Ethical Considerations of Imminent Death Donation

OPTN/UNOS Ethics Committee

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Ethical Considerations of Imminent Death Donation

Executive Summary

Beginning in 2014, the Ethics Committee (the Committee) coordinated an inter-committee work group to consider 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 work group limited its focus to the first scenario involving an individual with devastating neurological injury that would require surrogate consent, and determined that this specific type of potential organ donation could be described as Live Donation Prior to Planned Withdrawal of Life Sustaining Medical Treatment or Support from a Neurodevastated Patient. This report will use the shorthand phrase “live donation prior to planned withdrawal” or LD-PPW. This document will limit its focus to LD-PPW.

The work group’s motivations were to analyze whether, compared to existing practices of attempting donation after cardiac death (DCD), the practice of LD-PPW could:

- honor the preferences of the potential donor (if known, concerning organ donation or the potential donor’s end-of-life care);
- support the preferences of the potential donor’s family or surrogate;
- increase the number of potential organ donors
- increase the quality of organs donated for transplantation
- increase the total number of organs available for transplantation

Based on published research, organ donation does not occur among a substantial minority of individuals for whom donation after cardiac death (DCD) is attempted. For these unsuccessful DCD scenarios, withdrawal of life support leads to prolonged warm ischemia time that damages the organs, which are then not procured. While some tools to predict successful DCD exist, their predictive accuracy is uncertain. Occurrences of unsuccessful DCD may be viewed as both a lost opportunity for transplantation, as well as disappointing to the surrogates of the potential donor. In other cases, prolonged warm ischemia may damage organs that are transplanted, leading to post-transplant complications. Additionally, there may be potential non-brain dead donors for whom organ procurement is never attempted, because of the belief that DCD would be unsuccessful.

After a thorough examination of the potential of LD-PPW, the Committee ultimately determined that there could be circumstances where LD-PPW may be ethically appropriate and justified by the potential benefits to donors, donor families and recipients. However, based on the responses and substantial concerns
from nine other Committees, the Ethics Committee decided to discontinue work on LD-PPW because of its potential risks at this time, due to a lack of community support and substantial challenges to implementation. In the future, it may be possible to adequately address those challenges through additional research or careful policy development or revision.

What problem will this resource solve?

Members of the transplant community have asked questions regarding this issue and there is little information on in the public domain. Hospitals and OPOs could voluntarily review this resource to learn more about IDD.

Why should you support this resource?

The resource provides an ethical analysis of IDD, and should be beneficial to hospitals or OPOs that may be counseling the families or surrogates of potential donors who want an option for organ donation but the potential donor does not meet brain death criteria and is not considered to be a candidate for DCD. Ethical white papers can also guide the OPTN/UNOS committees as they consider whether to pursue guidance or policies related to IDD.

How was this resource developed?

Beginning in 2013, the Ethics Committee identified IDD as a potential donation practice being discussed in the literature and at national conferences. During its March 2014 meeting, the Committee began to consider the ethical issues that could be associated with IDD and approved the following position statement:

The Ethics Committee recognizes that Imminent Death Donation is an emerging donation practice that may be ethical under certain circumstances but understands that significant ethical, clinical and practical concerns must be addressed before policy development can be considered. The Committee therefore recommends that a joint subcommittee be formed including the Kidney, OPO, Living Donation, and Ethics Committees to further explore IDD and address concerns.

In June 2014, the Committee included this position statement in its report to the Board. The Board took no official action regarding the position statement, but did approve a proposed project to investigate the Ethical Considerations of Imminent Death Donation. In response, the Committee formed a work group with representatives from the Operations and Safety, OPO, and Living Donor Committees to begin work on this project.

The work group understood that 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 death1. 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. The work group decided to refer to this specific type of organ donation as follows: Live Donation prior to Planned Withdrawal of Life Sustaining Medical Treatment or Support from a Neurodevastated Patient to replace IDD. For this proposed new white paper, the work group decided to

use the shorthand phrase “live donation prior to planned withdrawal” or LD-PPW. This document will limit its focus to LD-PPW.

