

Simultaneous Liver Kidney (SLK) Allocation

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Simultaneous Liver Kidney (SLK) Allocation

Executive Summary

Current OPTN/UNOS policy prioritizes candidates seeking a simultaneous liver kidney (SLK) transplant *before* pediatric and adult transplant candidates who are listed only for a kidney (“kidney alone candidates”) when the liver candidate and the deceased donor are in the same Donation Service Area (DSA). Unlike kidney alone allocation, in SLK allocation, the kidney is not allocated based on a candidate’s kidney function. Instead, geographic proximity between the liver-kidney candidate and the donor is the single factor for allocating the kidney with the liver. Organ procurement organizations (OPOs) are not required to allocate the kidney with the liver beyond the local DSA, although they have the discretion to do so.

Working with many other groups in the transplant community, the Kidney Transplantation Committee has identified several problems with the current policy:

- Current rules for liver-kidney allocation are counter to requirements in the OPTN Final Rule, which specifies that organ allocation policies be based on sound medical judgment and standardized criteria.
- The lack of medical criteria results in the allocation of high quality kidneys to liver candidates who may regain renal function after liver transplant and decreased access for kidney alone candidates who would otherwise be highly prioritized in deceased donor kidney allocation.
- The lack of consistency for regional SLK allocation has been a tremendous concern for the liver transplant community, as deceased donor liver allocation prioritizes candidates with a certain medical urgency status or Model End Stage Liver Disease Score (MELD) score for regional allocation but regional liver-kidney allocation is not required for these candidates.

In order to provide more clarity and consistency in the rules for liver-kidney allocation, the Committee is recommending approval of this proposal which changes policies to:

- Establish medical eligibility criteria for adult candidates seeking an SLK transplant.
- Provide greater clarity for the rules around liver-kidney allocation and fix the inconsistency that exists between deceased donor liver allocation policy and liver-kidney allocation policy.
- Establish a “safety net” (new match classification priority on the kidney alone waiting list) for liver recipients with continued dialysis dependency or kidney dysfunction in the first year after liver transplant to address concerns about limitations with the SLK medical eligibility criteria.

These recommendations are the result of two consensus conferences and three rounds of formal public comment. It incorporates feedback from the OPTN/UNOS Board of Directors, 11 OPTN/UNOS regions, several professional transplant societies, patient advocacy groups, and various OPTN/UNOS committees. These new rules will further the OPTN strategic goal to “provide equity in access to transplants” by addressing the objective to “establish clearer rules for allocation of multiple organs to a single candidate, especially liver-kidney candidates.”

Simultaneous Liver Kidney (SLK) Allocation

Affected Policies: Policy 5.10 *Allocation of Multi-Organ Combinations*; Policy 9.6: *Liver Allocation, Classifications, and Rankings*, Policy 9.7 *Allocation of Liver-Kidneys* (new), Policy 8.5 *Kidney Allocation Classifications and Rankings*

Sponsoring Committee: Kidney Transplantation Committee

Public Comment Periods: 1) January 25—March 25, 2016; 2) August 14—October 14, 2015; 3) February 2009

What problem will this proposal solve?

Current OPTN/UNOS policy prioritizes candidates listed for a simultaneous liver kidney (SLK) transplant *before* pediatric and adult transplant candidates who are listed only for a kidney (“kidney alone candidates”) when the liver-kidney candidate and the deceased donor are in the same Donation Service Area (DSA)¹. Unlike kidney alone allocation, in SLK allocation, the kidney is not allocated based on medical criteria assessing the kidney function of the candidate. Instead, geographic proximity between the liver-kidney candidate and the donor is the single factor in allocating the kidney with the liver. OPOs are not required to allocate the kidney with the liver regionally, although they are given discretion to do so.

