A method for estimating solid organ donor potential by organ procurement region

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ABSTRACT

Objectives. This study sought to develop a methodology for estimating potential solid organ donors and measuring donation performance in a geographic region based on readily available data on the hospitals in that region.

Methods. Medical records were reviewed in a stratified random sample of 89 hospitals from 3 regions to attain a baseline of donor potential. Data on a range of hospital characteristics were collected and tested as predictors of donor potential through the use of hierarchical Poisson regression modeling.

Results. Five hospital characteristics predicted donor potential: hospital deaths, hospital Medicare case-mix index, total hospital staffed beds, medical school affiliation, and trauma center certification. Regional estimates were attained by aggregating individual hospital estimates. Confidence intervals for these regional estimates indicated that actual donations represented from 28% to 44% of the potential in the regions studied.

Conclusions. This methodology accurately estimates organ donor potential within 3 geographic regions and lays the foundation for evaluating organ donation effectiveness nationwide. Additional research is needed to test the validity of the model in other geographic regions and to further explore organ donor potential in hospitals with fewer than 50 beds. (Am J Public Health. 1998;88:1645–1650).

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Currently, nearly 53 000 Americans are awaiting organ transplants.¹ Only 20 109 transplants were performed in 1994. The waiting list for organs grew at an annual rate of 15.5% between 1988 and 1994, while the number of transplants performed grew 6.7% per year. The death toll among transplant candidates exceeded 3500 in 1995 and has been growing at an annual rate of 13.0%.²

A major impediment to increasing donation is the lack of a reliable and valid method to assess current donor potential and organ procurement organization performance. Such information is needed at the national and regional levels to assist in developing goals for organ donation, benchmarking procurement effectiveness, and tracking changes in donor potential and donor realization.

Several policy issues have preoccupied the field of transplantation, most revolving around how to allocate a scarce and lifesaving resource equitably. Issues of access are central. Ethnic minority populations are disproportionately affected by end-stage organ failure but often wait significantly longer than Whites to receive an organ.3 Economic and gender equity have also been concerns. Allocation issues would be considerably less difficult if more suitable organs were available. Proposals to increase organ availability include improving procurement effectiveness of hospitals and organ procurement organizations, changing the willingness of the public to donate, enacting presumed consent legislation, and providing financial incentives.5

Previous studies have generated a range of estimates of national and regional donor potential in the United States. Evans et al. suggest that national donor potential is between 6900 and 10 700 cases per year, although this estimate is limited by its reliance on death certificates and its exclu-

sion of nontraumatic deaths, which represent a growing percentage of potential organ donors (50% in 1994).² Gortmaker et al. completed medical records reviews in hospitals in 4 regions of the United States and extrapolated to a national estimate of 13 700 potential donors annually.⁷

The need for accurate and reliable estimates of donor potential at the regional level was recognized by the General Accounting Office in 1993. Their report noted the following:

Essential to determining OPO [organ procurement organization] procurement effectiveness is the development of an adequate measure by which to judge an OPO's procurement effectiveness. Knowing the size of the potential donor pool is important in assessing how well OPOs are performing their organ procurement responsibilities.

The General Accounting Office also emphasized that neither the Health Resources and Services Administration nor the United Network for Organ Sharing has developed uniform criteria or standards for organ procurement organization effectiveness.⁸

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The most widely used measure for describing and comparing organ procurement organization donor performance is "donors per million population." The General Accounting Office reported a range of 1 to 32 donors per million in 1990 and 1991, suggesting genuine differences in organ procurement organization performance. This measure assumes that the denominator, potential donors per million population, is uniform across the United States, but such an assumption has never been systematically tested.

Medical records review appears to be the most accurate method currently available for estimating donor potential within hospitals and regions. However, these reviews can be time and resource intensive if applied to all acute care hospitals. While 60 of the 68 organ procurement organizations surveyed by the General Accounting Office in 1993 reported conducting medical records reviews, there was no standard methodology in use at that time across organ procurement organization regions. 8

The present study hypothesized that readily available information about hospital characteristics could be used to predict organ donor potential at the hospital level and that, by aggregating individual hospital estimates, valid regional estimates of donor potential could be obtained. We used a standardized medical records review methodology in the study's 3 organ procurement organizations. This method yields the best available data on donor potential in hospitals.