(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, no surrogate decision making is needed. An example of this case might be an individual with high cervical spinal cord injury. This report will not address that scenario, but the Ethics Committee plans to provide guidance on this issue in the future.

The work group’s motivations were to analyze whether, compared to existing practices of attempting donation after cardiac death (DCD), the practice of LD-PPW could:

- honor the preferences of the potential donor (if known, concerning organ donation or the potential donor’s end-of-life care);
- support the preferences of the potential donor’s family or surrogate;
- increase the number of potential organ donors
- increase the quality of organs donated for transplantation
- increase the total number of organs available for transplantation

Based on published research, organ donation does not occur among a substantial minority of individuals for whom donation after cardiac death (DCD) is attempted. For these unsuccessful DCD scenarios, withdrawal of life support leads to prolonged warm ischemia time that damages the organs, which are then not procured. While some tools to predict successful DCD exist, their predictive accuracy is uncertain. Occurrences of unsuccessful DCD may be viewed as both a lost opportunity for transplantation, as well as disappointing to the surrogates of the potential donor. In other cases, prolonged warm ischemia may damage organs that are transplanted, leading to post-transplant complications. Additionally, there may be potential non-brain dead donors for whom organ procurement is never attempted, because of the belief that DCD would be unsuccessful. The Wall Street Journal recently published an article addressing the Difficult Ethics of Organ Donations from Living Donors.

The work group represented a wide range of opinions with some members initially expressed significant concerns about IDD and whether or not it should ever be permissible. Other members supported IDD as an organ donation option that could increase the availability of organs for transplantation. The work group took into consideration that cases of IDD have occurred in the past in the US. The OPTN is aware of five living kidney donors who were reported to have died shortly after donation from conditions that existed before their donations. Their causes of death include coma, brain hemorrhage, infant anencephaly, respiratory failure, and acute hemorrhage. The work group did ultimately support continued discussion regarding IDD.

The work group met several times via conference call and agreed, as a first step, to identify the primary ethical issues and to consider whether these ethical concerns could be adequately addressed by establishing specific conditions and limitations under which IDD might occur.

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As previously noted, the work group decided to limit its focus to LD-PPW. Revisions to membership requirements in the Bylaws and OPTN policies would be required in order to allow LD-PPW. For example, current policy requires an extensive psychosocial evaluation and informed process for a potential donor that would not be possible in LD-PPW. In LD-PPW, a surrogate would be required to provide consent on behalf of the neurodevastated patient. Policy that addresses the recovery and placement of living donor organs and the allocation of non-directed living donor organs would also need modification to allow LD-PPW. Furthermore, under current policy and bylaws, the living donor death could need to be reported as an adverse donor outcome, and could impact a hospital’s performance measures unless relevant policies and bylaws were amended.

During development of this report, nine OPTN/UNOS Committees (OPO, Living Donor, Membership and Professional Standards, Kidney, Minority Affairs, Patient Affairs, Transplant Administrators, Operations and Safety, and Transplant Coordinators) were asked to review the report and provide comments. The Committee considered all feedback. Most respondents raised concern with the potential for LD-PPW to erode public trust with the current organ donation and transplantation system.

The Committee ultimately determined that at this time the lack of data makes it impossible to conclude whether the net number of transplants might decline or increase if LD-PPW were widely adopted. The effect on the number of transplants may depend, to a substantial degree, on how many organs are typically procured through the practice of LD-PPW. LD-PPW might increase the number of donated organs and transplants if organs were procured from donors who would not have been considered for organ donation if DCD were the only option, or if LD-PPW took place in conjunction with DCD. LD-PPW could also decrease the number of organs procured if it became a preferred donation option and reduced the DCD cases where the donor is expected to meet DCD criteria.

