than 1.0 were to improve their performance to the current average, a substantial number of new organs would become available. For example, if an OPO with an average number of expected donors were to improve its SDR from 0.8 to 1.0, an increase of 30 donors, potentially facilitating more than 100 transplants, would result. Such improvements would likely reduce the regional disparities driving current efforts to implement a national organ sharing system.

Several innovative and controversial ideas for increasing organ donation have been proposed, including financial incentives, presumed consent, public education tailored to specific groups, greater enforcement of required request

laws, and donor registries (DeJong et al. 1995). Many of the options need to be tested in local areas to ascertain their effectiveness and changes in SDRs could be used to track their effects.

LIMITATIONS AND OPPORTUNITIES FOR FURTHER RESEARCH

The SDRs as developed here or modified later could improve the ability to assess the relative effectiveness of OPOs and could assist in developing policies designed to increase the number of transplantable organs. Nonetheless, using SDRs as performance measures does have certain drawbacks.

First, the methodology used to determine the potential number of organ donors could be refined. This research offers a process to estimate the number of potential organ donors. An alternative process being considered by OPOs is based on medical record review. Medical record review may prove more accurate, but entails significant difficulties of its own. Reviews are expensive, time consuming, and subject to inter-rater reliability problems and it would be difficult to standardize reviews nationally.

Second, medical professionals disagree about clinical criteria for identifying deaths suitable for organ donation. Attempts to increase agreement on criteria would be useful and the SDR calculation could be adapted to whatever criteria become accepted. In particular, our decision to use the upper end of OPOs' age cutoffs should be examined. Since only 4.4 percent of actual and expected donors were in the over-65 age group, excluding them is unlikely to change our findings substantially. Further, all OPOs currently consider donors older than 65 (personal communication, Remy Aronoff, Health Resources and Services Administration). The kidney is the most forgiving organ for transplantation and other vascular organs may have lower age ceilings. Organ specific age limits could be used in SDR calculations. High age cutoffs could also cause unintended consequences in terms of incentives to use marginal donors. Thus, monitoring the procurement process and subsequent transplant outcomes would be appropriate.

Third, there exist conditions beyond the OPO's control that impact the ability to obtain donors. In the regression model, the number of transplant programs per center and the percentage of whites in the general population significantly impacted the SDR. Other variables that may affect the ability and willingness to donate organs include education, income, urbanization, access

to trauma service, and state laws affecting organ donation. The feasibility of extending the SDR to account for these factors should be explored.

Fourth, our ability to draw specific inferences was hindered by confidentiality requirements. The UNOS bylaws prohibit the release of OPO-specific information. Although this level of confidentiality may be appropriate for donors and transplant recipients, it appears hard to justify for nonprofit, federally designated organizations that receive most of their funding from public sources and face no competition within their service areas. This confidentiality is particularly surprising given the regular dissemination of transplant center mortality rates. These restrictions precluded us from identifying OPOs, which limited the set of variables we could collect for inclusion in the regression model and made it impossible to pursue case studies of high and low performers.

Fifth, random variation limits the ability to determine if observed differences in SDRs reflect underlying OPO performance. Combining two years of data, more than 90 percent of the OPOs with SDRs less than 0.8 or greater than 1.2 were identified as significantly different from 1.0, so the power to detect clinically significant performance differences appears to be good. Nonetheless, accurate evaluation of small OPOs may be difficult.

Finally, cause-of-death data are available with an 18–24-month lag. The OPO performance may change over time due to changes in underlying performance or due to random variation. Examining the correlation of SDRs over time would help determine the extent to which lagged data availability is a serious problem for the SDR approach.

Performance of OPOs in the United States must be evaluated in order to increase the supply of transplantable organs. The most important role of the SDR is to provide information on OPO effectiveness to payers, regulators, policymakers, and the public, which will contribute to the OPO certification process and help focus improvement efforts.

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