

Improving the request process to increase family consent for organ donation

The greatest impediment to organ donation is refusal of family consent. This study examined the impact of 3 modifiable elements of the donation request on family consent rates: (1) decoupling (ie, the family understands and accepts brain death before discussion of organ donation is begun); (2) the procurement coordinator participates in the request for consent; and (3) donation is requested in a quiet, private place. Data on the request process were collected prospectively for 707 medically suitable potential donors who had been referred to 3 organ procurement organizations. The average rate of consent for donation was 62.2%. Higher consent rates were independently associated with the 3 characteristics studied. These components were summarized in the Request Process Scale. Multivariate regression analyses indicated that consent rates can be as high as 74% when all 3 process elements are present. Hospitals and organ procurement organizations should incorporate these elements into their standard of practice when requesting organ donation. (*Journal of Transplant Coordination*. 1998;8:210-217)

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Approximately 49,000 people in the United States were awaiting organ transplants by the end of 1996.¹ An average of 8 to 9 transplant candidates die each day because suitable organs are not available.² The shortage continues to worsen despite wide public support for organ donation³ and evidence indicating that the number of medically suitable, brain-dead patients far exceeds the actual number of organ donors.^{4,5} Research has also supported the view that organ donation is beneficial to the donating family, offering solace and meaning in the face of loss.⁶⁻¹²

Recent work has shed light on the underlying potential for organ donation in hospitals and on the outcomes of these cases. Two major causes of non-donation in hospitals have been identified: (1) failure of hospital staff to ensure that a request is made to family members of eligible patients, and (2) refusal of families to grant consent.

In a 1991 and 1992 research conducted in 23 hospitals, Siminoff et al¹³ estimated that 13% of potential organ donors were not properly identified or that their families were not approached for dona-

tion. Based on retrospective reviews of medical records in 125 hospitals in 1990 and 1993, Gortmaker et al¹⁴ estimate that 27% of potential donors were not identified or approached. Both studies determined that family refusal to donate was the principal reason for not obtaining donation. In the Siminoff study, 54% of families declined to grant consent to organ donation; in the Gortmaker study, the corresponding figure was 52%.

A number of initiatives have been considered or are underway to ensure that all eligible families are asked to donate organs.¹⁴⁻¹⁷ A consensus has emerged within the transplantation and organ donation fields that more work is needed to understand the dynamics of family consent and the modifiable factors leading to higher consent rates.³

Much work in the past has addressed the general experiences and needs of families facing severe illness or death of a family member.¹⁸⁻²⁴ In the case of brain death, the challenges facing the family and the healthcare team are especially severe.²⁵⁻²⁹

Research exists pertaining to the characteristics

of an optimal request for organ donation. A number of researchers have suggested that events within the hospital strongly influence families' decisions about donation,³⁰⁻³⁴ though they did not provide data regarding which practices were most effective. The literature on "breaking bad news" to families and individuals in a medical setting³⁵ contains general recommendations about pacing the sequence of the information provided and delivering bad news in a private and quiet location. These recommendations can be applied to the organ donation situation. Similarly, research^{36,37} on decision making under stress suggests that individuals and groups reach better decisions after a thorough search for information, an unbiased assimilation of this information, and a careful weighing of alternatives. These findings also seem relevant to organ donation decisions. Smaller studies on the request process in organ donation have shown that factors such as the timing of the request relative to the communication of brain death³⁸—as well as the types of professionals who are involved in the counseling³⁹—can influence rates of consent.

Whereas a number of studies point to the importance of the hospital process, to date there have not been large-scale studies examining multiple process factors and their impact. The goal of this study was to examine 3 factors—individually and combined—that may better meet the needs of families of recently deceased organ donor candidates, and that may lead to higher rates of consent to organ donation. The study was based in 3 regions of the United States. The factors analyzed were as follows: (1) decoupling, (2) the type of professionals involved in the request, and (3) the type of setting where the request is made.

