OPTN | UNOS Public Comment Proposal

The Ethics of Deceased Organ Recovery without Requirements for Explicit Consent or Authorization

OPTN/UNOS Ethics Committee

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Affected Policies:	*N/A*
Sponsoring Committee:	*Ethics*
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Executive Summary

Beginning in 1993, the Ethics Committee (the Committee) developed a series of white papers that are available through the OPTN website. In 2014, the Committee began a systematic review of these white papers to evaluate if each of the white papers were accurate and relevant, and therefore valuable resources for the transplant community. The original white paper addressing presumed consent was produced in 1993, and was written in response proposed presumed consent legislation under consideration in Maryland and Pennsylvania with the following features:

- The potential donor is presumed to have wished to donate if he or she had not expressed an objection during the individual's lifetime;
- If the potential donor had not expressed a preference for organ donation, the objection of the next of kin is sufficient to preclude donation, even though the potential donor's consent is presumed;
- The recorded preference of a potential donor for organ donation overrides the objection of that individual's next of kin;
- All reasonable efforts are to be made to contact the potential donor's next of kin.

Of note, this white paper was written at a time when there was limited access to personal computers and soon after the advent of the World Wide Web (1990). The original white paper proposed using mail to object to presumed consent, and cited Gallop surveys from 1985 and research from 1976.

The Committee determined that this white paper was neither accurate nor relevant. Over the past year, the Committee completed a line-by-line review and a substantive revision of the white paper. The white paper received a new title, contains new content addressing current issues with presumed consent which is supported by citations to current research and literature.

This project was completed before the OPTN/UNOS Board determined that all types of guidance documents would require public comment (June 2016). The Committee elected to follow the new process even though the requirement was not in effect at the time work on the project was completed.

What problem will this resource solve?

The resource provides an ethical analysis of deceased organ recovery without requirements for explicit consent or authorization. This resource should be helpful reference for families or surrogates of potential donors, organ procurement organizations and donor hospitals.

Why should you support this resource?

The proposed revisions to this white paper demonstrate that the Ethics Committee continues to consider and provide guidance on important issues faced by the transplant community. This white paper will be a resource that members could consult if considering deceased organ recovery without requirements for explicit consent or authorization especially in light of the new strategic focus to increase the number of transplants.

How was this resource developed?

Beginning in 1993, the Ethics Committee (the Committee) developed a series of white papers that are available through the OPTN website. In spring 2014, the Policy Oversight Committee and OTPN/UNOS Board approved a proposed project to review all existing white paper to determine the accuracy and relevancy of each resource. The Committee began a systematic review of 11 white papers to determine if the papers remained accurate and relevant. Some of the more recently developed white papers were accurate and relevant while other papers were determined to need minor revision or substantive revision. The white paper addressing presumed consent was determined to require substantive revision.

Over the past year, Committee members performed a line by line review of the presumed consent white paper and determined that some of the language was outdated, it did not reflect current practice, and the content was not supported by current literature. Committee members identified numerous questions or issues that should be reconsidered while revising the white paper.

In April 2016, the Committee supported sending this white paper for Board consideration.

In May 2016, Committee leadership elected to delay Board consider and supported sending this white paper for public comment.

Which populations are impacted by this resource?

This resource could be helpful to families or surrogates, OPOs or hospital considering deceased donation when there is not explicit consent of authorization.

How does this resource impact the OPTN Strategic Plan?

Increase the number of transplants: Guidance of the ethics of deceased organ donation without explicit consent or authorization could contribute to an increase the number of transplants

Improve equity in access to transplants: There is no impact to this goal.

Improve waitlisted patient, living donor, and transplant recipient outcomes: There is no impact to this goal.

Promote living donor and transplant recipient safety: There is no impact to this goal.

Promote the efficient management of the OPTN: There is no impact to this goal.

How will the OPTN implement this resource?

If this resource is supported during public comment and subsequently approved by the Executive Committee of the Board, it will be available through the OTPN website.

The resource will not require programming in UNet^{SM}.

How will members implement this resource?

Members will be able to access this resource through the OPTN website.

Will this resource require members to submit additional data?

This resource does not require additional data collection.

How will members be evaluated for compliance with this resource?

