

Determinants of Family Consent to Tissue Donation

Laura A. Siminoff, PhD, Heather M. Traino, PhD, and Nahida Gordon, PhD

Background: Family consent to tissue donation currently falls well below that for solid organ donation. Moreover, research suggests that Americans have limited understanding of tissue donation, an activity largely overshadowed by the more publicly visible organ donation. This research sought to identify determinants of families' consent to tissue donation.

Methods: Data collection included a brief, self-administered survey completed by tissue bank staff and telephone interviews with family for a sample of tissue donor-eligible deaths reported to a national sample of 16 United States Tissue banks from 2003 to 2006. Family members (N = 1,418) and tissue bank staff (n = 226) involved in the tissue donation decision participated in the research.

Results: The families of 1,015 (71.6%) tissue donor-eligible patients consented to tissue donation; 403 (26.8%) families refused. Results revealed a multitude of associations between study variables and the donation decision. A subsequent multivariable analysis identified determinants of family consent to tissue donation, including the discussion of key donation-related issues during the request (adjusted odds ratio [AOR], 17.22; 95% confidence interval [CI], 11.61–25.54), the quality of communication during the request (AOR, 12.39; CI, 7.76–20.02), families' tissue donation attitudes and knowledge (AOR, 10.01; CI, 6.47–15.50), families' initial reactions to the request (AOR, 7.86; CI, 5.13–12.05), families' advance notice of the request (AOR, 3.95; CI, 2.41–6.46), and patient and family sociodemographic characteristics (AOR, 3.32; CI, 2.01–5.48).

Conclusions: Family consent to tissue donation is affected by many of the same variables influencing consent to solid organ donation. Recommendations for practice are provided.

Key Words: Tissue donation, Family consent, Medical decision-making.

(*J Trauma*. 2010;69: 956–963)

Each year, ~1,000,000 American lives are improved through tissue donation.¹ Some tissue, such as skin and heart valves, may be used in life-saving capacities.² Donated skin can be used to prevent fluid loss for burn victims, whereas heart valves may be used to repair deformed or malfunctioning valves.² A previous study conducted by Siminoff et al.³ found that only 35% of the families of eligible deceased patients consent. This figure is startling because the

pool of potential tissue-eligible patients is much greater than that for organ donation. It is estimated that by increasing consent to tissue donation by a mere 10%, the pool of transplantable tissue would increase by 100,000 grafts.⁴

However, increasing consent is a daunting task. It has taken 20 years of concerted effort to increase family consent to solid organ donation from 40% to 60%.^{3,5} The challenge for tissue donation is greater because it is poorly understood by the public. A survey of families who donated tissues indicated only one-half distinguished tissue donation from organ donation.⁶ Moreover, the public is generally unaware of the details of tissue donation, such as the preparation and distribution process, which can involve for-profit companies.⁴

Previous studies examining tissue donation have been limited by scope, sample size, and analytic method. Most have small sample sizes (<100) and exclusively focus on families who consented to donation.^{6–9} Furthermore, only one study used a multivariate model to identify predictors of family consent.⁷ This study is the first to examine a large, national sample of potential tissue donors. The goals of this study were to describe the process and content of the requests for tissue donation and to identify the factors associated with family consent.

METHODS

Tissue Bank Sample

Sixteen tissue banks representing a spectrum of tissue procurement organizations across the United States were sampled. In addition, two organizations procured tissues nationally, whereas the remaining 14 procured tissues from within proscribed geographic areas. Specifically, five organizations were based in the Southwest, four in the Southeast, three in the Midwest, three in the Northeast, and one in the Northwest. Finally, 6 hired and trained their own requesters, whereas 10 contracted at least a percentage of their requests to services that provide full- or part-time telephone coverage for the purpose of contacting and requesting tissue donation from the families of tissue-eligible patients.

Data collection at each tissue bank involved (1) the identification of families from whom tissue donation was requested; (2) self-administered surveys completed by tissue bank requesters immediately after discussing donation with the families; and (3) audiotaped telephone interviews with the family decision makers (FDM) who participated in the donation decisions. Data were collected from February 2003 through 2006.

Tissue Bank Requester Sample

Eligible requesters were defined as those tissue bank staff who discussed donation with family members. Each

Submitted for publication May 20, 2009.

Accepted for publication February 10, 2010.

Copyright © 2010 by Lippincott Williams & Wilkins

From the Department of Social and Behavioral Health (L.A.S., H.M.T.), Virginia Commonwealth University, Richmond, Virginia; and School of Nursing (N.G.), Case Western University, Cleveland, Ohio.

Supported by the Agency for Healthcare Research and Quality (AHRQ) grant #R01 HS-13152. AHRQ played no role in the study's design, conduct, or reporting.

Address for reprints: Laura A. Siminoff, PhD, Department of Social and Behavioral Health, Virginia Commonwealth University, 1112 East Clay Street, PO Box 980149, Richmond, VA 23220; email: lasiminoff@vcu.edu.

