

# Public Comment Proposal

## Split Liver Variance

*OPTN/UNOS Liver and Intestinal Transplantation Committee*

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# Split Liver Variance

*Affected Policies:* 9.11 Variances for Segmental Liver Transplantation  
*Sponsoring Committee:* Liver and Intestinal Transplantation Committee  
*Public Comment Period:* January 22, 2019 – March 22, 2019

## Executive Summary

This proposal would create a variance to permit participating liver programs to split a liver and transplant the first segment into the candidate to whom it was allocated, and then transplant the remaining segment into another candidate at the same transplant hospital or an affiliated hospital after offering the remaining segment to the most urgent candidates within 500 nautical miles. The goal is to increase the number of livers that are split and thereby increase the number of liver transplants available from the same donor pool. It aims to reduce the logistical and technical challenges currently associated with splitting a liver. The variance would be used to determine whether it would in fact increase the number of transplants by increasing the number of livers that are split.

This variance was initially proposed by transplant hospitals and OPOs in region eight, who requested it as a regional variance. However, transplant hospitals in other regions expressed interest, and the Committee proposes that this be an open variance that other OPTN/UNOS members can also join.

## Is the sponsoring Committee requesting specific feedback or input about the proposal?

The Committee encourages all interested individuals to comment on the proposal in its entirety. Members are asked to comment on both the immediate and long-term impact on budgets and other resources that may be required if this proposal is approved; this information assists the Board in considering the proposal and its impact on the community. The Committee requests specific feedback on the following items:

1. Members are asked to comment on whether this variance should only be available to region eight, or if it should be available to other OPTN/UNOS members that would like to participate.
2. Members are also asked to comment on whether they would be interested in participating in this variance so that the Committee can gauge the level of interest in the variance.

## What problem will this proposal address?

As of December 14, 2018, there are 13,551 liver candidates listed and awaiting transplant.<sup>1</sup> In 2017, there were 8,740 liver donors.<sup>2</sup> Because there are not enough livers donated to meet the demand for liver transplantation, 1,217 candidates died while awaiting liver transplant in 2017.<sup>3</sup> Part of the OPTN/UNOS Strategic Plan for 2018-2021 is to increase the number of transplants.<sup>4</sup>

One way to increase the number of transplants is to split livers. Split liver transplantation (SLT) increases the number of transplants from the same donor pool by “creating two partial grafts from one donor organ which can be given to two recipients”.<sup>5</sup> The OPTN/UNOS match run identifies a donor liver as having the potential to be split if all of the following criteria are met:

1. Donor is less than 40 years old
2. Donor is on a single vasopressor or less
3. Donor transaminases are no greater than three times the normal level
4. Donor mass index (BMI) is 28 or less.<sup>6,7</sup>

More than 10% of all deceased donors meet these criteria, but less than 1.5% of donor livers have been split since the adoption of these criteria in 2010.<sup>8</sup> OPTN/UNOS published a White Paper in 2016 supporting consideration of a change in allocation policy to facilitate SLT so that the left-lateral segment or extended right lobe is allocated to the first candidate and the remaining liver segment is allocated to a second candidate.<sup>9</sup>

However, there are challenges specific to SLT. The recovery and the transplant are both more complex procedures than recovery and transplantation of a whole liver, requiring detailed knowledge of liver anatomy and expertise in hepatobiliary surgery<sup>10</sup>, and not all transplant hospitals have the expertise or willingness to perform SLT. In 2017, only 54 liver programs performed any SLT<sup>11</sup>. There are additional challenges in coordinating SLT when two different surgical teams are involved and the recipients are at different transplant hospitals.

Livers are split both in situ and ex vivo. In situ splitting can increase intraoperative time and increase the risk of impacting extrahepatic organ retrieval teams or causing the donor to become hemodynamically compromised.<sup>12</sup> Case coordination is further complicated when the intended recipients are at two different hospitals. It is likely that the transplant teams from both hospitals will want to participate in the recovery<sup>13</sup>, which can delay the donor recovery time and increase the amount of time required for the recovery procedure. When splitting occurs ex vivo in a recipient’s hospital and the other graft must be transported to a secondary transplant hospital, it adds cold ischemic time for the second segment.<sup>14</sup> In addition to

<sup>1</sup> OPTN data. <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data> (Accessed December 14, 2018)

<sup>2</sup> There were 367 living liver donors and 8,373 deceased liver donors in 2017. OPTN data. <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data> (Accessed December 14, 2018)

<sup>3</sup> OPTN data. <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data> (Accessed December 14, 2018)

<sup>4</sup> The OPTN Strategic Plan is a roadmap to help prioritize major initiatives of the OPTN over a three-year period. It was approved by the OPTN Board of Directors in June 2018. OPTN Strategic Plan 2018-2021. [https://optn.transplant.hrsa.gov/media/2546/optn\\_unos\\_strategic\\_plan.pdf](https://optn.transplant.hrsa.gov/media/2546/optn_unos_strategic_plan.pdf) (Accessed December 14, 2018)

<sup>5</sup> Jason Wertheim, Henrik Petrowsky, Sammy Saab, Jerzy Kupiec-Weglinski, and Ronald Busittil, “Major Challenges Limiting Liver Transplantation in the United States”, *Am J Transplant*, 2011 Sep; 11(9): 1773-1784

<sup>6</sup> OPTN Policy 9.6.A: Segmental Transplant and Allocation of Liver Segments.

