OPTN | UNOS

Briefing Paper

Living Organ Donation by Persons with Certain Fatal Diseases

OPTN/UNOS Ethics Committee

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Contents

Living Organ Donation by Persons with Certain Fatal Diseases

Affected Policies:	*None*
Sponsoring Committee:	*Ethics*
Public Comment Period:	*July 31, 2017 – October 2, 2017*
Board of Director's Date:	*December 4-5, 2017*

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 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. [1, 2]

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.

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) 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) An individual 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. (The second scenario described above.)

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

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

project was subsequently approved by the Policy Oversight Committee (POC) and the Executive Committee of the OPTN Board of Directors.

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.
- Concern that the patients with certain fatal diseases could be encouraged to consider living donation, specifically, the potential donor must initiate any discussion regarding 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 or 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 (e.g. reporting all living donor deaths within two years of the date of organ donation) 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 the Living Donor Committee would best suited to determine which policies for living donor informed consent, psychosocial and medical evaluation, and follow-up should or should not be necessary or appropriate for individuals with certain fatal diseases who wish to be living organ donors. Furthermore, since this white paper does not require changes in member actions, any policy decisions could be developed and approved subsequent to the development of this resource. The Committee approved sending the white paper for public comment.

Was this Resource Changed in Response to Public Comment?

This white paper was distributed for public comment from July 31 through October 2, 2017. This white paper was on the consent agenda for regional meetings. The consent agenda was approved in all regions. All general public response during the public comment period supported the proposal. All transplant professional societies, and most OPTN committees, supported the white paper with several recurrent themes identified in their responses. Of note, one advocacy group, Not Dead Yet, submitted a response in opposition to the white paper. The themes identified from public comment are displayed in Table 1.

Table 1 – Themes Identified from Public Comment

Themes	Group Submitting Response
Complexity of potential policy modification to operationalize this concept	American Society of Transplantation (AST), American Society of Nephrology, Operations and Safety Committee, Membership and Professional Standards Committee, Living Donor Committee
Need for public education to avoid erosion of public trust	American Society of Transplant Surgeons (ASTS), AST, American Society of Nephrology, Living Donor Committee, Patient Affairs Committee, Transplant Coordinators Committee, Transplant Administrators Committee
Need to remove barriers for transplant programs to participate in this donation scenario	ASTS, NATCO (The Organization for Transplant Professionals)
Impact on the donor pool, and total number of organs available for transplant	NATCO, American Society of Nephrology, Living Donor Committee
Difficulty of determining the level of risk to potential donors associated with organ donation	AST, Living Donor Committee
Importance of respecting donor autonomy in decision process	The Alliance, American Society of Nephrology

The Ethics Committee met on October 2, 2017, (the last day of the public comment period) and reviewed public comment responses.

The Committee determined that some of the themes identified from public comment, such as the need to remove disincentives and importance of respecting donor autonomy, were adequately addressed in the white paper and the paper would not need modification to address those themes.

The white paper was updated to acknowledge the complexity of potential policy modification that could be required to operationalize this concept. The original draft of the white paper proposed that a subset of existing living donor informed consent and medical evaluation policies should be adequate for potential living donors with life-limiting illnesses. The white paper recommends that the OPTN should work with the transplant community, including patients and families, to determine if current policies for living donor informed consent, psychosocial and medical evaluation and follow-up are adequate and appropriate for individuals with certain life-limiting illnesses who wish to be living donors. If not the OPTN could propose new and additional requirements that would require and would be evaluated through future public comment.

The white paper was revised to remove content addressing the potential impact on the donor pool, and total number of organs available for transplant. The white paper originally addressed whether there would there be a potential of recovering fewer organs through living donation, than could be recovered if the individual with certain life-limiting illnesses only donated organs as a deceased donor. The Committee understood there was a lack of data to address this question and that the question was ethically problematic because it would apply to any potential living donor (e.g. all potential living donors could be able to donate more organs as deceased donor than they could donate as a living donor).

The white paper was revised in response to questions concerning the difficulty of determining the level of risk to potential donors associated with organ donation. The Committee developed this white paper as an ethical analysis of organ donation by persons with certain fatal diseases. The Committee acknowledges there will be a need to determine the level of risk for each potential donor. The white paper clearly proposes that living donation should only be considered if both the potential donor and the transplant center mutually agree that the level of risk would be acceptable. It is beyond the scope of this white paper to address the general increased risk of organ donation by individuals with certain life-limiting or fatal

diseases. If this concept is support by the transplant community, then other OPTN Committees and transplant professional organizations could study and address the questions regarding risk.

