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Public Comment Proposal

Living Organ Donation by Persons with Certain Fatal Diseases Who Meet the Criteria to Be Living Organ Donors

OPTN/UNOS Ethics Committee

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Affected Policies: *None*
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. A white paper is an authoritative report or guide that informs readers concisely about a complex issue and presents the issuing body's philosophy on the matter. It is meant to help readers understand an issue, solve a problem, or make a decision.

In 2013, the OPTN implemented new informed consent policies (*Policy 14.3, Informed Consent Requirements*) for living kidney donors. New informed consent policies for other types of living donors followed in 2014. These new policies included absolute contraindications (Living Donor Exclusion Criteria) to living donation.

Some terminally ill patients may desire to be living donors but may not be afforded the opportunity to donate based on confusion with existing OPTN policies for living donor informed consent, medical evaluation, and post-donation reporting policy requirements. If a potential living donor patient is competent and can provide informed consent, a terminal disease should not preclude organ donation and would not violate existing policy. Based on published and anecdotal reports, members may need guidance regarding how to handle potential living donors with certain fatal diseases who meet the criteria to be living donors.

What problem will this resource address?

In February 2014, the OPTN implemented living donor informed consent requirements, which included some absolute contraindications to living donation.

Anecdotal and published reports[1] [2]reveal that transplant hospitals have been reluctant to approve persons with certain fatal diseases for living donation due to concerns over violating informed consent policy requirements and because all living donor deaths within two years of the organ donation date must be reported to the OPTN through the Improving Patient Safety Portal.

This white paper will address the scenario of an individual:

- Who wishes to be a living organ donor
- Who has a progressive, incurable, chronic disease that is fatal and will ultimately be terminal
- Whose fatal disease would not put the individual at unreasonably high risk, as determined mutually by the transplant hospital and the living organ donor, for an adverse outcome after

[1] http://www.nydailynews.com/news/national/dying-michigan-woman-leave-donate-organs-article-1.1421125
[2] Mezrich J & Scalea. As they lay dying. The Atlantic. April 2015, Health. http://www.theatlantic.com/magazine/archive/2015/04/as-they-lay-dying/386273/.1421125

donating
- Whose fatal disease has not led to substantial reduction in the medical quality of the organ to be recovered and transplanted

Why should you support this resource?

This white paper demonstrates that the Ethics Committee continues to consider and provide guidance on important and timely ethical issues faced by the transplant community. This white paper will be a resource that members could consult if considering living donation by persons with certain fatal diseases who meet the criteria to be living organ donors.

How was this resource developed?

In 2016, the Committee developed a new white paper addressing the ethical implications of Imminent Death Donation (IDD). IDD is a term that has been used for the recovery of a living donor organ immediately prior to an impending and planned withdrawal of ventilator support expected to result in the patient's death. IDD applies to at least two types of potential donors:

(1) IDD might be applicable to an individual who is not brain dead and has a devastating neurologic injury that is considered irreversible. The individual would be unable to participate in medical decision-making; therefore, decisions about organ donation would be made by a surrogate or might be addressed by the potential donor's advanced directive.
(2) IDD might also be applied to a patient who has capacity for medical-decision making, is dependent on life-support, has decided not to accept further life support and indicates the desire to donate organs prior to foregoing life support and death.

The Ethics Committee limited its focus to the first scenario involving an individual with devastating neurological injury that would require surrogate consent. This white paper was sent for public comment and subsequently approved by the OPTN/UNOS Board in December 2016[3].

During the development of the IDD white paper, the Committee received feedback indicating there was confusion in the transplant community regarding when it would be appropriate to consider living donation by competent terminally ill donors.

In response, in March 2016 the Committee proposed developing a white paper to provide guidance on living donation by persons with certain fatal diseases who meet the criteria to be living organ donors. This project was subsequently approved by the Policy Oversight Committee (POC) and the Executive Committee of the OPTN Board.

In January 2017, an Ethics Committee work group began meeting by web conference on a regular basis to develop this white paper. In April 2017, this white paper was reviewed at a full Ethics Committee meeting and the members discussed how to address some inconsistent feedback regarding some content in the white paper.

In April 2017, the Operations and Safety Committee was asked to provide feedback regarding this white paper during its final stages of development. The Operations and Safety Committee was generally supportive of the white paper. Specific feedback concerning the white paper included:

- Questions concerning the definitions of the terms "fatal" and "terminal."
- The timeline provided in the white paper was confusing.
- Questions whether the terminology used in the paper was widely accepted by the palliative care community.
- Questions concerning how the current requirement to report a living donor death within two years of the date of organ donation may change in response to the white paper.