Methods

Medical records review data were collected for calendar year 1993 in a stratified random sample of 89 hospitals. Data on a range of hospital characteristics hypothesized to predict donor potential were collected and tested for their correlation with the review results.

Selection of Stratified Random Sample

Hospitals located within 3 organ procurement organizations, California Donor Transplant Network, LifeSource Upper Midwest, and Washington Regional Transplant Consortium, were compiled and cross referenced to each organ procurement organization's hospital list, resulting in a sample of 541 hospitals. Non-acute care facilities (rehabilitation, psychiatric, chemical treatment, crippled children's, developmental, recovery institutions, and nursing homes) were eliminated from the sample (n = 63), as were 98 hospitals without an intensive care

unit or ventilator, leaving 380 hospitals in the regions

Stratifying on number of beds12 and using SCOMARS, 13 we selected a random sample of the 380 hospitals. The sampling plan and participation rates are described in Table 1. All of the 98 hospitals without an intensive care unit had fewer than 50 beds (45% of the 217 hospitals in the 3 regions with fewer than 50 beds). Power calculations indicated that 20% of the 119 eligible hospitals with fewer than 50 beds would be needed to accurately estimate potential in a hospital of this size. This was not possible within the budget constraints of the study; small hospitals were generally located in remote areas, increasing cost and travel time. Therefore, the sampling design included 2 years of medical records review in 10% of these hospitals with fewer than 50 beds, and the number of potential donors in each of the 2 years was considered to be independent. Nonparticipating hospitals fell primarily into 2 categories: armed forces/ Veterans Administration hospitals and smaller hospitals.

Medical Records Review

A consistent medical records review protocol, carried out by trained, clinically experienced organ procurement organization coordinators, has been used in the 3 organ procurement organization regions since 1990. All data collection tools and protocols were developed by the study team with input from participating organ procurement organization staff and advisory boards made up of critical care and transplant professionals.

Data collected for each potential donor case included cause of death, patient demographics, clinical and/or diagnostic evidence of brain death, and case outcome (whether the case patient became a donor or not). In instances in which data from the chart were unclear, senior organ procurement organization managers were consulted. Prior to data entry, all completed forms were reviewed for completeness and consistency with study definitions

An interrater reliability study was conducted to check the accuracy of the medical records review. Two hundred forty-five charts were randomly selected and reviewed by 2 independent reviewers at different times, with both reviews blinded. Very high agreement was observed between the first and second chart reviews, with perfect agreement in 99% (242/245) of the cases. One reviewer documented 35 potential donors, while the other reviewer documented 38 potential donors, suggesting that donor potential could be underestimated by 8%.

Variable Definitions

A potential organ donor was classified as a medically suitable patient who had conditions consistent with brain death as defined by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.¹⁴ Patients were excluded as potential donors if they were more than 70 years of age or exhibited 1 or more International Classification of Diseases (9th edition, Clinical Modification) (ICD-9-CM) codes that are contraindications for organ donation (e.g., HIV-1 seropositivity). Because medical suitability criteria vary by transplant center and by organ procurement organization, the study used criteria in effect in each organ procurement organization. The analysis showed differences in suitability criteria across organ procurement organizations to be minor. An organ donor was defined as a patient with a medically suitable case that resulted in organ recovery intended for transplant regardless of ultimate disposition of organs, consistent with United Network for Organ Sharing definitions. 13

Consistent with the goal to develop a predictive model based on publicly available information, the majority of hospital data were collected from the American Hospital Association guide¹² and the hospital blue book¹¹ databases, which rely on annual hospital surveys. Representatives from the 3 organ procurement organizations identified hospital characteristics that theoretically could be used to predict potential. These variables included the following:

Number of hospital deaths. The total number of deaths occurring in each hospital in 1993 was calculated. Data were not available publicly, so they were collected from hospital death lists or by direct telephone inquiry to the medical records department. Only partial death information was available for 11 hospitals and information was unavailable for 16 of the 89 study hospitals. In these instances, missing death counts were imputed for use in the model.