[https://optn.transplant.hrsa.gov/media/1200/optn\\_policies.pdf](https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf) (Accessed January 17, 2019)

<sup>7</sup> OPTN Split Versus Whole Liver Transplantation, OPTN Ethics Committee.

<sup>8</sup> OPTN Split Versus Whole Liver Transplantation, OPTN Ethics Committee.

<sup>9</sup> OPTN Split Versus Whole Liver Transplantation, OPTN Ethics Committee.

<sup>10</sup> Wertheim, et al., “Major Challenges Limiting Liver Transplantation in the United States”.

<sup>11</sup> This is approximately 1/3 of the 143 active liver programs during the same year. Based on OPTN data as of December 7, 2018.

<sup>12</sup> OPTN Split Versus Whole Liver Transplantation, OPTN Ethics Committee.

<sup>13</sup> OPTN Split Versus Whole Liver Transplantation, OPTN Ethics Committee.

<sup>14</sup> Wertheim, et al., “Major Challenges Limiting Liver Transplantation in the United States”.

recovery and transportation logistics, there are clinical decisions that must be coordinated between the two transplant teams, such as who has priority deciding the splitting technique and how the blood supply and bile duct will be shared, as well as a backup plan in the event that the SLT is aborted late in the process.<sup>15</sup> Although these decisions are most often made by the transplant team for the initial candidate, the ideal technique for the initial candidate may not be the best technique for ensuring that both segments have the best outcomes.<sup>16</sup>

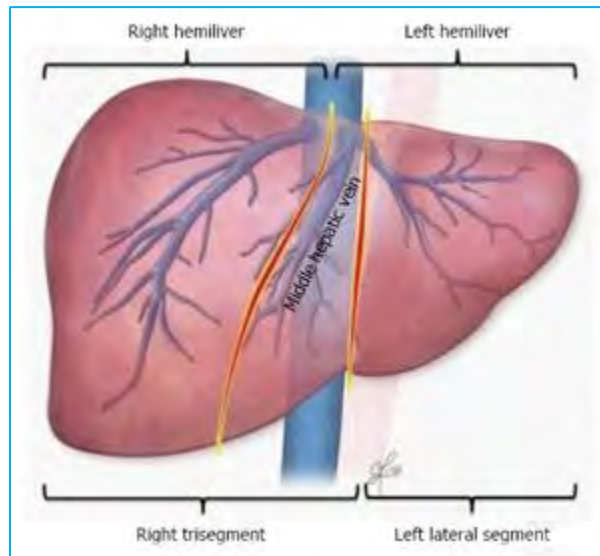
## Why should you support this proposal?

This proposal is a variance to investigate whether allowing a transplant hospital to allocate the second transplantable segment of a split liver to another potential recipient registered at the same transplant hospital or an affiliated hospital will incentivize splitting livers and increase the number of candidates transplanted with the same number of livers. If the Committee's hypothesis is correct, this will increase the number of liver transplants and net survival for waitlisted candidates.<sup>17</sup>

## How was this proposal developed?

SLT is typically performed by splitting a whole liver into a left-lateral segment and a right tri-segment.<sup>18,19</sup> The left lateral segment is smaller, and typically transplanted into pediatric candidates and the larger right right tri-segment is typically transplanted into an adult or larger pediatric candidate. It is less commonly split into right hemiliver and left hemiliver.<sup>20</sup>

Figure 1: Graft types for SLT<sup>21</sup>



<sup>15</sup> OPTN Split Versus Whole Liver Transplantation, OPTN Ethics Committee.

<sup>16</sup> Koji Hashimoto, Mastato Fujiki, Cristiano Quintini, Federico Aucejo, Teresa Diago Uso, Dymrna Keey, Bijan Eghtesad, John Fung, Charles Miller, "Split Liver Transplantation in Adults", *World J Gastroenterol*, 2016 Sep 7; 22(33): 7500-7506.

<sup>17</sup> OPTN Split Versus Whole Liver Transplantation, OPTN Ethics Committee.

<sup>18</sup> Wertheim, et al., "Major Challenges Limiting Liver Transplantation in the United States".

<sup>19</sup> Hashimoto, et al., "Split Liver Transplantation in Adults".

<sup>20</sup> Splitting the liver into right tri-segment and left lateral segment allows for avoiding multiple small branches and reduces the surgical complexity compared to splitting into hemi-liver segments. Hashimoto, et al., "Split Liver Transplantation in Adults".

<sup>21</sup> Hashimoto, et al., "Split Liver Transplantation in Adults".

