

## *At-a-Glance*

- **Proposed OneLegacy Split Liver Alternative Allocation System**
- **Liver and Intestinal Organ Transplantation Committee**

OneLegacy and the five liver transplant programs in its donation service area (DSA) are proposing a variance, or alternative allocation system (AAS), to Policy 3.6.11 (Allocation of Livers for Segmental Transplantation). This AAS would permit the institution to accept a liver for an acceptable candidate at their institution, split that liver and transplant one lobe into that candidate (known as the index patient) and then transplant the other lobe into any other medically suitable patient listed at the same institution. The index patient is defined as the first candidate for whom a deceased donor liver is offered and accepted, in accordance with the match run, who is medically suitable and willing to accept a segmental liver. The AAS is intended to increase the donor pool by providing an incentive to the institution receiving a liver offer to split a good-quality organ and transplant it in two recipients rather than transplanting the entire organ in one recipient.

- **Affected Groups**  
One Legacy Director of Organ Procurement, Executive Director, Medical Director, and Coordinators, Transplant Administrators, Transplant Data Coordinators, Transplant Physicians/Surgeons, PR/Public Education Staff, Transplant Program Directors, Transplant Social Workers, Organ Candidates, and Donor Family Members at the programs served by OneLegacy
- **Specific Requests for Comment**  
The Liver Committee and OneLegacy are seeking comments on the feasibility of this AAS, and any potential unintended consequences.

## Proposed OneLegacy Split Liver Alternative Allocation System

### Liver and Intestinal Organ Transplantation Committee

#### Summary and Goals of the Proposal:

OneLegacy and the five liver transplant programs in its donation service area (DSA) are proposing a variance, or alternative allocation system (AAS), to Policy 3.6.11 (Allocation of Livers for Segmental Transplantation). This AAS would permit the institution to accept a liver for an acceptable candidate at their institution, split that liver and transplant one lobe into that candidate (known as the index patient) and then transplant the other lobe into any other medically suitable patient listed at the same institution. The index patient is defined as the first candidate for whom a deceased donor liver is offered and accepted, in accordance with the match run, who is medically suitable and willing to accept a segmental liver. The AAS is intended to increase the donor pool by providing an incentive to the institution receiving a liver offer to split a good-quality organ and transplant it in two recipients rather than transplanting the entire organ in one recipient.

#### Background and Significance of the Proposal:

Small children with end-stage liver disease suffer the most from the extreme shortage of deceased donor organs due to the difficulty of finding size-matched donors. The allocation of organs from small pediatric donors to multiorgan recipients has made the problem even worse for small pediatric candidates who do not have the option of a living donor transplant. The OneLegacy DSA has one of the largest liver transplant waiting lists in the country, totaling 1,430 candidates, which means that pediatric liver candidates in this DSA may suffer disproportionately. As of December 11, 2009, there were 114 pediatric candidates on the local waiting list between the ages of 3 months and 18 years.

Split-liver transplantation (SLT), a procedure where one deceased donor liver is divided to provide for two recipients, offers immediate expansion of the existing deceased donor pool. This is done by dividing appropriate donor livers in such a way that the left lateral liver graft can be transplanted into a small child and the right extended liver graft into a medically suitable adult or teenager. Since its introduction in 1988, improved donor and recipient selection for SLT have increased the donor pool and decreased pediatric pretransplant mortality. To date, the principal beneficiaries of SLT have been adult/pediatric recipient pairs with excellent outcomes reported. This innovative technique **did not harm the adult recipient pool**<sup>1</sup>.

While the results of such SLT are comparable to whole organ transplantation, surgeons rarely employ this technique for a variety of reasons. Significant obstacles to the widespread application of SLT exist and the transplant community must resolve these obstacles before greater utilization can be realized<sup>2</sup>. The major obstacle is the experience and skill of the surgeon. Although splitting a liver maximizes the number of patients receiving an organ transplant, it may increase the morbidity and mortality for the individual patient receiving the split liver.

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<sup>1</sup> Kim JS, Broering DC, Tustas RY, Fischer L, Ganschow R, Burdelski M, Rogiers X. Split liver transplantation: past, present and future. *Pediatr Transplant*. 2004 Dec;8(6):644-8.

<sup>2</sup> Renz JF, Yersiz H, Reichert PR, Hisatake GM, Farmer DG, Emond JC, Busuttil RW. Split-liver transplantation: a review. *Am J Transplant*. 2003 Nov;3(11):1323-35.

Because split liver transplantation is so technically challenging, and because they are responsible for the lives of their transplant patients, surgeons typically wish to perform the surgery themselves. However, the current OPTN/UNOS allocation requires that a split liver must be offered sequentially down the combined OPO-wide liver match run, rather than just the center that performs the split. This policy therefore poses another major obstacle to splitting. When the match run sequence requires that the left lobe or left lateral segment must be offered to another center, surgeons will often abandon the idea of the split. Transplant centers often do not see the benefit of increasing the risk of morbidity for the right lobe recipient, when the remaining liver segment is sent to another center. Thus, the current incentive, both in terms of workload and potential outcome for the patient, is for the surgeon to accept the entire liver for a single patient when the offer is made.