DOI: 10.1097/TA.0b013e3181d8924b

case was associated with at least one staff requester; 13 cases included more than one requester. Requesters completed a self-administered survey at the completion of each request for tissue donation. A total of 226 tissue requesters participated in the study, and 99.1% of cases had a completed tissue requester survey. Because of the high volume of tissue donation requests made each month, tissue banks were randomized to specific data collection days. During these days, requesters completed a brief, self-administered survey after each request.

Family Decision Maker (FDM) Sample

FDM were identified using the tissue banks' records. Two months after the death of adult patients and 3 months after the death of pediatric patients, a letter explaining the purpose and methods of the study were sent to a random sample of families from whom requests were made. Past research examining family consent to organ donation has found that this time period allows families to grieve without compromising recall of the events surrounding the patient's death.¹⁰ Ten days after the letters were mailed, families were contacted through telephone and invited to participate in the study. We interviewed 62.5% ($n = 1,471$) of individuals contacted about tissue donation (4,002), of whom 1,008 (68.5%) donated tissues and 463 (31.5%) did not. Because the interviews relied on FDMs' memory of the donation request, only those reporting good recollection of the donation conversation were included in these analyses; 53 cases in which respondents reported poor recall were excluded for a final sample of 1,418 cases.

The family interview consisted of two parts. The first contained a series of structured and semistructured questions that systematically collected data on the quality of care the patient received at the hospital, interactions with tissue bank requestors, the donation decision, and the reasons for that decision. The second section measured family members' attitudes about and knowledge of tissue donation and transplantation. The interview was a modified version of a well-validated interview used extensively with families that were asked to donate solid organs.¹⁰ All interviews were audiotaped and transcribed verbatim; interviews lasted 45 minutes to 60 minutes. The study was approved by the appropriate institutional review board, and verbal informed consent was obtained from all participants.

Outcomes

The primary outcome measure was the decision whether to donate tissue (consented/refused). Consent data obtained from FDMs during the interviews were verified through tissue bank reports. Basic demographic information, including sex, ethnicity, and age, were collected for all subjects. In addition data such as income, education, and marital status were obtained for FDMs. Factors thought to influence family consent were assessed during the interviews and are described later. For all scales, higher scores indicate higher levels of the measured variable.

Family members rated the quality of care the patient received while in the hospital, the quality of communications with the health care providers, and health care provider's care

and concern using three 5-point Likert Scales. In addition, FDMs indicated who first approached them about the option of tissue donation and their level of comfort with that person. FDMs also reported their initial response to the donation request and level of surprise at being asked to donate. Both variables were measured on a 7-point Likert Scale. Decision makers provided the rationale behind their donation decision. Similarly, tissue requesters reported their perceptions of families' initial response to the request. Congruence between requesters' and family members' reports of FDMs' initial response was also ascertained through a paired comparison yielding a variable scored as either concordant or discordant. The relationship between this variable and consent was then assessed to determine whether requesters' ability to accurately gauge FDMs' reactions to the donation request influenced the donation decision.

Two measures were used to examine FDMs' understanding of donation: (1) the sum of correct responses to seven tissue donation knowledge questions; and (2) correctly identifying the tissue requester's organizational affiliation. A 14-item, 5-point Likert Scale of attitudes toward donation and transplantation used and validated in several studies of organ donation was modified for tissue donation and administered to FDMs.¹⁰ Scores are summative and range from 14 to 70. Family respondents also recalled the donation-related topics discussed with the tissue requester, the type(s) of tissue requested, and the total time spent in discussion with the requester.

FDMs' level of satisfaction with their decision was obtained using the Decisional Regret Scale, a standard 5-item, 5-point Likert Scale.¹¹ To contextualize this measure, an open-ended question allowed respondents to indicate what, if anything, they would have changed about their decision. By using three 7-point Likert questions, requesters rated their comfort speaking with the family and answering the family's questions as well as their overall satisfaction with the process.

Berlo's Source Credibility Scale, a 5-item, 7-point Likert Scale, assessed FDMs' perceptions of requesters' training, experience, qualifications, skill, and knowledge. Scores on the scale were summed and ranged from 5 to 35.¹² Family respondents also indicated whether the tissue requester asked if they had any questions and, if so, how satisfied they were with the requesters' answers. Satisfaction was rated using a 7-point Likert Scale of agreement. Two 5-point Likert Scales assessed respondents' perception of requesters' display of care and concern and the quality of the requester's communications during the donation conversation. Families also completed a 14-item, 7-point Relational Communication Scale.¹³ Item responses were based on level of agreement and were summed to range from 14 to 98.