There is an existing open variance under which participating centers can choose to split a liver and utilize either the right lobe (right hemiliver) or the right tri-segment in the patient to whom that liver was allocated and then use the left hemiliver or the left lateral segment for another candidate at the same center or an affiliated pediatric center.<sup>22,23</sup> The Committee reviewed data on the existing variance at its meeting on March 29, 2018<sup>24</sup>. There are currently four OPOs and one region participating in the existing variance. Only four of the split liver transplants performed between the 2010 implementation of the variance and December 31, 2017 appear to have been allocated using the existing open variance.<sup>25</sup>

The purpose of the existing split liver variance was to incentivize SLT when livers are initially allocated to adult candidates, in order to create more left lateral segments for pediatric transplants. Since there have only been four transplants that may have fallen under the current split liver variance in seven years<sup>26</sup>, any impact on this goal has been minimal. Part of the reason for this may be that initial results showed SLT using the right tri-segment had an increased risk of morbidity and mortality in adult recipients.<sup>27,28,29</sup> Outcomes have improved with experience, but because of the procedure's complexity, the incidence of complications can be higher for right tri-segment grafts.<sup>30</sup> However, when risk factors, including longer ischemic times, are avoided, right tri-segments are no longer considered marginal by experienced centers.<sup>31,32,33</sup> The Committee hypothesized that a transplant program would be more likely to perform SLTs if it was able to primarily transplant the left lateral segment and also use the remaining right lateral segment at their center, as data supports better outcomes associated with right tri-segments.

A member of the Committee from region eight championed the idea that allowing both segments of split livers to be transplanted at the same center, regardless of which segment was transplanted in the first

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<sup>22</sup> *Proposed Committee-Sponsored Alternative Allocation System (CAS) for Split Liver Allocation*, OPTN Liver and Intestinal Organ Transplantation Committee, December 2018.

<sup>23</sup> OPTN Policy 9.11.A: Open Variance for Segmental Liver Transplantation (approved but not yet implemented). "Under this variance, a transplant program may offer the remaining left lobe or left-lateral segment into a different, medically suitable, potential recipient registered at the same transplant hospital or an affiliated pediatric institution instead of offering the remaining segment to potential recipients at other transplant programs. The transplant program must determine potential recipient for the second segment by using the same match run used to allocate the right lobe or tri-segment. Additionally, the transplant program must document all refusals of potential transplant recipients that are prioritized ahead of the potential transplant recipient that received the second segment."

OPTN Policy 9.9.A: Open Variance for Segmental Liver Transplantation.  
[https://optn.transplant.hrsa.gov/media/1200/optn\\_policies.pdf](https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf) (Accessed January 17, 2019).

<sup>24</sup> Meeting Summary for March 29, 2018 meeting, OPTN Liver and Intestinal Organ Transplantation Committee, [https://optn.transplant.hrsa.gov/media/2498/20180329\\_liver\\_meetingsummary.pdf](https://optn.transplant.hrsa.gov/media/2498/20180329_liver_meetingsummary.pdf) (Accessed December 14, 2018).

<sup>25</sup> S. Noreen and T. Baker, Evaluation of Open Variance for Segmental Liver Transplantation, OPTN Liver and Intestinal Transplantation Committee Meeting, March 29, 2018.

<sup>26</sup> S. Noreen and T. Baker, Evaluation of Open Variance for Segmental Liver Transplantation, OPTN Liver and Intestinal Transplantation Committee Meeting, March 29, 2018.

<sup>27</sup> Hashimoto, et al., "Split Liver Transplantation in Adults".

<sup>28</sup> J. Emond, P. Whittington, J. Thistlethwaite, D. Cherqui, E. Alonso, I. Woodle, P. Vogelbach, S. Busse-Henry, A. Tucker, and C. Broelsch, *Transplantation of Two Patients with One Liver: Analysis of a Preliminary Experience with "Split Liver" Grafting*, *Ann Surg.*, 1990, Jul; 212(1): 14-22.

<sup>29</sup> C. Broelsch, J. Emond, P. Whittington, J. Thistlethwaite, A. Baker, and J. Lichor, *Application of Reduced-Size Liver Transplants as Split Grafts, Auxiliary Orthotopic Grafts, and Living Related Segmental Transplants*, *Ann Surg.*, 1990 Sep; 212(3): 368-377.

<sup>30</sup> Hashimoto, et al., "Split Liver Transplantation in Adults".

<sup>31</sup> Hashimoto, et al., "Split Liver Transplantation in Adults".

<sup>32</sup> V. Corno, M. Colledan, M. Dezza, M. Guizzetti, A. Lucianetti, G. Maldini, D. Pinelli, M. Giovanelli, M. Zambelli, G. Torre, et al. "Extended Right Split Liver Graft for Primary Transplantation in Children and Adults", *Transpl Int.* 2006;19:492-499.

<sup>33</sup> U. Maggi, T. De Feo, E. Andorno, U. Cillo, L. De Carlis, M. Colledan, P. Burra, N. De Fazio, G. Rossi, "Fifteen Years and 382 Extended Right Grafts from *in situ* Split Livers in a Multicenter Study: Are These Still Extended Criteria Liver Grafts?" *Liver Transpl.* 2015;21:500-511.

recipient, would increase split liver transplantation<sup>34</sup>, and gathered support from others to test the idea with a variance in region eight. Transplant hospitals and OPOs in region eight unanimously agreed in early 2018 to request a variance for the transplantation of split livers that would allow participating programs more opportunities to transplant both segments at the same center.

The variance as proposed would permit participating transplant hospitals to split a liver and use any segment of the liver for the patient the liver was allocated to and then use the remaining segment for another candidate at their center or an affiliated hospital after it was offered to candidates on the match run classifications for Status 1 or with a model for end-stage liver disease (MELD) or pediatric end-stage liver disease (PELD) score of 33 or higher at liver transplant programs within 500 nautical miles of the donor hospital.