[3] UNOS Ethics Committee. Ethical Considerations of Imminent Death Donation. 2016.

- Concern that the patients with certain fatal diseases could be encouraged to consider living donation.

The Living Donor Committee reviewed this white paper on June 14, 2017. The Living Donor Committee was generally supportive of the white paper but opined that some of the final recommendations may be too strong. The Living Donor Committee commented that if the white paper is supported by the OPTN, the OPTN should determine which policies for living donor informed consent, psychosocial and medical evaluation, and follow-up should not be necessary or appropriate for, individuals with certain fatal diseases who wish to be living organ donors. Additionally, the OPTN should take steps to remove disincentives and undue scrutiny of transplant hospitals that undertake the recovery of organs from individuals with certain fatal diseases who wish to be living organ donors.

The Committee met by web conference on June 15, 2017, and reviewed a final draft of the white paper. The Committee revised the white paper to clarify some content and address some concerns raised by the Operations and Safety Committee. The Committee considered the comments from the Living Donor Committee. The Committee opined that the final recommendations in the paper were appropriate and other committees should be responsible to determine which policies for living donor informed consent, psychosocial and medical evaluation, and follow-up should and should not be necessary or appropriate for, individuals with certain fatal diseases who wish to be living organ donors. The Committee approved sending the white paper for public comment.

Which populations are impacted by resource?

This resource could be helpful to all patients with certain terminal illnesses, potential living donors, families or surrogates, and hospitals considering living donation by persons with certain fatal diseases who meet the criteria to be living donors.

How does this resource impact the OPTN Strategic Plan?

1. *Increase the number of transplants*: Guidance on living donation by the terminally ill could contribute to an increase the number of transplants.
2. *Improve equity in access to transplants*: Guidance on living donation by the terminally ill could improve equity in access to transplants. Terminally ill patients are not permitted to donate. So, disparities in donation based on a patient's medical condition is a concern.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes*: There is no impact to this goal.
4. *Promote living donor and transplant recipient safety*: There is no impact to this goal.
5. *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 approved, it will be available through the OTPN website.

How will members implement this resource?

Members will not need to take any action to implement this resource. Members could choose to consult this resource on a voluntary basis.

Will this resource require members to submit additional data?

No, 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.

White Paper

Living Organ Donation by Persons with Certain Fatal Diseases who Meet the Criteria to be Living Organ Donors

Summary and Goals

The purpose of this paper is to propose changes to Organ Procurement and Transplantation Network (OPTN) Policy and the evaluation of some potential living donors. The changes would enable the OPTN and transplant programs to respect the autonomy of persons with certain fatal diseases who want to be living organ donors. Transplant hospitals may be reluctant to consider living donation by persons with certain fatal diseases because:

- The individual is not "healthy" in the sense that is commonly required for living organ donation by transplant hospitals or regulatory guidelines.
- The individual may be at increased risk of complications or death during or after donation surgery.
- Transplant hospitals must report living donor deaths to the OPTN or other regulatory authorities.

The goals of this white paper are to:

- Address the ethical issues pertaining to living organ donation by persons with certain fatal diseases.
- Review the potential benefits and harms of living organ donation to persons with certain fatal diseases.
- Propose recommendations to the transplant community for adapting, revising, or developing polices related to living organ donation to accommodate persons with certain fatal diseases.

This white paper will address the scenario of an individual**:**

- Who wishes to be a living organ donor.
- Who has a progressive, incurable, chronic disease that is fatal and will ultimately be terminal.
- Whose fatal disease would not put the individual at unreasonably high risk, as determined mutually by the transplant hospital and the living organ donor, for an adverse outcome after donating.
- Whose fatal disease has not led to substantial reduction in the medical quality of the organ to be recovered and transplanted.

The OPTN/UNOS Ethics Committee (the Committee) reviewed and considered the limited published research and anecdotal reports on living organ donation by persons with certain fatal diseases, and the reasons transplant hospitals may be reluctant to consider persons with certain fatal diseases as living organ donors. The Committee considered the ethical principles guiding living donation, and concluded that living organ donation by persons with certain fatal diseases should be not be prohibited or obstructed if those individuals can provide informed consent and meet relevant psychosocial and medical evaluation criteria required by the OPTN for living donation.

