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Author manuscript

Prog Transplant. Author manuscript; available in PMC 2019 October 03.

Published in final edited form as:

Prog Transplant. 2013 March ; 23(1): 99–104. doi:10.7182/pit2013801.

Consent to organ donation: a review

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Abstract

Successful transplant medicine hinges on consent to deceased organ donation. Yet rates of consent remain suboptimal. To increase the availability of transplantable organs, several policy strategies along with a rich body of evidence aimed at identifying best practices for obtaining consent have accumulated. This review describes past and current policies and practices, presents evidence illustrating the impact of these policies and practices on consent, and summarizes future directions and recommendations for the field. Key findings include evidence that although past policies such as required request have been unsuccessful, the recent policy, first-person authorization, shows promise. Additionally, practices such as decoupling and detailed discussions of brain death are unwarranted. On the other hand, the Organ Donation Breakthrough Collaboration was successful. We also underscore the impact of alternative procedures such as donation after cardiac death. Last, effective communication that is delivered by trained, caring requesters at the appropriate time, in a supportive environment, and allows sufficient time for families to make an informed decision, optimizes the request process. Organ procurement organizations' adoption of such request practices, implementation of evidence-based policies regarding donation after cardiac death, and further investigations of the medical basis for dual brain death examinations are recommended.

Obtaining consent to deceased organ donation is essential to transplant medicine. Yet at least 25% of families refuse to consent to organ donation and another 23.2% of donated organs are lost during the procurement process; overall 75% of potential donors are estimated to consent annually.¹ The range in organ procurement organizations' (OPOs') self-reported consent rates is wide, with a low of 58% and a high of 91%.¹ In light of these facts and the number of patients on the transplant waiting list (currently >114000), substantial efforts have been focused on identifying effective policies and practices for increasing consent to organ donation. These efforts have yielded a growing body of evidence that can inform OPO and hospital practices and guide future policies.

This review aims to (1) describe past and current policies and practices, (2) present evidence illustrating the impact of these policies and practices on consent, and (3) summarize future directions and recommendations for the field.

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Financial Disclosures
None reported.

Past and Current Policies

Few specific areas of medicine have been the subject of as much legislation to effect behavior change as transplant medicine. In efforts to provide enough lifesaving organs to an ever-increasing number of patients, state and federal legislators have enacted a series of policies, including required request, required referral/routine notification, and first-person authorization.

Required request, first enacted by states in the 1980s, mandated that hospitals present families of all potential deceased donors with the option of organ donation.² Specifically, hospitals and their staff were responsible for making requests to the families of donor-eligible patients. By 1986, more than half of US states had passed required request laws, which had become compulsory for Medicare reimbursement and for Joint Commission accreditation.² Nonetheless, by the end of the decade it became apparent that required request had not had the desired impact on consent rates.

Recognition of the legislation's failure to increase the availability of transplantable organs prompted another federal policy change in 1998. Guided by the belief that health care providers (HCPs) were not the most effective requesters,³ a new routine notification policy² required that hospitals report all deaths to regional OPOs for assessment of organ-donation eligibility and that those making requests for donation be trained. The law, first passed in Pennsylvania in 1994, aimed to increase donation through identification of all potential donors and by shifting responsibility for requests from hospital HCPs to specially trained staff, most frequently OPO staff.²

The most recent legislative effort to increase consent is first-person authorization or "donor designation," which was first enacted in Pennsylvania in 1994. Currently, all 50 states and the District of Columbia have first-person authorization laws, which recognize the primacy of the deceased's documented desire to become a posthumous organ donor. These laws permit organ donation without family consent if the deceased has designated him/herself as a donor on a driver's license, donor card, or a donor registry. First-person authorization addresses concerns that pursuing organ retrieval without family consent could result in legal action. The policy is a guarantor of patient autonomy and the legal authority of OPOs and hospitals to uphold individuals' documented donation wishes.⁴ By prioritizing the deceased's wishes, first-person authorization also circumvents discrepancies between the deceased's and families' organ donation preferences and provides assurances to the family of the deceased's wishes at a time of uncertainty and great emotional distress.⁵

Policy Successes and Failures

Policies and legislative activities have had differential effects on the availability of transplantable organs. This may be because the policies, especially required request, lacked an empirical evidentiary base.