Statistical Analysis

Associations between the independent variables and family consent were performed using the Fisher exact test or the χ^2 test, for variables with two categories or three or more categories, respectively. The Mann-Whitney U test was used to examine ordinal-level variables; the Student's t test was used for interval- or ratio-level variables. Because the sample

was skewed toward FDMs who consented to tissue donation, a weighted analysis was conducted. No significant differences were found between the analysis weighted for sampling bias and the unweighted analysis; the results of the unweighted analysis are presented here.

We performed a log-linear regression to describe the relationship between family consent to tissue donation and factors describing the consent process. A theoretical model of donation decision making was used to determine the constituents of each factor.¹⁰ First, the study's independent variables were grouped to create six factors, each representing a different conceptual domain (the Supplementary Table provides a summary of each factor). Second, variables that were significantly associated with donation within each of the domains using bivariate techniques were retained. Third, separate logistic regression analyses were performed on each of the domains using consent as the outcome. This process created six variables representing the estimated probability of consent for each conceptual domain. A cut point of 0.5 was chosen to transform each of these variables into a dichotomous variable. Finally, a log-linear regression was conducted to analyze the interrelationships between the six dichotomous variables and consent. The analyses were performed using SPSS 16.0 for Microsoft Windows and SAS (SPSS Inc., Chicago, IL; SAS Institute Inc., Cary, NC).

RESULTS

Sociodemographics and Consent

Patients' mean age was 56.1 years (standard deviation [SD], 18.4); 83.3% were white and 68.6% were men. Younger, white patients were more likely to become donors than older, nonwhite patients.

FDMs were predominantly white (85.8%) and women (72.6%) with a mean age of 51.3 years (SD, 13.4). Although most decision makers (44.1%) were the spouse of the deceased, others were adult children (28.1%), parents (13.7%), siblings (9.7%), or other relatives, significant others, or legal guardians (4.4%). Fifty-one percent of family members reported their religious affiliation as Protestant and 22.8% as Catholic. Nearly three quarters of the families (72.4%) had yearly incomes > \$30,000 and 14.0 years (SD, 2.4) of education. A minority of family members held health-related occupations (13.0%). Although only 66.5% of families had signed a donor card, nearly all (91.8%) stated a willingness to donate their own tissue.

FDMs who donated were more likely to be white (92.3% vs. 69.2%, *p* < 0.001) and Catholic (24.5% vs. 18.6%, *p* < 0.05), to have an annual income >\$59,000 (41.1% vs. 25.9%, *p* < 0.001), and more years of education (14.2% vs. 13.5%, *p* < 0.001), compared with FDMs who refused donation. Donor families, compared with nondonors, were also more likely to have signed a donor card (66.6% vs. 32.0%, *p* < 0.001; see Table 1).

Donor families cited implicit or explicit knowledge that the patient wanted to be a donor (66.1%), families' desire to help others (60.8%), and families' general inclination toward donation (39.3%) as reasons for their final decision. Of the families who donated, 150 (10.6%) donated with conditions—

TABLE 1. Patient and Family Decision Maker Sociodemographics by Donation Decision

Demographic Characteristic	Consented to Donation (n = 1,015)	Refused Donation (n = 403)
Patient		
Age, mean years (SD) [†]	55.1 (18.34)	58.7 (18.20)
Sex		
Female	306 (30.1)	139 (34.5)
Race [‡]		
Nonwhite	104 (10.2)	133 (33.0)
Family decision maker		
Age, mean years (SD)	51.4 (13.3)	51.0 (13.6)
Sex		
Female	723 (71.2)	306 (75.9)
Race [‡]		
Nonwhite	78 (7.7)	124 (30.8)
Marital status		
Single	73 (7.2)	34 (8.5)
Married/cohabit	364 (35.9)	141 (35.2)
Divorced/separated	91 (9.0)	48 (12.0)
Widowed	486 (47.9)	178 (44.4)
Religious affiliation [†]		
Protestant	492 (48.5)	230 (57.1)
Catholic	249 (24.5)	75 (18.6)
Other	144 (14.2)	58 (14.4)
None	130 (12.8)	40 (9.9)
Household income [‡]		
<\$30,000	226 (24.3)	127 (36.2)
\$30,000–59,999	322 (34.6)	133 (37.9)
>\$59,999	382 (41.1)	91 (25.9)
Health-related occupation		
Yes	132 (13.0)	55 (13.8)
Willing to donate own tissue [‡]		
Yes	932 (91.8)	208 (51.6)
Donor card signed [‡]		
Yes	676 (66.6)	129 (32.0)
Education, mean years (SD) [‡]	14.2 (2.4)	13.5 (2.3)

Values are count (percent) unless noted otherwise.

[†] *p* < 0.01.