Based on recommendations from the Committee, the OPTN:

- Recognizes the ethical justification of honoring persons with certain fatal diseases as eligible living organ donors.
- Supports transplant hospitals by reducing disincentives and impediments to organ donation by persons with certain fatal diseases.
- Avoids undue scrutiny of transplant hospitals when fatally ill individuals die from their underlying disease, and not from the living donation process itself.

Therefore, the appropriate OPTN Committees should work to establish explicit guidelines, amend policy, or delineate which elements of existing policy should be necessary and appropriate for living organ donation by persons with certain fatal diseases.

Background

Problem

As of March 2017, over 75,000 people were active on the organ transplant waitlist in the United States (U.S.).[1] The gap between those needing an organ transplant and organ availability continues to increase. Therefore, increasing the pool of organ donors, both deceased and living, is a critical public health need.

Since 2006, transplant hospitals have been required to report to the OPTN living donor deaths within two years of the donation date.

In 2013, the OPTN implemented new informed consent policies (Policy 14.4. D, *Living Donor Exclusion Criteria*) for living kidney donors. New informed consent policies for other types of living donors followed in 2014. These new policies included absolute contraindications (Living Donor Exclusion Criteria) to living donation (such as an active malignancy or diabetes) which may contribute to concern or reluctance to considering living donation by person with certain fatal diseases.

Under current OPTN Policy, transplant hospitals may be reluctant to consider a potential donor with certain fatal diseases even if they meet medical and psychosocial and informed consent criteria for living organ donation. Transplant hospitals could be concerned that under current OPTN Policy 18.6 (*Reporting of Living Donor Adverse Events*), it would be required to report a living donor death and could face scrutiny even if the death was due to the fatal disease, and not the donor surgery. When a transplant hospital reports a living donor death, the hospital reporting the event would typically provide a narrative describing the circumstances of the death, and the death may not require further investigation. Because individuals with a fatal disease are expected to die from their disease, transplant hospitals recovering an organ from a living donor with certain terminal disease could have higher rates of living donor adverse events that could result in regulatory scrutiny for the transplant hospital by the OPTN.

This Committee previously developed a white paper addressing the ethical considerations of imminent death donation (IDD). (See OPTN/UNOS White Paper entitled *Ethical Consideration of Imminent Death Donation*) IDD is a term that has been used for the recovery of a living donor organ immediately prior to an impending and planned withdrawal of ventilator support expected to result in the patient's death. IDD applies to at least two types of potential donors:

1. IDD might be applicable to an individual with devastating neurologic injury that is considered irreversible and who is not brain dead. The individual would be unable to participate in medical decision-making; therefore, decisions about organ donation would be made by a surrogate or might be addressed by the potential donor's advanced directive.
2. IDD might also be applied to a patient who has capacity for medical-decision making, is dependent on life-support, has decided not to accept further life support and indicates the desire to donate organs prior to foregoing life support and death. In such cases, the potential donors can provide informed consent and consequently no surrogate decision making is needed. An example of this case might be an individual with high cervical spinal cord injury.[2]

This white paper considers potential living donors who have the capacity to provide informed consent and make their own medical decisions.

Definitions

The following definitions will apply for this white paper:

[1] UNOS. Transplant Trends. https://www.unos.org/data/transplant-trends/#transplants_by_donor_type

[2] UNOS Ethics Committee. Ethical Considerations of Imminent Death Donation. 2016.

- **A fatal disease** refers to a disease or condition which is expected to cause the death of the patient directly or indirectly via complications (e.g., Alzheimer's disease, Huntington's disease, and Multiple Sclerosis). Individuals with a fatal disease are expected to eventually develop a terminal disease as the disease progresses.
- **A terminal disease** refers to a disease or condition which is expected to cause the death of the patient within six months or less (e.g., Advanced Chronic Obstructive Pulmonary Disease, Amyotrophic Lateral Sclerosis).
- **Capacity** refers to the ability of an individual to comprehend relevant information, to understand the meaning and consequences of a decision, to determine if the decision is consistent with their values and preferences, and to effectively communicate their decision.[3]
- **Competency** is a specific legal term used to indicate that an individual understands an act. Competency is a prerequisite and the first element in the informed consent process.
- **Life Support** refers to a therapy or device designed to preserve life and includes, but is not limited to, supplemental oxygen or mechanical ventilation, intravenous fluid therapy, sugars and salts, drugs to improve circulation, antibiotics, transfusions, surgery, nutritional supplementation (e.g., parenteral nutrition or feeding via a feeding tube), dialysis, pacemaker, electrical defibrillation, heart or lung assistance devices, transplantation of organs, and sedation and temporary paralysis.