Total staffed beds. We determined the number of beds actively staffed in each hospital. ¹²

Medicare case-mix index. The case-mix index is a measure of the costliness of cases treated by a hospital relative to that of a national average of all Medicare hospital cases, using diagnostic-related group weights as a measure of relative costliness of cases. ¹⁶

Trauma center certification. This was a certified facility that provides emergency and specialized intensive care to critically ill and injured patients. ¹² An indicator variable was created for the 19% of hospitals for which this measure was not available.

TABLE 1—Characteristics of 89 Hospitals Sampled in 3 Regions of the United States, 1993

	Less than 50 Beds ^a	50-149 Beds	150-349 Beds	More than 350 Beds
No. of hospitals	7	17	27	38
Mean no. of potential donors (SD)	0.3 (0.5)	1.3 (1.4)	6.3 (5.8)	10.6 (8.1)
Mean no. of deaths ^b (SD)	43.6 (28.0)	109.9 (52.0)	306.7 (134.0)	545.2 (186.8)
Mean no. of staffed beds (SD)	38.3 (8.7)	98.7 (27.3)	245.8 (53.0)	493.0 (160.7)
Mean Medicare case-mix index (SD)	1.05 (0.17)	1.30 (0.11)	1.52 (0.19)	1.59 (0.22)
Medical school affiliation, %	0	0 '	7	24
Trauma center, %	0	12	22	47
Trauma unknown, %	29	24	7	24

Note. There were 380 hospitals in the 3 regions, distributed as follows: <50 beds: 119; 50–149 beds: 120; 150–349 beds: 97; and ≥350 beds: 44. The sampling plan called for 10%, 20%, 30%, and 100% of the 4 strata, respectively. Participation rates were 58%, 74%, 93%, and 86%, respectively. In 5 of the 7 participating hospitals with less than 50 beds, we collected 2 years of data. Stratification on AHA beds

Medical school association. We used the blue book11 variable indicating medical school affiliation because there were significantly fewer missing data with this variable.

Other variables. Data on the following variables were also collected and analyzed: number of admissions, average daily census, full-time employee equivalents, presence of intensive care units, proprietary status, nonprofit status, number of emergency room beds, organ procurement organization region, and number of surgical, medical, and neurointensive care unit beds. We considered using a daily census measure; however, the daily census measure from the American Hospital Association database was missing information on 18% of our study hospitals, whereas there were no missing data on staffed beds. For hospitals with both measures, the 2 measures were correlated (r = 0.97).

Statistical Analysis

A hierarchical Poisson regression model¹⁷ was used to estimate regression coefficients and to obtain estimates and standard errors for the number of potential donors in the 3 regions. Recent studies of provider profiling encourage the use of hierarchical models in assessing performance differences. 18,19 Generally, standard errors for regression coefficients are appropriately larger in hierarchical models than in standard models (e.g., general linear models). A hierarchical model was needed in our setting to account for 2 levels of uncertainty, within hospitals and between hospitals. The Poisson model assumed that a potential organ donor is a rare occurrence and that the logarithm of the expected number of potential donors in a hospital during a 1-year period is related to the covariates linearly. S-Plus²⁰ was used for all of the analyses.

Assuming statistical independence between the prediction estimates for individual hospitals and relying on large sample theory, the estimated number of potential donors for a region is the sum of the predictions for the hospitals within the region. The standard error is the square root of the sum of the variances associated with the estimates.

Predictive Model

Our predictive model assumes that the number of potential donors in a hospital in a given year is proportional to the number of deaths at the hospital and the number of staffed beds and that potential donors are more likely in hospitals with more trauma victims and more severely ill patients. Prior research has indicated the importance of trauma deaths and cerebrovascular deaths for organ donation.7 We thus included variables indicating the number of deaths in a hospital in a given year, the number of staffed beds in the hospital, the Medicare case-mix index, whether the hospital had a certified trauma center, and whether the hospital had a medical school affiliation.