The Committee discussed the scope of the variance and whether this should be an open or closed variance. An open variance permits members across the country who meet the requirements of the variance to apply and join the variance.<sup>35, 36</sup> A closed variance contains specific limitations for participation and does not allow other members to apply to join it. The variance as originally proposed by region eight was a closed variance that only applied to members in region eight. At the December 3, 2018 OPTN/UNOS Board of Directors (Board) meeting, an amendment to the policy to Eliminate the use of DSAs and Regions in Liver Allocation was offered by a member of the Board.<sup>37</sup> The amendment would have created an open variance that would have allowed any participating liver transplant hospital to split an allocated liver, and transplant the first liver segment into the candidate to whom the organ was allocated, while transplanting the second liver segment to a candidate registered at the same transplant program. After some discussion by the Board, the amendment was voluntarily withdrawn by the sponsor with a request that the Committee consider broadening the concept of a variance for region eight to permit other members to join. Following the Board meeting, the Committee discussed this scope and agreed that the variance should be released as an open variance. Although the Committee is currently recommending an open variance, the Committee is seeking feedback on whether this is best as an open or closed variance.

## Variance Requirements

All variances are required to meet the requirements contained in OPTN/UNOS Policy<sup>38</sup> and the Final Rule<sup>39</sup>. The Final Rule requires that the variance be accompanied by a research method, include data collection and analysis plans, and be time limited.<sup>40</sup> The Final Rule also requires that variances to improve allocation must be developed “in accordance with §121.4”, which in turn incorporates the requirements in §121.8 that allocation policies “(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;...(8) Shall not be based on the candidate’s place of residence or place of listing, except

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<sup>34</sup> “More widespread use of split liver transplantation could be encouraged by allocating both liver segments to the same transplant center.” Leigh Anne Dageforde and William Chapman, “Split Liver Grafts Can Benefit Both Pediatric and Adult Liver Transplants Recipients and Programs”, *Pediatric Transplant*, 2017; 21: e12934.

<sup>35</sup> Compare OPTN Policy 1.1 “Closed Variance” and “Open Variance.”

<sup>36</sup> OPTN Policy 15.7: *Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors* is an example of an open variance.

<sup>37</sup> OPTN Board of Directors Meeting Transcript, Dallas, TX, December 3-4, 2018.

[https://optn.transplant.hrsa.gov/media/2767/board\\_liver\\_discussion\\_transcript\\_201812.pdf](https://optn.transplant.hrsa.gov/media/2767/board_liver_discussion_transcript_201812.pdf) (Accessed December 21, 2018).

<sup>38</sup> OPTN Policy 1.3 Variances

<sup>39</sup> 42 C.F.R. § 121.8(g)

<sup>40</sup> 42 C.F.R. § 121.8(g)

to the extent required by paragraphs (a)(1)-(5) of this section.” This proposal meets the requirements of the Final Rule.

1. *Sound Medical Judgment:* The Committee proposes the variance based on sound medical judgment, including literature that supports potential positive outcomes from SLT for more candidates and donors than it is currently used for<sup>41</sup>, and that some of the challenges of SLT can be reduced when both segments are transplanted at the same program, or closely affiliated programs<sup>42</sup>. The variance is being used to test the theory that permitting more segments to remain at the same program will increase SLT, and the outcomes from the variance will be carefully considered to inform whether this should become policy for the nation.
2. *Best Use of Donated Organs:* The Committee believes that maximizing the gift of organ donation by using each donated organ to its maximum potential achieves the best use of donated organs. This variance seeks to achieve the best use of donated organs by encouraging SLT, which will result in two transplants from one donated organ.
3. *Preserve Ability to Decline an Offer:* This does not affect the ability of a transplant program to decline an offer.
4. *Specific to Organ Type:* This proposed variance is specific to an organ type. In this case, the proposed variance is specific to the allocation of deceased donor livers.
5. *Avoid Wasting Organs:* Under the current policy, it is possible that partial livers are being used and the remaining segment is not being transplanted.<sup>43</sup> This is viewed by the Committee as an example of organ wastage. The variance is designed to avoid wasting organs by encouraging the transplantation of both liver segments.  
*Avoid Futile Transplants:* A futile transplant may occur if a recipient is transplanted with an organ that does not continue to function soon after transplantation. This proposed variance does not incentivize futile transplants. Transplantation of both segments of a liver can result in successful post-transplant outcomes.<sup>44,45,46</sup>  
*Promote Patient Access to Transplantation:* This proposal promotes liver candidate access to transplants by increasing the total overall number of livers available for transplant. Additionally, this proposal is likely to result in better pediatric patient access to liver transplantation, because when a liver is split, at least one of the segments is typically used for a pediatric patient.<sup>47</sup>  
*Promote Efficient Management of Organ Placement:* A proposal that reduces logistical complications associated with procuring an organ and transporting it from the donor to the candidate promotes efficient management of organ placement. This proposed variance promotes the efficient management of organ placement by reducing the transportation and coordination required in SLT cases by more specifically detailing when a transplant program can allocate the remaining segment to a candidate at the same transplant program.
8. *Geographic Considerations:* A proposed variance may be based in a candidate’s residence or place of listing only to the extent required to achieve the considerations listed above. This proposed variance considers geography with regard to the distribution of the remaining segment. The Committee proposed allocating the remaining segment to the most urgent candidates within 500 NM of the donor before the transplant program can allocate it to a candidate at its own program or affiliated program. The Committee decided to limit the allocation of the remaining segment to these proximate, urgent candidates in order to achieve the goals stated above, particularly making best use of donated organs, avoiding organ wastage, promoting access to transplantation, and efficient management of organ placement. The Committee determined that the liver is more likely to be split if the remaining segment will be transplanted by the transplant

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<sup>41</sup> OPTN Split Versus Whole Liver Transplantation, OPTN Ethics Committee.