History of Living Organ Donation and Related Policies

Between 5,500 and 6,000 living solid organ donor transplants are performed each year.[4] In September 2006, the OPTN Board approved a requirement for transplant hospitals to report to the OPTN all living donor deaths, and the failure of the live donors' native organ function, within 72 hours of transplant. The intent of the policy (*Reporting of Living Donor Adverse Events*) is to require timely reporting of deaths and serious events that affect the well-being of living donors. In 2013, the OPTN implemented new policy requirements for informed consent and for the psychosocial and medical evaluation of potential living donors.

Currently, transplant hospitals may face barriers to the evaluation and acceptance of living organ donors with certain fatal diseases due to several important issues such as:

- The individual is not "healthy" in the sense that is usually required by the transplant hospital.
- The individual may be at increased risk of complications or death during or after surgery.
- Transplant hospitals must report living donor deaths to the OPTN, and may be heavily scrutinized for such events.

Empirical Evidence and Public Support

A literature review yielded only one published study on outcomes of living donors who were "seriously ill". The study, conducted in the Netherlands by Rakke and colleagues, included five kidney donors who were "seriously ill" (4.7% of all the living donors evaluated at this center).[5] The "serious diseases" (comparable to what is referred to as "fatally ill" in the U.S.) of the living organ donors included Huntington's disease (two living donors), stage III GOLD (Global Initiative for Chronic Obstructive Lung Disease) criteria for chronic obstructive pulmonary disease and severe emphysema, and grade II oligodendroglioma of right front lobe and multiple cerebral and caudal ependymomas (central nervous system tumors with extremely low capacity to metastasize from the central nervous system to the body).[5] According to the authors, prior to donation, all five individuals were non-directed donors and were reported to be psychologically healthy, had genuine motivations to donate, had adequate risk perceptions of the surgery, and their cognitive

[3] Appelbaum & Grisso (1988). Assessing patients' capacity to consent to treatment. NEJM, 319: 1635-1638

[4] United Network for Organ Sharing: Data. https://www.unos.org/data/

[5] Rakke YS, Zuidema WC, Hillhorts MT, Erdman RAM, Massey EK, Betjes MCH., Dor FJMF, Ijzermans JNM, Weimer W. Seriously ill patients as living unspecified kidney donors: Rational and Justification. Transplantation, 2015; 99(1):232-235.

functioning was within the normal range.[5] The motivations of the five seriously ill living donors are included in Table 1.

Table 1: Motivations to Donate (Rakke et al, 2015)

Living Donor	Reported Motivations
Donor 1	The reason for kidney donation was partly feelings of "uselessness" and "insecurity" about his own body. With the donation, he wanted to help a person in need of a kidney transplantation. Furthermore, donation was driven by his Christian beliefs.
Donor 2	She reported that her main reason to donate was her experience of not being able to help a loved one with a kidney disease who ultimately died because of the organ shortage. Furthermore, she was afraid that her organs would not be usable after her death and therefore wished to donate a kidney while still alive.
Donor 3	The reason for donation was based on his opinion that, at the moment, he was physically and mentally still healthy enough to donate a kidney. Moreover, he was aware of the fact that kidneys from living-donors function better than those from deceased donors. He reported: "By doing this I can give something back to society, just like my Mother would have done, because she was a really helpful person. I am sure she would have been proud of what I am going to do."
Donor 4	His reason for donation was driven by the death of his cousin, who died from cystic fibrosis. He reported: "I know what it feels like to be critically ill and how much it would mean for one to recover. Now I'm seriously ill, but my kidneys are still suitable for transplantation purposes."
Donor 5	The motivation to donate a kidney was the desire to help someone. Furthermore, her friend experienced kidney insufficiency for which she had received a kidney from an acquaintance.