Based on feedback from its members, the Committee discussed and ultimately supported removing all content regarding living donation prior to physician assisted suicide from the white paper. The Committee determined that the content on physician assisted suicide distracted from the main focus of the white paper. This topic could be reconsidered in the future if it becomes legal in more states.

Committee leadership prepared a revised draft of the white paper to address public comment concerns and recommendations for improving the white paper submitted by Committee members. The Committee met by web conference on October 19, 2017, and reviewed a revised draft of the white paper. Significant changes in the revised draft included:

- Using the phrase "life-limiting illness" rather the "fatal disease", a term found in current palliative care and disability research literature and is used to describe a medical condition, disease or illness which is progressive and fatal and which cannot be reversed by treatment
- Emphasizing that the life-limiting illness (at the point of donation) should not put the individual at unreasonably high risk, as determined mutually by the transplant hospital and the potential donor
- Clarifying that any changes to existing policy to facilitate living donation by persons with life-limiting illness would need to be proposed by other OPTN Committees and would require public comment

In November, the leadership of the Ethics and Living Donor Committee met to reach consensus regarding some areas of concerns in the white paper. Following the meeting, a letter was sent to the leadership of the Living Donor Committee to outline how each of their concerns had been addressed.

In November, a final draft of the white paper was distributed to members of the Ethics Committee. Members were asked to respond to approve sending the white paper for consideration by the OPTN/UNOS Board.

In November, Ethics Committee leadership prepared and sent a written response to Not Dead Yet to address their response to the white paper during public comment. The response included an updated draft of the white paper reflecting post public comment changes.

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. Potential donor with terminal illnesses currently are not considered as potential living organs donors in most hospitals. 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 OPTN 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

RESOLVED, that the white paper entitled "Living Organ Donation by Persons with Certain Life-Limiting Illness," as set forth below, is hereby approved, effective December 5. 2017.

Living Organ Donation by Persons with Certain Life-Limiting Illness

Summary and Goals

The purpose of this white paper is to provide an ethical analysis of living donation (kidney or liver segment) by persons living with life-limiting illness who want to be living organ donors. The paper concludes that living donation by clinically eligible individuals with life-limiting illnesses is, conceptually, an ethically sound practice, and that the determination of eligibility for living donation should be made by the individual's healthcare team.

Transplant hospitals may be reluctant to consider living donation by persons with certain life-limiting illnesses because:

- The individual may not meet standards currently required for living organ donation by transplant hospitals or regulatory guidelines because of a having a life-limiting illness.
- The individual may be at increased risk of complications or death after donation related to their life-limiting illness.
- Transplant hospitals must report living donor deaths to the OPTN or other regulatory authorities.

The goals of this white paper are to:

- Identify and address the ethical issues pertaining to living organ donation by persons with certain life-limiting illnesses.
- Identify the potential benefits and harms of living organ donation to persons with certain life-limiting illnesses.
- Provide an ethical analysis for the transplant community to consider if they decide to adapt, revise, or develop polices related to living organ donation to accommodate persons with certain life-limiting illnesses.

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 life-limiting (e.g., patients recently diagnosed with Amyotrophic Lateral Sclerosis (ALS) or Multiple Sclerosis (MS)). This white paper does not define or delineate the specific clinical criteria of life-limiting illnesses that would enable individuals with life-limiting illnesses to become living donors. Rather, the Ethics Committee recognizes that healthcare providers are in the optimal position to make the determination of

whether an individual with life-limiting illnesses is clinically eligible for living donation on a case-by-case basis.