Additionally, the Committee concluded that there could be circumstances where LD-PPW may be ethically appropriate and justified by the potential benefits to donors, donor families and recipients. However, based on the responses and substantial concerns from nine other Committees, the Ethics Committee declined to endorse LD-PPW at this time because it is not worth the potential risks due to a lack of community support and substantial challenges to implementation. In the future, it may be possible to adequately address those challenges through additional research or careful policy development or revision.

The original plan for this project was for the resource to be considered by the Board in June 2016. The Committee was aware that the Board would consider if all guidance documents should require public comment at this same meeting. The Committee elected to delay sending the white paper for Board consideration in June and to send the white paper for public comment.

This white paper was on the consent agenda for regional meetings and was approved in all regions. This white paper was presented during two national webinars during the public comment period. No comments were submitted regarding the white paper following either of the national webinars.

The Committee met on September 12, and October 20, 2016 and reviewed public comment responses (Exhibit A). Committee members were asked to consider and to respond with questions or concerns if the white paper should be revised based on public comment. The white paper was not changed in response to public comment.

The North American Transplant Coordinators Organization (NATCO) and the Organization of Organ Procurement Organizations (AOPO) responded in support of the white paper but also commented that work on this issue should continue.

The American Society of Transplant Surgeons responded that the white paper should not be released due to a current study by the Greenwall Foundation designed to understand current societal views toward imminent death donation. The Ethics Committee understands that the Greenwall Foundation study will not
provide an ethical analysis of imminent death donation. The Ethics Committee opined that this resource needs to be available for the transplant community and should not be delayed.

The Committee met on November 17, 2016 and voted in support of sending this white paper for Board consideration.

**How well does this resource address the problem statement?**

The resource provides an ethical analysis of LD-PPW, and should be beneficial to hospitals or OPOs that may be counseling the families or surrogates of potential donors who want an option for organ donation when the potential donor does not meet brain death criteria and is not a candidate for DCD.

It is not clear which potential donors would be suitable for LD-PPW. It may be necessary to establish objective clinical criteria or parameters for a potential donor who would be evaluated for LD-PPW, especially criteria addressing the degree of neurologic damage because the potential donor would not meet brain death criteria.

There is an unmet need to understand the potential impact on the number of organs available for transplant with LD-PPW vs. existing practice. If research does not demonstrate the potential for significantly increasing the number of organs available with the practice of LD-PPW, it may not be worth further efforts to develop this practice.

The field is not very accurate in predicting whether potential DCD donors will become actual donors. If a potential donor does meet DCD criteria, that donor could potentially donate two kidneys and other organs. Therefore, it is possible that LD-PPW, in which only a single kidney is recovered, could negatively impact the current volume of organs available for transplant. The possibility of offering LD-PPW followed by DCD might mitigate this negative impact. If LD-PPW was viewed as an alternative to DCD or a preferred pathway to DCD (rather than an additional option when DCD is not viable), it could result in a single kidney available for transplant compared to the potential for two kidney and other organs that might be recovered under DCD protocols.

**Was this resource changed in response to public comment?**

No, the resource was not changed in response to public comment.

**Which populations are impacted by this resource?**

There is no known impact to any specific populations.

**How does this resource impact the OPTN Strategic Plan?**

1. Increase the number of transplants: If ultimately supported by the transplant community, LD-PPW would be a new category of living donor organ donation and could contribute to an increase in the total number of transplants.

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

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?
The resource will be available through the OPTN website.

How will members implement this resource?
Members are not required to take any action regarding this resource. This is a resource that members may consider on a voluntary basis. Members may access this resource through the OPTN website.

Will this proposal 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?
As this resource does not create any new member requirements, it does not affect member compliance. Members could consult this resource on a voluntary basis.
White Paper

RESOLVED, that the white paper entitled *Ethical Considerations of Imminent Death Donation*, as set forth below, is hereby approved, effective December 6, 2016.