The average length of stay in the hospital for the living donors was five days and the median follow up was 24.2 months. No surgical complications were reported.[5] Normal serum creatinine and blood pressure were observed in all living donors after surgery.[5] Pain and fatigue were reported by two living donors at three months post-surgical follow up. Neither of the two remaining donors showed a decrease in renal function at their last annual medical follow-up.[5] During the post-donor nephrectomy follow-up period, three donors died from their disease: one donor died from ependymomas (2.4 years after donating), one donor died with physician assisted suicide (0.6 years after donating), and the third donor died with physician assisted suicide (4.9 years after donating).[5] It should be noted that the sample size of this study was small (n=5), and that similar outcomes may not be replicated at other centers or with other individuals with serious or fatal diseases. The OPTN does not have comparable outcomes data for non-seriously ill living donors in the Netherlands or seriously ill living donors in other countries including the U.S.

In the last decade, public interest in and awareness of fatally ill individuals' desire to donate an organ has increased. Several news stories have been reported in the popular press in the last five years.[6,7] The stories describe potential living donors with fatal diseases (e.g., MS, Amyotrophic Lateral Sclerosis (ALS)) who were not approved for organ donation by transplant hospitals. Motivations of these donors included a desire to save someone's life; the desire to donate one or more viable organs, which may ultimately not be possible as a deceased organ donor and could be more feasibly accomplished in a living organ donation setting; and a desire "to control her own destiny".

[6] http://www.nydailynews.com/news/national/dying-michigan-woman-leave-donate-organs-article-1.1421125

[7] Mezrich J & Scalea. As they lay dying. The Atlantic. April 2015, Health. http://www.theatlantic.com/magazine/archive/2015/04/as-they-lay-dying/386273/.1421125

Ethical Considerations of Living Donation by Persons with Certain Fatal Diseases

Living organ donation by persons with certain fatal diseases is supported by the ethical principles of autonomy, beneficence, justice, and nonmaleficence. These principles designate what would make an action ethically sound insofar as the specified ethical principle is involved, and are usually considered to help determine what would be "right, other things being equal," but may also be overridden by the weight of other ethical principles or virtues.

- ***Respect for Autonomy*** refers to the idea that actions are morally right insofar as they permit people to live according to their own life plans. It supports the idea of self-determination in that an individual's functioning is independent or free from interference from others, and the individual can make decisions on their own behalf. Individuals who are fatally ill and who are not permitted by the transplant community to be living organ donors are denied their autonomy and meaningful choice. Living organ donation may be perceived by individuals with certain fatal diseases as a meaningful aspect of end-of-life decision-making. Living donation by persons with certain fatal diseases reflects the increase in patient-centered decision making for patients/donors. This acknowledges a living donor's desire to provide greater input into treatment decision-making with regard to acceptable risks as well as determining whether the benefits of living donation outweigh the risks to themselves and the potential recipient.[8]
- ***Justice*** is the principle that refers to the fair and equitable distribution of benefits and burdens. Allowing fatally ill individuals to donate their organs permits the equitable distribution of the potential psychological benefits of donation as well as sharing the potential burden of donation.
- ***Beneficence*** is the principle that an action is right insofar as it produces benefit to the self or others. Living organ donation by persons with certain fatal diseases potentially benefits the recipient by improving their length of life and quality of life. A recipient's family members may also gain benefit especially if they have been involved in the transplant candidate's care or are affected by the transplant candidate's disease. Living donor organ transplantation may also benefit the living organ donor as it may accord with the living donor's sense of self-esteem and life meaning.[9]
- ***Nonmaleficence*** refers to the principle of "do no harm" or doing the least harm possible. If the surgery does result in unacceptable harm, it violates the principle of nonmaleficence. However, as described below, at times, other principles may be considered that can justify taking actions that cause harm (such as the principle of double effect). In medicine, nonmaleficence may be better conceptualized as avoiding unreasonable risks rather than "do no harm" because medical treatments and surgery carry a potential for side effects and complications which may be harmful.

By taking these four principles into account, determining what is ethically sound medical practice requires trade-offs. Hence, nonmaleficence may be compromised in medicine to attempt to do good for the living organ donor (beneficence) and to respect the living organ donor's wishes (autonomy). In the case of living organ donation by persons with certain fatal diseases, although the act of surgery may bring harm, the potential benefits to the recipient and the living donor (beneficence), coupled with expressing respect for the donor's autonomy, may be more important considerations than the inherent medical risk to the living donor from organ donation. We recognize that, compared to a living donor without a terminal or fatal disease, a donor with a terminal or fatal disease may be at elevated risk of complications from surgery due to frailty or other comorbidities. Yet, to respect the donor's autonomy, the most important consideration is that the magnitude of these risks are considered reasonable by a well-informed patient

[8] Thiessen C, Gordon EJ, Reese PP, Kulkarni S. Development of a Donor-Centered Approach to Risk Assessment: Rebalancing Nonmaleficence and Autonomy. Am J Transplant. 2015 Sep;15(9):2314-23.