[‡] *p* < 0.001.

donating some, but not all tissues requested. Reasons for families' decision to donate conditionally included concern for potential disfigurement or mutilation of the patient's body (66.0%), assessment of the patient's eligibility (15.3%), an emotional attachment to a certain body part (12.0%), family compromise (6.7%), and the implicit or explicit knowledge of the patient's wishes (6.7%). The most common reason for refusing donation was patient and family fatigue (feeling they or the patient "had been through enough"; 39.5%). Other reasons why nondonors refused included implicit or explicit knowledge that the patient did not want to donate (31.3%), concern over potential disfigurement (22.1%), a belief that the patient was not eligible to donate (19.9%), and feeling uninformed about tissue donation (6.5%). Overall, FDMs were generally satisfied with their donation decisions (mean

decisional regret, 6.7; SD, 3.3), although families refusing donation exhibited greater regret than did donating families (9.0 vs. 5.8, $p < 0.001$).

Tissue requesters ($n = 226$) were predominately women ($n = 155, 68.2\%$) and white ($n = 174, 77.0\%$). The average age of a requester was 34.2 (SD, 9.5) years and most had at least a college education ($n = 138, 61.1\%$). On average, requesters had 1.5 years of job experience (SD, 2.8); half (50.4%) of the requesters held degrees in a health-related field. Requesters' sociodemographics were not significantly associated with consent.

Families' Initial Reactions to the Request and Consent

Thirty-three percent ($n = 468$) of families were surprised to be asked about tissue donation. Consistent with research examining families asked to donate solid organs,¹¹ family members who refused donation reported higher levels of surprise than consenting family members (4.7 vs. 3.3, $p < 0.001$; see Table 4). Although many families were surprised at the request, the majority of family members (60.2%) reported being in favor of donation when first asked; 24.3% of families were initially unsure about donation and 15.5% were unfavorable. Tissue requesters correctly judged families' initial reactions to the donation request 64.4% of the time. Family consent was more likely when the tissue requester correctly assessed the FDM's reaction to the request than when the assessment was discordant (70.4% vs. 29.6%, $p < 0.001$).

Attitudes, Knowledge, and Consent

Donor families reported significantly more favorable attitudes toward donation than did nondonor families (50.5

vs. 44.3 of 70, $p < 0.001$). Conversely, nondonors were more likely to feel "squeamish" about the idea of tissue donation (35.7% vs. 13.0%, $p < 0.001$), to agree that donor families should share in any monies made from donated tissue (38.4% vs. 30.6%, $p < 0.01$), and to agree that families should have some degree of control over how donated tissue is used (57.1% vs. 48.1%, $p < 0.01$) than donors. Few families (donors or nondonors) were in favor of using donated tissue for cosmetic purposes or involving for-profit companies in the processing and distribution of donated tissue (see Table 2).

On average, respondents' knowledge about tissue donation was moderately high, with a mean of 5.4 correct answers out of 7 (SD, 1.4). However, donating families displayed more knowledge of tissue donation than families declining donation (5.6 vs. 4.8, $p < 0.001$). Nondonors commonly and incorrectly thought that tissue donors could not have open casket funerals and that a signed donor card or a license marked "donor" did not apply to tissues or corneas (see Table 3). In addition, although more than half (60.1%) of all FDMs were able to identify the organizational affiliation of the tissue requester by name or type of organization, significantly more donors than nondonors did so correctly (67.6% vs. 40.9%, $p < 0.001$).

Request Process Factors and Consent

Past research in organ donation has indicated that family members' perceptions of the care and concern exhibited by the patient's health care team affect the decision to donate.¹⁰ The use of the telephone in requests for tissue donation is standard practice. In this sample, 61.0% of the requests for donation were initiated by telephone, and all requests were followed up and completed by telephone.

TABLE 2. Family Respondents Agreeing or Strongly Agreeing to Attitude Statements

Attitude Item	Consented to Donation (n = 1,015)	Refused Donation (n = 403)
Tissue donation makes something positive come out of death*	997 (98.2)	341 (84.6)
If my doctor told me that I needed a tissue transplant, I would want one*	961 (94.7)	311 (77.2)
It is acceptable for donated tissues to be made into medical products (e.g., screws made from bone for surgical use)*	912 (89.9)	297 (73.7)
It is acceptable that tissues can be stored or packaged for long periods of time before their use*	897 (88.4)	317 (78.7)
People who have received tissue transplants are able to lead full, productive lives*	866 (85.3)	271 (67.2)
It is not acceptable for donated tissues to be bought and sold, for any purpose	744 (73.3)	313 (77.6)
Tissue donation helps families to grieve*	661 (65.1)	123 (30.5)
It is ok for tissues donated in the United States to be sent to other countries*	633 (62.4)	213 (52.9)
Families should not have a say in how the tissues are distributed	544 (53.6)	198 (49.1)
Families should be able to have a say in deciding what the donated tissues will be used for†	489 (48.1)	230 (57.1)
Donor families should share in any money that is made through medical products made from donated tissues†	310 (30.6)	155 (38.4)
It is acceptable for donated tissues to be processed and distributed by for-profit companies*	289 (28.5)	62 (15.4)
It is acceptable for donated tissues to be used for cosmetic purposes such as smoothing out wrinkles or enlarging lips‡	249 (24.5)	77 (19.1)
The idea of tissue donation makes me feel squeamish and uncomfortable*	132 (13.0)	144 (35.7)

Values are count (percent) unless noted otherwise.