Because of difficulties in obtaining death data, we report the results from 2 statistical models. Model 1 included number of deaths and, hence, was the more dynamic model, changing over time in response to changes in the number of deaths. Model 2 used a proxy variable, number of hospital beds, instead of deaths and thus was less dynamic. There was a strong correlation between hospital deaths and hospital beds (r=0.72). For theoretical and statistical reasons, we included variables indicating whether the hospital was certified as a trauma center and associated with a medical school in both models 1 and 2. We included indicator variables for missing data on trauma center certification and number of hospital deaths in model 1 and trauma center certification in model 2. We also tested to determine whether any of the other covariates added substantially to the explanatory power of the models; we added the covariates to the models one at a time and tested to see if the coefficient on each additional variable was statistically significant at P < .05.

Results

Data Summary

A total of 594 potential organ donors were identified in the 89 study hospitals, an average of 6.7 (range: 0 to 33) potential donors per hospital; all but 2 potential donors were identified in hospitals with 50 or more beds. Table 1 lists summary statistics for the variables used in the prediction models. Extrapolating from the sample to the full population of hospitals in the study regions shows that hospitals with 350 or more beds accounted for 12% of the hospitals but were estimated to contain 38% of potential donors. Hospitals with 150 to 349 beds accounted for 25% of all hospitals (48% of potential); hospitals with 50 to 149 beds accounted for 32% (13% of potential); and hospitals with fewer than 50 beds accounted for 31% (1% of potential). Regression models were developed with only hospitals having more than 50 beds, because of the small sample (7) of hospitals with fewer than 50 beds.

Regression Equations

Regression coefficient estimates appear in Table 2. An increase in the number of deaths (model 1) or total beds (model 2), along with Medicare case-mix index, medical school affiliation, and/or trauma center certification, increases the predicted number of potential donors at a hospital. The logarithmic transformation of number of deaths and total number of beds was used. There-

^bSome death counts were imputed.

fore, the interpretation of the 0.72 coefficient for log (deaths) in model 1 is that the estimated mean number of potential donors at a hospital is equal to a constant (determined by the other variables and their regression coefficients) multiplied by deaths exponentiated to 0.72. A similar interpretation is given for the 0.69 coefficient on log (total staffed beds) in model 2.

Although the coefficient on log (deaths) was significantly different from zero, it was not significantly different from one. This implies that the number of potential donors was approximately proportional to the number of deaths across all of the hospitals after control for the other variables included in the model. A comparison of regression models in which missing death data were imputed via the staffed beds variable (Table 2) and the subsample for which there were complete death data revealed less than a 0.5 standard error difference in the estimated regression coefficients (0.72 vs 0.80). These results indicate no substantial bias due to imputation. Both predictive models had the expected signs (positive) for the Medicare case-mix index and the trauma center and medical school coefficient estimates.

As indicated by the shrinkage values, model 1 fit the data better than model 2. When a difference in deviance χ^2 test was used, this difference in fit was significant (P < .01). The actual difference in final predictions between the models, however, was small. Model 2 produced predictions and standard error estimates similar to those in model 1 for the study hospitals by region. There was no significant improvement in fit when both deaths and hospital beds were included in the prediction equation, and the variable for number of hospital beds became insignificant when both were included in the model. The shrinkage estimates were roughly similar to R^2 statistics. We fit linear regressions predicting log (0.1 + potential donors), and R^2 statistics were 0.64 for model 1 and 0.58 for model 2.

Predictions of Donor Potential

To test the results, we predicted the potential for the study hospitals in one organ procurement organization by using the data from the other two. The estimates from the resulting equation were compared with the potential (as documented in medical records review), as well as with the earlier predictions of organ procurement organization potential. For model 1, the predicted potential and 95% confidence intervals (CIs) were as follows (medical records review results in parentheses): region 1, 215 ± 25.1 (212); region 2, 218 ± 39.1 (195); and region 3,

TABLE 2—Coefficient Estimates From Hierarchical Poisson Regression Models of Potential Donors in 3 Regions of the United States, 1993 (82 Hospitals with 50 or More Beds)