This resource does not affect member compliance. Members could consult this resource on a voluntary basis.

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Date: June 23, 2016

Note: This report is circulated for informational purposes and to stimulate discussion. The report is a revision of a document previously prepared by the UNOS/UNOS Ethics Committee in 1993.

Introduction

The OPTN/UNOS Ethics Committee was charged with revising a previous report submitted to the OPTN/UNOS Board of Directors in 1993 entitled, “An Evaluation of The Ethics of Presumed Consent and a Proposal Based on Required Response.” Many elements of that report remain true today, particularly the ethical arguments advocating and opposing such a system. Significant events and debates have occurred in the transplant community since the preparation of that report, thus, the OPTN/UNOS Ethics Committee felt it was necessary to readdress the issue of “presumed consent,” or more accurately described as “deceased organ recovery without explicit consent or authorization,” with updated information and ethical analysis.

While considerable efforts have been made to increase public awareness of deceased organ and tissue donation, data show that the deceased and living donor rates cannot keep pace with the growing need for organs[1]. Overall, deceased donation has increased since 1988 (the first year of data collection for OPTN/UNOS) with the exception of a few outlying years. However, the transplant waiting list and waiting list morbidity and mortality continue to increase. In three decades, the national waiting list has grown 8-fold, from 15,029 people in 1988 to over 124,000 people in 2015[2]. Approximately every 10 minutes someone is added to the national transplant waiting list, while 22 people die every day waiting for a transplant[3]. The transplant community has implemented multiple strategies to increase the number of transplantable organs including: allowing organ donation following circulatory determination of death (DCDD), transplanting organs from Public Health Service increased risk donors, utilizing novel technology to preserve organ function following recovery, and creating the Organ Donation Collaborative, where best practices for organ recovery and preservation are shared nationally among organ procurement organizations (OPOs)[4,5].

The Ethics of Consent for Deceased Organ and Tissue Recovery

Currently, the United States (US) uses the “donation model”, a consent model for deceased organ recovery that prioritizes the rights of the individual (or of the surrogate decision maker) over the needs of society by requiring authorization or explicit consent prior to deceased organ and tissue recovery. However, in order to evaluate additional strategies that may increase the deceased organ donor pool, the OPTN/UNOS Ethics Committee was asked to evaluate different models of deceased organ and tissue recovery that do not require explicit consent or authorization from anyone, a model utilized by many other countries[6,7,8,9,10]. This model, sometimes referred to as “presumed consent[11.12.13.14]” or more loosely as “opt-out” in other literature[15,16], is more accurately described as “deceased organ and tissue recovery without explicit consent or authorization” for various reasons discussed below. The most plausible reasoning for using this model is to increase the number of organs recovered for transplantation.

The following goals of this white paper include:

1) Describe models of deceased organ and tissue recovery with and without explicit consent or authorization by the individual or surrogate decision makers
2) Analyze the relative merits and weaknesses of each model in the context of deceased organ and tissue recovery
3) Explain why shifting to a model of deceased organ and tissue recovery without explicit consent or authorization in the US is not justified

4) Briefly describe other approaches to increase the number of organs and tissues available for transplant

Two Models of Deceased Organ and Tissue Recovery

Countries around the world use two general models of deceased organ and tissue recovery. One model assumes that society has a legitimate interest in deceased donor organs and tissues and may recover them without any form of permission or authorization from the individual or surrogate. In general, this model prioritizes the needs of the society over individual rights, and is referred to as “deceased organ and tissue recovery without explicit consent or authorization” in this white paper.

The other model presumes that organs and tissues belong to the individual and cannot be appropriated without some kind of permission or authorization from that individual or surrogate. This is the current model in the US, which is referred to as “the donation model.”