Collaborating with many others in the transplant community, the Kidney Transplantation Committee (“the Committee”), has identified several problems with this current policy:

1) Final Rule Compliance

The current allocation for SLK transplants is counter to requirements in the OPTN Final Rule (“Final Rule”) specifying that organ allocation policies must be based on sound medical judgment and standardized criteria.² These requirements are in place to ensure equity and efficiency in the U.S. organ allocation system—to promote a system where all candidates are assessed and organs are allocated equitably based on some level of medical need, rather than the candidate’s place of listing. However, the current SLK policy fails to meet this requirement. Instead of allocating kidneys (as part of a SLK) using medical criteria specific to kidney function, the current system utilizes the medical criteria specific to the liver allocation system. While these may be standardized, it is not sound medical judgement to use the allocation rules developed for one organ to allocate a different organ type.

2) Lack of equity

The lack of medical criteria results in allocation of high quality kidneys to liver candidates who may regain renal function after liver transplant and decreased access for kidney alone candidates who would otherwise be highly prioritized in deceased donor kidney allocation. This has become an increasing concern among the kidney transplantation community, especially as it relates to prioritizing high quality kidneys for pediatric candidates. The Committee recently reviewed data showing approximately half of the kidneys allocated to SLK recipients had a kidney donor profile index (KDPI) less than 35% (**Exhibit**

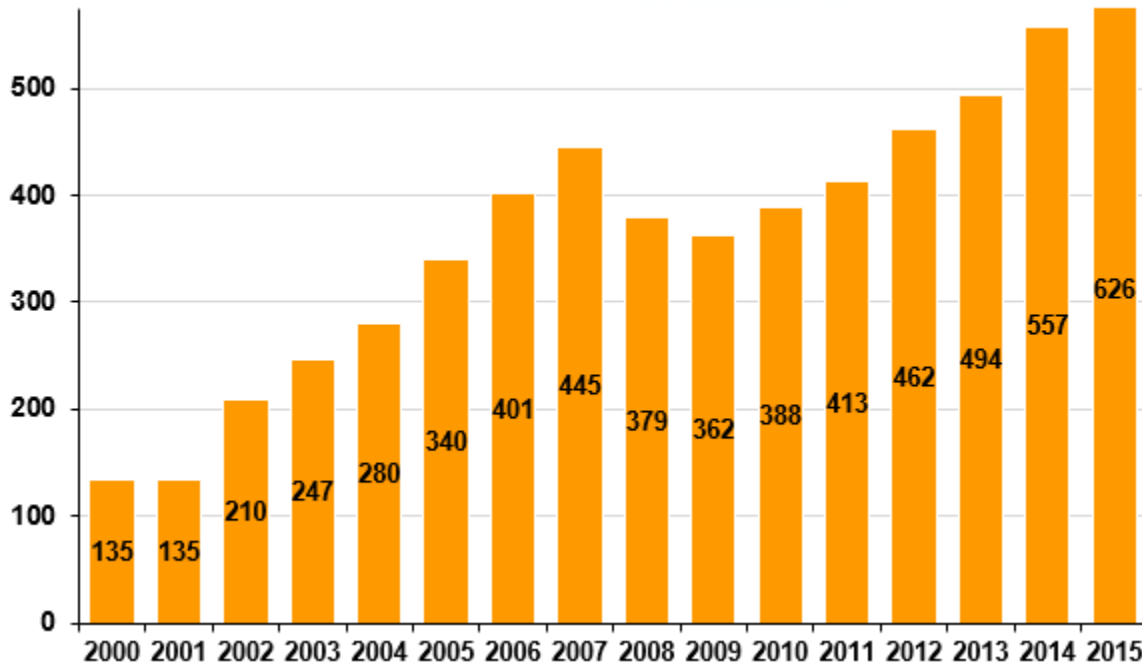
¹ OPTN policy 5.8 *Allocation of Multi-Organ Combinations*. <http://optn.transplant.hrsa.gov/governance/policies/>

² 42 CFR §121.8, available at: <http://www.ecfr.gov/cgi-bin/text-idx?SID=e3fd0c2a70bb895235e55fac41f87701&mc=true&node=se42.1.121.18&rqn=div8>

A³), which are kidneys prioritized for local pediatric candidates in kidney alone allocation. Recent data also shows that the number of SLK transplants has substantially increased in the past couple of years, with more than 600 transplants performed in 2015 (Figure 1).