- Whose life-limiting illness (at the point of donation) would not put the individual at unreasonably high risk for an adverse outcome after donating, as determined by the individual's healthcare team at the transplant hospital.
- Whose risks of living donation, once the individual is deemed eligible for living donation by the transplant hospital, are evaluated mutually through a shared decision making process between the transplant team and the potential living organ donor.
- Whose life-limiting illness 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 life-limiting illness, and the reasons transplant hospitals may be reluctant to consider persons with such illnesses as living organ donors. Living donation by persons with certain life-limiting illnesses is not specifically prohibited under current OPTN Policy. The Committee considered the ethical principles guiding living donation, and concluded that persons with certain life-limiting illness should not be precluded from donation if those individuals can provide informed consent and meet current required informed consent and psychosocial and medical evaluation criteria required by the OPTN. The Committee understands that there may likely be a need for other OPTN Committees, in consultation with the transplant community, patients and their families, to propose and establish new and additional informed consent and psychosocial and medical evaluation criteria to adequately evaluate and protect potential living donors with certain life-limiting illnesses.

Based on this analysis, the OPTN could:

- Revise and expand criteria for living donation among those with life-limiting illnesses.
- Recognize the ethical justification of honoring the autonomy of persons with certain life-limiting illnesses as potential living organ donors.
- Support transplant hospitals and potential living donors by reducing disincentives and impediments to organ donation by persons with certain life-limiting illnesses.
- Make OPTN/UNOS regulatory oversight of transplant hospitals reasonable when individuals with life-limiting illnesses die from their underlying disease, and not from the living donation process itself.

OPTN Committees could establish explicit guidelines, propose new policy or amend existing policy to facilitate living organ donation by persons with certain life-limiting illnesses.

Background

Problem

As of March 2017, over 75,000 people were active on the organ transplant waitlist in the United States (U.S.).[4] 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 life-limiting illnesses.

Under current OPTN Policy, transplant hospitals may be reluctant to consider a potential donor with certain life-limiting illnesses 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 life-limiting illness, 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 life-limiting illness are expected to die from their disease, transplant hospitals recovering an organ from a living donor with certain life-limiting illness could have higher rates of living donor events that could result in unreasonable regulatory scrutiny for the transplant hospital by the OPTN, which may serve as a disincentive.

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. 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. An individual 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

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

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.[5]

In contrast, this white paper provides an analysis of potential living donors who:

- Have a life-limiting illness.
- Meet the informed consent and psychosocial and medical evaluation policy requirements to be a living donor.
- Would donate and donation would be unlikely to dramatically alter their disease course.
- Would donate when it would not put the potential donor at unreasonably high risk, as determined by the transplant hospital, and decided upon mutually by the transplant team and the living organ donor.

Definitions

The following definitions will apply for this white paper:

- ***Life-limiting illness*** is a term found in current palliative care and disability research literature and is used to describe a medical condition, disease or illness which is progressive and fatal and which cannot be reversed by treatment.

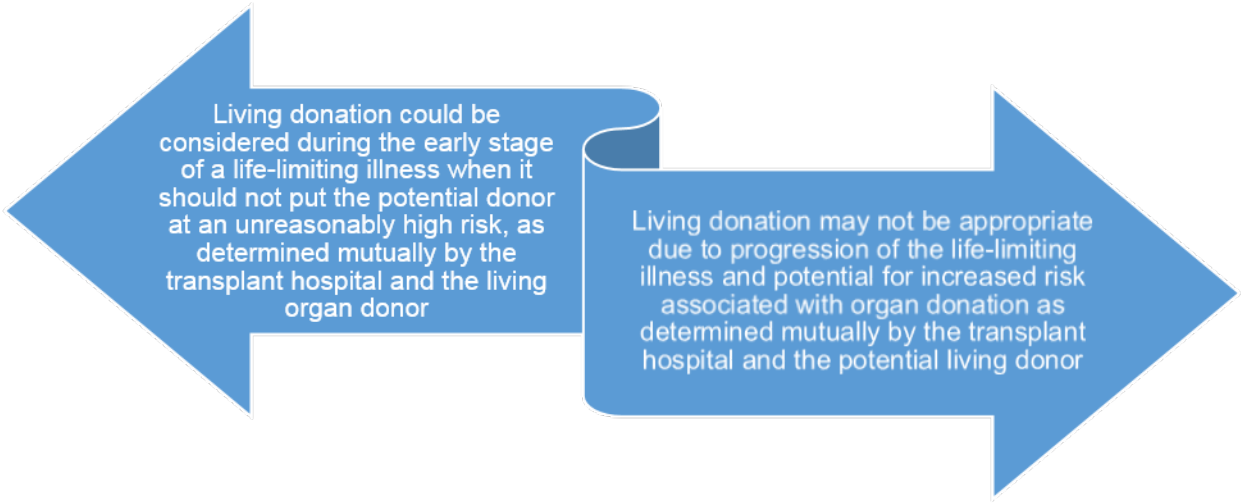

Figure 1 – Visual representation for when it may be appropriate for living organ donation by persons with life-limiting illness

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

- ***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.[6]
- ***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.[7] 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 life-limiting illnesses 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 are concerned that they could be scrutinized for reporting such events.

