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The National Organ Transplantation Act after Twenty Years:

A Time for Reform ?

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Abstract

Organ transplantation has become a proven, cost-effective lifesaving treatment, but its promise is contingent on the number of available organs. The growing gap between the demand and supply results in unnecessary loss or diminished quality of life as well as high costs for surviving patients and their insurers. Twenty years after the enactment of the National Organ Transplantation Act, it is time to rethink the moral basis and overall design of organ transplantation policy. We propose a system of national organ insurance based on a social contract of reciprocal obligation under which aggregated present consent to donate guarantees future availability of organs for those who need them, at least to the level that prevents death while awaiting an organ. The national insurance plan will cover all peri- and post-transplantation costs to all. By presuming consent to enroll, we align the default with widespread expectations of reciprocity and mutual self-interest, and surmount barriers to consent that have undermined the spirit of the current legal regime. Individuals who prefer not to be either recipients or donors would be able to opt out of the insurance system.

Introduction

Organ transplantation remains one of modern medicine's remarkable achievements. It saves lives, improves quality of life, diminishes health care expenditures and enjoys high success rates. Yet the promise of transplantation is substantially compromised by the scarcity of organs. The gap between the number of patients on waiting lists and the number of available organs continues to grow. As of January 2005, the combined waiting list for all organs in the United States was 87,240 (60,491, 17,256, and 3,246 for kidney, liver, and heart respectively).¹ More than 6,000 patients die every year while awaiting an organ (over 3,000, 1700, 500, 400 patients waiting for kidney, liver, heart or lung respectively).¹ Thousands of potential organs are wasted, primarily due to lack of consent from the deceased in advance or from the family thereafter.² The costs attributed to organ shortage are substantial – e.g., Medicare paid over 15.5 billion dollars in 2002 for treating the patients with end-stage renal disease who predominate on organ waiting lists.^{3, 4}

Although live donation is a valuable source for organs, cadaveric salvage remains morally preferable and practically essential. Unfortunately, however, the longstanding debate about how to increase the availability of cadaveric organs in this country is now at a stalemate. Among the proposals on the table, “mandated choice”, endorsed by the AMA in 1994, represents the least change in the present system.⁵ Individuals would be required to state their preferences regarding organ donation when performing state-mandated tasks, such as renewing driver licenses or filing tax returns. This approach would leave the current autonomy-driven regime in place while trying to counteract and overcome the psychological influences that currently tend to prevent people who are inclined to be donors from recording their desire to do so and that tend to dissuade their families from authorizing organ removal upon death. However, a decade later, no government has embraced this approach, and its critics have argued that it has a coercive tone and that it could be counterproductive in the American context if ambivalent or even distrustful people are forced to make a decision on the record.^{6, 7}

Flanking “mandated choice” on either side are approaches that depart more substantially from the existing regime. On the one side is a cluster of incentive-based approaches that appeal to the self-interest of potential donors rather than to their altruistic disposition – e.g., giving priority on waiting lists to people who have declared their willingness to be donors, or providing financial incentives for donation.^{8, 9, 10, 11} Despite their psychological plausibility as instruments for increasing the donation rate, incentive-based approaches have been strongly resisted by most bioethicists¹² because they would displace altruism with self-interest as the driving force in the system, and would offend the spirit, if not the letter, of the National Organ Transplantation Act (NOTA) prohibition against “valuable consideration” for organ donation.¹³

Flanking “mandated choice” on the other side are approaches that give greater weight to collective concerns. Some would explicitly anchor the organ procurement system in the idea that the public interest in saving lives overrides the interests of either the deceased or the deceased’s family in determining post-mortem disposition of the body.¹⁴ In contrast, a communitarian approach would preserve the priority of individual autonomy, but would try to shift the social norm governing organ donation from personal altruism to a spirit of collective obligation.¹⁵

In this paper, we present a practical model combining the best elements of these competing approaches, while building on the foundation already laid by NOTA in 1984.

First, we would shift social understanding about the moral premise of organ donation from altruism to reciprocal social obligation, emphasizing that everyone is a potential recipient as well as a potential donor.

Second, we would establish a system of insurance for organ procurement and transplantation, but the insurance regime would be based not on market incentives but rather on a social contract of reciprocal obligation (analogous to the safety net for people whose future disabilities will prevent them from working).