Figure 1. Number of SLK transplants by year

SLK transplants with other organs were excluded from the tabulation.



3) Lack of clear liver-kidney allocation rules outside of DSA

The lack of consistency for regional SLK allocation has been a tremendous concern for the liver transplant community, as deceased donor liver allocation prioritizes candidates with a certain status or Model End Stage Liver Disease (MELD) score for regional allocation but regional liver-kidney allocation is not required. The Liver and Intestinal Organ Transplantation Committee (“the Liver Committee”) is concerned with the substantial variation in regional allocation of SLK transplants⁴ because survival outcomes for these liver recipients can be dependent on also receiving a kidney transplant (Figure 2, page 16). The OPO community has also expressed concern that the lack of clear rules for allocating a kidney with the liver beyond the local level causes conflicts at the time of allocation because the OPO must decide whether to allocate the kidney to a liver-kidney candidate or kidney alone candidate. There are factors (other than the medical urgency status) that can influence this decision, including but not limited to the types of organ transplant programs that are operating in the OPO’s DSA.

³ This exhibit can be accessed in the public comment document at https://optn.transplant.hrsa.gov/media/1240/05_slk_allocation.pdf

⁴ Nadim, et al. “Simultaneous Liver-Kidney Transplantation: A Survey of US Transplant Centers” *Am J Transplantation* 2012; 12: 3119-3127

How does the proposal address these problems?

The Committee is proposing new policies that include three elements:

1. Medical eligibility criteria for adult candidates seeking an SLK transplant. Since there is somewhat limited data to establish new rules, the Committee has relied on clinical consensus and feedback from experts in kidney and liver transplantation to establish the criteria. Pediatric SLK candidates will be exempt from the medical eligibility criteria.
2. New rules for liver-kidney allocation that fix the inconsistency that exists between deceased donor liver allocation policy and liver-kidney allocation policy and will provide a clear indication to OPOs whether liver-kidney allocation is required, permissible, or prohibited.
3. A “safety net” (new match classification priority on the kidney alone waiting list) for liver recipients with continued dialysis dependency or kidney dysfunction in the first year after liver transplant as an added element to address concerns about limitations associated with the SLK medical eligibility criteria.

Medical eligibility criteria [Table 9.6 in policy language]

The Committee is proposing that adult liver-kidney candidates be required to meet certain medical eligibility criteria related to kidney function in order to receive a kidney with a liver offer from the same deceased donor. To be clear, this proposed change does *not* prevent a transplant program from registering an adult candidate on the kidney waiting list if they do not meet the criteria. This is consistent with kidney alone allocation, since there are no medical requirements that a patient is required to meet to be placed on the kidney waiting list but rather a number of criteria related to the candidate’s medical status are used to prioritize the candidate for allocation order. Instead, the change requires adult liver-kidney candidates to meet certain criteria related to kidney function in order to be prioritized ahead of all kidney alone candidates at the time of their liver offer. In order for the adult candidate to receive this priority, the adult candidate must meet one of the below criteria.

[Note: The table below is to be read from left to right. The diagnosis confirmed in the left column *must* be accompanied by data reporting on the liver waiting list and medical record documentation, as described in the right column, in order for the candidate to qualify.]