* $p < 0.001$.

† $p < 0.01$.

‡ $p < 0.05$.

TABLE 3. Percent of Correct Responses to Knowledge Questions

Question	Consented to Donation (n = 1,015)	Refused Donation (n = 403)
Donor card applies to organs*	974 (96.0)	372 (92.3)
Family is responsible for costs related to donation†	959 (94.5)	338 (83.9)
Family can choose which tissues to donate†	900 (88.7)	323 (80.1)
Tissue donors can have open casket funerals†	824 (81.2)	235 (58.3)
Donor card applies to corneas†	823 (81.1)	265 (65.8)
Donor card applies to tissues†	767 (75.6)	227 (56.3)
Donor card/license legally binding	427 (42.1)	163 (40.4)

Values are count (percent) unless noted otherwise.

* $p < 0.01$.

† $p < 0.001$.

Requests initiated by telephone were significantly more likely to result in refusals than when families were given advance notice in person about the request by hospital personnel (70.0% vs. 30.0%, $p < 0.001$; see Table 4). Families who consented to donation were most likely to have their first substantive conversation about tissue donation with a tissue requester (36.7%); nondonor families were most likely to have the issue first discussed with clergy, social workers, coroners, funeral directors, or other unspecified hospital personnel (48.9%; $p < 0.001$). A similar discussion pattern was observed in requests for organ donation.¹⁰ Consenting families also reported greater comfort with requesters than did families who refused donation (mean comfort scores 6.2 vs. 4.4, $p < 0.001$). In addition, families who knew of the patient's desire to become a donor or who thought the patient would have wanted to donate were more likely to grant consent than FDMs who did not (64.0% vs. 36.0%, $p < 0.001$).

Quality of Communication and Consent

Discussions with families about donation ranged from 1 minute to 240 minutes, with a median length of 20 minutes (mean, 14.6; SD, 3.1). Consenting families spent considerably more time discussing donation than did families who refused consent (23.0 minutes vs. 4.6 minutes, $p < 0.001$). Family members consenting to donation discussed significantly more topics with requesters than did family members who refused (9.8 vs. 1.7, $p < 0.001$). For donors, conversations about donation most often included discussions of the patients' medical history and the use of donated tissue to save lives and treat disease (see Table 5). The least commonly discussed topics for donors included the involvement of for-profit organizations, families' religious or spiritual beliefs, and the tissue requesters' point of view on donation. For nondonors, the most frequently discussed topics were the time to make the decision and the patient's donation wishes, whereas the processing and storage of donated tissue and the involvement of for-profit companies were discussed least.

Almost three quarters (69.4%) of respondents recalled being asked whether they had any questions concerning donation. Families consenting to donation were more likely to be solicited for questions than were families who refused (86.7% vs. 25.8%, $p < 0.001$). Donor families also rated the communication with the requester of higher quality than nondonors (4.3 vs. 3.4, $p < 0.001$). Donors thought that the requester was more caring and concerned (4.7 vs. 3.7, $p < 0.001$), more credible (31.8 vs. 22.8, $p < 0.001$), and possessed stronger communication skills (79.3 vs. 64.1, $p < 0.001$) than did nondonors.

Multivariable Analysis of Determinants of Consent

Six key aspects of the tissue request process known to affect consent (see Supplementary Table) were examined to determine how interrelations among the factors affected consent in this population. Results revealed that all six factors were directly related to consent (see Table 6). The strongest association was found between the tissue donation-related topics discussed with FDMs. Families who discussed key issues, such as costs associated with donation, the time available to make the donation decision, the impact of donation on funeral arrangements, and the ability to have an open casket funeral, were 17 times more likely to donate (adjusted odds ratio, 17.22; 95% confidence interval, 11.61–25.54). The quality of communication was also associated with consent, as were donation-related attitudes and knowledge, the role of the individual who raised the issue of donation, and patient and family sociodemographics. Significant associations among the individual factors were also found.