Third, we would shift the default, assuming everyone is a participant while allowing individuals who prefer not to be either recipients or donors to opt out. By setting the default

on participation, we embrace what has been termed “presumed consent”, but this move is designed not to override autonomous choices as its critics claim, but rather to align the default with widespread expectations of reciprocity and mutual self-interest, and to surmount psychological barriers to consent that have undermined the current legal regime.

Inviting public discussion of this problem, while emphasizing that organ procurement is morally grounded in a norm of reciprocity and fairness, could serve as a powerful tool for building popular public support for a new governmental policy and a new legal regime to implement it.

Reframing the Act of Organ Donation

The first, and most important, step to be taken is to reframe public understanding of the moral premise of organ donation, shifting from a strategy of inviting acts of sheer altruism to one of helping people recognize that they share a reciprocal social obligation, grounded in norms of fairness and justice. It seems undeniable that most people would want to enjoy the proven remedies offered by organ transplantation if their own organs were to fail. (The exceptional cases involving religious objections are addressed later.)

Reciprocity couples the conditional expectation of being a recipient with the willingness to donate, thereby guaranteeing to *everyone* a much higher probability of receiving a needed organ.

Regrettably, the reciprocal interest in an organ – a potentially powerful social and psychological instrument – has so far been overlooked in communicating with the public. Organizations and programs promoting organ donation have not expressly and persuasively drawn the connection between the chances of being a future recipient and prospective statement of willingness to donate. Even the best health insurance program that money can buy cannot provide the needed organ. Organs can be guaranteed only if most members of society, regardless of class or race, are willing to participate. Other policy changes designed to assure access and coverage are discussed below.

We do not believe that focusing on mutuality requires a change in social values. Nor

are we suggesting that platitudes about the virtue of giving be replaced by others touting our mutual dependency. Such a message would be too discordant with the tones of American individualism and would do little to engage the poor and uninsured. We believe instead that a widespread public recognition of reciprocal obligation and interdependency in the transplantation domain has been obscured by decades of misguided preaching about altruism and the “gift of life”.

Some have proposed that preference be given to those willing to donate, thereby in effect creating a large insurance pool of people whose premium (a promise to donate) is paid in consideration for being accorded priority over others who have not promised to donate.^{11, 16, 17, 18} We oppose this approach because: it relies on *individual* contracts instead of a *social* contract (and may therefore confront the same obstacles we now confront), it ignores the interests of people who have legitimate reasons for declining to donate, it is likely to require morally problematic distinctions between people who promise to donate before and after they learn of a risk-enhancing diagnosis, and it does nothing to address the needs of the poor and uninsured.

National Organ Insurance [NORI]

Coupling willingness to be a recipient with the willingness to donate transforms the way we regard organ transplantation. Instead of focusing on altruistic consent to become potential donors, the underlying principle is that *aggregated present consent to donate guarantees the future availability of organs for those who need them to survive*. Such an understanding implicates the fundamental idea of insurance, assuring protection against future life-threatening risks.

Once people recognize that organ procurement is a component of a system of social insurance, individuals will easily see why willingness to be an organ contributor is in everyone’s rational self interest. We do not propose an individual quid pro quo (analogous to a premium). Instead, the system is based on the established expectation that everyone is a member of the pool of potential recipients and stands to gain from participation in it. The best

analogy is immunization, and the mutual protection afforded by herd immunity. Because Americans are generally receptive to insurance models and no monetary payment is involved, we expect this approach to yield high participation in the consenting pool.

Some may find the term “insurance” inappropriate in this setting, as no tangible acquisitions or explicit contracts are involved; for them, a substitute term “National Organ Assurance” could more accurately describe the practical elements involved, while maintaining the principle of future coverage in regard to organs.

Translating an insurance model in organ donation into a concrete policy will require many specific decisions about financing, the role of the national government, and mechanisms of enrollment and eligibility. We offer here an exploratory proposal rather than a detailed plan.

Federal Financing of Organ Transplantation

Federally subsidized transplantation and post-transplantation expenses for patients in need is an essential and economically sensible element of NORI.¹⁹ Although the United States currently lacks a national system for either the financing or delivery of healthcare, organ transplantation is uniquely well-suited to national financing. The federal Medicare program is already responsible for the overall treatment of 92% of patients with end-stage renal-disease who predominate on organ waiting lists;³ and all patients’ clinical, epidemiological and economical information is assembled and monitored by the United State Renal Data System (USRDA).²⁰

Access to organs must be guaranteed to all, regardless of financial ability to pay. In the American context, this element is crucial in order to assure participation by minorities and the uninsured. In light of the substantial economic benefits accruing to taxpayers from successful transplantation (a saving of \$27,000 per year for each successful kidney transplantation beginning 2.7 and 4.9 years after live and cadaveric transplantation respectively),^{3, 15, 21} this scheme should be welcomed.