[9] Allen MB, Abt PL, & Reese PP. What are the harms of refusing to allow living kidney donation? An expanded view of the risks and benefits. American Journal of Transplantation, 2014; 14: 531-537.

and the medical team. An individual with a terminal or fatal disease may plausibly have a higher (or lower) tolerance for the risk of donation-related complications compared to potential living donors in excellent health. Overall, the benefits to the transplant candidate and living donor frequently outweigh the risks.

Important Considerations for Living Donation by Persons with Certain Fatal Diseases

The following issues and scenarios may be considered in the context of living organ donation by persons with certain fatal diseases.

Capacity and Informed Consent

In order to demonstrate an individual's capacity for informed consent, individuals with certain fatal diseases must be able to engage in medical decision making, which entails comprehending the information, understanding the meaning and consequences of a decision, making an informed decision, and communicating the decision. Under existing OPTN Policy, a licensed psychologist, psychiatrist or master's level social worker can make the determination of capacity. However, to avoid conflict of interest, the clinicians performing the evaluation to determine capacity of the potential donors should ideally not be involved in the care of the intended transplant recipient to prevent a conflict of interest. Specific to persons with certain fatal diseases, the informed consent process for living organ donation must address potential peri-operative and post-operative risks.

Withdrawal of Life Support After Donation

We recommend that the fatally ill individual have the right to refuse life support after donation. This right to refuse life support should be the same for all living donors regardless if they have a fatal disease.

Do Not Resuscitate (DNR) Orders

If a potential donor with a fatal disease is approved for organ donation, the recovery hospital and the living donor should have clear documentation of the donor's pre-, peri-, and post-surgical DNR status.

Transition from Capacity to Non-Capacity Prior to Living Donor Surgery

Living organ donation by persons with certain fatal diseases must have the capacity to provide informed consent at the time of the donor surgery to proceed with donation.

Living organ donation by persons with certain fatal diseases and plans for physician assisted suicide

The ethics and decisions surrounding organ donation and physician assisted suicide should be independent of one another.[10] Physician assisted suicide is legal in some states in the U.S. There is concern that individuals considering physicians assisted suicide may have a psychiatric condition that is motivating their desire for suicide. Current OPTN Policy prohibits living organ donation by any individual with an uncontrolled diagnosable psychiatric condition requiring treatment before donation including any evidence of suicidality, this Policy could preclude individuals with plans for physician assisted suicide to first undergo living organ donation. We recommends that individuals with certain fatal diseases be allowed to donate their organs prior to an assisted suicide, but only in those U.S. states where physician assisted suicide is legal and individuals meet the criteria for physician assisted suicide. Organ donation after physician assisted suicide is outside the scope of this paper.[11-12]

Organ Euthanasia

[10] Pullen LC. A death-and donation-of one's own: Ethical considerations in planned death and organ donation. The AJT Report, 17: 1149-1150.

[11] Bollen J, de Jongh W, Hagenaars J, van Dijk G, Ten HoopenHooper R, Ysebaert D, Ijzermans J, van Heurn E, van Mook W. Organ Donation After Euthanasia: A Dutch Practical Manual. Am J Transplant. 2016 Jul;16(7):1967-72.

[12] Bollen J, van Smaalen T, ten Hoopen R, van Heurn E, Ysebaert D, van Mook W. Potential number of organ donors after Euthanasia in Belgium. JAMA Letter, 317(14) 1476.

Organ euthanasia is defined as the intentional removal of life-preserving organs in order to end a person's life, and is prohibited by the Dead Donor Rule. Organ euthanasia is presently illegal in the U.S. and outside the scope of this paper.

Discussion of Living Organ Donation with Fatally Ill Patients

Organ donation is a reasonable and important dimension of discussions about end-of-life planning. However, it would not be ethically appropriate for transplant professionals to initiate discussions about living organ donation with individuals with fatal diseases, who are already in a vulnerable position. Instead, consistent with the usual practice with potential living donors without fatal diseases, individuals with fatal diseases should make the initial contact with the transplant hospital if they are interested in considering living organ donation. Moreover, medical professionals should not encourage such individuals with fatal diseases to consider living organ donation simply because they have fatal diseases.