**Ethical Considerations of Imminent Death Donation**

An inter-committee work group was formed to consider 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.1 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. We will refer to this specific type of organ donation as follows: Live Donation prior to Planned Withdrawal of Life Sustaining Medical Treatment or Support from a Neurodevastated Patient to replace IDD. For this report, we will use the shorthand phrase “live donation prior to planned withdrawal” or LD-PPW. This document will limit its focus to LD-PPW.

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, no surrogate decision making is needed. An example of this case might be an individual with high cervical spinal cord injury.2 This report will not address that scenario.

The work group’s motivations were to analyze whether, compared to existing practices of attempting donation after cardiac death (DCD), the practice of LD-PPW could:

- honor the preferences of the potential donor (if known, concerning organ donation or the potential donor’s end-of-life care);
- support the preferences of the potential donor’s family or surrogate;
- increase the number of potential organ donors
- increase the quality of organs donated for transplantation
- increase the total number of organs available for transplantation

We note that organ donation does not occur among a substantial minority of individuals for whom donation after cardiac death (DCD) is attempted.3 For these unsuccessful DCD scenarios, withdrawal of life support leads to prolonged warm ischemia time that damages the organs, which are then not procured. While some tools to predict successful DCD exist, their predictive accuracy is uncertain.4 Occurrences of unsuccessful DCD may be viewed as both a lost opportunity for transplantation, as well as disappointing to the surrogates of the potential donor.5 In other cases, prolonged warm ischemia may damage organs that are transplanted, leading to post-transplant complications. Additionally, there may
be potential non-brain dead donors for whom organ procurement is never attempted, because of the belief that DCD would be unsuccessful. However, at this time, a lack of data renders the work group unable to conclude whether the net number of transplants might decline or increase if LD-PPW were widely adopted. The effect on the number of transplants may depend, to a substantial degree, on how many organs are typically procured through the practice of LD-PPW. LD-PPW might increase the number of donated organs and transplants if organs were procured from donors who would not have been considered for organ donation if DCD were the only option, or if LD-PPW took place in conjunction with DCD. After the transplant community considered possible intended and unintended consequences, and if analysis supported LD-PPW as an ethically acceptable practice, then OPTN bylaws and policy would need modification to accommodate LD-PPW. Additionally, it would be important to determine if LD-PPW would violate any regulations from the Centers for Medicare and Medicaid Services or any other relevant laws or guidelines.

**Background:**
Beginning in 2013, the Ethics Committee (the Committee) identified IDD as a potential donation practice being discussed in the literature and at national conferences. During its March, 2014 meeting, the Committee began to consider the ethical issues that could be associated with IDD and approved the following position statement:

The Ethics Committee recognizes that Imminent Death Donation is an emerging donation practice that may be ethical under certain circumstances but understands that significant ethical, clinical and practical concerns must be addressed before policy development can be considered. The Committee therefore recommends that a joint subcommittee be formed including the Kidney, OPO, Living Donor, and Ethics Committees to further explore IDD and address concerns.

In June 2014, the Committee included this position statement in its report to the Board. The Board took no official action regarding the position statement. However, at this same meeting, the Board did approve a set of new proposed projects which included a project to investigate the Ethical Considerations of Imminent Death Donation.

In response to this approved project, a work group was established with representatives from the Operations and Safety, OPO, Living Donor and Ethics Committees.

The work group represented a wide range of opinions with some members initially expressing significant concerns about IDD and whether or not it should ever be permissible, while other members supported IDD as an organ donation option that could increase the availability of organs for transplantation. The work group took into consideration that cases of IDD have occurred in the past in the US. The OPTN is aware of 5 living kidney donors who were reported to have died shortly after donation from conditions that existed before their donations. Their causes of death include coma, brain hemorrhage, infant
anencephaly, respiratory failure, and acute hemorrhage. The work group did ultimately support continued discussion regarding IDD.

