At-a-Glance

- **Proposed Committee-Sponsored Alternative Allocation System (CAS) for Split Liver Allocation**

- **Affected/Proposed Policy: New Policy 3.6.12 Committee-sponsored Alternative Allocation System (CAS) for Segmental Liver Transplantation**

- **Liver and Intestinal Organ Transplantation Committee**

  This Committee-sponsored AAS (CAS) is intended to increase the number of transplants and reduce waiting list deaths by transplanting the right lobe into an adult patient and the remaining lobe/segment into a second candidate. The CAS will potentially reduce waiting times for liver candidates overall, because the liver pool would be expanded by splitting livers that otherwise would not be split. In November 2010, the Board of Directors approved two alternative allocation systems (AAS) to Policy 3.6.11 (Allocation of Livers for Segmental Transplantation). At that time, the Board asked that the Liver Committee consider developing a Committee-sponsored AAS (CAS) that would allow other Regions and OPOs to participate in a split liver AAS. This proposed CAS is based on the approved Region 2 and OneLegacy AASs, but will provide one standard model for all participants to follow. In summary, if an adult candidate is offered a liver through the standard policy or an approved-AAS (i.e., via the match run) who has been determined to be suitable for a segmental liver transplant (known as the index patient), the candidate's transplant center may transplant the right lobe into the index patient. The center may then transplant the left lobe/segment into any other medically suitable listed patient at that institution or an affiliated pediatric institution (if applicable), in order of the match run.

- **Affected Groups**
  This is a list of transplant professionals and lay persons (public, recipients, candidates, donor families, etc.) who are expected to be impacted by the proposed change(s). Please include those professions and other groups most likely to be affected by the policy change.

  Directors of Organ Procurement, OPO Executive Directors, OPO Medical Directors, OPO Coordinators, Transplant Administrators, Transplant Data Coordinators, Transplant Physicians/Surgeons, PR/Public Education Staff, Transplant Program Directors, Transplant Social Workers, Organ Candidates

- **Number of Potential Candidates Affected**
  The proposed CAS will likely affect fewer than ten percent of recipients in those donation service areas or regions that adopt the CAS.

- **Compliance with OPTN Strategic Goals and Final Rule**
  Section 121.8 of the OPTN Final Rule states that allocation policies shall seek to achieve the best of donated organs. This CAS would achieve this goal by transplanting two candidates with one donor liver.

- **Specific Requests for Comment**
  The Liver Committee is seeking comments on the feasibility of this CAS, and any potential unintended consequences.
  - Should the remaining segment be eligible for transplant in either an adult or pediatric patient?

Proposed Committee-Sponsored Alternative Allocation System (CAS) for Split Liver Allocation

Liver and Intestinal Organ Transplantation Committee

Summary and Goals of the Proposal:

This Committee-Sponsored AAS (CAS) is intended to increase the number of transplants and reduce waiting list deaths by transplanting the right lobe into an adult patient and the remaining lobe/segment into a second candidate. The CAS will potentially reduce waiting times for liver candidates overall, because the liver pool would be expanded by splitting livers that otherwise would not be split. In November 2010, the Board of Directors approved two alternative allocation systems (AAS) to Policy 3.6.11 (Allocation of Livers for Segmental Transplantation). At that time, the Board asked that the Liver Committee consider developing a Committee-Sponsored AAS (CAS) that would allow other Regions and OPOs to participate in a split liver AAS. This proposed CAS is based on the approved Region 2 and OneLegacy AASs, but will provide one standard model for all participants to follow. In summary, if an adult candidate is offered a liver through the standard policy or an approved-AAS (i.e., via the match run) who has been determined to be suitable for a segmental liver transplant (known as the index patient), the candidate's transplant center may transplant the right lobe into the index patient. The center may then transplant the left lobe/segment into any other medically suitable listed patient at that institution or an affiliated pediatric institution (if applicable), in order of the match run.

Background and Significance of the Proposal:

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[1].

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 recently exacerbated the organ shortage for small pediatric candidates who do not have the option of a living donor transplant. Pediatric liver transplant candidates in some areas of the country may suffer disproportionately due to the large number of pediatric candidates waiting in those areas.

While the results of such SLT are comparable to whole organ transplantation, it is a rarely employed technique for a variety of reasons. Significant obstacles to the widespread application of SLT exist and must be resolved by the transplant community before greater utilization can be realized[2]. The major obstacle is the experience of the procuring surgeon and transplant team with split technique. 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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[1] 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.

[2] 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 technically challenging and requires experience, and because they are responsible for the lives of their transplant patients, surgeons typically wish to perform the split procedure and transplant 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 and provides a disincentive to splitting. Because the match run sequence requires that the left lobe or left lateral segment must be offered to another center, the split is usually not considered. 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. Data presented to the Committee in October 2010 showed that an average of 137 split liver transplants have occurred each year between 2003 and 2009, despite the fact that a majority of liver candidates indicate a willingness to accept a segmental liver transplant[3]. This analysis also showed that post-transplant graft and patient survival rates for both adult and pediatric recipients of split livers were similar to those with whole liver and live donor liver transplants.