Empirical Evidence and Public Support

The Committee acknowledges that there is very limited available research on this issue.

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

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

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

evaluated at this center).[8] The "serious diseases" (comparable to what is referred to as "life-limiting disease" 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 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 life-

[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.

limiting illnesses. 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 individuals with life-limiting illnesses who desire to donate an organ has increased. Several news stories have been reported in the popular press in the last five years.[9,10] The stories describe potential living donors with life-limiting illnesses (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". A recent survey of ALS neurologists across the U.S. indicates that one in four ALS patients may be interested in living donation. The survey found that a majority of these neurologists would support this opportunity for their patients, and that half of their patients had already inquired about such an opportunity.[11]

With any new transplant initiative, there is a potential to inadvertently affect public trust in unanticipated ways. The OPTN supports the importance of maintaining public trust and seeks to promote and preserve the integrity of the transplant system. The OPTN supports measures to uphold public trust which could include public education campaigns on the ethical and legal principles involved in living donation by persons with life-limiting illnesses. Additionally, if living donation by persons with life-limited illnesses is supported by the transplant community, the OPTN should investigate potential implications of this initiative on living donation rates, viability of transplantable organs, transplant centers, and effects, if any, on public trust.

Ethical Considerations of Living Donation by Persons with Certain Life-Limiting Illnesses

Living organ donation by persons with certain life-limiting illnesses 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 have life-limiting illness **and who are potentially eligible to be living donors**, but who are not permitted by the transplant community to

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

[11] Physician perceptions about living organ donation in patients with Amyotrophic Lateral Sclerosis" (Clin Neurol Neurosurg. 2017 Sep; 160: 125-129)

be living organ donors, are denied their autonomy and meaningful choice. People with life-limiting illness are entitled to no less autonomy than those without life-limiting illness. As such, efforts should be made to allow interested persons the opportunity to donate if their health permits. Living organ donation may be perceived by individuals with certain life-limiting illnesses as a meaningful aspect of end-of-life decision-making. Respect for autonomy entails affirming the individual's willingness to proceed with donation, and not that an individual's decision to donate can overrule the transplant hospital's determination of eligibility. Living donation by persons with certain life-limiting illness reflects the increased emphasis placed in the healthcare setting on patient-centered decision making and shared decision making approaches. These approaches entail a living donor's desire to provide greater input into treatment decision-making process with the healthcare team with regard to acceptable risks as well as determining whether the benefits of living donation outweigh the risks to themselves and the potential recipient.[12,13]

- ***Justice*** is the principle that refers to the fair and equitable distribution of benefits and burdens. Allowing individuals with life-limiting illness 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 life-limiting illness potentially benefits the recipient by improving their length of life and quality of life. Accordingly, respecting the autonomy of persons with certain life-limiting illness who want to be living organ donors could save more lives through transplantation. 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.[14]
- ***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

[12] 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.
[13] Gordon EJ, Butt Z, Jensen S, Lehr AL, Franklin JF, Sherman L, Becker Y, Chon J, Beauvais N, Hanneman J, McNatt G, Penrod D, Ison MG, Abecassis MM. Opportunities for Shared Decision Making in Kidney Transplantation. American Journal of Transplantation 2013;May;13(5):1149-58.

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to attempt to do good for the living donor organ recipient (beneficence) and to respect the living organ donor's wishes (autonomy). As with all cases of living donation, donors undergo medical risks, but the benefits of the donation may outweigh the risks to donors. Similarly, in the case of living organ donation by persons with certain life-limiting illness, 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.

Because this white paper aims to conceptually evaluate the ethical soundness of living donation by individuals with life-limiting illness, it is beyond the paper's scope to generate specific criteria or clinical practice standards to help establish equivalency between healthy and people with life-limiting illness in the context of living organ donor evaluation and selection. Living donation should only be considered if and when the individual would not be subject to unreasonably high risk as determined mutually by the transplant hospital and the living organ donor.

