

Ethical Considerations of Imminent Death Donation

OPTN/UNOS Ethics Committee

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Affected Policies: N/A
Sponsoring Committee: Ethics
Public Comment Period: August 15, 2016 – October 15, 2016

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

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 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.

Is the sponsoring Committee requesting specific feedback or input about this resource?

The Committee is seeking feedback concerning if there could be circumstances where IDD may be ethically appropriate and justified by the potential benefits to donors, donor families and recipients.

Does the risk for the erosion of public trust in the organ donation system outweigh the potential for IDD to increase in the number of organs available for transplant?

What problem will this resource solve?

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 when the potential donor does not meet brain death criteria and is not considered to be a candidate for DCD.

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.

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 Morrissey PE. The case for kidney donation before end-of-life care. *The American journal of bioethics* : AJOB. 2012;12(6):1-8.

- (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. 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 injury². 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 attempted³. 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 uncertain⁴. Occurrences of unsuccessful DCD may be viewed as both a lost opportunity for transplantation, as well as disappointing to the surrogates of the potential donor⁵. 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 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 US⁶. 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

² Rakke YS, Zuidema WC, Hilhorst MT, et al. Seriously ill patients as living unspecified kidney donors: rationale and justification. *Transplantation*. Jan 2015;99(1):232-235.

³ Scalea JR, Redfield RR, Rizzari MD, et al. When Do DCD Donors Die? Outcomes and Implications of DCD at a High-volume, Single-center OPO in the United States. *Annals of surgery*. Jul 15 2015

⁴ Rabinstein AA, Yee AH, Mandrekar J, et al. Prediction of potential for organ donation after cardiac death in patients in neurocritical state: a prospective observational study. *The Lancet. Neurology*. May 2012;11(5):414-419.

⁵ DeOliveira ML, Jassem W, Valente R, et al. Biliary complications after liver transplantation using grafts from donors after cardiac death: results from a matched control study in a single large volume center. *Annals of surgery*. Nov 2011;254(5):716-722; discussion 722-713.

⁶ Truog RD, Miller FG, Halpern SD. The dead-donor rule and the future of organ donation. *The New England journal of medicine*. Oct 3 2013;369(14):1287-1289

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.

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 decided to discontinue work on LD-PPW because it is not worth the 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.

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.

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?

Increase the number of transplants: There is no impact to this goal.
Improve equity in access to transplants: There is no impact to this goal.
Improve waitlisted patient, living donor, and transplant recipient outcomes: There is no impact to this goal.
Promote living donor and transplant recipient safety: There is no impact to this goal.
Promote the efficient management of the OPTN: There is no impact to this goal.

How will the OPTN implement this resource?

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

This resource will not require programming in UNetSM.

How will members implement this resource?

Members will be able to 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.

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:

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- (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);
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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.

37 However, at this time, a lack of data renders the work group unable to conclude whether the net number
38 of transplants might decline or increase if LD-PPW were widely adopted. The effect on the number of
39 transplants may depend, to a substantial degree, on how many organs are typically procured through the
40 practice of LD-PPW. LD-PPW might increase the number of donated organs and transplants if organs were
41 procured from donors who would not have been considered for organ donation if DCD were the only option, or
42 if LD-PPW took place in conjunction with DCD.

43 After the transplant community considered possible intended and unintended consequences, and if
44 analysis supported LD-PPW as an ethically acceptable practice, then OPTN bylaws and policy would
45 need modification to accommodate LD-PPW. Additionally, it would be important to determine if LD-PPW
46 would violate any regulations from the Centers for Medicare and Medicaid Services or any other relevant
47 laws or guidelines.