Methods

Data Collection and Variable Definitions

Data on specific elements of the request process were collected from April 1991 to December 1992. Information was gathered on all medically suitable potential donors that were referred to 3 organ procurement organizations. A total of 124 hospitals were represented in the sample. The participating OPOs were California Transplant Donor Network, LifeSource Upper Midwest OPO, and Washington Regional Transplant Consortium. The OPOs covered Northern California, Minnesota, North Dakota, South Dakota, the Washington, DC metropolitan area, as well as portions of Maryland and Virginia. Together they served a total population of 18.3 million in 1991 and 1992.⁴⁰

Data on all requests made to families of medically suitable potential donors ($N=1261$) were collected by 40 data collectors using a standardized Donor Tracking Instrument. The data collectors were OPO coordinators

who had medical training; most were critical care nurses. Training is described below.

Using the 2-page instrument, the data coordinator recorded information on donor demographics and the request process. This demographics information included age, sex, race, admission time and date, death time and date, and referral data. Information on the request process included the following: the date and time brain death was confirmed and explained to the family; when the request for donation was made; who was involved in making the request; and whether the request was made in a quiet, private setting.

Members of the study team held 3 day-long training sessions for the 40 OPO coordinators who were responsible for data collection. These coordinators received educational materials explaining the concept of decoupling and what constituted a "quiet, private setting." Requests for donation were classified as decoupled if the OPO coordinator concluded that family members acknowledged or understood their loved one was brain dead *before* they were asked to make a decision about organ donation.

Two patterns of professional involvement were defined: requests that involved an OPO coordinator and another hospital professional, and those that involved only hospital professionals. "Private settings" included locations such as family conference rooms or private offices. Requests that were made by telephone, in the patient's room, at the nursing station, or in the hallway were not considered to be private.

Before data entry, data were reviewed for accuracy and consistency across all 3 OPO regions. An intensive quality-assurance process included case review in monthly OPO staff meetings and, in many cases, retrospective conferences with participating hospital staff. Accuracy of consent and donation data was verified by cross-checking with OPO referral reports, medical record reviews, and formal family-consent documentation. Data forms were checked for completeness, and coordinators and other OPO staff were contacted to see whether missing data could be obtained.

Information on age, sex, and ethnicity or race of potential donors was collected from review of medical charts. Ethnicity or race was coded as either African American, Hispanic, Asian/Indian, Native American, non-Hispanic white, or other. In multivariate statistical models, the categories of Asian/Indian, Native American, and other were combined under 1 heading "other," due to the low numbers in each category.

Transplant hospitals were identified by the presence of an organ transplant program as reported by the United Network for Organ Sharing's annual report.² Unit refers to the patient's unit in the hospital at the time of referral to the OPO. These were coded as follows: emergency, an emergency room or

combined emergency room/trauma service; pediatric, the pediatric critical care unit in a regular hospital or any critical care unit (ie, surgical, medical, cardiac) in a pediatric hospital; surgical/neurological intensive care unit (ICU), a surgical unit in a hospital with a separate medical ICU; medical ICU/coronary care unit, a medical unit in a hospital with a separate surgical unit or any cardiac care unit; combined surgical/medical ICU, a combined surgical/medical unit or the ICU in a hospital that has only 1 ICU; operating room; and other. In multivariate statistical models, operating room was included in the "other" category, due to the low number of cases in that category.

Cause of death was coded into 7 categories. These categories, in addition to being familiar to the OPO staff, were consistent with those used by the United Network for Organ Sharing: cerebrovascular; motor vehicle crash; gunshot wound or stabbing; other head trauma; cardiovascular; asphyxiation including asthma; other causes including drowning, drug or alcohol intoxication, sudden infant death syndrome, and cancer of the central nervous system.⁴ In multivariate statistical models, asphyxiation was labeled as "other" due to the small number of cases in that category.

Data Analysis

Request Process Scale. Using the 3 elements of the request process under study (ie, decoupling, private setting, and OPO involvement), the Request Process Scale (RPS) was constructed. One point was given for each element that was present. Each request process in review received an integer score ranging from 0 to 3.

Exclusions and Missing Data. Cases in which the family initiated the discussion of donation were excluded ($n=167$). When families initiated the discussion, the rate of consent was 88%. Cases in which any data on the 3 request process variables were missing were also excluded ($n=387$). To assess the possibility of selection bias for the remaining cases, the 387 cases with incomplete data were compared to the 707 cases that were included in the study. No significant differences were found between the 2 groups in terms of sex, age, race, hospital unit, and most causes of death. A slightly lower percentage of study cases compared to excluded cases reported "other" causes of death (7% vs 15%, respectively).