Despite OneLegacy performing an average of 400 donors per year, the number of split liver procedures performed has remained stable (see Table 1).

**Table 1**  
**Number of Split Liver Transplants by Year**  
**at OneLegacy Liver Transplant Programs**

2000	08
2001	05
2002	10
2003	12
2004	06
2005	10
2006	05
2007	11
2008	07
2009	05

OneLegacy would like to increase liver availability and ensure the best outcomes in graft survival by allowing the surgeon to split appropriate livers, using the other segment (that the surgeon is familiar with since he or she split the graft) in another patient at the particular center where the first graft was used.

One Legacy estimates that no more than 10 percent of its liver donors might be used for such splits because the AAS does not affect the current sharing system of whole liver transplant when needed and appropriate. Nationally, it is estimated that split liver transplantation technique including the pediatric splits, although attractive, will apply to fewer than 25 percent of the donors<sup>3</sup>.

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<sup>3</sup> Liver transplantation in adults. Durand F, Belghiti J. *Med Sci (Paris)*. 2005 Jan;21(1):89-94.

### *Advantages of the Proposed AAS*

This AAS will allow more transplants to be done due to a single liver being divided into two segments for transplantation; removing two patients from the waiting list instead of one. Without the AAS, these grafts would likely be transplanted into a single adult as a whole organ transplant.

It is important to remember that the offer made to the index patient is in accordance with the match run per the national policy; the difference between the proposed AAS and the national system is that the second segment may be offered to a candidate listed at the index patient's center without first being offered to the local DSA list.

### *Process for AAS Approval*

Policy 3.4.8.1 (Application) states that "Applications to allocate organs using alternative point assignment systems or to distribute organs using sharing arrangements or ALUs are submitted to the appropriate organ-specific committees for consideration before being issued for public comment according to processes for public comment. Such applications are then reconsidered by the relevant Committee in light of public comment. Final applications to allocate organs locally using alternative point assignments or to distribute organs using sharing arrangements or ALUs must be presented to and approved by the Board of Directors before they can be implemented or used in organ allocation/distribution."<sup>4</sup>

In February 2010, the Liver and Intestinal Organ Transplantation Committee approved circulating this AAS for public comment, citing the Final Rule's requirement that allocation policies "shall seek to achieve the best use of donated organs"<sup>5</sup>. However, several concerns were raised about the potential lack of transparency in the acceptance process, and suggested that the AAS review should include information about which candidates are bypassed in the split liver allocation. Others were concerned about the degree of informed consent required for a candidate to understand that he/she is being offered a whole liver, but is being asked to accept only part of the liver in order to benefit another patient (i.e., a child) on the list. Committee members felt that the index patient should receive the liver even if the final decision is to keep the whole liver. Ultimately, the Committee still agreed that the proposal should be circulated for public comment, with these concerns noted. The AAS proposal was also reviewed and approved by the Policy Oversight Committee for distribution for public comment.

Policy 3.4.8.1 also states that "In cases where unanimity cannot be achieved at the local level, applications to allocate organs using either an alternative point assignment system, sharing agreement or ALU must have approval of 75% of the Member OPOs and or transplant centers." In this case, all participants agree with the AAS.

### **Supporting Evidence and/or Modeling:**

Research shows that outcomes for recipients of split liver grafts for pediatric/adult splits are similar to that of whole liver transplantation.<sup>6</sup> Adult/adult SLT is showing promising results as well. Individual

<sup>4</sup> [http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy\\_8.pdf](http://optn.transplant.hrsa.gov/PoliciesandBylaws2/policies/pdfs/policy_8.pdf)

<sup>5</sup> 42 CFR Part 121, see [http://optn.transplant.hrsa.gov/policiesAndBylaws/final\\_rule.asp](http://optn.transplant.hrsa.gov/policiesAndBylaws/final_rule.asp)

<sup>6</sup> Azoulay D, Astarcioglu I, Bismuth H et al. Split-liver transplantation. The Paul Brousse policy. Ann Surg 1996; 224: 737-746; discussion 746-748.

center data on adult/adult SLT are summarized in Table 2. The Paul Brousse group has reported the largest series on adult/adult SLT<sup>7</sup>. In 1996, Bismuth reported 1- year patient and graft survival of 79% and 78%, respectively, on 27 SLT grafts, with the routine application of *ex vivo* SLT increasing overall graft availability at their center by 28%.<sup>8</sup> A later series comparing 1- and 2-year SLT patient and graft survival to adults receiving deceased donor whole-organ transplantation over the same time period demonstrated right- and left-SLT graft 1-year recipient survival of 74% and 88% respectively, with 1-year graft survival of 74% for right-SLT vs. 75% for left-SLT recipients.