Required request was based in assumptions drawn from bioethicists, public opinion polling, and donor family surveys.⁶ Siminoff et al⁶ hypothesized that such policies would increase organ availability by ensuring that families of all donor-eligible patients are asked about

donation and standardizing the request process, thereby reducing HCP and family burden while preserving individuals' right to refuse.⁶ The assumption was that most individuals wanted to donate, but that the health system failed to provide all families with the option of donation. It was presumed that consent rates would increase simply by increasing the number of requests, an assumption lacking empirical support.³ Two critical facets of gaining consent were wholly overlooked: (1) the manner in which the request is made and (2) families' knowledge of the deceased's wishes.² Subsequent research overwhelmingly demonstrated the failure of required request to increase consent rates significantly. Although some studies reported increases in referrals and requests after the policy's enactment, only small, statistically insignificant increases in consent were identified. In some instances, consent rates actually declined after the law was passed.⁶

Routine notification, implemented to improve identification of donor-eligible patients and referral and request processes, also failed to have a notable impact on consent rates.² The policy was based on the premise that HCPs were not engaging in effective communication with families during requests.³ Although informed by empirical evidence that OPO staff involvement in requests yield higher consent rates,⁷ routine notification policies failed to address the organizational structures of OPOs and hospitals, which often hinder donation procedures. Moreover, the legislation did not address the timing of the referrals; many hospitals fail to report deaths to OPOs in a timely manner, that is, within 1 hour of meeting a clinical trigger for referral.⁸ Additionally, the lack of useful metrics to assess and monitor the policy's implementation and OPO performance was problematic. Consequently, routine notification had only a small, positive impact on donation rates.²

Although routine notification alone has had little impact on consent rates, some of its underlying principles are evident in the Organ Donation Breakthrough Collaborative, a national quality improvement effort initiated by the Health Resources and Services Administration's Division of Transplantation (HRSA/DoT). Both routine notification and the collaborative emphasized OPOs' participation in the request process. The collaborative also specified time-sensitive notification of OPOs about potential donor-eligible patients and standardization of the request process to ensure that all donor-eligible patients' families are approached.⁹ Furthermore, and perhaps most importantly, the collaborative encouraged partnerships between OPOs and hospitals, facilitating shared responsibility and accountability for donation outcomes, and advocated that all donation opportunities be pursued aggressively, including reproaching refusing families, implementing policies for donation after cardiac death (DCD), and optimizing the management of donation from referral to recovery.⁹

The first evaluation of the collaborative¹⁰ compared conversion rates between 95 participating and 125 control hospitals before (1 year prior) and after (6 months after) implementation of the collaborative. Before the collaborative was implemented, both groups of hospitals had similar conversion rates—54% and 51%. After implementation, participating hospitals' conversion rates increased to 60% while control hospitals' conversion rates remained unchanged. The authors ascribe the increase to the collaborative's quality improvement strategies; whether the observed effects can be sustained is an open question.¹⁰ Another study reported increases in average conversion rates in collaborative

hospitals from 51.5% in 2003 to 65% in 2005, and these hospitals experienced a 70% gain in organ donors during the first year of the collaborative as compared with controls.¹¹

In contrast to required request and routine notification, first-person authorization is informed by substantial empirical evidence that finds more positive and uniform public and HCP attitudes when conclusive documentation of donation wishes is available.¹² Unequivocal evidence supports knowledge of deceased's donation wishes as a critical factor in families' decision making.⁷ Indeed, initial evaluations of first-person authorization have been positive. A study of Ohio's First Person Authorization Donor Registry shows that, in addition to an increase in donor registration rates 4 years after implementation of the registry, the percentage of actual deceased donors increased from 44% to 57%.¹³ Recent evidence shows that first-person authorization accounts for an increasing proportion of recovered donors (19% in 2007 vs 33% in 2010).¹⁴

The potential success of first-person authorization will be due in no small part to the availability of appropriate technology, namely electronic state registries that facilitate the process of recognizing individuals' wishes to become posthumous organ donors. Electronic registries offer OPOs instantaneous access to individuals' documented donor status, which solves the problem that donor cards are usually unavailable at the time of death⁵ and family members are often unaware of the deceased's donation wishes.⁷ In 2010, 32.8% of organ donors, 37.3% of tissue donors, and 42.2% of eye donors were authorized or identified through donor registries, and in some states, as many as 76% of individuals with drivers licenses have joined their state registries.¹⁴ It will take some years, however, before donor rates see the fruits of this campaign. Yet nationwide, registry participation remains modest, estimated at 40.3% of US residents 18 years and older.¹⁴ This is not to diminish the great gains in registry participation, a 36.5% increase in the past 4 years.¹⁴