48 **Background:**

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

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

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

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

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

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

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

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

87 **Analysis:**

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

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

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

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

- 101 a) The ability to donate a single kidney, while not risk-free, is routinely performed in living donors
102 and the attendant risks of death have been considered acceptable. However, because the LD-
103 PPW candidate is critically ill, there may be heightened concerns that a nephrectomy could
104 hasten death (as compared to the healthy living kidney donor).
- 105 b) If the donor died due to procurement of a kidney (or other organs), this could be viewed as a
106 violation of the Dead Donor Rule. The doctrine of double effect could help address this concern.
- 107 c) The doctrine (or principle) of double effect is often invoked to explain the permissibility of an
108 action that causes a serious harm, such as the death of a human being, as a side effect of
109 promoting some good end. However, this doctrine is not universally accepted.

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

115 2. Appropriateness of surrogate consent for LD-PPW

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

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

126 a) The potential donor had previously expressed a desire or had taken prior action towards
127 becoming a living donor. Prior action could include expressed wishes, documented evidence,
128 or prior evaluation for living organ donation. Evidence of this would show the patient's intent
129 to be a living donor and could be considered as part of a substituted judgment.

130 The substituted-judgment doctrine is a principle that allows a surrogate decision-maker to
131 attempt to establish, with as much accuracy as possible, what decision an incompetent
132 patient would make if he or she were competent to do so. In theory, the doctrine of
133 substituted judgment looks to the individual to determine what he or she would do in a
134 particular situation if she were competent. This doctrine is applicable to situations where a
135 person, once competent, is rendered incompetent to consent to medical procedures through
136 injury or disease. The once competent person had developed a system of morals and
137 beliefs, and patterns of behavior, which the court can examine when evaluating what he or
138 she might (or would likely) do in a particular situation.

139 b) The potential donor had registered to be a deceased donor or expressed the desire to be a
140 deceased donor. While authorizing deceased donation is not ethically or legally equivalent to
141 consent for living donation, the fact that the patient wanted to be an organ donor could be
142 relevant to a substituted judgment analysis.

143 c) It is important that the decision-maker be an appropriate surrogate for the patient. This
144 principle is generally well established by law and hospital policy. In the context of LD-PPW,
145 there is already a surrogate making the decision to withdraw the mechanical support (with
146 death an expected outcome). Additional criteria could be developed to establish

- 147 requirements that the surrogate knew the background and values of the patient relating to
148 donation. One possibility is, as a matter of OPTN policy, to limit surrogate consent for LD-
149 PPW to an appointed durable power of attorney or health care proxy. However, others
150 questioned why durable power of attorney or health care proxy status would be appropriate,
151 if they were not required for the surrogate to make the decision to withdraw support.
- 152 d) Parameters for surrogate consent in cases of potential pediatric donors need to be
153 established. As an alternative, LD-PPW could be limited to adult patients. In the pediatric
154 context, the best interest standard is commonly utilized rather than substituted judgment as
155 the patient may be too young to have formed values or wishes relevant to donation. Also, in
156 most circumstances there will not be a health care proxy agent or power of attorney.
157 Alternatively, a guardian ad litem could be appointed although again this would add a
158 significant step beyond what is required for the parents to consent to withdrawal of ventilator
159 support.
- 160 e) For initial cases of LD-PPW, an ethics consultation could add value to assess the adequacy
161 of the surrogate and to assist in ensuring a surrogate decision for LD-PPW is ethically
162 appropriate given the specifics of a case.

163 3. LD-PPW Candidates as a Vulnerable Population.

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

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

173 4. Identifying appropriate candidates for LD-PPW.

- 174 b) Families or surrogates should not be approached regarding LD-PPW as an option until
175 withdrawal of support had been discussed and planned to occur within a relatively short
176 period of time (within days, not weeks).
- 177 c) The work group discussed the importance and difficulty of assessing the probability of death
178 after planned withdrawal of life support on a case-by-case basis.
- 179 d) The work group discussed options for presenting LD-PPW and reconciling the practices of
180 LD-PPW and DCD. The decision to withdraw life support must be separated from the
181 discussion of the options for donation, just as has been established for DCD. After the
182 decision to withdraw life support is made, several approaches to discussing LD-PPW could
183 be considered:

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

194 5. Public Trust.