Deceased Organ and Tissue Recovery Without Explicit Consent or Authorization

The model of “deceased organ recovery without explicit consent or authorization” was first proposed in discussions in the US as early as 1968 by Dukeminier and Sanders and currently remains under debate[17,18,19,20]. This model has been ethically justified in some countries either because: (a) the interests of the society (referred to as the “common good”) take precedence over the interests of individual choice, or (b) the consent of the deceased person is “presumed”. These justifications are explained below.

a) Ethical Justification: The Moral Priority of Society (or the “Common Good”)

In general, proponents of this model believe that individual needs and rights are subordinated to the needs and interests of the broader society, the “common good[21]”. The state is authorized to recover organs and tissues from deceased persons without explicit consent or authorization to benefit the overall needs of society and to prevent additional deaths due to organ failure. A number of countries in Southern Europe, Scandinavia, and Asia have laws allowing for deceased organ and tissue recovery that generally stand in this tradition[22,23,24,25,26.].

In the US, while this model is not allowed for deceased organ and tissue recovery as explained below, the ethical justification is applied to other practices in public health. For example, medical examiner laws authorize the autopsy of deceased persons for unexplained deaths without requiring consent or permission by the deceased person’s family. The justification for this practice is that the health and safety of the public overrides the interests of a deceased individual.

b) Ethical Justification: “Presumed Consent”

A few countries, mainly in South America, including Argentina, Chile, Ecuador, Uruguay, Panama, and Venezuela, as well as Wales in the United Kingdom have laws that explicitly refer to a “presumption of consent” and allow deceased organ and tissue recovery without explicit consent or authorization[27,28,29,30,31]. “Presumed consent” implies that the deceased person would consent if asked, placing the ethical justification for this model on respecting the rights of the individual while prioritizing public health[32].

Although recent scholarly work and the laws in some of these countries frequently use the terminology of “presumed consent” to represent this model of deceased organ recovery, several members of the OPTN/UNOS Ethics Committee argue that this terminology is inaccurate[33]. Presuming consent rests on the moral premise that consent justifies an invasion of an individual to support the public’s health that would otherwise be a violation of a moral right of the individual not to be touched. The ethical justification for this model requires empirical evidence demonstrating that most citizens of the particular country would consent if they were asked and had the ability to do so.

However, most countries with the presumed consent model have a significant minority of citizens who would not consent if asked[34]. The national rate of authorization for eligible donors in the United States is approximately 75%[35,36]. Therefore, justifying deceased organ and tissue recovery without explicit consent or authorization based on the "presumption of consent" appears to be flawed[8]. The only remaining ethical justification for this approach is that the interests of society take precedence over the choice by the individual or by the deceased individual's family or representative, as discussed in the prior section on the moral priority of society.

Presumed consent holds precedence in other clinical contexts in the US because some medical relationships rely on a presumption of informed consent. For, example, patients brought unconscious to an emergency room are treated without explicit consent by relying on the legal notion of presuming consent, acknowledging that virtually all individuals would consent to life saving treatment if they could be asked. The presumption is morally controversial because if the presumption is wrong, an important right of the patient is violated (the right not to be touched without consent). However, only in rare cases, patients brought to an emergency department would refuse treatment if only they could do so. This raises the question of how confident society must be in believing that the patient would consent if he or she could do so. Since a mistaken presumed consent involves violating an important right of the patient, the ethical claim is that we must be very confident that the great majority of patients would consent. This is not empirically demonstrated when considering consent rates to organ donation[37,38].

Hard and Soft Models of Deceased Organ and Tissue Recovery without Explicit Consent or Authorization: the Opt-Out Option

Deceased organ and tissue recovery without explicit consent or authorization may or may not include an opt-out option. The "hard" approach excludes an opt-out option, whereas the "soft" approach allows an individual or individual's surrogate, often the family, to explicitly prohibit the state from recovering the individual's organs or tissues[39,40]. The majority of countries that have laws permitting deceased organ and tissue recovery without explicit consent or authorization allow the individual or surrogate to opt-out in practice, even if the law does not explicitly describe the "opt-out" option[41,42,43].

Deceased Organ and Tissue Recovery that Requires Explicit Consent or Authorization: The Moral Priority of the Individual

Even though most countries give some weight to the interests of society, some countries, including the United States, tend to give greater priority to the interests of the individual. Individualism is a key feature of American culture. Many Northern European countries (e.g., Germany, The Netherlands, the United Kingdom (except Wales), and Ireland) and the countries of North America balance the competing interests so as to require approval from the perspective of the individual or surrogate before organs and tissues are recovered from deceased persons.