If the candidate’s transplant nephrologist confirms a diagnosis of:	Then the transplant program must report in the UNOS computer system and document in the candidate’s medical record:
Chronic kidney disease (CKD) with a measured or calculated glomerular filtration rate (GFR) less than or equal to 60 mL/min for greater than 90 consecutive days	At least <i>one</i> of the following: <ul style="list-style-type: none"> • That the candidate has begun regularly administered dialysis as an end-stage renal disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting. • At the time of registration on the kidney waiting list, that the candidate’s most recent measured or calculated creatinine clearance (CrCl) or GFR is less than or equal to 30 mL/min. • On a date after registration on the kidney waiting list, that the candidate’s measured or CrCl or GFR is less than or equal to 30 mL/min.

If the candidate’s transplant nephrologist confirms a diagnosis of:	Then the transplant program must report in the UNOS computer system and document in the candidate’s medical record:
Sustained acute kidney injury	<p>At least <i>one</i> of the following, or a combination of both of the following, for the last 6 weeks:</p> <ul style="list-style-type: none"> • That the candidate has been on dialysis at least once every 7 days. • That the candidate has a measured or calculated CrCl or GFR less than or equal to 25 mL/min at least once every 7 days. <p>If the candidate’s eligibility is not confirmed at least once every seven days for the last 6 weeks, the candidate is not eligible to receive a liver and a kidney from the same donor.</p>
Metabolic disease	<p>A diagnosis of at least <i>one</i> of the following:</p> <ul style="list-style-type: none"> • Hyperoxaluria • Atypical HUS from mutations in factor H or factor I • Familial non-neuropathic systemic amyloidosis • Methylmalonic aciduria

The diagnosis and the specific medical criteria that is required to accompany the diagnosis will be programmed as required data fields on the liver waiting list when the liver transplant program indicates that the liver candidate is also registered for a kidney transplant. At the time of implementation of this new medical eligibility criteria, all adult candidates registered for a liver-kidney transplant will be required to meet the criteria in order to receive a liver-kidney offer (adult candidates who do not meet the criteria will still be eligible for a liver alone offer). UNOS will release new data fields at least two months in advance of implementation in order to allow transplant programs time to prepare for implementation.

Pediatric liver-kidney candidates (those registered on the liver waiting list prior to their 18th birthday) are not required to meet any medical eligibility criteria for liver-kidney allocation. Instead, pediatric liver-kidney candidates will be eligible when registered on both the liver and kidney waiting lists.

See sections “How will the OPTN implement this proposal?”, “How will members implement this proposal?”, and “How will members be monitored for compliance of this proposal?” for additional implementation details. For more information on how the medical eligibility criteria was developed, see “How was this proposal developed?” below.

Liver-Kidney Allocation Rules [Policy 9.7, 9.7.A, and 9.7.B in policy language]

The Committee is also proposing new rules for liver-kidney allocation that direct OPOs as to when liver-kidney allocation is prohibited, required, or permissible. Liver-kidney combinations will continue to be offered using the liver match run and OPOs will follow the match run to determine ordering of candidates. As proposed, the following rules will apply for liver-kidney allocation:

- OPOs will be prohibited from offering the kidney with the liver to any adult candidate who does not meet the medical eligibility criteria outlined above. The adult candidate’s SLK eligibility status will be indicated to the OPO in DonorNet® at the time of offer and to the transplant program on the liver waiting list.
- If the match run lists a pediatric liver-kidney candidate (regardless of whether the candidate is local, regional, or national), the OPO will be required to offer the kidney along with the liver before allocating the kidney to the kidney alone waiting list.

- If the match run lists an adult local liver-kidney candidate who meets medical eligibility criteria, the OPO will be required to offer the kidney along with the liver before allocating the kidney to a kidney alone candidate.
- If the match run lists an adult regional liver-kidney candidate who meets medical eligibility criteria and has a MELD of at least 35 or a status 1A, the OPO will be required to offer the kidney along with the liver before allocating the kidney to a kidney alone candidate.
- If the match run lists a regional or national liver-kidney candidate who meets medical eligibility criteria but has a MELD lower than 35, the OPO may offer the kidney with the liver but is not required to do so.
- If the OPO has met all required offers (including those required by other multi-organ policies), the OPO may offer the kidney to a kidney alone patient.