<sup>42</sup> Wertheim, et al., “Major Challenges Limiting Liver Transplantation in the United States”.

<sup>43</sup> OPTN Split Versus Whole Liver Transplantation, OPTN Ethics Committee.

<sup>44</sup> Hashimoto, et al., “Split Liver Transplantation in Adults”.

<sup>45</sup> V. Corno, et al. “Extended Right Split Liver Graft for Primary Transplantation in Children and Adults”.

<sup>46</sup> U. Maggi, et al., “Fifteen Years and 382 Extended Right Grafts from *in situ* Split Livers in a Multicenter Study: Are These Still Extended Criteria Liver Grafts?”

<sup>47</sup> V. Corno, et al. “Extended Right Split Liver Graft for Primary Transplantation in Children and Adults”.

program that is performing the split<sup>48</sup>, therefore limiting the distance through which the remaining segment is offered is necessary to achieve the best use of donated organs as well as to avoid organ wastage. Likewise, as this would result in more SLTs, limiting the distance through which the remaining segment is offered will promote patient, particularly pediatric and small adult patient, access to transplantation.<sup>49</sup> Finally, it would be inefficient to require the remaining segment to be offered according to the entire match run. It is difficult to find candidates to accept the remaining segment<sup>50</sup>, and requiring an exhaustion of the match run would likely result in more organ wastage, as a candidate would be less likely to be identified. The time required to do so, as well as the time required to transport the remaining segment from the donor to that candidate, would also likely result in more organ wastage, as there may be too much cold ischemic time on the organ at the point that it makes it to its final destination.<sup>51</sup>

This proposed variance is not otherwise based in a candidate's place of residence or place of listing. A transplant program can determine whether it wishes to join the variance, and there is no geographic restriction for programs that wish to join.

OPTN/UNOS Policy requires that proposed variances include:

1. The purpose for the proposed variance and how the variance will further this purpose.
2. If a member's application to create, amend, or join a variance will require other members to join the variance, the applicant must solicit their support. Committees will not review a member's variance application unless the applicant receives affirmative support from at least 75% of the members required to join the proposed variance.
3. A defined expiration date or period of time when the variance will end, the participating members will report results, and the sponsoring Committee will evaluate the impact of the variance.
4. An evaluation plan with objective criteria to measure the variance's success achieving the variance's stated purpose.
5. Any anticipated difficulties in demonstrating whether the variance is achieving its stated purpose.
6. Whether this is an open variance or closed variance and, if this is an open variance, any additional conditions for members to join this variance<sup>52</sup>

### 1. Purpose

The purpose of this variance is to encourage SLT, as discussed further below in *How well does this proposal address the problem statement?*

### 2. Member Support

The members of region eight specifically asked for the creation of this variance. All of the liver transplant hospitals and OPOs in region eight expressed their affirmative support for the variance to apply to region eight. After the Committee received the letter of support from the members in the region, the Committee reviewed the variance application and proposed this open variance, which would also allow other OPTN/UNOS members to apply to participate. The Committee is asking for feedback on whether it should be an open variance as proposed.

### 3. Time Limited

The variance is proposed to expire three years after implementation.

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<sup>48</sup> OPTN Split Versus Whole Liver Transplantation, OPTN Ethics Committee.

<sup>49</sup> V. Corno, et al. "Extended Right Split Liver Graft for Primary Transplantation in Children and Adults".

<sup>50</sup> Wertheim, et al., "Major Challenges Limiting Liver Transplantation in the United States".

<sup>51</sup> V. Corno, et al. "Extended Right Split Liver Graft for Primary Transplantation in Children and Adults".

<sup>52</sup> OPTN Policy 1.3.B: Application for a Variance



#### 4. Evaluation

The Committee's plan for evaluating the impact of the variance is outlined below under: *How will the sponsoring Committee evaluate whether this proposal was successful post implementation?*

#### 5. Anticipated Difficulties

The Committee recognizes that not all donors or candidates are good candidates for SLT.<sup>53</sup> Even if there are behavior changes as a result of the variance, the increase in SLT will likely be small.

#### 6. Conditions

The Committee is seeking feedback on whether this should be an open variance or a closed variance that is only applicable to region eight. The Committee proposes an open variance. As proposed, members interested in joining the variance would not need to be members of a particular OPTN/UNOS region or approved by other OPTN/UNOS members in order to join.