Under our plan, organ transplantation coverage would be removed from all health insurance plans and would be covered by the federal government. Individual health premiums

should be reduced accordingly, providing concrete evidence of the shift from the currently illogical arrangement (under which people pay premiums to cover transplantation costs without any assurance that organs will be available) to a system of national organ insurance (under which universal participation assures the availability of organs, at least to the point of eliminating death on the waiting list due to organ's scarcity). NOTA might have to be amended to allow this arrangement.

A National Procurement System

The federal government must also assume a leading role in ameliorating the current scarcity of organs.²² NORI is aligned with the premises of NOTA, and represents a natural progression of its underlying aims. It is designed to establish a national system of organ *procurement* to complement the national system of organ *allocation* established by NOTA and implemented through the contract between the federal Health Resources and Services Administration and the United Network for Organ Sharing (UNOS). Regional coordination of organ retrieval and allocation should remain the norm, as dictated by NOTA. The federal government should assume greater responsibility for coordinating the system, stewarding this highly-sensitive resource on behalf of society. The government would not hold property interests in the organs or utilize them for its own purposes. Our proposal is limited to for-treatment organ donation.

Under NORI, Congress would preempt the current state laws governing organ donation and direct a suitable agency in the Department of Health and Human Services (DHHS) to promulgate regulations and policies governing participation in the system and authority to retrieve organs. As discussed below, participation in the system of national insurance will be the "default," while allowing individuals to opt out. The DHHS would maintain and monitor a central opt-out registry, accessed by all means of telecommunication.²³ All organ procurement must be legally conditioned on a documented verification that the potential donor's name does not appear on the opt-out registry. If the opt-out registry records an individual's objection, it would be non-refutable by family members, an option unavailable under current opt-in policies.

Enrollment and the Right to Opt Out

The coverage promised by NORI is critically dependent on the size of the participating pool. Once a critical threshold of potential donors has been achieved, availability of organs to patients on waiting lists can be secured to a much higher probability, at least to the point of preventing death of people on the waiting lists due to organ scarcity.^{2, 24} Yet if the number of consenting individuals falls below what is statistically needed, the promised coverage might be imperiled. It is therefore essential to address several important issues relating to the design of the system, in particular the mechanisms for eliciting consent to participate.

Participation as the Default

Currently, most people who die in circumstances that make them potentially suitable donors have not expressed their wishes one way or the other (less than 30% hold donor cards, and the percentage of adults in state registries ranges between 1-56).^{23, 25} How should silence be interpreted – as a refusal to donate? Oversight? Indecision? Indifference? Under the current legal regime, a person is not regarded as an eligible donor in the absence of his or her explicit consent or the consent of a family member after death. In other words, the default is non-participation, and the organ may be retrieved only with expressed consent. It is well-known that setting the default is a key element of many public policies and has a significant impact on participation rates.^{26, 27} In the context of organ procurement, rates of donation are lower in countries requiring an affirmative expression of consent (e.g., the USA, UK) than in countries presuming it instead (e.g., Austria, Belgium, Denmark, Finland, France, Singapore).

^{26, 27}

Research and public opinion polls show that the low rate of documented consent in the United States is not an indication of genuine unwillingness to donate. Instead, it can be explained by a tendency to prefer the status quo, reluctance to think about death, and an aversion to the bodily dissection that organ donation entails. These barriers are inadequately addressed under current opt-in systems. In effect, these attitudes translate into a high

psychological cost for individuals to change the default, – i.e. to opt in,²⁶ and push aside the well-documented support for organ transplantation expressed by most people in attitudes surveys.^{5, 25, 26, 28}

Silence by potential donors effectively leaves the decision in the hands of family members who are present at the time of death. Yet actual practices reveal a fundamental ambiguity. Although the rhetoric of altruism and bodily autonomy implies that the disposition of organs should be based on the preferences of the deceased, practice shows that the preferences of families are determinative. When the deceased has not signed a donor card, family members may base the decision on their own preferences, regardless of the deceased's wishes. Even when the deceased has explicitly authorized donation, which by law should suffice, most Organ Procurement Organizations (OPO) will yield if a family refuses to abide by it.^{29, 30}