**Table 2**  
**Adult/Adult Split-Liver Transplantation<sup>2</sup>**

Center	Author	Year	N	Recipient Survival	Graft Survival	Comp
Ulsan <sup>9</sup>	Hwang	2004	2	100%	100%	N/A
Minneapolis <sup>10</sup>	Humar	2001	18	89%	89%	43%
Villejuif <sup>5</sup>	Azoulay	2001	34	81%	75%	24%
Minneapolis <sup>11</sup>	Humar	2001	12	83%	83%	58%
Hamburg <sup>12</sup>	Broering	2001	12	93%	85%	N/A
Genoa <sup>13</sup>	Andorno	2001	10	100%	80%	N/A
Bergamo <sup>14</sup>	Colledan	2000	8	87%	63%	75%
Eppendorf <sup>15</sup>	Gundlach	2000	4	100%	100%	N/A
Villejuif <sup>4</sup>	Azoulay	1996	27	79%	78%	37%

Comp = overall complication rate

N/A = data not reported

<sup>7</sup> Azoulay D, Marin-Hargreaves G, Castaing D, Bismuth H. Ex situ splitting of the liver: the versatile Paul Brousse technique. Arch Surg 2001; 136: 956-961.

<sup>8</sup> Azoulay D, Castaing D, Adam R et al. Split-liver transplantation for two adult recipients: feasibility and long-term outcomes. Ann Surg 2001; 233: 565-574

<sup>9</sup> Hwang S, Lee SG, Park KM, Kim KH, Ahn CS, Moon DB, Ha TY. A case report of split liver transplantation for two adult recipients in Korea. Division of Hepatopancreatobiliary Surgery and Liver Transplantation, Department of Surgery, Asan Medical Center, Ulsan University College of Medicine, Seoul 138-736, Korea. Transplant Proc. 2004 Nov;36(9):2736-40

<sup>10</sup> Humar A, Kandaswamy R, Sielaff T, Gruessner RW, Knaak M, Lake JR. Split-liver transplants for 2 adult recipients: an initial experience, American Transplant Congress, Transplant 2001, Chicago, IL, May 12-16, 2001.

<sup>11</sup> Humar A, Ramcharan T, Sielaff T et al. Split liver transplantation for two adult recipients: an initial experience. Am J Transplant 2001; 1: 366-372.

<sup>12</sup> Broering D, Gundlach M, Topp S, Mueller L, Rogiers X, In-situ full-right-full left splitting: the ultimate expansion of the adult donor pool, Transplant 2001, Chicago, IL. May 12-16, 2001.

<sup>13</sup> Andorno E, Genzone A, Morelli N et al. On liver for two adults: in-situ split liver transplantation for two adult recipients. Transplant Proc 2001; 33: 1420-1422

<sup>14</sup> Colledan M, Broering D, Topp S, Sterneck M, Rogiers X. Split-cava technique: liver splitting for two adult recipients. Liver Transpl 2000; 6: 703-706.

<sup>15</sup> Gundlach M, Broering D, Topp S, Sterneck M, Rogiers X. Split-cava technique: liver splitting for two adult recipients. Liver Transpl 2000;6: 703-706.

**Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:**

This AAS is intended to achieve the best use of donated organs, achieve equitable organ allocation, and maximize the number of donors and transplants. The AAS will increase the donor pool by providing incentive for the first receiving institution on a liver offer to split a good quality organ and use it in two adult recipients or an adult and a child, rather than using the entire organ in one recipient.

**Plan for Evaluating the Proposal:**

All split liver cases will be reviewed at OneLegacy on a regular basis. OneLegacy will review all the data in meetings that are held three times per year. However if the re-transplant rate exceeds 5 out of 20 grafts before one of these meetings or if any concerns are raised in the process by any of our liver transplant programs including the OPO, an automatic hold will be placed on the AAS until the results and surgical practices can be reviewed. The time period for operation of this AAS is one year.

**Additional Data Collection:**

This proposal does not require additional data collection.

**Expected Implementation Plan:**

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

**Communication and Education Plan:**

If approved, this AAS will be communicated to OneLegacy and its affiliated liver transplant programs using the consolidated policy notice that is distributed after each Board meeting.

**Monitoring and Evaluation:**

The Department of Evaluation and Quality (DEQ) Allocation Analysis staff will monitor each allocation to ensure the available liver was allocated according to approved AAS guidelines. If a member institution should deviate from the outlined guidelines of the AAS, the DEQ may inquire further for clarification of allocation details. If DEQ staff identify a potential violation of OPTN/UNOS policies or bylaws, the staff will forward all related information to the Membership and Professional Standards Committee for review and due process.

**Proposal:**

The OneLegacy proposal is that the institution splitting the liver be allowed to transplant both lobes into that institution's index patient and any other medically suitable listed patient at the institution, in their order on the match-run. The policy will only apply when the index case will receive the right portion of the liver.

The organs will be divided into the right and left lobes or right and left lateral segment. Each lobe will then be transplanted into recipients listed with the institution performing the split, with one recipient being the index case (right side recipient). The remaining liver segment will be allocated by the splitting

team to the pediatric patient they feel would benefit the most, based on the size and quality of the graft, current recipient medical condition, and patients own willingness to accept a split liver graft.

Split livers for which the index case is a left side graft recipient will be excluded, as those livers must be split in order to accomplish the index case. In such cases, the current UNOS policy will remain. The left lateral segment allocated to the pediatric index case first and the right-segment allocated to the highest MELD score in the OPO.