The work group met several times via conference call and agreed, as a first step, to identify the primary ethical issues and to consider whether these ethical concerns could be adequately addressed by establishing specific conditions and limitations under which IDD might occur.

The work group subsequently decided to limit its focus to LD-PPW. Revisions to membership requirements in the Bylaws and OPTN policies would be required in order to allow LD-PPW, such as accommodating surrogate consent on behalf of the neurodevastated patient. Policy that addresses the recovery and placement of living donor organs and the allocation of non-directed living donor organs would also need modification to allow LD-PPW. Furthermore, under current policy and bylaws, the living donor death could need to be reported as an adverse donor outcome, and would impact a hospital’s performance measures unless relevant policies and bylaws were amended.

During development of this report, nine OPTN/UNOS Committees (OPO, Living Donor, Membership and Professional Standards, Kidney, Minority Affairs, Patient Affairs, Transplant Administrators, Operations and Safety, and Transplant Coordinators) were asked to review the report and provide comments. A summary of their feedback is presented near the end of this document.

Analysis:

The work group identified the following ethical concerns, operational considerations and possible policy modifications regarding LD-PPW.

1. Potential for the perception that LD-PPW erodes the Dead Donor Rule.

   The dead donor rule is an ethical norm related to deceased organ donation that is often expressed as (1) organ donors must be dead before procurement of organs begins; or (2) organ procurement itself must not cause the death of the donor.

   The person being considered for LD-PPW would be categorized as a living donor at the time of organ recovery. It is expected that the living donor would not be adversely impacted by organ procurement and would subsequently die when life support is withdrawn. However, organ procurement through LD-PPW could itself cause the donor’s death in the event of a surgical complication. Consequently, preserving the Dead Donor Rule was identified by the work group as a primary concern. In response, the work group supported initially limiting LD-PPW to donation of one of two functioning kidneys, and donation of no other organs. The work group determined that:

   a) The ability to donate a single kidney, while not risk-free, is routinely performed in living donors and the attendant risks of death have been considered acceptable. However, because the LD-PPW candidate is critically ill, there may be heightened concerns that a nephrectomy could hasten death (as compared to the healthy living kidney donor).

   b) If the donor died due to procurement of a kidney (or other organs), this could be viewed as a violation of the Dead Donor Rule. The doctrine of double effect could help address this concern.
c) The doctrine (or principle) of double effect is often invoked to explain the permissibility of an action that causes a serious harm, such as the death of a human being, as a side effect of promoting some good end. However, this doctrine is not universally accepted.

d) The work group recognizes that, compared to single nephrectomy, the donation of some other organs or combinations of organs or tissues via LD-PPW may have a higher probability of hastening death. However, if the option for LD-PPW is pursued, a reasonable first step could be to commence the practice using single nephrectomy which presumably has a lower risk of hastening death compared to double nephrectomy, liver lobe donation or multi-organ donation.

2. Appropriateness of surrogate consent for LD-PPW

Because the potential donor is incapacitated, he or she would not be able to provide informed consent for living donation, and consent for donation would need to be provided by a surrogate in most cases. Some work group members expressed concerns about the appropriateness of surrogate consent for surgery that does not benefit the donor’s health or well-being. The work group opined that it could be appropriate for a surrogate to provide authorization for LD-PPW if they knew the potential donor had been supportive of organ donation. However, the work group also noted that surrogates have a high level of responsibility for many other, highly consequential aspects of the potential donor’s care, including the decision to withdraw life support.