Property Rights of Individuals (The Market Model)

Some view the authority of the individual when it comes to organ recovery to rest on a property right of the individual in his or her organs[44,45,46,47,48]. Accordingly, if people putatively 'own' their organs, then they should be able to have the final say over their organs' disposition. However, since the notion of a property right to one's body is controversial and generally not supported in American law[49], this justification for organ recovery is beyond the scope of this white paper and will not be discussed further.

Quasi-Property Rights of Individuals (The "Donation Model"): Explicit Consent and/or Authorization

Another approach that relies on the moral priority of the individual is sometimes called the "donation model[50]" Legally, the "donation model" is associated with the idea that individuals have a "quasi-property right" to their bodies, including their organs. That gives them the right of certain kinds of control, without implying an ownership right to buy or sell body parts. The "donation model" requires that society respect the right of an individual to control the disposition of his or own organs and tissues. The model is one of gift-giving. An individual, or in some instances, his or her authorized agent or surrogate, can make a gift of the body or parts of the body even though selling is legally prohibited.

A gift may come as a result of explicit consent such as the model for informed consent for living donors in the United States—requiring: a) that the donor exhibits an adequate level of competency, b) information disclosure, and c) donor understanding. In contrast, in deceased donation, the gift is given through a process referred to as donor "authorization" based on gift law[51]. Registries, such as those at departments of motor vehicles, authorize deceased organ recovery in the form of a gift, and therefore informed consent is not required[52,53]. (Uniform Law Commission, Donate Life America)

Just as in other medical consents and authorizations, within certain limits, the gift of organs can also come via the authorization by certain agents of the individual, or surrogates, such as parents, guardians, legal proxies for a patient, next-of-kin, and the like. Typically, such agents must first attempt to do what the patient would have wanted based on substituted judgement and then attempt to make a best interest determination, also known as the best interest standard. These legal agents are considered to have the authority to make gifts on behalf of a deceased person whose organs are being recovered. Such agents also have the authority to refuse to make such gifts, provided such refusal does not contravene the prior wishes of the deceased person.

Authorization and/or Explicit Consent in the United States: Uniform Anatomical Gift Act (UAGA) and the Donation Model

In deceased organ and tissue recovery in the US, organ donation behavior is regulated by the Uniform Anatomical Gift Act (UAGA)[54]. There are multiple purposes for the 2006 UAGA Act: 1) to establish a system that honors and respects an individual's right to donate their organs; 2) to strengthen an individual's right to refuse to be an organ, tissue, or eye donor by prohibiting others from overriding an individual's wish regarding their right not to make an anatomical gift; and 3) to allow other people to make an anatomical gift on behalf of the individual who is incapacitated. Through this law, the individual documents his/her wishes to be an organ donor via a donor registry, driver's license, or living will. This process is defined as "first person authorization" and is regarded as a gift. First person authorization is not a form of informed consent, as authorization typically does not give each person all important information about the choices presented. Through first person authorization, the individual's wishes are carried out in the event he/she is eligible to be a deceased organ and tissue donor upon death, either through determination of death by neurological (DNDD) or circulatory criteria (DCDD). Determining death based on circulatory criteria requires that the heart irreversibly stop beating, whereas death based on neurological criteria requires the irreversible loss of all brain function, including the brain stem[55].

According to UAGA, when individuals are incapacitated and there is no documentation of their wishes regarding making an anatomical gift, legally identified healthcare agents may represent the deceased patient. However, if a healthcare agent has not been identified, an anatomical gift decision can be made by another surrogate decision maker according to law, such as a spouse, adult child, parent, adult sibling, adult grandchild, grandparent, guardian, or an adult exhibiting special care/concern for the patient. In these instances, the surrogate decision maker makes the decision on the individual's behalf upon his/her death.

Ethical Analysis of Models of Deceased Organ and Tissue Recovery

In order to increase the number of organs available for transplant in the US, some transplant community members have advocated for shifting the current donation model of deceased donor organ and tissue recovery to a model that permits deceased organ and tissue recovery without explicit consent or authorization. The following discussion highlights the pros and cons of the latter model.