	Model 1		Model 2	
	Effect Estimate (SE)	P	Effect Estimate (SE)	P
Intercept	-5.13		-4.95	
Log (deaths)	0.72 (0.16)	<.01		
Death data incomplete	0.45 (0.22)	.04		
Log (hospital beds)			0.69 (0.19)	<.01
Log (case mix)	1.55 (0.45)	<.01	1.61 (0.50)	<.01
Trauma center	0.39 (0.21)	.06	0.50 (0.22)	.02
Trauma center missing	0.35 (0.22)	.12	0.40 (0.24)	.09
Medical school affiliation	0.64 (0.23)	<.01	0.52 (0.25)	.04
Shrinkage	0.41		0.35	

 155 ± 28.5 (185). These tests indicate that even with the handicap of smaller sample sizes, the models predict well to regions outside of those in the sample.

Having developed the model using the sample data, we then made predictions for each organ procurement organization region using model 2; it was not possible to use model 1 for predicting at the regional level because of the lack of readily available hospital death data. The prediction of donor potential for a region of $i = 1, \ldots, k$ hospitals (non–Armed Forces or Veteran's Administration facilities with at least 50 beds and a ventilator), denoted $\hat{\theta}$, is calculated as

$$\begin{split} \hat{\theta}_i &= \exp[-4.95 + .69 log(beds_i) + \\ &1.61 \ log(case-mix_i) + .50(trauma\ center_i) + \\ &.40(trauma\ missing_i) + .52(medical\ school_i)]. \\ \hat{\theta} &= \sum_i \hat{\theta}_i. \end{split}$$

The estimate of the standard error associated with the prediction is

$$\hat{\omega} = \sqrt{\sum_{i} \frac{\hat{\theta}_{i}^{2}}{2.58} + \hat{\theta}_{i}}.$$

The formulas for prediction with model 1 would use the regression coefficients from Table 2, and the divisor in the standard error estimate would be 3.29 instead of 2.58.

Table 3 lists the predictions of the total number of potential donors and their standard errors using model 2. For the 246 eligible hospitals in the 3 organ procurement

organization regions, the model predicts 1022 potential donors per year. This estimate has a standard error of 47.2 (95% CI = 929, 1114). The 95% confidence intervals for the regional estimates and actual donations are displayed in Figure 1; these data indicate that actual donations represent from 28% to 44% of the potential in the regions studied.

To test the model for the effect of the small hospitals on the prediction equation, we reanalyzed the complete sample of 89 hospitals. Results were very similar. The estimated regression coefficients were essentially the same, with the larger differences as follows: in model 1, the coefficient estimate for log (deaths) increased by 0.5 standard error; in model 2, the coefficient estimate of log (total beds) increased by 0.6 standard error.

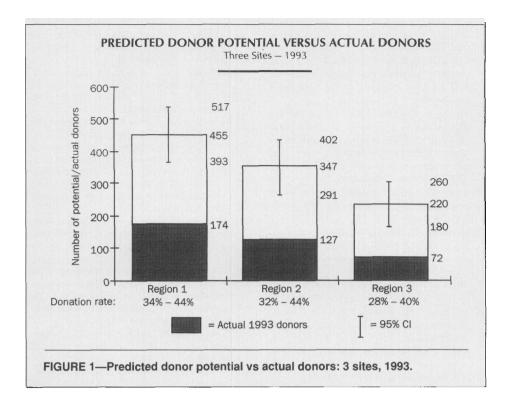
Discussion

We developed a predictive model for estimating solid organ donor potential in groups of hospitals that is not reliant on individual hospital medical records review and uses publicly available data. Medical records review data showed that larger hospitals have, on average, higher numbers of potential donors than smaller hospitals. Using hierarchical regression models, it is possible to generate accurate estimates of donor potential in a geographic region based on a few key variables for hospitals within the region.

TABLE 3—Prediction of the Number of Potential Donors in 3 Regions of the United States, 1993

	No. of Hospitals	Prediction	tion
		Model 2	SE
Region 1 hospitals	128	454.5	31.6
Region 2 hospitals	84	346.5	28.5
Region 3 hospitals	34	220.4	20.4
Total	246	1021.5	47.2

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We tested 2 regression models using number of deaths as a predictor variable (model 1) and using number of beds as a predictor variable (model 2) The other variables—case-mix index, trauma status, and medical school association—were present in both models. The 2 models produce similar estimates.