The intent of this CAS is to increase liver availability and ensure the best outcome in graft survival by allowing the surgical team experienced in split procurement to split appropriate livers, transplanting the right lobe in the index patient, and using the left lobe or left lateral segment (with which the surgeon is familiar since he/she split the graft) in another medically appropriate candidate at the center (or affiliated pediatric center) where the right lobe was transplanted. It is estimated that split liver transplantation technique including the pediatric splits, although attractive, is applicable to less than 25 % of the donors.[4]

Advantages of the Proposed CAS

Organ scarcity and increasing wait-list mortality were the impetus for the development of SLT. The discrepancy between organ supply and recipient demand has never been greater. This has renewed interest in increasing the application of traditional adult/pediatric SLT and performance of adult/adult SLT.[2] This CAS 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 CAS, these grafts would likely be transplanted into a single adult as a whole organ transplant.

Process for CAS Approval

Policy 3.4.10.1 (Development and Application) states that Committee-Sponsored Alternative Systems are "developed by the applicable reviewing committee(s), submitted for public comment according to processes for public comment, and reconsidered by the sponsoring committee in light of public comment. Final proposals for Committee-Sponsored Alternative Systems must be presented to and approved by the Board of Directors prior to implementation [on UNet^{SM}][5]. Once approved, notice of the Committee-Sponsored Alternative System will be included in the policies.

OPOs and their affiliated transplant centers may apply to participate in an approved Committee-Sponsored Alternative System by demonstrating unanimous agreement to such participation among the OPO(s) and their transplant centers with programs for transplantation of the applicable organ(s). For those OPOs with multiple units (ALUs), signatures must be obtained from each transplant center within the OPO (with programs for transplantation of the applicable organ(s)) indicating that they agree to participate in the system. Applicants also must provide member contact and other information as may

[3] Cherikh, WS, Optimizing Utilization of Potentially "Splittable" Livers

[4] Liver transplantation in adults. Durand F, Belghiti J. Med Sci (Paris). 2005 Jan;21(1):89-94.

[5] Note: This AAS would not require implemented in UNet^{SM}

be determined by the appropriate committees and Board of Directors. Once the Board of Directors has approved a Committee-Sponsored Alternative System, individual participant applications do not require committee or region review or Board approval prior to implementation. Participants in Committee-Sponsored Alternative Systems are required to stay aware of all applicable provisions of the organ allocation policies and any amendments thereto as well as other bylaws and policies.

Summary of Regional, Committee, and Public Comments for Region 2 and OneLegacy AASs, Fall 2010

Public comments received for the OneLegacy proposal were 77% in support, with 23% opposed. All 11 regions supported the proposal as written. The following committees were in support of OneLegacy's proposal Operations, OPO, PAC, and TCC. The OAC and Pediatric Transplantation Committee were opposed. The Ethics Committee stated some concerns with the proposal, but no vote was taken.

Public comments received for the Region 2 proposal were 91% in support, with 9% opposed. Regions 1, 2, 3, 4, 6, 7, 9, 10, and 11 supported the proposal as written, with Region 8 in support of an amended proposal and Region 5 opposed. The following committees were in support of the Region 2 proposal: Operations (with condition), OPO, PAC, and TCC. The OAC and Pediatric Transplantation Committee were opposed to the proposal.

Several concerns were expressed about the level of consent provided to the index patient. Current OPTN/UNOS policy does not specify any requirements for consent for split liver transplants. Several comments expressed the concern that the match run would not be followed under these AASs. However, offers will be made in the order of the standard match run, and turndown reasons are reported to UNOS when documenting the placement of the remaining segment. Other commenters were concerned that the AASs might lead to splitting livers for two adults, based on fears of poorer outcomes and the need for re-transplant, thus taking an additional liver out of the pool.

Based on the high level of regional, committee, and individual support, the Committee submitted these proposals to the Board in November 2010, with minor amendments. Both AASs were approved in a single vote. Liver programs in Region 2 and within the OneLegacy DSA were notified of the AASs approval for implementation subsequent to Board approval.

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.[6] Outcomes for recipients of split liver grafts for pediatric/adult splits are similar to that of whole liver transplantation.[7] Adult/adult SLT is showing promising results as well. Individual center data on adult/adult SLT are summarized in the table below. The Paul Brousse group has reported the largest series on adult/adult SLT[8]. 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%.[9] 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.

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

[7] Azoulay D, Astarcioglu I, Bismuth H et al. Split-liver transplantation. The Paul Brousse policy. Ann Surg 1996; 224: 737-746; discussion 746-748.

[8] 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.

[9] 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.