If families' decisions were reasonably aligned with the apparent preferences of most people, families would donate organs in a significant majority of cases. However, documented rates of family refusals in various international studies range between 40 to 75 percent.^{2, 5, 31, 32, 33, 34} Families are probably not being guided by the deceased's wishes (exercising "substituted judgment") under these stressful circumstances. They are being asked to allow for their loved one's organs to be harvested at a most painful moment and under the acute pressure of time; indeed the request itself most likely augments their pain and sorrow. This can hardly be regarded as good timing, and the high refusal rates should not come as a surprise. The practical effect of this practice is to translate family ambivalence and uncertainty about the wishes of the deceased into a pattern of refusal that precludes what most people actually want – a robust system of organ retrieval that would save their lives if they turned out to need one.

Under these circumstances, prescribing non-participation as the default is a mistake. It reflects neither people's actual preferences nor their self-interest. Although requiring explicit consent might be a sensible default in a legal regime grounded in altruism, presumed participation is the logical default in a system predicated on a norm of reciprocity. Indeed, the

present default has the unfortunate side effect of forcing most individuals into the position of being what economists call “free riders” — they are eligible to receive an organ even though they have not agreed to be donors.

“Presumed consent” proposals are sometimes subject to the criticism that they amount to “obliged altruism” by failing to present people with genuine opportunities to exercise their prerogative to decline participation.^{5, 15, 35} In our proposal, however, we couple frequent reminders of the reciprocal nature of the obligation with genuine opportunities to opt out. We envision ongoing messages regarding the reciprocal nature of the insurance system and its appeal to mutual self-interest and fair allocation of burdens and benefits. For the great majority of individuals who have private health insurance, the annual reduced-premium notice would serve as a yearly reminder of each individual’s consenting status, with a perpetual option of opting out. The opportunity to opt out can also be included in the standard form used for advance directives in health care or annual mailings to Medicare and Medicaid recipients and participants in other health insurance programs. These mechanisms use appropriate instruments to communicate information about the choices required under NORI (compared for example to DMVs) and should erase the concern that organs will be harvested contrary to real-but-unstated wishes of people who overlooked their opt-out opportunities. As for the uninsured, targeted public education campaigns and notices attached to other state-mandated activities (e.g., driver licensing) can also assure ample opportunities to opt out.

Careful consideration of the unique circumstances of vulnerable groups (e.g., prisoners, mentally incapable, aliens) would be needed. It is especially important to address the concerns of minorities who are distrustful of the health care system and the motives of people who seek consent for organ retrieval. For example, potential minority donors may be fearful that life-sustaining treatment may be selectively withheld from minority patients, hastening the declaration of death, in order to harvest organs for white patients. Unless this problem is successfully addressed, NORI’s central aim (guaranteeing an adequate organ supply) could be thwarted. Special measures will be required to counteract these fears, including, e.g., focused dialogue with communities, participation of minority representatives

on death-determining teams, transparency of procurement and allocation policies and practices, and active monitoring and dissemination of information regarding the demographic characteristics of organ donors and recipients. Obviously it will be essential to show that the benefits of NORI accrue equally to all social groups.

The Right to Opt-Out

The proposed insurance system, which aims to guarantee access to organs, could be undermined if too many people opt out of the potential donor pool. In Europe, opt-out rates range from 2-15%.²⁶ In a firmly reciprocal system, such as private insurance schemes, willingness to donate and eligibility to receive organs would be linked, and opting out would erase eligibility to benefit. However, no country has conditioned eligibility to receive an organ on consent, and there is no need to take such a drastic action, as long as the necessary supply of organs can be assured. Our proposal relies on moral suasion and meaningful incentives to promote participation and reduce optin g out. We acknowledge that some people cannot bear the emotional cost of possible corporal dismemberment and may have religious scruples as well. Exemption for religious objections and other reasons of conscience are allowed in most otherwise mandatory vac cination laws,³⁶ and we should try to accommodate them in the present context as well.

Advantages of allowing an opt-out option should also be acknowledged. Respect for individual autonomy further fortifies its importance as a preeminent social value in Western society. Additionally, the sincere tenacity of objectors may provide valuable information needed to improve the process of procurement and distribution of organs: for example, it might expose flaws in practices relating to determining and declaring the time of death;³⁰ respect for the human corpus; avoiding conflict of interests, and assuring fair allocation of organs to minorities and the underprivileged. Under the current regime, such issues may be overlooked and therefore may be inadequately addressed. With no “watchdog”, systems tend to go astray.