Arguments FOR Models of Deceased Organ and Tissue Recovery that Do Not Require Explicit Consent or Authorization

Organ and Tissue Recovery is a Public Health Priority of United States

In the US, many laws and regulations are implemented that restrict the rights of individuals in order to protect the health and safety of the public. For example, seatbelt and helmet laws exist to protect the public. Similarly, because end-stage organ disease has become an epidemic (at least for kidneys), public health measures are needed to increase the number of transplantable organs to improve the well-being of the public[56]. Accordingly, the rights of the individual could be superseded by the need to address the epidemic in a way that increases the number of organs for transplantation.

Organ Recovery Rates are Potentially Higher in Countries that Do Not Require Explicit Consent

Current literature demonstrates an association between higher organ recovery rates among countries that allow deceased organ recovery without explicit consent when compared with countries that require explicit consent or authorization[57,58,59,60]. Analyzed data from 22 countries and found that countries that do not require explicit consent had approximately 25%-30% higher deceased organ recovery rates than countries with explicit consent or authorization policies[61]. In a systematic review of the literature,) An analysis of five studies comparing deceased donation rates within a country before and after the introduction of policies that do not require explicit consent, eight studies comparing countries that do and do not require explicit consent, and 13 surveys of public and professional attitudes to policies that do not require explicit consent[62]. In both the within-country and among-country comparisons, all of the analyzed data demonstrated increased deceased organ recovery rates in countries that do not require explicit consent when compared to countries that require explicit consent. In a study of kidney transplantation as a proxy for organ recovery, Researchers found that the kidney transplantation rate from deceased persons was higher in countries where explicit consent was not required when compared to countries that required explicit consent or authorization (22.5 versus 13.9 transplants per million population)[63]. The net kidney transplantation rates of both deceased and living kidneys combined was higher in countries that did not require explicit consent compared to countries with a donation model or that required explicit consent. A separate publication in (2014 found similar results[64].

However, the data reported above need to be interpreted within the broader sociocultural context of the transplant system as each country's government devotes different levels of resources and holds different cultural expectations of its citizens toward the donation enterprise, which may explain the high donation rates in such countries. Within both models of deceased organ recovery, models that do and do not require explicit consent or authorization, there is significant national variability in practice. Some countries that do not require explicit consent or authorization require surrogate consent or allow for opt-out options while others do not[65,66]. Furthermore, there is variability in the extent to which there is monetary support and/or a regulatory requirement for each hospital to have a trained team on-site to discuss the potential for organ recovery with surrogates of critically ill or deceased patients[67]. For example, in Spain, the government devotes extensive resources to educating the public about deceased donation and to hiring and supporting organ recovery staff[68,69,70]. (These factors likely contribute to organ recovery rates which makes it difficult to differentiate the extent to which each of these factors impact organ recovery rates. Thus, correlating deceased organ recovery rates with the specific type of consent process for deceased organ and tissue recovery remains highly contested.

Including an Opt-Out Option or Requiring Surrogate Input in Countries that Do Not Require Explicit Consent

In countries that allow for deceased organ recovery without explicit consent or authorization, some argue that permitting the option of opt-out, or the “soft” model, partially respects the interests of the individual or family over the interests of society. In other words, policies that allow an opt-out provision are driven by the interests of society, but softened to acknowledge the concern of individuals and surrogates who have strong objections to deceased organ recovery.

Arguments AGAINST Models of Organ Recovery without Explicit Consent or Authorization in the United States

There are many barriers including legal, empirical, cultural, and transplant system factors that would make shifting the donation model in the US to a model of deceased organ recovery without explicit consent or authorization extremely challenging. Such a process would require government action as expressed through federal legislation or otherwise to compel donation, leading to legal and even constitutional barriers. Furthermore, from a US cultural perspective, individual rights are deeply embedded in our values and beliefs. Individualism is deeply woven into US cultural fabric especially within the healthcare system as highlighted by endeavors to promote patient-centered care, informed consent for treatment, and decision aids that foster informed decision making. A deceased organ recovery model that does not require explicit consent would not gain sufficient support in the US to merit a policy change[71]. The risks to individuals and to US culture would not be outweighed by the potential for protecting the public's health. Thus, in the US, where individual rights are highly prioritized, recovering organs without explicit consent or authorization is unlikely to be embraced by society.