“Safety Net” [Policy 8.5.H, 8.5.J, 8.5.K, and 8.5.L in policy language]

The Committee is proposing to create a new match classification priority on the kidney alone waiting list for liver recipients with post-operative dialysis dependency and significant kidney dysfunction in the first year after liver transplant. This will allow the Committee to monitor the policy after its implementation to ensure the new medical eligibility criteria are appropriate, while providing a safeguard for liver recipients that require a kidney post-transplant.

The new kidney match classification priority will apply to all liver recipients (with the exception of SLK recipients, unless the SLK recipient experienced immediate and permanent non-function of the transplanted kidney) who meet certain medical criteria in the period between two and twelve months after liver transplant. During this period, the candidate must be a candidate on the kidney waiting list *and* be on dialysis or have a GFR at or below 20 mL/min in order to receive the additional priority. This criteria is similar to that used to assign waiting time points and prioritization for kidney alone allocation except that this criteria must be met *within* the specified period after liver transplant and the transplant program is responsible for reporting updates in order for the candidate to remain eligible after the first 30 day period. Eligibility will apply as follows:

- The candidate will be eligible for a 30-day period with the first report in the UNOS computer system during this timeframe that the candidate has met the criteria.
- To remain eligible, the transplant program must confirm at least once every 30 days that the eligibility criteria continues to be met.
- Once the transplant program has confirmed this for 90 consecutive days after the qualifying test date or administration of dialysis, the candidate will remain eligible for this priority until the candidate is removed from the kidney waiting list and the transplant program will no longer need to provide updated data.

In instances where the candidate was on the kidney waiting list and met the required criteria but the transplant program was late in reporting the criteria, UNetSM (the UNOS computer system) will allow the program to select the appropriate date to allow for safety net priority. If the transplant program did not register the liver recipient on the kidney waiting list within the 365 day timeframe, but clearly had a documented intent to do so, the transplant program can apply for the registration date to be corrected through the same process the program currently uses to apply for kidney waiting time modifications under *Policy 3.7: Waiting Time Modifications*. If the program’s application for the liver recipient meets the requirements specified for kidney waiting time modifications (and, therefore, the candidate is eligible to have the registration data backdated on the candidate’s UNetSM record), the liver recipient will also be eligible for safety net priority.

At the time of implementation of this new policy, all liver recipients who meet the medical criteria outlined above within 60-365 days after liver transplant will be eligible for this new priority. UNOS will program new fields in order to implement this new match classification priority and the new fields will be available at

least two months in advance of implementation. See sections “How will the OPTN implement this proposal?”, “How will members implement this proposal?”, and “How will members be monitored for compliance of this proposal?” for additional details.

The safety net match classification priority is limited within each KDPI sequence (see below table).

Safety net: Match classification priority for liver recipients by KDPI sequence

Sequence A KDPI ≤ 20%	Sequence B KDPI >20% but <35%	Sequence C KDPI ≥35% but ≤85%	Sequence D KDPI >85%
Highly sensitized	Highly sensitized	Highly sensitized	Highly sensitized
0-ABDR mismatch	0-ABDR mismatch	0-ABDR mismatch	0-ABDR mismatch
Prior living donor	Prior living donor	Prior living donor	Local SLK safety net
Local pediatrics	Local pediatrics	Local SLK safety net	Local + regional
Local top 20% EPTS	Local SLK safety net	Local candidates	National candidates
0-ABDR mismatch (all)	Local adults	Regional candidates	
Local (all)	Regional pediatrics	National candidates	
Regional pediatrics	Regional adults		
Regional (top 20%)	National pediatrics		
Regional (all)	National adults		
National pediatrics			
National (top 20%)			
National (all)			