The procedure for opting out should be carefully designed to assure the availability of information to those contemplating opting out, and to guarantee that they are aware of the

community's norms as well as the available coverage. It also should be consciously designed to call attention to, and minimize, the free-riding problem. As noted above, one of the serious flaws of the present system is that the vast majority of the population, including most organ recipients, are concealed free-riders – they reap the benefits (available organs) while avoiding the burden of donation. Although our proposal would permit free-riding, it should dramatically reduce the scope of the problem. Fundamentally, the system should not make it easy to opt out. Specifically:

1. Before a decision to opt out is recorded in the registry, the person could be encouraged (though not required) to give reasons for doing so and should be supplied with relevant facts and a clear statement of the relevant moral positions from various religious and philosophical perspectives.
2. The option of declining to be a donor should be accompanied by an explicit choice about whether or not to be a recipient—that is, people should be required to indicate whether they choose to remain eligible to receive an organ or to exclude themselves voluntarily from being an eligible recipient. The discrepancy between the willingness to receive an organ while refusing to donate will be then well illuminated. Such an option will further diminish unintentional free-riding while honoring the wishes of those interested in forgoing participation in the organ transplantation system altogether, perhaps for religious reasons.
3. The registry should make experts available to answer thorny issues (e.g. disparities, access, brain death etc.).
4. People who have chosen to opt out should be given periodic opportunities to reconsider their position.

In sum, *the process* of opting out should be regarded not only as a legal procedural *necessity* (as a mean of documenting one's objection) but also as a substantive opportunity for promoting genuinely informed decisions.

The Role of Families

Families will remain an important element in any procurement scheme. However, NORI puts them in a different position than current practice which generally accords families

a veto over organ donation, even when the deceased has expressed consent. Perhaps it would be possible to leave this practice unchanged, and hope that the norms of reciprocity and justice will change families' reactions. We are somewhat skeptical, however, at least in the early phases. Legally, the Uniform Anatomical Gift Act adopted in most states has already explicitly negated the possibility of family overruling the deceased's consent.³⁷ Moreover, family prerogatives relating to the deceased's body are also curtailed in other circumstances of social concern, such as the need to conduct an autopsy in criminal contexts. We wish to fortify this position. By choosing not to opt out and receiving organ "coverage" (and the associated insurance benefits) throughout the period prior to death, the deceased has consented to participation. Hence, framing the interaction with the family should be focused on notifying them of the declaration of death, of the long-standing consenting status of the deceased, and of the organs' suitability for life-saving donation. Familial objection will be therefore limited to predetermined exemptions such as revealing explicit documentation of refusal by the deceased or well-recognized religious objections.

Conclusion

Implementation of the ambitious goals of the NOTA has been plagued by a growing gap between the number of organs needed for transplant and the number of organs available. We believe that the chronic organ shortage can be eliminated by replacing the present legal regime, which depends on individual altruism, with one that is grounded in a social contract based on norms of reciprocity and fairness.

The scheme we have proposed is a system of insurance under which the community and all its members are provided concrete benefits (organ transplantation) in return for general acceptance of the reciprocal obligation to donate. While this approach emphasizes collective engagement, it also accords respect to the autonomy of those who do not want to be donors. This proposal draws on what we believe to be a latent social understanding of the most compelling moral basis of organ donation, and would attract widespread public support.

From a societal perspective, NORI would increase the number of organs while

reducing healthcare costs because the costs of transplantation are less than costs of care for people on waiting lists. It would also protect everyone equally, without regard to ability to pay.

From an individual perspective, NORI would improve the lot of the uninsured or underinsured (by covering their costs of transplantation). More importantly, however, it would offer to all the security of knowing that an organ will be available if it is needed because everyone is expected to allow organ retrieval in the absence of a deep moral or religious objection.

This proposal is not a mere academic exercise. Pursuant to Congressional direction,³⁸ HRSA has requested the IOM to conduct a comprehensive study of “proposals and efforts to increase organ donation,” including the ethical implications, feasibility and cost-effectiveness of contending approaches. We think NORI merits serious consideration as a morally sound and practical solution to the current organ shortage.

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