The Supply of Organs Will Likely Not Increase with the Model of Deceased Organ Recovery that Does Not Require Explicit Consent

The empirical data regarding organ recovery rates demonstrate an *association* of higher rates of deceased organ recovery with a model that lacks the requirement for explicit consent or authorization, rather than actual cause and effect. Variability in the government's commitment of resources to supporting organ recovery and public education, in addition to cultural views regarding organ transplantation, may contribute to these associations. In a country like the US, with a high donor authorization rate of about 70-75%[72,73], the additional organs that could be recovered through a system that permits deceased organ recovery without explicit consent or authorization likely would be minimal. Assuming that the deceased organ recovery without explicit consent or authorization model is well publicized and that the refusal rate is already accounted for in authorization refusals, more organs are not likely to be recovered. If a policy permitting deceased organ recovery without explicit consent or authorization creates additional hostility in the public toward organ donation, particularly for individuals who previously may have authorized donation, the additional gain in deceased organ recovery likely would be quite small.

In addition, other national characteristics that impact organ recovery rates need to be considered, and include (but are not limited to) population size, gross domestic product per capita, health care expenditures per capita, physician density, relative causes of mortality, transplant volume, education, public access to information, religion, and political values/affiliations of citizens and leader. Public education on the importance of donation, government support for programs to increase transplant awareness, support for families when deciding whether or not to donate, and the development of transparent and just policies for organ allocation that are supported by the public may also impact deceased organ recovery rates[74,75].

Incorporating an opt-out option into a model of deceased organ recovery that does not require explicit consent or authorization may overcome legal obstacles. However, informing the public about the change in policy in order to increase the organ supply may be difficult. Unlike other countries that do not require explicit consent, the US does not have the same extensive federal investment in the deceased organ recovery system needed to support an expected increase in organ recovery. Currently, the infrastructure of organ procurement specialists has a high turnover rate[76]. Thus, a shift in policy would increase the number of potential eligible deceased donors and demand for organ procurement specialists, fundamentally requiring a greater investment and re-organization of the organ recovery system to ensure successful increase in organ recovery rates.

Opt-Out System *Is Not Adequate to Ensure Individual Rights to Refuse or to Presume Consent*

Adding an "opt-out" provision so that those who oppose deceased organ recovery can express their preferences may reduce the risk of erroneously presuming consent or authorization for deceased organ recovery. Providing adequate information about the process for opting out is necessary to increase public awareness and to minimize negative impact on marginalized populations in the community. Any opt-out system that does not adequately inform US citizens of their right to opt out would be subject to legal challenge. Furthermore, the "opt-out" provision probably is not sufficient to justify the presumption of consent, or in other words, to presume that those who did not opt out would have consented to deceased organ recovery if only they had been asked. We would thus be left violating the rights of citizens at a rate considered unacceptable.

Model of Deceased Organ Recovery without Explicit Consent may Increase Distrust and Decrease Organ Recovery Rates, Especially among Underserved or Marginalized Populations

It is well documented that minority ethnic and underserved or marginalized socioeconomic groups have disproportionately lower rates of transplantation for all types of organs[77]. At the same time, many of those groups have higher rates of risk factors that generate the need for organ transplantation. For instance, African American, Hispanic, Native American, and other populations have higher rates of diabetes and consequently of end-stage renal disease. These populations have a higher need for kidney transplantation than do European American populations, yet they have lower rates of organ transplantation.

Various factors contribute to the lower transplantation rates among many minority ethnic and underserved or marginalized socioeconomic groups. The causes can be divided into three broad groups: biological, such as higher prevalence of obesity or of immunologic factors common to them but less common in the majority population[78]; issues of the health care system, such as delayed average time before assessment for kidney transplantation for some minority patients or disparate rates of living kidney donation[79,80]; and issues related to lack of knowledge, and cultural values and behaviors of the groups themselves, such as a lower willingness to do living or deceased organ donation[81,82,83,84,85,86,87].