Requesting Communication: Best Practices

A wealth of evidence on current request practices has also accumulated; however, much is unapplied in practice. For instance, decoupling or separating requests for organ donation from declarations of death has long been discounted but continues to be implemented in the field. This practice endures even though 2 large studies have observed higher rates of family consent when requests are made before notification of brain death as compared with requesting donation after brain death is pronounced.³

A related practice of distinguishing "brain death" from "death" (cardiopulmonary death) when making organ donation requests continues, although that practice actually confuses families. Although it is important that families understand that brain death means that their loved one has died, this should be communicated in a simple, clear, and concise manner.¹⁵ It is unnecessary to provide complex medical explanations of brain death, which only confuse and overwhelm already grieving families. Moreover, both HCPs and the general public continue to have difficulty understanding this concept.¹⁶ Some evidence suggests that limited understanding of brain death by HCPs and the general public also impedes consent.¹⁶ For example, a study of attitudes toward brain death among 2366 HCPs showed that understanding and acceptance of brain death were related to confidence in performing key

tasks in the donation process, such as approaching the family about organ donation and informing the transplant coordinator about a potential donor.¹⁷

For family decision makers, however, evidence indicates that understanding or acceptance of brain death makes little difference to their donation decision. One study, for example, found that families who refused to donate were just as likely as families who donated to define brain death correctly, understand the tests necessary for establishing brain death, and to describe the tests.¹⁸ A survey of public beliefs and attitudes also indicated that although more than half of respondents did not understand that brain death met legal criteria for death, nearly one-third were willing to donate organs in scenarios where they classified patients as alive.¹⁹ Similarly, in another study,²⁰ researchers found that although 47% of respondents falsely believed that a patient declared brain dead is legally alive, 80% expressed support for retrieving organs from brain-dead donors. In light of these findings, detailed and complex discussions of brain death may not be a critical practice for increasing consent, although it is ethically preferable that a simple explanation of brain death be provided to the family.

Even the current practice of declaring brain death using dual examinations may inhibit consent.²¹ The 6- hour delay between brain death tests is thought to heighten families' distress and confusion,²¹ increase the risk for additional complications such as cardiac arrest,²¹ and adversely affect family consent. Results of 1 study²² indicate that single examinations are easier, more time- and cost-efficient, and do not decrease the likelihood of consent. The American Academy of Neurology recommends single brain-death examinations,²³ a guideline that the Association of Organ Procurement Organizations has endorsed²⁴; however, clinical practice differs across states and across institutions as well.^{25,26} Some institutions require single examinations,²⁶ and some states, including New York, have revised their guidelines to recommend single examinations.²⁷ However, dual examinations remain the norm.

A critical factor of consent that is often taken for granted in practice is the manner in which the request for donation is made. Effective communication affects donation by improving the request process and thereby increasing the likelihood of obtaining family consent. Effective communication during requests involves 5 key tasks: (1) initiating the request in an empathic manner with the appropriate introductions, role clarifications, and an acknowledgment of the loss of the patient; (2) soliciting family and patient information by using clear, open-ended questions while avoiding interruptions; (3) soliciting the family's perspectives and beliefs about organ donation and the patient's donation wishes; (4) developing and maintaining a supportive, trust-based relationship with the family that includes addressing concerns and questions with sensitivity and providing information underscoring the benefits of donation; and (5) providing closure by summarizing the family's position regarding donation, outlining the next steps in the process, and expressing gratitude for the family's time and consideration of donation.²⁸ Indeed, communication that attends to families' relational and informational needs has proven success in securing consent to organ and tissue donation.⁷

Requesters' communicative style also affects rates of family consent. Successful requests are delivered by OPO requesters who are perceived as sensitive, compassionate, and caring.⁷ Requesters who are passionate about organ donation, skilled at clearly conveying essential

information to families, confident in their skills, and able to engage in productive collaborations with other members of the hospital staff are more likely to secure consent.²⁸ Conversely, families are less likely to consent if they are surprised by the request or if they report feeling harassed or pressured during the request.⁷ Requesters should allow adequate time for families to discuss issues of concern such as the costs of donation, disfigurement of body, and the impact of donation on funerals.^{7,28}

Contextual elements (eg, setting, the timing of the request) are key to successfully implementing the tasks just outlined. Moreover, the hospital environment can increase families' stress during the request process. Consequently, creating a supportive environment for families to make their organ donation decisions, such as allowing sufficient time with the patient,²⁹ enhances communication during the request.

Timing is also crucial to making effective requests. When families perceive that the request was made at the appropriate time, they are more likely to consent.⁷ As mentioned earlier, requests are more likely to be successful if they are made before or during notification of brain death rather than when they are made after notification.³ Therefore, approaches made early afford requesters the time needed to establish strong, positive relationships with families and to gauge the best moment to broach the topic of donation.