All of the predictor variables are publicly available with the exception of deaths for individual hospitals. (Although hospitals report death data to state departments of health, for example, hospital-specific data are not available to the public.) If data for both models were equally accessible, we would prefer model 1 over model 2 because changes within hospitals or regions might be reflected more rapidly by changes in the number of deaths than by changes in staffed beds. Also, there is a precedent for predicting donor potential from death data.²¹ However, since hospital death information must currently be collected individually for each hospital, practical considerations may favor model 2.

The reliability of the model would be improved if hospitals were required to provide data not only on numbers of deaths but also on the age and major diagnoses of the patients who died. While age criteria for organ donation have been relaxed over the past several years, it is still extremely rare to accept organ donors over the age of 80 years, and these deaths could be excluded. Having relevant *ICD-9-CM* codes would facilitate the exclusion of patients who exhibit absolute contraindications for organ donation (such as metastatic cancer or HIV infec-

tion). Conversely, those patients showing diagnoses associated with severe brain injury could be included. Databases containing these variables exist for other purposes (i.e., insurance claims), but it is not currently feasible to access them for purposes of modeling organ donation potential.

We believe the current methodology has important strengths when compared with the commonly used measure of donors per million population. As is the case with the donors per million measure, most of the data used are readily available. Unlike our model, the donors per million measure has never, to our knowledge, been systematically validated against medical records review. Our model uses statistical methods and thus allows for the calculation of confidence intervals. These useful ranges of donor potential can then be compared across regions. Our method yields proportionately larger standard errors for smaller regions than for larger ones, reflecting the greater difficulty of detecting significantly higher or lower performance levels in smaller organ procurement organizations or regions, rather than being uniformly applied to all organ procurement organizations regardless of size. Based on the tests of the model using 2 regions to predict the third, we believe that the model will also predict well when used in regions outside of this study. Finally, the hierarchical Poisson modeling approach reflects each organ procurement organization's unique set of hospitals, providing more accurate estimates of performance relative to desirable or optimal outcomes.²²

Because these are the first models of their type in this field, a number of limitations are recognized. First, the models are based on only 3 geographic areas, and despite our tests of the model as described above, we do not know how well they will predict potential in other regions. Second, it is expected that the models will need to be adjusted over time. Clinical criteria for donor acceptability are continually changing, and there may be changes in health care practices or mortality that affect the donor pool. Third, reliance on publicly available data introduces other limitations. A number of variables that were hypothesized as predictors were not included, often because of missing observations (as in the case of intensive care unit beds). Finally, further work is needed to predict donor potential in small hospitals (those with fewer than 50 beds). We have taken the conservative approach of excluding the smallest hospitals from the model because of the small sample collected.

A major application of this model is to provide a baseline against which donation performance can be assessed. Using model 2, we see actual donors by region against estimated ranges of donation potential (Figure 1), confirming that significant opportunities remain to increase organ donation. Given the size of the gap between current performance and estimated potential, even a conservative estimate, using the lower bound of the 95% confidence interval, can be highly useful to organ procurement organizations in setting goals.

It is clear that a donation rate of 100% is not a realistic goal. Based on evidence from public opinion polls, a small proportion of the public appears to be adamantly opposed to organ donation.²⁴ Currently, for a variety of reasons, consent rates are lower among certain ethnic minorities.⁷ When interpreting donation rates based on our model, demographic differences among regions must explicitly be taken into account.

Measuring and improving donation performance has been a major goal of recent legislation and policy in organ donation, and the federal regulations governing organ procurement organizations now reflect this concern. While it would be premature to adopt our model nationally, we believe that contrasting this approach with the current method of measuring organ procurement organization performance can highlight ways in which the current system could be improved. In sum, we believe that this study provides useful methods that have potential for estimating organ donor potential in regions, based on easily available hospital data. While we recognize the current limitations, the approach of using medical records review as a basis for developing easier estimating methods is one that provides a strong foundation for this methodology and will allow further refinements in the future. \Box

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