Chi-square tests were used to examine differences between consent and nonconsent cases. A 95% confidence interval (CI) was estimated using approximate standard errors as described in Fleiss.⁶ Because the research design was nonexperimental, multivariate linear regressions were calculated to estimate the independent association of the donor, the request process, and the hospital characteristics with the out-

come of consent cases using SAS PROC REG software.⁶ When the dependent variable was dichotomous, linear regression estimates could be interpreted as estimated changes in probabilities. The regression estimates were unbiased but inefficient.^{6,7} All P values were 2-sided.

The regressions were also estimated using weighted least squares method⁸ taking into account the heteroscedasticity of the variances. This approach resulted in 95% CIs that were essentially the same as those using an ordinary least squares approach.

Results

Predictors of Consent

During the study period, complete data were obtained on 707 medically suitable potential organ donors. In all cases, families themselves did not initiate the subject of organ donation. The rate of consent was 62.2% for the sample and varied by race or ethnicity, cause of death, and OPO (Table 1).

Higher values on the RPS were associated with higher rates of consent. When none of the factors occurred (ie, RPS=0), the consent rate was 28.4%. When all 3 factors were present (ie, RPS=3), the consent rate was 73.5% ($P<.0001$).

For each of the 3 components on the RPS, a significant relationship was found with consent (Table 1). Decoupling occurred in 49.7% of the cases. In decoupled cases, the consent rate was 71.5%, versus 53.1% in cases that were not decoupled ($P<.0001$).

Differences in consent rates were also observed, depending on which professionals were involved in the request. In 39.5% of the cases, both hospital staff and OPO coordinators spoke with families about donation (consent rate, 71.7%). In 41.4% of the cases, the request was handled by the hospital staff without assistance from the OPO coordinator (consent rate, 53.2%). The OPO was solely responsible for the request in 15.1% of the cases (consent rate, 61.7%) (Table 1).

More than three quarters of the requests were in private settings, a factor that was associated with higher consent rates. The consent rate for requests made in private settings was 67.2%, compared to 44.5% for requests that were not made in private settings ($P<.0001$).

Neither the existence of a transplant center nor the volume of a hospital's requests was associated with higher consent rates. Nearly three quarters of the cases occurred in hospitals that did not perform transplants. The average consent rate of those cases was 63.6% compared to 58.4% in institutions that performed transplants (difference not significant). The number of cases per institution ranged from 1 to 41 over the study period. No association was observed between the number of cases and the rates of consent. Hospitals with 1

Table 1 Family consent rates for organ donation by predictor variables, 1991 to 1992 (n=707)*

Variable	n	%	Rate of family consent for donation %	P value†
Age, y				=.112
0-18	131	18.5	65.7	
19-29	169	23.9	63.3	
30-39	116	16.4	65.5	
40-49	122	17.3	60.7	
50-59	102	14.4	64.7	
60-75	67	9.5	46.3	
Sex				=.501
Male	423	59.8	61.2	
Female	284	40.2	63.7	
Race/ethnicity				<.0001
White	420	59.4	77.1	
African American	115	16.3	38.3	
Hispanic	117	16.6	46.2	
Asian/Indian	42	5.9	31.0	
Native American‡	6	0.9	-	
Other	7	1.0	-	
Cause of death				=.002
Cerebrovascular	295	41.7	59.3	
Motor vehicle crash	153	21.6	75.8	
Gunshot wound/stab	122	17.3	54.9	
Other head trauma	78	11.0	64.1	
Cardiovascular	14	2.0	35.7	
Asphyxiation	12	1.7	41.7	
Drowning	2	0.3	-	
Drug intoxication	4	0.6	-	
SIDS	4	0.6	56.5	
Other/missing	23	3.3	-	
Hospital unit				=.249
Surgical/neurological ICU	340	48.1	62.4	
Combined surgical/medical ICU	222	31.4	66.7	
Medical ICU/CCU	50	7.1	64.0	
Pediatric	45	6.4	51.1	
Emergency	39	5.5	51.3	
Operating room	3	0.4	-	
Other/missing	8	1.1	-	
Transplant center				=.208
Transplant	185	26.2	58.4	
Other	522	73.8	63.6	
OPO region				<.0001
1	366	51.8	60.1	
2	168	23.8	81.6	
3	173	24.5	48.0	
Request Process Scale				<.0001
Number of factors present				
0	74	10.5	28.4	
1	177	25.0	54.8	
2	256	36.2	68.4	
3	200	28.3	73.5	
Request was decoupled				<.0001
Yes	351	49.7	71.5	
No	356	50.4	53.1	
Professionals involved in request				<.0001
Hospital and OPO staff	279	39.5	71.7	
OPO staff alone	107	15.1	61.7	
Hospital staff alone	293	41.4	53.2	
Request occurred in a private setting				<.0001
Yes	552	78.1	67.2	
No	155	21.9	44.5	