The following considerations are relevant and may reduce the ethical concerns regarding surrogate consent:

a) The potential donor had previously expressed a desire or had taken prior action towards becoming a living donor. Prior action could include expressed wishes, documented evidence, or prior evaluation for living organ donation. Evidence of this would show the patient’s intent to be a living donor and could be considered as part of a substituted judgment. The substituted-judgment doctrine is a principle that allows a surrogate decision-maker to attempt to establish, with as much accuracy as possible, what decision an incompetent patient would make if he or she were competent to do so. In theory, the doctrine of substituted judgment looks to the individual to determine what he or she would do in a particular situation if she were competent. This doctrine is applicable to situations where a person, once competent, is rendered incompetent to consent to medical procedures through injury or disease. The once competent person had developed a system of morals and beliefs, and patterns of behavior, which the court can examine when evaluating what he or she might (or would likely) do in a particular situation.

b) The potential donor had registered to be a deceased donor or expressed the desire to be a deceased donor. While authorizing deceased donation is not ethically or legally equivalent to consent for living donation, the fact that the patient wanted to be an organ donor could be relevant to a substituted judgment analysis.
c) It is important that the decision-maker be an appropriate surrogate for the patient. This principle is generally well established by law and hospital policy. In the context of LD-PPW, there is already a surrogate making the decision to withdraw the mechanical support (with death an expected outcome). Additional criteria could be developed to establish requirements that the surrogate knew the background and values of the patient relating to donation. One possibility is, as a matter of OPTN policy, to limit surrogate consent for LD-PPW to an appointed durable power of attorney or health care proxy. However, others questioned why durable power of attorney or health care proxy status would be appropriate, if they were not required for the surrogate to make the decision to withdraw support.

d) Parameters for surrogate consent in cases of potential pediatric donors need to be established. As an alternative, LD-PPW could be limited to adult patients. In the pediatric context, the best interest standard is commonly utilized rather than substituted judgment as the patient may be too young to have formed values or wishes relevant to donation. Also, in most circumstances there will not be a health care proxy agent or power of attorney. Alternatively, a guardian ad litem could be appointed although again this would add a significant step beyond what is required for the parents to consent to withdrawal of ventilator support.

e) For initial cases of LD-PPW, an ethics consultation could add value to assess the adequacy of the surrogate and to assist in ensuring a surrogate decision for LD-PPW is ethically appropriate given the specifics of a case.

3. LD-PPW Candidates as a Vulnerable Population.

Potential donors being considered for LD-PPW are a vulnerable population because they are neuro-devastated, incapacitated and near death. There are additional related considerations:

a) A mechanism is needed to ensure adequate perioperative pain management. Pain control would be important both during and after nephrectomy. After nephrectomy, it is not clear how withdrawal of ventilator support would occur. Would the ventilator be discontinued while the potential donor is still under anesthesia to ensure pain relief? This raises similar issues faced at end of life care regarding a balance between pain management and hastening death. Again, the doctrine of double effect may be helpful to resolve the ethical issue but some practical considerations remain.

4. Identifying appropriate candidates for LD-PPW.

a) Families or surrogates should not be approached regarding LD-PPW as an option until withdrawal of support had been discussed and planned to occur within a relatively short period of time (within days, not weeks).

b) The work group discussed the importance and difficulty of assessing the probability of death after planned withdrawal of life support on a case-by-case basis.
c) The work group discussed options for presenting LD-PPW and reconciling the practices of LD-PPW and DCD. The decision to withdraw life support must be separated from the discussion of the options for donation, just as has been established for DCD. After the decision to withdraw life support is made, several approaches to discussing LD-PPW could be considered:

- Both DCD and LD-PPW could be presented as equal options without indicating preference for either option
- LD-PPW could only be discussed with surrogates in certain circumstances, such as when DCD is unlikely to be successful
- DCD could be framed as the usual practice (default option), but LD-PPW would also need to be discussed
- LD-PPW could be offered only when the family independently requests this option, however this would limit it to better informed families or surrogates
- Additionally, when LD-PPW is discussed, teams must be prepared to decide whether LD-PPW followed by DCD is an option