DISCUSSION

The results of this study reveal that family consent to tissue donation is affected by many of the same factors that influence consent to organ donation. For example, the number of donation-related topics discussed with the FDM and the family member's degree of surprise at the request predict family consent. In addition, the role of the person who first approached the family about donation (i.e., tissue bank staff or other), the amount of time spent discussing donation, and the FDM's attitudes toward and knowledge of tissue donation were significantly associated with families' donation decision. These findings are mirrored in work on organ donation by Siminoff et al. and others.^{10,14–16}

There are several significant differences between organ and tissue donation. First, tissue donation can take place many hours after the patient dies. This has encouraged the use of telephone requesting. Indeed, much attention has been paid to the use of the telephone in requests for tissue donation.^{4,6,17–19} We found that FDMs were more likely to consent when approached first in person rather than by telephone; this is consistent with past research examining the use of the telephone in requests for corneal donation.^{17–19} However, the large number of individuals eligible for tissue donation coupled with the substantial numbers of eligible deaths occurring outside hospitals, make in-person requests often impracticable. Furthermore, Wilson et al.⁶ found that >90% of families

TABLE 4. Univariate Analyses of Study Variables and Consent

Variable	Consented to Donation (n = 1,015)	Refused Donation (n = 403)
Family knew patient's donation wishes*		
Yes	391 (38.5)	25 (6.2)
No	315 (31.0)	264 (65.5)
Unsure	309 (30.4)	114 (28.3)
Family thought patient wanted to donate*		
Yes	872 (85.9)	82 (20.3)
No	32 (3.2)	160 (39.7)
Unsure	111 (10.9)	161 (40.0)
Family first approached about donation*		
In person	432 (42.6)	121 (30.0)
By phone	582 (57.4)	282 (70.0)
Family first approached by*		
OPO coordinator or tissue bank requester	372 (36.7)	138 (34.2)
Doctor or nurse	228 (22.5)	63 (15.6)
Family	105 (10.3)	5 (1.2)
Other	310 (30.5)	197 (48.9)
Initial reaction to request*		
Favorable	796 (78.4)	58 (14.4)
Unsure	190 (18.7)	155 (38.5)
Unfavorable	29 (2.9)	190 (47.1)
Congruence in TR and families' assessment of initial reaction*		
Concordance	715 (70.4)	198 (49.1)
Family correctly identified requester's organization*		
Yes	686 (67.6)	165 (40.9)
Tissue requester solicited questions†		
Yes	880 (86.7)	104 (25.8)
Families' perception of HCP care and concern, mean (SD)‡	4.09 (1.06)	3.96 (1.09)
Families' rating of quality of HCP communications, mean (SD)†	3.73 (1.19)	3.54 (1.27)
Families rating of patient care at hospital, mean (SD)	5.95 (1.41)	5.79 (1.52)
Families' comfort with person who first approached them, mean (SD)*	6.2 (1.31)	4.4 (2.23)
Families' level of surprise at request, mean (SD)*	3.3 (2.50)	4.7 (2.50)
Families' tissue donation attitudes, mean (SD)*	50.5 (6.77)	44.3 (7.60)
No. of correct knowledge items, mean (SD)*	5.6 (1.20)	4.8 (1.63)
Time spent discussing donation (minutes), mean (SD)*	23.0 (2.22)	4.6 (2.94)
No. of tissues requested, mean (SD)*	4.5 (3.12)	1.3 (1.07)
No. of topics discussed, mean (SD)*	9.8 (4.90)	1.7 (3.17)
Families' level of decisional regret, mean (SD)*	5.8 (2.12)	9.0 (4.48)
Families' rating of quality of communication with requester, mean (SD)*	4.3 (0.82)	3.4 (1.1)
Family felt requester was caring and concerned, mean (SD)*	4.7 (0.68)	3.7 (1.12)
Families' rating of requesters' credibility, mean (SD)*	31.8 (4.06)	22.8 (9.51)
Families' rating of requesters' communication skill, mean (SD)*	79.3 (9.30)	64.1 (12.33)
Families' rating of requesters' handling of questions, mean (SD)*	6.7 (0.75)	6.1 (1.41)
Tissue requesters' comfort talking with the family, mean (SD)*	6.6 (0.81)	6.0 (1.19)
Tissue requesters' comfort answering questions, mean (SD)	6.6 (0.77)	6.3 (1.07)
Tissue requesters' satisfaction with the request process, mean (SD)*	6.6 (0.92)	5.2 (1.72)

Values are count (percent) unless noted otherwise.

* $p < 0.001$.

† $p < 0.05$.

‡ $p = 0.05$.

were satisfied with the telephone request process; they and others find that telephone requests can be acceptable for requesting tissue donation.^{4,6,17-19}

Tissues and organs are also differentiated because tissues are frequently processed and go through several levels of

handling before transplantation. As such, some tissue come to resemble a commercial product much more than we might like, given that these are tissue donated freely by deceased individuals. Moreover, for-profit companies may ultimately sell some of the donated tissue, a fact only 12% of families