Finally, DCD represents the most significant opportunity to expand the actual donor pool. Although DCD was once the standard, it quickly fell out of favor with the conceptualization, definition, and legalization of brain death. In recent years, however, rates of DCD have been increasing; a 6-fold increase in DCD donors was observed from 1995 to 2004,³⁰ and a nearly 12% increase was observed from January 2010 to December 2011.³¹ This increase compares to a 2.9% decrease in expanded criteria donors and a 2.5% increase in standard criteria donors in the same time period,³¹ making DCD the fastest growing category of organ donation. The Institute of Medicine estimates that DCD can contribute approximately 22000 additional donors annually.³² Moreover, the collaborative identified retrieving organs from non-heart-beating donors as a major strategy for increasing the availability of transplantable organs. A 2005 study at a single health system validated this assertion, showing that the implementation of a DCD protocol augmented the potential donor pool by 33% and the number of transplanted kidneys by 24% during the study period.³³ Recent findings from a cross-sectional study using a nationally representative Internet-based panel of US adults (N = 1049) to assess public support for DCD, suggest growing support for DCD, 70% for controlled DCD and 69% for uncontrolled DCD, over brain death.³⁴

Barriers to DCD include the lack of consistent policies among OPOs and acceptance of the practice among the general public and HCPs, which are lower than the acceptance rates for organ recovery from braindead donors.³⁵ To address these barriers, an interventional study to increase understanding and support for DCD among HCPs in 1 health system was conducted. This intervention used educational materials including brochures, a website, multimedia presentations, and interpersonal discussions to increase knowledge and address barriers to implementing DCD. The health system subsequently reported a 93% increase in DCD donors the following year and a 173% increase to date.³⁶

Recommendations for Future Directions

For more than 20 years, the United States has implemented policies and practices designed to improve outcomes of donation procurement. During that period, a research literature has paralleled, documented, and assessed the impact of those policies and practices. Given the findings of that rich literature, our recommendations are as follows:

First, current practice in organ donation must keep up with and reflect available knowledge. Despite a fairly extensive literature on best practices for approaching and discussing the donor option with donor-eligible families, many requesters fail to use best current practices. For example, decoupling requests from brain death pronouncements and offering families detailed definitions of the term continue within some donation service areas. Moreover, these practices most likely increase family confusion and decrease the time available to make well-informed decisions about donation.

Similarly, effective communication techniques have been identified, but many hospitals and OPOs have yet to adopt them. Translating and diffusing these best practices to OPOs and hospitals was a major goal of the collaborative that reached only a modest segment of the relevant health care community. OPOs should make it their mission to stay current with the literature and actively adapt their practices, as new information is available. Certain OPOs that have actively developed sophisticated training and communication practices have had notable success. For example, Gift of Life Donor Program in Pennsylvania and University of Wisconsin Hospital and Clinics are exemplars in this effort, providing educational and training resources to enhance organ donation practices among their own staff and other health care providers.

Second, continued research is needed to establish a medical basis for dual brain-death examinations. Prospective studies examining the impact of subsequent testing for brain death determination on patient diagnosis and survival as well as organ donation consent are advisable.

Third, it is time to document the impact of first-person authorization. If, as early studies indicate, this policy is highly effective, it will be critical to even more aggressively educate and provide access to the public for donor designation. Although public education research has been funded by the Health Resources and Services Administration since the 1980s, surprisingly little has identified the specific message design factors (eg, content, delivery, channel) effecting the largest gains in organ donation knowledge and behaviors for specific segments of the population.³⁷

Fourth, the history of organ donation policies clearly demonstrates the need to develop evidence-based legislation. The extant literature suggests that policy changes in brain death declarations and DCD may be warranted, although more research is needed to ensure any legislation concerning the pronouncement of brain death is based in objective knowledge. DCD was for many years the primary means of securing transplantable organs and remains a relatively untapped source of organs today.

Finally, the stress of the consent environment can be mitigated before a potential donor is admitted through the seamless integration of OPO staff into hospital environments, whether through an in-house coordinator or other coordination mechanisms, and the promotion of a positive culture for donation within the hospital. OPO staff should be seen as part of the health care team, for indeed they are. They are the only individuals, by law and by regulation, who can coordinate and advance the donation process. A positive donation culture can be achieved through emphasis on organ donation as an integral component of end-of-life care and a commitment to employing data monitoring tools to evaluate performance and use of data for continuous quality improvement efforts.¹⁰

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