Table 1 Adult/Adult Split-Liver Transplantation[2]

Center	Author	Year	N	Recipient Survival	Graft Survival	Comp
Ulsan[10]	Hwang	2004	2	100%	100%	N/A
Minneapolis[11]	Humar	2001	18	89%	89%	43%
Villejuif[5]	Azoulay	2001	34	81%	75%	24%
Minneapolis[12]	Humar	2001	12	83%	83%	58%
Hamburg[13]	Broering	2001	12	93%	85%	N/A
Genoa[14]	Andorno	2001	10	100%	80%	N/A
Bergamo[15]	Colledan	2000	8	87%	63%	75%
Eppendorf[16]	Gundiach	2000	4	100%	100%	N/A
Villejuif[4]	Azoulay	1996	27	79%	78%	37%

Comp = overall complication rate N/A = data not reported

Expected Impact on Living Donors:

No specific impact on living donors is anticipated.

Expected Impact on Organ Allocation and Waiting Times for Transplant Candidates:

Overall, all waiting times would be expected to decrease if more people are transplanted. The Committee will reassess the CAS after 12 months in order to see if waiting time for any particular patient population is adversely affected.

Expected Impact on Organ Allocation and Waiting Times among the Various Categories of Medical Urgency:

The CAS will potentially reduce waiting times for patients overall because the liver pool would be expanded by splitting livers that otherwise would not be split.

Expected Impact on Organ Allocation and Waiting Times for Transplant Candidates who are Pediatric, Female or Represent Racial Minorities:

The CAS should not adversely affect any transplant candidates who are pediatric, female or represent racial minorities. The proposal should increase access for pediatric candidates and decrease their waiting times.

[10] 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.

[11] Humar A, Kandaswarmy 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.

[12] 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.

[13] 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.

[14] 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.

[15] 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.

[16] 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 CAS is intended to achieve the best use of donated organs, achieve equitable organ allocation, and maximize the number of donors and transplants. The CAS 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:

Each participating Region or DSA will meet to review the results of the first 10 segmental liver transplants performed as a result of this CAS, and each 10 thereafter. If the retransplant rate for segmental liver transplants at any participating liver transplant program exceeds 3 of 20 grafts prior to the meeting, an automatic hold will be placed on the procedure until the results and surgical practices can be reviewed.

In accordance with Policy 3.4.10.1, the Committee will assess the CAS' success in achieving its stated purpose. This will include candidate waiting time and post-transplant graft survival, both stratified by the appropriate candidate/recipient populations. The Committee will also assess the impact on the number of transplants performed.

The time needed to evaluate the impact of the CAS will be dependent on the number of transplant programs enrolled in the CAS, the size of their patient population, and the number of split liver transplants that result from the CAS. The Committee anticipates that the CAS will be in place for a minimum of 3 years, at which point the results will be evaluated and communicated to the Board.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

This proposal will not require programming in UNet^{SM}.

Communication and Education Plan:

If approved, this CAS will be communicated to all participating liver transplant programs and OPOs.

Monitoring and Evaluation:

The Department of Evaluation and Quality (DEQ) staff monitors all liver organ allocations and makes a written inquiry into any allocations that do not follow the match run sequence. The OPTN/UNOS Membership and Professional Standards Committee (MPSC) reviews instances of allocations that do not follow the match run sequence.

Proposal[17]:

3.6.12 Committee-sponsored Alternative Allocation System (CAS) for Segmental Liver Transplantation. Under this CAS, livers must be offered in sequence, as determined by the deceased donor liver allocation algorithm set forth in Policy 3.6 (Allocation of Livers). If a liver is accepted for a potential recipient who is medically suitable for segmental liver transplantation, the center may choose to transplant the right lobe/right trisegment into that individual. The transplant center may then transplant the left lobe/left-lateral segment into a medically suitable potential recipient listed at their center or an affiliated pediatric institution (if applicable). The potential recipient of the left lobe/left-lateral segment must be determined by following the same match run used to allocate the liver (right lobe/trisegment), documenting all refusals.

This CAS will only apply when the potential recipient receives the right lobe/right trisegment of the liver. If the potential recipient receives the left lobe/left lateral segment of the liver, then the right lobe/right trisegment of the liver must be allocated as per policy 3.6.11 (Allocation of Livers for Segmental Transplantation).

Each participating Region or DSA will meet to review the results of the first 10 segmental liver transplants performed as a result of this CAS, and each 10 thereafter. If the re-transplant rate for segmental liver transplant recipients at any liver transplant program participating in the CAS exceeds 3 of 20 grafts, an automatic hold will be placed on the procedure at that program until the results and surgical practices can be reviewed by the transplant program.

[17] This will replace current policies 3.6.12 (Transition of Currently Listed Candidates) and 3.6.12.1 (Transition for Currently Listed Status 2B HCC Candidates), which are obsolete.