Case Examples of Potential Living Donors with Fatal or Terminal Diseases

The following case examples are provided as guidance on the option of living organ donation by persons with certain fatal diseases. These examples are not intended to be exhaustive. For each example, individuals with certain fatal diseases could likely be considered as a living organ donor if the individual meets the revised criteria of the living donor medical and psychosocial evaluation, the individual provides informed consent for the donor evaluation and surgery, and if the surgery would not be expected to have an undue risk of worsening the health status of the individual or hastening the death of the individual.

- ***Progressive Neurological Diseases:*** Individuals with Huntington's Disease (HD, Amyotrophic Lateral Sclerosis (ALS), and Multiple Sclerosis (MS): Individuals with these progressive neurological diseases could likely be considered as a living donor if the individual meets the criteria of the living donor medical and psychosocial evaluation, and the surgery would not be expected to unacceptably hasten the death of the individual.
- ***Potential Donors with Advanced Chronic Obstructive Pulmonary Disease (COPD):*** COPD is an inflammatory lung disease that results in obstructed airflow from the lungs. Individuals with chronic obstructive pulmonary disease may not be considered for living donation due to the increased risk for peri-operative complications and hastening of death with surgery. However, there is a wide range of disease severity and symptom burden such that living donation may be acceptable for some individuals.
- ***Potential Donors with Pulmonary Arterial Hypertension (PAH):*** PAH is high blood pressure in the lungs and can lead to heart failure. Individuals with pulmonary arterial hypertension may also be acceptable as living donors depending on the seriousness of their disease and symptom burden.
- ***Potential Donors with Cystic Fibrosis (CF):*** CF is an inherited disorder that results in severe damage to the lungs and digestive system. Individuals with cystic fibrosis may or may not be considered for living donation due to the increased risk for peri-operative complications and hastening of death with surgery. The severity of the disease will likely influence whether the individual with this fatal or terminal disease is an appropriate living donor.
- ***Potential Donors with Non-Metastasizing Cancers, usually of the Central Nervous System:*** Individuals with non-metastasizing cancers, usually of the central nervous (brain and spinal cord) system may be appropriate living donors.

Potential Benefits of Living Organ Donation by Persons with Certain Fatal Diseases

Potential benefits of permitting living organ donation by persons with certain fatal diseases include:

- Psychological benefits to the donor (e.g., providing improved self-esteem, providing enhanced meaning to one's life).
- Psychological benefit to the family or community of the donor, from knowing that their loved one was generous to other people prior to death.
- An increase in the number and quality of organs available for transplantation (i.e. a benefit to society).

Potential Harms of Living Organ Donation by Persons with Certain Fatal Diseases

Potential harms of living donation by persons with certain fatal diseases include:

- The living donor's quality of life could be compromised as the donor may experience pain, or other complications that exacerbate their underlying fatal disease.5
- Living organ donation could hasten the living donor's death.
- Medical professionals involved in the donor's care (e.g. intensive care personnel), might feel concerned about the donor's welfare.
- Public trust in organ donation and transplantation could be eroded.

By recognizing the potential harms for various stakeholders, transplant hospitals, and other regulatory entities may plan for mitigation of such consequences.

Recommendations

1. Individuals with certain fatal diseases who express interest in donation should be considered for living donation.
    - Some elements of current OPTN Policies for living donor informed consent, psychosocial and medical evaluation and follow-up should be modified to accommodate the circumstances of individuals with certain fatal diseases who wish to be living organ donors.
2. The OPTN should work with the community to determine which Policies for living donor informed consent, psychosocial and medical evaluation and follow-up should not be necessary or appropriate for individuals with certain fatal diseases who wish to be living organ donors. Potentially, this process could be handled similarly to how Policy was modified to address the special circumstances of domino donors and non-domino therapeutic donors (Policy 14.9, *Requirements for Domino Donor and Non-Domino Therapeutic Donors* and Policy 18, *Data Submission Requirements).*
3. The OPTN should take steps to remove disincentives and undue scrutiny of transplant hospitals that undertake the recovery of organs from individuals with certain fatal diseases who wish to be living organ donors.

Conclusion

Where feasible, the OPTN should honor the individual's wish to donate. Living donor transplant hospitals should accept well-informed and qualified individuals with certain fatal diseases for living organ donation without fear of penalty. Furthermore, we recommends that the OPTN committees consider the specific circumstances when responding to death of a living organ donor with a fatal disease.