* Donation was not family initiated (ie, requests for donation were made)

† P values refer to tests for differences in rates of consent

‡ Rates were not calculated if the cell size was less than 10

SIDS indicates sudden infant death syndrome; ICU, intensive care unit; CCU, critical care unit

to 15 cases exhibited a 61.5% consent rate, whereas hospitals with 16 or more cases exhibited a 63.3% consent rate (difference not significant).

Multivariate Regression Results

The relationship between the RPS and consent rates was estimated using multivariate linear regressions, controlling for the potential confounding influence of age, sex, race or ethnicity, cause of death, hospital unit, whether the hospital was a transplant center, and OPO region (Table 2). Each RPS score greater than zero was associated with higher rates of consent: for a RPS score of 1, consent rates were 21% higher (95% CI, 9 to 32; $P < .0006$); for a RPS score of 2, consent rates were 37% higher (95% CI, 26 to 49; $P < .0001$); and for the maximum RPS score of 3, consent rates were 47% higher (95% CI, 35 to 59; $P < .0001$).

The interaction effects between the RPS score and sex and race or ethnicity were tested; no differences were found to be statistically significant.

In addition to race, 2 demographic categories—age and OPO region—had statistically significant linear regression coefficients. Cases in which the decedent's age was less than 60 years or occurring in the service area of OPO region 2 were more likely to result in consent (Table 2). Because these factors were not modifiable, they were outside the scope of this study. However, they warrant further investigation and explanation.

Attributable Risk Estimates

To determine the potential magnitude of the improved request process on consent for organ donation, the attributable risk was estimated. The attributable risk was defined as the proportion of nonconsent that is attributed to request cases having an RPS score of less than 3, assuming that the observed relationship is causal. The unexposed group was composed of cases in which the RPS score was zero, providing a broad definition of exposure.⁴⁶ Using this approach, the attributable risk estimate was calculated to be 37%; that is, 37% of nonconsent is attributed to the fact that donation requests did not include all 3 process elements.

Discussion

A broad consensus has emerged among transplant and organ procurement professionals that the acute shortage of donors will not be relieved as long as family consent rates hover close to 50%. Higher consent rates were documented when the request was decoupled, when both hospital staff and an OPO coordinator participated in the request, and when the request took place in a private setting. When all 3 of these factors are present, hospitals and OPOs could expect to achieve a consent rate of 74%, nearly a 50%

increase over the currently reported consent rate.^{4,13}

The consistency of these effects across racial and ethnic groups is noteworthy. Improving African-American consent rates is a high priority because the need for transplants is disproportionately high in this group. Although African Americans represented only 11% of the US population in 1992,⁴⁷ 36% of patients awaiting kidney transplants in 1996 were in this population.⁴⁸ In the present study, consent rates among African-American families ranged from 20.0% (RPS score=0) to 47.2% (RPS scores=3), suggesting that consent among African Americans could be substantially higher if the request process is improved.

Donation requests involving both hospital and OPO professionals were associated with high rates of consent. This finding underscores the importance of (1) providing continuity of care, (2) minimizing the family's perception of conflict of interest between the caregiver and donation requester, and (3) including trained experts in the request process.

Another significant finding involved the setting in which the request was made. A quiet, private setting presumably allowed the family to absorb the death of their loved one without distractions, undue stress, and confusion. On the other hand, bringing up donation in a public area or in proximity to the deceased may lead the family to feel coerced or offended.

Although the present study reported nonexperimental data, all known predictors of consent were controlled for in the multivariate models. Nevertheless, unknown and uncontrolled variables might have influenced outcomes in the donation request process.