TABLE 5. Most and Least Commonly Discussed Donation-Related Topics

Topic	Count (%)	Influenced Donation Decision Count (%)
Donors		
Patient's medical history	786 (77.4)	259 (33.0)
Use of donated tissue to save lives	763 (75.2)	693 (90.8)
Use of donated tissue to treat disease	762 (75.1)	677 (88.8)
Patient's eligibility to donate	751 (74.0)	315 (41.9)
Use of donated tissue for research	651 (64.1)	482 (74.0)
Autopsy in relation to donation	243 (23.9)	38 (15.6)
Use of donated tissue for cosmetic purposes	185 (18.2)	67 (36.2)
Involvement of for-profit organizations	125 (12.3)	32 (25.6)
Religious or spiritual beliefs	119 (11.7)	30 (25.2)
Tissue requesters' point of view on donation	112 (11.0)	47 (42.0)
Nondonors		
Time available to make decision	75 (18.6)	36 (48.0)
Patients' wishes	64 (15.9)	53 (82.8)
Use of donated tissue to save lives	60 (14.9)	26 (43.3)
Use of donated tissue to treat disease	55 (13.6)	22 (40.0)
Patients' eligibility	52 (12.9)	36 (69.2)

TABLE 6. Log-Linear Regression Hierarchical Model of the Relationship Between Family Consent to Tissue Donation and Factors Describing the Consent Process (N = 1,418)

Significant Two-Way Interactions in Model*	Adjusted OR†	95% CI
Topics–consent	17.2	11.6–25.5
Communication quality–consent	12.4	7.7–20.0
Family attitudes–consent	10.0	6.5–15.5
Family's initial response–consent	7.9	5.1–12.1
Who raised issue–consent	3.9	2.4–6.5
Topics–communication quality	3.7	2.5–5.6
Who raised issue–family's initial response	3.7	2.3–5.0
Family/patient demographics–consent	3.3	2.0–5.5
Family/patient demographics–family's initial response	1.9	1.2–3.0
Family attitudes–family's initial response	1.9	1.3–2.8
Who raised issue–communication quality	1.9	1.2–2.9
Family attitudes–communication quality	1.8	1.2–2.8
Family/patient demographics–family attitudes	1.7	1.1–2.7

* Factors were examined in relation to each other and the donation decision. Only statistically significant interactions are reported.

† Adjusted OR is the odds ratio after controlling for other factors in the model.

knew. Nearly a quarter of family members interviewed were also unaware that a signed donor card was, in effect, an agreement to donate tissues and corneas as well as organs. Even fewer family members understood that these documents were legally binding and the respondents often confused tissues and organs. Data from this study and others show that families frequently know little about tissue donation, confuse tissue and organ donation, and are surprised to receive these

requests. It is notable that the element of surprise significantly decreases consent rates.^{4,6,9} Clearly, the American public still lacks basic knowledge of the differences between organ and tissue donation.

The study also demonstrates that information that might be considered critical to informed consent—the uses, procurement, and distribution of tissue—go largely undisclosed. Indeed, both the Department of Health and Human Services' Office of the Inspector General²⁰ and the National Kidney Foundations' National Donor Family Council²¹ consider these topics critical to families' decision-making process. The Office of the Inspector General²⁰ also recommends that, at minimum, families should be provided with, among other things, a copy of the consent form. Nonetheless, only 28.8% of consenting families in this study were asked if they would like a copy of the consent form and, of those responding affirmatively, only 32.7% reported they received one.

Given these findings, we propose the following suggestions for improving consent to tissue donation in the United States. First, a general education campaign, targeted primarily to minority communities, is needed to inform the American populace about the nature and benefits of tissue donation. A simple solution would be to distribute pamphlets about tissue donation to all families and patients in hospitals. Our data indicate that preparing families to receive a telephone request can add to the likelihood of a successful request. However, research promoting family consent to organ donation has shown that requesters spending more time with families are more likely to obtain consent.¹⁶ Although requesting tissue donation by telephone may be cost effective, consent rates may improve if more requests for tissue were made in person, like those for organs.

Tissue banks should also routinely ensure that all families are provided information on the processing and distribution of donated tissue and of the involvement of for-profit companies. Because families stated these topics would be influential to their choices about donation, they should be included in discussions about donation to provide families with the information needed to make informed donation decisions. Moreover, tissue banks must be vigilant in distributing informed consent documentation to all families who consent to donation. Informed consent is a standard element of medical care and should not be overlooked in this context.

Although this is the largest, most comprehensive examination of the process of requesting tissue donation in the United States, it has limitations. Few minority respondents were of Hispanic (3.8%) or Asian (0.6%) descent; most were African American (11.3%). However, this study's demographic profile is similar to that of the US population.²² Future research should use stratified sampling techniques to provide a more in-depth analysis of Asian and Hispanic attitudes and behaviors regarding tissue donation. In addition, because the interviews were held 2 months to 4 months after the patient's death, there is a chance that some FDMS' failed to accurately recall these events. Recall error is a common threat to validity in retrospective studies but was minimized in this study by careful cognitive interviewing techniques and

the vividness of the events. Finally, although the sample was large for a study of this type, there was a significantly higher participation rate for families consenting to donation than for those who refused (71.6% vs. 26.5%, $p < 0.001$). Nondonors' participation in similar studies examining organ and tissue donation ranges from a low of 21% to a high of 60%.^{4,23,24}

ACKNOWLEDGMENTS

We thank the 16 tissue banks for their participation and Ms. Aruna Swaminathan, MS, for her skillful data management.