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

201 6. Operational / practical / policy considerations.

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

- 204 a) Much of the policy and clinical practice of living donor evaluation is focused on establishing that
205 the long-term risks of donation to the donor’s health are reasonable in relation to the benefits to
206 be gained (i.e. health benefits for the recipient and non-medical benefits for some donors), and
207 that the donor has a thorough understanding of the potential risks and benefits of the donation
208 decision. However, neither of those considerations pertains to the LD-PPW scenario. In this
209 scenario, the potential donor is not expected to have long-term survival. The potential donor does
210 not have the ability to participate in medical decision-making. The surrogate’s decisions about
211 organ donation may be primarily viewed from the perspective of appropriate end-of-life care,
212 rather than weighing adverse long-term health effects due to organ procurement. Given these
213 distinctions between the existing practice of live organ donation versus LD-PPW, some OPTN
214 policy related to living donation (as it applied to LD-PPW) would merit revision if LD-PPW were to
215 be more widely adopted.
- 216 b) As currently considered, LD-PPW could only occur in an OPTN member hospital. This is because
217 OPTN policy restricts recovery of living donor organs to OPTN member transplant centers. .Also,
218 transplant surgeons cannot travel to a different hospital to perform a living donor nephrectomy
219 given medical licensure and credentialing requirements under applicable state law and hospital
220 policy. Accordingly, in some cases, an LD-PPW candidate would need to be transferred to an

221 OPTN member hospital to facilitate organ recovery. Transferring a LD-PPW candidate would add a
222 significant step beyond what is required for the candidate's family or surrogate to consent to
223 withdrawal of ventilator support. There would be significant costs and logistical challenges to
224 moving a patient from the primary donation hospital to a transplant center. Other stakeholders,
225 such as anesthesia providers and hospital administrators responsible for allocation of scarce
226 resources such as ICU beds and operating room suites would also need to be engaged.

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

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

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

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

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

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

250 h) OPTN policy that covers living donation, including informed consent, medical evaluation,
251 psychosocial evaluation, follow-up, and required reporting of living donor death, would need to
252 be reviewed and modified to accommodate LD-PPW.

253 i) There is a lack of relevant or predictive data concerning LD-PPW and its potential impact on
254 the total number of organs that could be made available for transplant.

255 7. Potential Benefits:

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

- 258 • Potential for increased availability of organs for transplantation; non-progression during
259 attempted DCD results in hundreds or thousands of non-donated organs each year³
- 260 • Reduced organ ischemic time with better recipient outcomes (less delayed graft failure)
- 261 • Fulfilling the patient's previously indicated or documented decision to be a donor
- 262 • Emotional benefit to donor family's grief process through the increased potential of
263 LD-PPW donation versus DCD. In some cases, the LD-PPW has been requested
264 and driven by donor families.
- 265 • Better process and timing for some families than DCD
- 266 • Avoiding wasted hospital resources and reducing costs and staff frustration that may follow
267 when DCD does not occur

268 8. Potential Harms:

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

274 Finally, as described above, LD-PPW would be performed in circumstances where a thorough evaluation
275 has determined that the potential donor's neurological injury is severe and unlikely to reverse. Despite
276 this evaluation, it is possible that, rarely, an individual might still be capable of neurologic recovery and
277 survive withdrawal of life support.³ That individual's long-term health might be harmed by organ
278 procurement. A recent cohort study of 136 attempted DCD cases reported one individual who survived
279 withdrawal of mechanical life support and was alive 1.5 years later. Minimal information was available
280 about the circumstances of this attempted DCD. To guard against this type of situation, OPTN policy
281 might require that certain standards for neurological prognosis be met before LD-PPW was permitted.

282 9. Potential Unintended Consequences:

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

291 10. Feedback from other Committees:

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

- 294 • LD-PPW may violate the Dead Donor Rule.

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

311 **Conclusion**

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

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