Related SLK allocation problems and efforts to address those concerns

Many in the transplant community have commented that one of the other problems with SLK allocation is that the outcomes of liver-kidney transplants are currently not included in the Program Specific Reports (PSRs) published by the Scientific Registry of Transplant Recipients (SRTR) and are not reviewed by the Membership and Professional Standards Committee (MPSC). This has also been a concern for the Committee, as it stands to reason that this could serve as further incentive for a transplant program to accept a kidney with the liver offer even if the physician or surgeon is unsure whether the candidate needs the kidney transplant. While this proposal does not address these issues (and both are out of scope for this policy), the Committee feels it important to let the community know that both of these issues are being reviewed and addressed through separate efforts. The SRTR recently reported to the Committee that liver-kidney transplants will be newly included in the PSRs and the timeline for publishing those reports will likely coincide with implementation of these new allocation rules. In addition, the MPSC has been actively discussing how to most appropriately review post-transplant patient and graft survival for multi-organ transplants with a major focus on liver-kidney transplants. The MPSC will be seeking feedback from the transplant community before making a final determination on whether and how to most appropriately review these outcomes.

The Committee also acknowledges that members of the transplant community have expressed frustrations about the lack of clarity in policies directing order of allocation for multi-organ candidates. This proposal does not address this problem in a comprehensive way, in that it does not mandate liver-kidney allocation before other types of multi-organ allocation involving a kidney. However, the proposal seeks to begin this effort by establishing clearer policies for one of the most common types of multi-organ allocation—liver-kidney transplants.

Why should you support this proposal?

For over a decade, the transplant community has discussed the need for SLK allocation policy that is based on sound medical criteria. The elements of this proposal (SLK medical eligibility criteria, rules for SLK allocation, and a safety net for liver recipients with a continued need for kidney transplant) address the problems identified through different perspectives in the community to combine the most commonly discussed solutions for addressing the problems with the current policy. The Committee has solicited and responded to feedback from many different stakeholder groups in the development of this policy. The proposal being recommended for approval by the Board of Directors enjoys the highest level of support and consensus achieved in over a decade.

To review feedback from different stakeholders and the Committee's response, see "How was this proposal developed?" below.

How was this proposal developed?

Since the introduction of the MELD score into deceased donor liver allocation policy in 2002, SLK transplants have significantly increased in the United States (Figure 1). Concerns about the lack of clear rules for SLK allocation have increased alongside the growing number of SLK transplants.

In 2006 and 2007, the professional transplant societies held a consensus conference to discuss and develop recommendations for SLK medical listing criteria. Following the conference, the Kidney and Liver Committees jointly sponsored a 2009 public comment proposal (**Exhibit B**⁵) that adopted some of those recommendations. The majority of the OPTN/UNOS regions and individuals who offered feedback were supportive of the 2009 proposal. However, several national professional groups, notably the American Society for Transplant Surgeons (ASTS), the National Kidney Foundation (NKF), and the American Urological Association (AUA) opposed portions of the proposal for different reasons. The main concern from ASTS was that the medical criteria established was too strict. The main concern from the NKF and the AUA was that the medical criteria was too loose and the additional priority on the kidney waiting list would impede access for kidney alone candidates.

Further complicating the effort was the fact that many of the proposed changes involved very complex and expensive IT programming—mostly due to the vast number of kidney allocation policy variances that existed at the time and the unknown factor of when the new kidney allocation system (KAS) would be approved and implemented. Because of these concerns, the committees decided not to move forward with sending the 2009 proposal to the Board of Directors for approval. Once the new KAS was approved by the Board of Directors in June 2013, the Committee formed a working group ("the working group") with members from the following OPTN/UNOS Committees to again discuss possible changes:

- Liver and Intestinal Organ Transplantation Committee
- Ethics Committee
- Minority Affairs Committee
- OPO Committee
- Operations and Safety Committee