### How well does this proposal address the problem statement?

Since 2011, there have been between 61 and 89 livers split each year, in which the majority of the time, the primary recipient was a pediatric candidate and the secondary recipient was an adult (Table 1). Only four of these transplants were potentially under the existing variance.<sup>54,55</sup>

Table 1: SLT Events in the U.S. 12/2/2010-12/31/2017<sup>56</sup>

Age of Primary Recipient	Age of Secondary Recipient	All		2010		2011		2012		2013		2014		2015		2016		2017	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Pediatric	Pediatric	41	8.6	1	12.5	6	10.0	8	13.1	8	11.6	4	6.7	2	3.6	4	4.9	8	9.6
	Adult	438	91.4	7	87.5	54	90.0	53	86.9	61	88.4	56	93.3	54	96.4	78	95.1	75	90.4
	<b>Total</b>	<b>479</b>	<b>100.0</b>	<b>8</b>	<b>100.0</b>	<b>60</b>	<b>100.0</b>	<b>61</b>	<b>100.0</b>	<b>69</b>	<b>100.0</b>	<b>60</b>	<b>100.0</b>	<b>56</b>	<b>100.0</b>	<b>82</b>	<b>100.0</b>	<b>83</b>	<b>100.0</b>
Adult	Pediatric	10	27.0	1	100.0	2	33.3	1	20.0	4	66.7	0	0.0	1	20.0	1	16.7	0	0.0
	Adult	27	73.0	0	0.0	4	66.7	4	80.0	2	33.3	3	100.0	4	80.0	5	83.3	5	100.0
	<b>Total</b>	<b>37</b>	<b>100.0</b>	<b>1</b>	<b>100.0</b>	<b>6</b>	<b>100.0</b>	<b>5</b>	<b>100.0</b>	<b>6</b>	<b>100.0</b>	<b>3</b>	<b>100.0</b>	<b>5</b>	<b>100.0</b>	<b>6</b>	<b>100.0</b>	<b>5</b>	<b>100.0</b>

The Committee posits that this is because a transplant hospital that initially receives the liver offer for an adult candidate who would be appropriate to transplant with the right tri-segment may not be as likely to have a pediatric candidate who would benefit from the left lateral segment.<sup>57</sup> The Committee proposes a new variance to test the theory that reducing the difficulty of coordinating two transplant hospitals with two transplant teams will achieve better efficiency in the placement of SLT organs, increase the frequency of SLT and thereby increase the number of transplanted organs and net survival.

<sup>53</sup> Visual and manual examination of the liver during recovery, as well as consideration of factors such as a low platelet counts, history of heavy alcohol use, or age of younger donors are essential in SLT. Hashimoto, et al., "Split Liver Transplantation in Adults".

<sup>54</sup> S. Noreen and T. Baker, Evaluation of Open Variance for Segmental Liver Transplantation, OPTN Liver and Intestinal Transplantation Committee Meeting, March 29, 2018.

<sup>55</sup> The Committee reviewed data based on SLT that were performed at the same hospital, participating in the variance, with the right tri-segment or right lobe transplanted into the first candidate. There was no identifier to know for sure that the variance was being used in these cases. S. Noreen and T. Baker, Evaluation of Open Variance for Segmental Liver Transplantation, OPTN Liver and Intestinal Transplantation Committee Meeting, March 29, 2018.

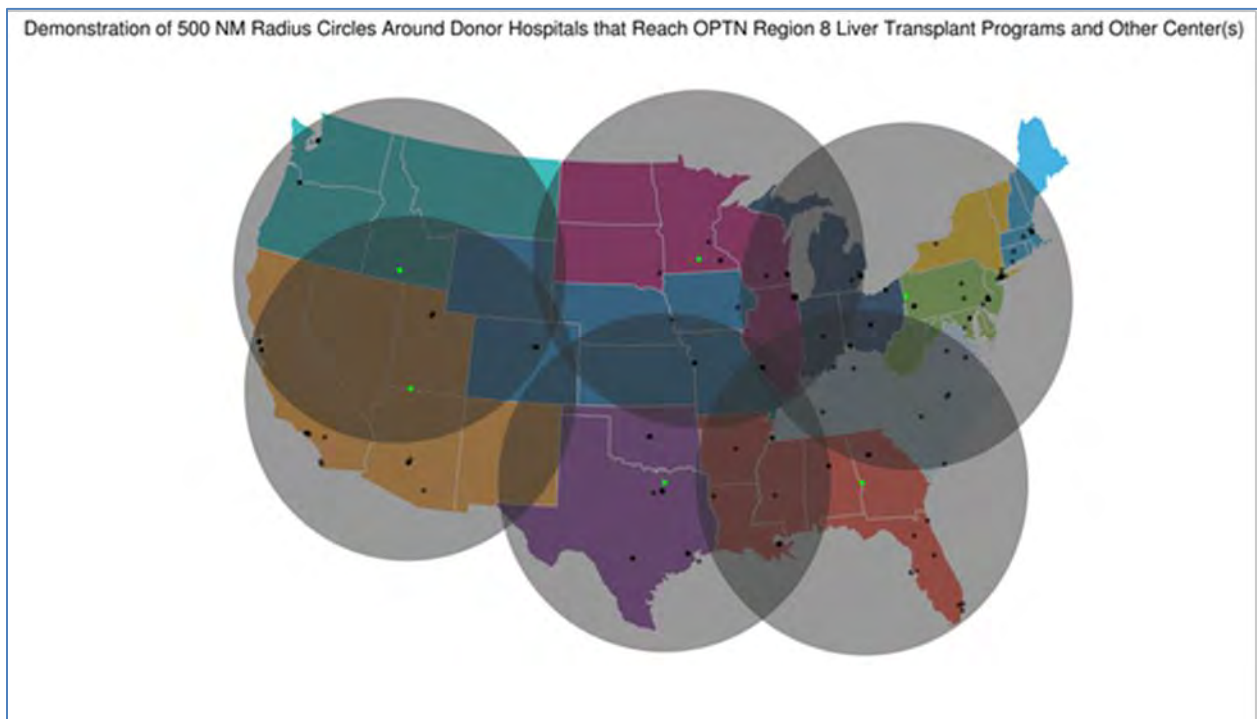
<sup>56</sup> S. Noreen and T. Baker, Evaluation of Open Variance for Segmental Liver Transplantation, OPTN Liver and Intestinal Transplantation Committee Meeting, March 29, 2018.