Yet, to respect the donor's autonomy, the most important consideration is that the transplant hospital properly disclose the magnitude of these risks to potential living donors so that potential living donors can evaluate these risks in light of their values and beliefs to make an informed decision. An individual with a life-limiting illness 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 Life-Limiting Illnesses

The following issues and scenarios may be considered in the context of living organ donation by persons with certain life-limiting illnesses.

Capacity and Informed Consent

In order to demonstrate an individual's capacity for informed consent, individuals with certain life-limiting illnesses 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 life-limiting illnesses, the informed consent process for living organ donation must: a) address potential peri-operative and post-operative risks, and b) be tailored to the specific situation of each potential living donor with life-limiting illness to ensure appropriate protections. Any revisions to the informed consent process, and peri-operative and post-operative care for living donors would require future public comment.

Withdrawal of Life Support After Donation
All living donors, as with all patients utilizing the healthcare system, currently have the right to refuse life-sustaining treatment (i.e., mechanical ventilation or 'life support'). Accordingly, individuals with certain life-limiting illnesses also have the right to refuse life support after donation.

Do Not Resuscitate (DNR) Orders
If a potential donor with a life-limiting illness 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 life-limiting illness 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 life-limiting illness and plans for physician assisted suicide
The white paper does not include an analysis of living organ donation by persons with life-limiting illnesses prior to physician assisted suicide in this white paper.

Organ Euthanasia
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.

Initiating a Discussion Regarding Living Organ Donation with Persons with Certain Life-Limiting Illnesses
Consistent with the usual practice with potential living donors without life-limiting illnesses, individuals with life-limiting illnesses should make the initial contact with the transplant hospital if they are interested in considering living organ donation. Medical professionals should not encourage such individuals with life-limiting illnesses to consider living organ donation simply because they have a life-limiting illness.

Case Examples of Potential Living Donors with Certain Life-Limiting Illnesses

The following case examples are provided as guidance on the option of living organ donation by persons with certain life-limiting illness. These examples are not intended to be exhaustive. For each example, individuals with certain life-limiting illnesses could be considered as a living organ donor if the individual:

- Meets the required criteria for the living donor medical and psychosocial evaluation,
- Provides informed consent for the donor evaluation and 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, as determined mutually by the transplant hospital and the living organ donor.

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 life-limiting illness 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 Life-Limiting Illnesses

Potential benefits of permitting living organ donation by persons with certain life-limiting illnesses 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 Life-Limiting Illnesses

Potential harms of living donation by persons with certain life-limiting illnesses include:

- The living donor's quality of life could be compromised as the donor may experience pain, or other complications that exacerbate their underlying life-limiting illness.[5]
- Living organ donation could hasten the living donor's death.

- Unintended effect on public understanding or trust in the transplant system.

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

Recommendations

1. Transplant hospitals should consider individuals with certain life-limiting illnesses who express interest in living donation for living donor evaluation. That is, transplant hospitals should not automatically prevent such individuals from initiating the evaluation process.
    - Some elements of current OPTN Policies for living donor informed consent, psychosocial and medical evaluation and follow-up could be modified to accommodate the circumstances of individuals with certain life-limiting illnesses who wish to be living organ donors.
2. The OPTN should work with the transplant community, including patients and families, to determine if current policies for living donor informed consent, psychosocial and medical evaluation and follow-up are adequate and appropriate for individuals with certain life-limiting illnesses who wish to be living organ donors. If not, the OPTN could propose new additional requirements that would require and would be evaluated through future public comment.
3. Operationalizing and implementing the concept of living donation by persons with certain life-limiting illnesses will likely be challenging because of the concept's complexity. The OPTN could proactively identify ways to remove disincentives and to increase opportunities for living donation by persons with certain life-limiting illnesses, and refine assessment of transplant hospitals that undertake the recovery of organs from individuals with certain life-limiting illnesses who wish to be living organ donors.
4. The OPTN should engage in public and stakeholder education to inform potential clinical processes and ensure widespread understanding.

Conclusion

The autonomy of persons with certain life-limiting illnesses who want to be living organ donors should be honored and living donor transplant hospitals should be able to consider potential living donors with certain life-limiting illnesses without unreasonable regulatory consequence. Evaluation of any new related process or requirements needed in order to enable living donation by person with certain life-limiting illnesses can be considered through future public comment.