Much research has investigated willingness to donate among minority ethnic and/or underserved or disadvantaged socioeconomic groups[88]. Many studies of deceased donation have identified common attitudes: higher levels of distrust of the health care system in general and distrust specifically related to organ donation[89]. In qualitative research, interview respondents commonly express concerns that "doctors will do not do all they can to save me" and that "doctors will not use donated organs to benefit us [i.e., people in the same minority group] but to benefit others[90,91,92]". Even though transplant professionals know such statements to be incorrect, such attitudes and beliefs are based on long histories of discrimination in health care in general. Although such attitudes and beliefs are changeable by special programs and intense educational efforts for a specific group[93,94], they appear to be not easily changed by the general public educational efforts.

Adopting a policy that permits organ and tissue recovery without explicit consent or authorization potentially will directly feed into attitudes and beliefs of high distrust. Such a policy may contribute to the false perception of prioritizing deceased organ recovery without prior consent over exerting maximal efforts to save severely injured patients of ethnic minority or disadvantaged socioeconomic groups. Furthermore, such a policy may aggravate and worsen the already existing disparities for people in these groups, and further decrease deceased organ recovery rates. Ethical concerns for equity relative to documented need, numbers and rates of organs transplanted, and quality of life all suggest that any policy regarding consent processes for deceased organ recovery should not aggravate or worsen existing disparities in organ transplantation among minority ethnic and disadvantaged socioeconomic groups[95].

Alternative Opportunities to Increase Deceased Organ and Tissue Supply

Although increasing the total number of organ transplants remains a priority, changing the current US "donation model" for deceased organ recovery to a model that does not require explicit consent or authorization will not necessarily improve deceased organ recovery and transplantation rates. Rather, implementing comprehensive strategies to improve the systematic approach to organ recovery and transplantation, ranging from increasing public awareness and education, expanding federal support, and advancing technology and scientific knowledge in organ recovery, preservation, and transplantation, may increase the actual number of organs recovered and successfully transplanted. The following section highlights several examples of strategies that may improve deceased organ recovery rates.

Increasing organ donation after circulatory determination of death (DCDD) following trauma

Although the number of deceased donors after circulatory death continues to grow, only a tenth (9.6%) of deceased donors after circulatory determination of death (DCDD) are trauma victims. Potentially, there are missed opportunities for DCDD donation in this patient population. Increasing donation rates may be achieved by extensive education and collaboration among involved stakeholders, including OPOs and members of the medical community, to streamline organ donation process via DCDD[96].

Improving the organizational aspects of donation and healthcare systems

Several major reasons for refusal to consent to donate organs are based on a lack of understanding, lack of trust, and misgiving of families. The current consent rate in the US is 26 donors/million. Educational efforts targeted at specific populations, such as people in minority and lower socio-economic status, show mixed results in increasing donation. While studies have shown the donation rate is not related to socio-economic indicators, donation rates correlate with organizational improvements using culturally congruent in-hospital coordinators[97]. Statutory in-patient coordinators and integrated healthcare systems are essential to improve consent and donation rates[98].

Improvement of organ preservation and resuscitation techniques

Organ preservation and resuscitation techniques need to be employed more frequently to increase organ survival from expanded criteria donors. Expanded donor criteria correlate with delayed graft function. While the risk for delayed graft function is multi-factorial, machine perfusion can reduce delayed graft function from 38% to 23%. Composite risk scoring systems need to be developed and indications for machine perfusion should be identified. Advances in this technology may lead to increase in acceptance of DCDD donors and expanded criteria donors[99,100].

Implementation of ethically and socially acceptable features of the Spanish model

Spain has the highest rate of deceased organ donation in the world (33-35 donors per million population)[101,102]. The US should consider adopting some of the organizational factors used in Spain, which may lead to increased organ donation rates. Organizational factors include increasing political and legal support of transplant and organ procurement professionals, implementing a comprehensive program of education, encouraging collaborative communication, improving public relations, and developing hospital reimbursement[103,104,105].

Reimbursement for medical resources is imperative. In Spain, all hospitals are public and have no vested interest based on finances. Although cities in the United States have more ICU beds than they can fill, smaller community hospitals may not have enough resources to accommodate acutely injured patients who are potential donors. Identification of and appropriate medical management of potential donors is very important, which requires education in medical management and regarding ethical concerns or challenges surrounding donation.