A potential limitation of the study was the reliance on the OPO staff as data collectors. Ideally, in a study of this nature, an unbiased observer should collect the data on each donation request. However, several factors prevented the use of independent observers in this study. The first one is that because organ donation is a relatively rare event, the cost of employing an observer who is available at all times is prohibitive. In addition, involving observers in the donation request may be considered by the grieving family to be an unwarranted intrusion, one that inadvertently influences their consent decision.

Although the present study was based on only 3 regions of the United States, the observed consent rate (74%) when all 3 RPS factors were present was remarkably close to the reported consent rate (75%) in Spain in 1993 (308 family refusals out of a total 1232 donation requests). In Spain a highly systematized approach to organ donation has been established by the Spanish Department of Health. As a result, the donation rate per million population in that country is one of the highest in the world. A key feature of the Spanish system is the designation and formal training of donation coordinators in every

Table 2 Estimated coefficients from multiple regression* predicting family consent for organ donation (n = 100)

Predictor variable and categories	Coefficient estimate	95% confidence interval	P value
Age, y	0.22	0.07 to 0.37	= .005
0 - 18	0.16	0.03 to 0.30	= .02
19 - 29	0.19	0.06 to 0.33	= .005
30 - 39	0.15	0.02 to 0.28	= .03
40 - 49	0.14	0.01 to 0.28	= .03
50 - 59			
60 - 75 (reference)			
Sex	0.02	-0.05 to 0.09	= .60
Male			
Female (reference)			
Race/ethnicity	-0.31	-0.41 to -0.20	<.0001
African American	-0.28	-0.37 to -0.18	<.0001
Hispanic	-0.38	-0.51 to -0.24	<.0001
Asian			
White (reference)			
Request Process Scale			= .0006
0 (reference)	0.21	0.09 to 0.32	<.0001
1	0.37	0.26 to 0.49	<.0001
2	0.47	0.35 to 0.59	<.0001
3			
Cause of death	-0.19	-0.46 to -0.08	<.16
Cardiovascular	0.0007	-0.15 to 0.16	<.99
Cerebrovascular	0.02	-0.15 to 0.19	<.85
Other head trauma	0.07	-0.09 to 0.22	<.41
Motor vehicle crash	0.03	-0.14 to 0.19	<.76
Gunshot wound/stab			
All other (reference)			
Hospital unit			
Surgical/neurological ICU	0.03	-0.05 to 0.11	<.43
(reference)			
Combined medical/surgical ICU	0.005	-0.13 to 0.14	<.94
Medical ICU/CCU	-0.13	-0.27 to 0.02	<.08
Emergency	-0.12	-0.28 to 0.04	<.15
Pediatric	-0.14	-0.42 to 0.15	<.35
Other			
Transplant center	-0.06	-0.15 to 0.03	<.17
Transplant			
Other (reference)			
OPO region			<.003
1 (reference)	0.14	0.05 to 0.23	<.26
2	-0.06	-0.16 to 0.04	
3			

* Estimated from linear regression equations controlling for all variables shown, in which 1=consent and 0=no consent. R^2 (adjusted) = 0.24

ICU indicates intensive care unit; CCU, critical care unit

hospital where there are potential donors.⁴⁹ Although no systematic data exist yet on the characteristics of the request process in Spain, the standards of practice include the provision of a clear explanation of brain death to ensure understanding by the family before donation is introduced, and the use of a private setting where possible.⁵⁰

Significant opportunity exists for hospitals and OPOs to incorporate these elements into standard protocols.⁵¹ Specific options include the following: establishing in-house donation committees that are responsible for overseeing donation quality; formulating practice guidelines or protocols that incorporate the 3 basic elements of the request process; prospective

tracking of requests using the RPS; designating specialized teams with lead responsibility for coordinating communication with families; and having regular case reviews to ensure that guidelines are being followed. All of these methods have been shown to facilitate the adoption of a new, improved request process. Currently, there are no such standard protocols, as evidenced by the average RPS score of less than 2. More than 70% of the requests did not have all 3 of the factors associated with higher rates of consent.

If these factors prove broadly applicable, the national impact could be dramatic. In 1996, there were 5417 brain-dead organ donors in the United States⁴⁴ out of an estimated 9000 to 15,000 per year.⁴⁵ The findings of the present study suggest that donation could increase substantially, resulting in thousands of additional transplants annually, as well as a more systematic and effective process for offering donation to surviving family members.

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