5. Public Trust.

The work group discussed the possibility that LD-PPW could be perceived by the public as violating the Dead Donor Rule. The concern was raised that LD-PPW would reinforce the perception that the donation and transplant community look like “vultures.” However, the effect of LD-PPW is difficult to predict. Some ethicists have suggested that practices such as LD-PPW might instead be welcomed by some families if it were perceived as another viable approach to supporting the surrogate’s preferences for end-of-life care for the potential donor.6

6. Operational / practical / policy considerations.

There are a number of operational and practical concerns - some of which raise ethical issues that would need to be carefully considered.

a) Much of the policy and clinical practice of living donor evaluation is focused on establishing that the long-term risks of donation to the donor’s health are reasonable in relation to the benefits to be gained (i.e. health benefits for the recipient and non-medical benefits for some donors), and that the donor has a thorough understanding of the potential risks and benefits of the donation decision. However, neither of those considerations pertains to the LD-PPW scenario. In this scenario, the potential donor is not expected to have long-term survival. The potential donor does not have the ability to participate in medical decision-making. The surrogate’s decisions about organ donation may be primarily viewed from the perspective of appropriate end-of-life care, rather than weighing adverse long-term health effects due to organ procurement. Given these distinctions between the existing practice of live organ donation versus LD-PPW, some OPTN policy related to living donation (as it applied to LD-PPW) would merit revision if LD-PPW were to be more widely adopted.
b) As currently considered, LD-PPW could only occur in an OPTN member hospital. This is because OPTN policy restricts recovery of living donor organs to OPTN member transplant centers. Also, transplant surgeons cannot travel to a different hospital to perform a living donor nephrectomy given medical licensure and credentialing requirements under applicable state law and hospital policy. Accordingly, in some cases, an LD-PPW candidate would need to be transferred to an OPTN member hospital to facilitate organ recovery. Transferring a LD-PPW candidate would add a significant step beyond what is required for the candidate’s family or surrogate to consent to withdrawal of ventilator support. There would be significant costs and logistical challenges to moving a patient from the primary donation hospital to a transplant center. Other stakeholders, such as anesthesia providers and hospital administrators responsible for allocation of scarce resources such as ICU beds and operating room suites would also need to be engaged.

c) Under current policy, OPOs are responsible for the deceased donor authorization process, medical evaluation, organ recovery and allocation of deceased donor organs, while living donor hospitals are responsible for the informed consent process, medical evaluation, organ recovery and placement of living donor organs.

There could need to be reconsideration and potential changes to these roles in the setting of LD-PPW. Aspects of the LD-PPW process could be similar to deceased donation in which the OPO coordinates the evaluation of the potential donor and the organ recovery in a compressed period of time. Aspects of LD-PPW could be similar to DCD which is required to be coordinated by the OPO.

d) As currently envisioned, responsibility for the informed consent of the donor surrogate and medical evaluation of the potential LD-PPW donor would remain the responsibility of the medical staff that could perform the nephrectomy.

e) If the potential donor is a LD-PPW candidate, the OPO could take responsibility for approaching the donor’s surrogate to first evaluate the candidate as a potential DCD donor. If the potential living donor does not meet DCD criteria (including the possibility that the family expresses preference for LD-PPW), the OPO could discuss LD-PPW with the donor’s surrogates.

f) As described, the OPO could need to coordinate allocation of the donated kidney to the deceased donor waitlist. Under this scenario, the roles and responsibilities of the recovery hospital and the OPO would need to be carefully delineated.

g) The OPTN/UNOS and Centers for Medicaid and Medicare Services (CMS) could need to segregate outcome data from LD-PPW so that the anticipated death after donation would not be characterized as a living donor death which could negatively impact living donor programs’ outcome metrics.

h) OPTN policy that covers living donation, including informed consent, medical evaluation, psychosocial evaluation, follow-up, and required reporting of living donor death, would need to be reviewed and modified to accommodate LD-PPW.
There is a lack of relevant or predictive data concerning LD-PPW and its potential impact on the total number of organs that could be made available for transplant.