Universal access to healthcare, including organ transplantation, leads to solidarity, trust, and positive attitude towards the transplant profession. The Organ Donation Breakthrough Collaborative work in the US improved the organ recovery rates significantly through better coordination between hospitals and Organ Procurement Organizations (OPOs)[106,107]. Additional improvement may occur through education of all healthcare professionals in the system, similar to Spanish model. In Spain, all healthcare professionals who are in acute care settings are offered training in[33]

- Maximization of donation by donor detection
- Determination of death by neurological criteria
- Donor management
- Family-centered approach
- Communication of bad news and grief
- Cultural issues and management of refusals
- Approach to media and legal issues

In the Spanish model, critical care providers are key players in donation. In some circumstances, they are paid incentives, however ethical and conflict of interest issues may arise. Full disclosure may help manage conflicts of interest, however, a distinct separation between critical care, end-of-life care, and organ donation must be transparent. In order to achieve an increase in organ donation rates, the boundaries of ethical behavior must be well defined in order to maintain societal trust[2].

Additional administrative improvements in Spain involve[108]:

- Quality assessment program
- External retrospective audits
- Identification of missed opportunities
- Detailed protocols to identify causes of refusal and methods to reverse them

Other countries that have employed models incorporating these processes have found initial success[109,110,111].

Reduction of the need for organ transplantation

The transplant community should also invest in public education related to prevention of progressive chronic disease and reduction of end-stage organ disease. This process may be similar to how the tobacco and gambling industry organize campaigns against addiction and its harms[112].

Social media and networking

Social media can be used to create a donor registry and increase communication with friends and families. In order to be successful, the efforts need to be persistent and should be complimentary to other promotional activities. In addition, allowing open dialogue over time is required for social media to effectively engage and influence rates of donation and health issues affecting the society.

Legally sound avenues for conversations about organ donation need to be kept open. Facebook has shown to accomplish this goal in the short term, but like any other campaign, persistence is important for changing attitudes and increasing trust. As stated by Cameron, this “chronic virality” may give social media organ donor initiatives a chance of sustained impact that other traditional mass media campaigns have lacked. Future research should direct focus on improving the durability of using social media[113,114,115].

Financial and non-financial incentives

In the US, some have argued that financial and non-financial incentives for deceased organ donation may increase the rates of deceased organ recovery. However, this process remains ethically controversial and requires extensive discussion. Therefore, this subject will not be addressed further in this paper[116,117,118,119,120,121,122,123,124,125].

Conclusions and Recommendations

There is a tremendous gap between the organ supply and current demand. In the US, systematic changes in the current organ recovery and transplantation system are needed to increase the organ supply. Some argue that increasing the organ supply may be achieved by shifting to a model of deceased organ and tissue recovery that does not require explicit consent or authorization.

However, this argument is extensively debated. The OPTN/UNOS Ethics Committee contends that shifting to a model of deceased organ recovery without explicit consent in the United States is not ethically justified for the following reasons:

1) The “donation model” in the US is current public policy, embedded in a culture of individualism. Shifting this model would require extensive legal and potentially constitutional changes that would challenge fundamental, deep-seated American cultural values.
2) Changing the model to deceased organ recovery without explicit consent likely would adversely affect the public’s trust in the healthcare system, particularly by marginalized populations, potentially resulting in lower organ recovery rates.
3) Authorization rates for deceased organ recovery in the United States are already high at 75%. Practically speaking, particularly if an opt-out option is included, shifting the model to deceased organ

recovery without explicit consent or authorization would not necessarily increase deceased organ recovery rates.

4) Although empirical data suggest an association between deceased organ recovery rates and models that do not require explicit consent or authorization, additional factors such as public education, federal support, and efficiencies in the organ recovery and transplantation system, likely play a substantial role in increased organ recovery rates.

Alternative options to improve deceased organ and tissue recovery rates exist. These options do not violate individual rights or public policy. Some examples include:

1) Improve organizational aspects, efficiency, and efficacy of organ recovery and transplantation systems
2) Increase public awareness of organ and tissue donation through mass media campaigns, social media and national donor registries

   Promote scientific advancement in organ resuscitation, recovery, preservation, and transplantation techniques

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