<sup>57</sup> As of December 14, 2018, there are 433 pediatric candidate on the liver transplant waitlist and 13,118 adult candidates. OPTN data. <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/> (Accessed December 14, 2018).

By more explicitly permitting the transplant hospital that performs the split and transplants the first candidate to use the remaining segment<sup>58</sup> for another candidate at that hospital or an affiliated hospital, many of the difficulties associated with SLT are removed or reduced. This includes coordinating recovery times and deciding the type of split and division of blood vessels and bowl duct since there is only one hospital involved, or in the case of affiliated hospitals, the two involved hospitals are physically close to one another and already have an established working relationship.

In permitting allocation of the second segment to candidates at the same transplant hospital, it is possible that this will change behavior for hospitals that are already splitting livers, and the remaining liver segment will stay at the same transplant hospital or its affiliates instead of being allocated to a more urgent candidate listed at a different hospital. In that case, it could disadvantage patients who would otherwise be allocated within the distribution area. For instance, if there is a donor at a hospital in Pittsburgh, Pennsylvania and the liver is accepted for a candidate at a hospital in Chicago, Illinois, then the second candidate at the Chicago hospital would have access to the offer of the remaining segment before candidates in six other regions with hospitals that may not be participating in the variance, but are all within 500nm of the donor hospital.

Figure 3: Demonstration of 500 NM Radius Circles around Donor Hospitals



For this reason, the proposed variance includes a provision that requires that the second segment be offered to candidates with Status 1A or 1B and MELD/PELD scores of 33 and higher at transplant programs within 500nm of the donor hospital before they are used for a candidate at the initial transplant hospital. This will ensure that candidates who are most medically urgent receive offers for the remaining graft.

<sup>58</sup> This would be different from the current default allocation rules, under which the full liver is offered according to the match run for that organ, and the surgeon for the candidate that accepts the organ has the option to split the liver. If it is split, the remaining segment must also be offered according to the match run. OPTN/UNOS Policy 5.9 Released Organs. [https://optn.transplant.hrsa.gov/media/1200/optn\\_policies.pdf](https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf). (Accessed December 22, 2018).

The question of whether to allow a transplant hospital to use both segments of a divided organ was also considered by the OPTN/UNOS Kidney Transplantation Committee (Kidney Committee) when developing the proposal for *Improving Allocation of En Bloc Kidneys* in 2017.<sup>59</sup> For kidneys that are initially allocated *en bloc*, but then split, the second organ must be allocated according to the match run, and there is no exception allowing them to be used at the same transplant hospital.<sup>60</sup> However, this is distinguishable from split livers because the kidneys that qualify to be offered *en bloc* are smaller and more marginal and less likely to be used for transplant if they are used alone, so the increase in transplants that can be gained from *en bloc* allocation is more likely to result from the initial *en bloc* allocation instead of the split.<sup>61</sup>

## Which populations are impacted by this proposal?

This proposal aims to increase the number of transplants and provide greater net survival by decreasing time on the waitlist and therefore waitlist mortality.<sup>62</sup> As most commonly performed, split-liver transplantation involves the division of a donor liver from a deceased adult, and transplantation of one segment into an adult candidate and another into a pediatric candidate.<sup>63</sup> Therefore, if more livers are split, the expectation is that it will increase the number of split livers transplanted into both adult and pediatric candidates. SLT may be appropriate for smaller adult candidates who may not be able to accept a whole liver from a larger donor<sup>64</sup>, but may be able to use a left lateral segment that may be too small for larger candidates<sup>65</sup>. For this reason, it may improve access for small women who are currently disadvantaged in liver allocation<sup>66</sup>.

It is unknown specifically how many more livers will be split under this variance, and therefore how many additional transplants will be performed. The recovery and the transplant are both more complex procedures than recovery and transplantation of a whole liver.<sup>67</sup> The changes as a result of the variance will be analyzed by the Committee on an ongoing basis to evaluate the effectiveness and impact of the variance as discussed below in the section, *How will the sponsoring Committee evaluate whether this proposal was successful post implementation?*.

## How does this proposal impact the OPTN/UNOS Strategic Plan?

1. *Increase the number of transplants*: The proposal is expected to increase the number of transplants by increasing the incentive to use a single liver to transplant two candidates.
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 expected impact on this goal. However, the Committee will review the outcomes as part of the evaluation of the variance to ensure that it does not negatively impact recipient outcomes.