**Potential Benefits:**

The work group identified potential benefits of LD-PPW to organ recipients, donor families and donor hospitals including, but not limited to:

- Potential for increased availability of organs for transplantation; non-progression during attempted DCD results in hundreds or thousands of non-donated organs each year.
- Reduced organ ischemic time with better recipient outcomes (less delayed graft failure).
- Fulfilling the patient’s previously indicated or documented decision to be a donor.
- Emotional benefit to donor family’s grief process through the increased potential of LD-PPW donation versus DCD. In some cases, the LD-PPW has been requested and driven by donor families.
- Better process and timing for some families than DCD.
- Avoiding wasted hospital resources and reducing costs and staff frustration that may follow when DCD does not occur.

**Potential Harms:**

The work group recognized that the controversy over LD-PPW has the potential to erode public trust in donation in general. There could be a misperception that families will be under undue pressure to donate organs prior to the patient’s death and withdraw ventilator support in circumstances where a patient would otherwise recover. This potential harm needs to be carefully considered. Clear requirements for when LD-PPW could proceed could help address this concern.

Finally, as described above, LD-PPW would be performed in circumstances where a thorough evaluation has determined that the potential donor’s neurological injury is severe and unlikely to reverse. Despite this evaluation, it is possible that, rarely, an individual might still be capable of neurologic recovery and survive withdrawal of life support. That individual’s long-term health might be harmed by organ procurement. A recent cohort study of 136 attempted DCD cases reported one individual who survived withdrawal of mechanical life support and was alive 1.5 years later. Minimal information was available about the circumstances of this attempted DCD. To guard against this type of situation, OPTN policy might require that certain standards for neurological prognosis be met before LD-PPW was permitted.

**Potential Unintended Consequences:**

The field is not very accurate in predicting whether potential DCD donors will become actual donors. If a potential donor does meet DCD criteria, that donor could potentially donate two kidneys and other organs. Therefore, it is possible that LD-PPW, in which only a single kidney is recovered, could negatively impact the current volume of organs available for transplant. The possibility of offering LD-PPW followed by DCD might mitigate this negative impact. If LD-PPW was viewed as an alternative to DCD or a preferred pathway to DCD (rather than an additional option when DCD is not viable), it could...
result in a single kidney available for transplant compared to the potential for two kidneys and other organs that might be recovered under DCD protocols.

10. Feedback from other Committees:

In each case, the committees did not necessarily come to a consensus, but provided responses to the proposal that included viewpoints of individual or multiple members.

- LD-PPW may violate the Dead Donor Rule.
- The risk to public trust in the organ donation system outweighs the potential increase in the number of transplants through LD-PPW. Myths, misperceptions, and lack of education about brain death already inhibit donation in the general public. The LD-PPW concept is complex, which may compound problems with public trust in it.
- In particular, LD-PPW might negatively impact organ donation in minority communities that may already distrust the medical system.
- It is not clear which potential donors would be suitable for LD-PPW. It may be necessary to establish objective clinical criteria or parameters for a potential donor who would be evaluated for LD-PPW, especially criteria addressing the degree of neurologic damage because the potential donor would not meet brain death criteria.
- After the process of evaluation of LD-PPW has begun, the transplant team may decline a donor and an unfulfilled donation request could worsen the family grieving process.
- There is an unmet need to understand the potential impact on the number of organs available for transplant with LD-PPW vs. existing practice. If research does not demonstrate the potential for significantly increasing the number of organs available with the practice of LD-PPW, it may not be worth further efforts to develop this practice.

**Conclusion**

The Committee initially determined that there could be circumstances where LD-PPW may be ethically appropriate and justified by the potential benefits to donors, donor families and recipients. However, based on the responses and substantial concerns from nine other Committees, the Ethics Committee decided to discontinue work on LD-PPW at this time, due to its potential risks, the lack of community support and substantial challenges to implementation. In the future, it may be possible to adequately address those challenges through additional research, careful policy development or revision.

**References**


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