REFERENCES

- American Association of Tissue Banks. Available at: <http://www.aatb.org/>. Accessed 24 March 2009.
- Kent B. Tissue donation and the attitudes of health care professionals. In: Sque MRJ, ed. *Organ and Tissue Donation: An Evidence Base for Practice*. Buckingham, UK: Open University Press; 2007:102–121.
- Siminoff LA, Arnold RM, Caplan AL, Virnig BA, Seltzer DL. Public policy governing organ and tissue procurement in the United States. Results from the National Organ and Tissue Procurement Study. *Ann Intern Med*. 1995;123:10–17.
- Rodrigue JR, Scott MP, Oppenheim AR. The tissue donation experience: a comparison of donor and nondonor families. *Prog Transplant*. 2003;13:258–264.
- Garrison RN, Bentley FR, Raque GH, et al. There is an answer to the shortage of organ donors. *Surg Gynecol Obstet*. 1991;173:391–396.
- Wilson P, Sexton W, Singh A, et al. Family experiences of tissue donation in Australia. *Prog Transplant*. 2006;16:52–56.
- Lawlor M, Dobbins T, Thomas KA, Billson F. Consent for corneal donation: the effect of age of the deceased, registered intent and which family member is asked about donation. *Br J Ophthalmol*. 2006;90:1383–1385.
- Beard J, Ireland L, Davis N, Barr J. Tissue donation: what does it mean to families? *Prog Transplant*. 2002;12:42–48.
- Haire MC, Hinchliff JP. Donation of heart valve tissue: seeking consent and meeting the needs of donor families. *Med J Aust*. 1996;164:28–31.
- Siminoff LA, Gordon N, Hewlett J, Arnold RM. Factors influencing families' consent for donation of solid organs for transplantation. *JAMA*. 2001;268:71–77.
- Brehaut JC, O'Connor AM, Wood TJ, et al. Validation of a decision regret scale. *Med Decis Making*. 2003;23:281–292.
- Berlo DK, Lemert JB, Mertz RJ. Source credibility scale. In: Rubin RB, Palmgreen P, Sypher HE, eds. *Communication Research Measures: A Sourcebook*. New York, NY: Guilford Press; 1994.
- Burgoon JK, Pfau M, Parrott R, Birk T, Coker R, Burgoon M. Relational communication, satisfaction, compliance gaining strategies, and compliance in communication between physicians and patients. *Commun Monogr*. 1987;54:307–324.
- DeJong W, Franz HG, Wolfe SM, et al. Requesting organ donation: an interview study of donor and nondonor families. *Am J Crit Care*. 1998;7:13–23.
- Rodrigue JR, Cornell DL, Howard RJ. Organ donation decision: comparison of donor and nondonor families. *Am J Transplant*. 2006;6:190–198.
- Siminoff LA, Marshall HM, Dumenci L, Bowen G, Swaminathan A, Gordon N. Communicating effectively about donation: an educational intervention to increase consent to donation. *Prog Transplant*. 2009;19:35–43.
- Gain P, Thuret G, Pugniet JL, et al. Obtaining cornea donation consent by telephone. *Transplantation*. 2002;73:926–929.
- Rodríguez-Villar C, Ruiz-Jaramillo MC, Paredes D, Ruiz A, Vilardell J, Manyalich M. Telephone consent in tissue donation: effectiveness and efficiency in postmortem tissue generation. *Transplant Proc*. 2007;39:2072–2075.
- Geissler A, Paoli K, Maitrejean C, Durand-Gasselín J. Rates of potential and actual cornea donation in a general hospital: impact of exhaustive death screening and surrogate phone contact. *Transplant Proc*. 2004;36:2894–2895.
- Office of the Inspector General (OIG). U.S. Department of Health and Human Services. Informed consent in tissue donation: expectations and realities. 2001. Available at: http://www.fda.gov/OHRMS/DOCKETS/ac/01/briefing/3736b2_02.pdf. Accessed January 24, 2008.
- National Donor Family Council (NDFC). National Kidney Foundation. Informed consent policy for tissue donation. 2007. Available at: <http://www.kidney.org/transplantation/donorFamilies/infoPolicyConsent.cfm>. Accessed January 24, 2008.
- U.S. Census Bureau. United States Census 2000. Demographic Profiles. Available at: <http://censtats.census.gov/cgi-bin/pct/pctProfile.pl>. Accessed March 23, 2009.
- Sque M, Long T, Payne S. Organ donation: key factors influencing families' decision making. *Transplant Proc*. 2005;37:543–546.
- Frutos MA, Blanca MJ, Mansilla JJ, et al. Organ donation: a comparison of donating and nondonating families. *Transplant Proc*. 2005;37:1557–1559.