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<sup>59</sup> *Improving Allocation of En Bloc Kidneys*, OPTN Kidney Transplant Committee, December 2017, [https://optn.transplant.hrsa.gov/media/2327/kidney\\_boardreport\\_enbloc\\_2017.12.pdf](https://optn.transplant.hrsa.gov/media/2327/kidney_boardreport_enbloc_2017.12.pdf) (Accessed December 27, 2018).

<sup>60</sup> *Improving Allocation of En Bloc Kidneys*, OPTN Kidney Transplant Committee, December 2017, pages 11-14.

<sup>61</sup> *Improving Allocation of En Bloc Kidneys*, OPTN Kidney Transplant Committee.

<sup>62</sup> OPTN Split Versus Whole Liver Transplantation, OPTN Ethic Committee, December 2016, <https://optn.transplant.hrsa.gov/resources/ethics/split-versus-whole-liver-transplantation/> (Accessed December 14, 2018).

<sup>63</sup> Jonathan Roach, "Split Liver Transplantation", *MedScape*, January 18, 2017.

<https://emedicine.medscape.com/article/1014235-overview> (Accessed December 14, 2018).

<sup>64</sup> Alina Allen, Julie Heimbach, Joseph Larson, Kristin Mara, W. Kim, Patrick Kamath, Terry Therneau, "Reduced Access to Liver Transplantation in Women: Role of Height, MELD Exception Scores, and Renal Function Underestimation", *Transplantation*: October 2018 - Volume 102 - Issue 10 - p 1710–1716, doi: 10.1097/TP.0000000000002196.

<sup>65</sup> Roach, "Split Liver Transplantation".

<sup>66</sup> Allen, et al., "Reduced Access to Liver Transplantation in Women: Role of Height, MELD Exception Scores, and Renal Function Underestimation".

<sup>67</sup> Wertheim, et al., "Major Challenges Limiting Liver Transplantation in the United States".

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/UNOS implement this proposal?

OPTN/UNOS will provide information to interested members about how to apply to participate in the variance. OPTN/UNOS will evaluate the variance, as detailed below in *How will the sponsoring Committee evaluate whether this proposal was successful post implementation?* The variance will expire three years after implementation.

This proposal will not require programming in UNet<sup>SM</sup>.

## How will members implement this proposal?

### Transplant Hospitals

Transplant hospitals that wish to participate in the variance will have to submit a request to the OPTN/UNOS to participate. Transplant hospitals who choose not to participate will not need to do anything.

### OPOs

OPOs may need to use a different bypass code for certain candidates when the variance is used and the organ is allocated by the OPO.

## Will this proposal require members to submit additional data?

Members that wish to participate will be required to submit an application to participate in the variance. Data that would be required for evaluation of this variance is already routinely collected.

## How will members be evaluated for compliance with this proposal?

The proposed language will not change the current routine monitoring of OPTN/UNOS members. Any data submitted to the OPTN Contractor may be subject to review, and the OPTN Contractor will continue to review deceased donor match runs to ensure that allocation is carried out according to OPTN/UNOS Policy. Members are required to provide documentation as requested.

## How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

This variance will be formally evaluated approximately 6 months, 1 year, and 2 years post-implementation.

The following questions, and any others subsequently requested by the Committee, will guide the evaluation of the proposal after implementation:

- Has the number of split liver transplants increased?
- Have the characteristics of split liver recipients changed?
- Has there been a change in liver discards?
- If livers are split, did the remaining segment stay at the same or affiliated center?
- Has the number of programs performing split liver transplants increased?

The following metrics, and any others subsequently requested by the Committee, will be evaluated as data become available to compare performance before and after the implementation of this variance:

- The number (and percent) of liver transplants (whole vs. split) overall, and by both recipient and donor demographics, including but not limited to:
  - Recipient age, allocation MELD/PELD at transplant, index recipient liver segment (left lobe or left-lateral segment vs. right lobe or right tri-segment)
- Descriptive statistics on index and secondary recipient of split liver, including but not limited to:
  - Allocation MELD/PELD at transplant, gender, OPTN/UNOS region
- The number (and percent) of livers recovered that are utilized vs. discarded, overall and by demographics, including but not limited to:
  - Organ type (whole vs. split), OPTN/UNOS region
- Geography of secondary recipient of liver segment as it relates to index recipient (de-identified center, OPTN/UNOS region)
- The number (and percent) of deceased donor liver transplant programs performing split liver transplants

## Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

### **9.11.B Variance for Segmental Liver Transplantation**

Under this variance, a participating transplant program may offer the remaining split liver into a different, medically suitable, potential recipient registered at the same transplant hospital or an affiliated institution after the split portion of liver has been offered to the following candidates:

- Status 1A and 1B candidates within 500 nautical miles of the donor
- Candidates with a MELD or PELD of 33 or higher that are within 500 nautical miles of the donor

The transplant program must determine the potential recipient for the second segment by using the same match run used to allocate the liver.

[Subsequent heading numbers, classifications, numbered lists, table captions, and any cross-references affected by the re-numbering of these policies will also be changed as necessary.]

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