The working group met throughout 2013 and 2014 to review previous work on the proposal, the public comments received in 2009, recent literature on SLK and kidney after liver transplants, and available OPTN data. In December 2014, the working group came to consensus on a set of recommendations. The recommendations were then presented to the 11 OPTN regions and distributed to several of the professional transplant societies who commented on the 2009 proposal. The Committee made some

⁵ This exhibit can be accessed in the public comment document at https://optn.transplant.hrsa.gov/media/1240/05_slk_allocation.pdf

adjustments in response to the pre-public comment feedback and sponsored another public comment proposal in the fall 2015.⁶

The working group and Committee reviewed public comments received on the fall 2015 proposal and began amending the proposal in response. In December 2015, the Committee presented the updated proposal during a breakout session at the OPTN/UNOS Board of Directors meeting. The Committee then made a few changes in response to feedback received during that session. Below is an overview of the changes made for the Spring 2016 public comment proposal.

Overview of Changes Made to Medical Eligibility Criteria for 2016 Spring Public Comment

Fall 2015 Public Comment Proposal	Spring 2016 Public Comment Proposal	Who requested the change?
Along with a diagnosis for CKD, the candidate must be on dialysis for ESRD or eGFR at or below 35 mL/min.	Along with a diagnosis for CKD, the candidate must be on dialysis for ESRD or eGFR at or below <u>30</u> mL/min.	Several members of the OPTN/UNOS Board of Directors commented that the GFR criteria for the CKD category is too high.
In the sustained acute kidney injury category, the candidate must have one or a combination of dialysis or eGFR at or below 25 mL/min during any 6 week period.	In the sustained acute kidney injury category, the candidate must have one or a combination of dialysis or eGFR at or below 25 mL/min during the 6 week period <i>prior to the SLK transplant</i> .	The working group/Kidney Committee wanted to ensure that the criteria is being met in the period that immediately precedes the SLK transplant.
In the sustained acute kidney injury category, the transplant program must report that the medical criteria is met every 7th day.	In the sustained acute kidney injury category, the transplant program must report that the medical criteria is met <i>at least once every 7 days</i> (the report does not have to take place on the 7 th day).	A question was raised in the comments from Region 2 and the Committee clarified the language.
Pediatric and adult SLK candidates are required to meet medical eligibility criteria in order to be eligible to receive liver-kidney offers.	<i>Only adult SLK candidates</i> will be required to meet medical criteria. Pediatric SLK candidates (those registered on the liver waiting list prior to their 18 th birthday) will only be required to be registered on both the kidney and liver waiting list in order to be eligible to receive liver-kidney offers.	Many of the regions supported the proposal with this change. Regions 5, 7, and 10 specifically requested this change in the comments. The Pediatric and Liver Committees also requested the change.
The proposal did not explain how existing SLK candidates would be treated upon implementation.	Upon implementation, all adult SLK candidates must meet medical eligibility criteria in order to receive SLK. UNOS will release data fields in advance of implementation to allow programs to prepare.	The question was raised by UNOS staff in the process of developing an implementation plan for the proposal.

⁶ <http://optn.transplant.hrsa.gov/governance/public-comment/simultaneous-liver-kidney-allocation/>

Fall 2015 Public Comment Proposal	Spring 2016 Public Comment Proposal	Who requested the change?
Programs are required to report diagnosis in UNet, document specific medical factors around dialysis, GFR, etc. in the medical record.	Programs are required to report diagnosis info and specific medical factors in UNet SM , and must document data in the medical record.	This was requested by the working group and the Committee to ensure that there will be sufficient data to analyze after implementation of the policy to determine whether the medical criteria selected is appropriate.

Overview of Changes Made to SLK allocation for 2016 Spring Public Comment

Fall 2015 Public Comment Proposal	Spring 2016 Public Comment Proposal	Who requested the change?
Local SLK candidates must meet medical eligibility criteria and have MELD score of at least 35.	Local adult SLK candidates must <i>only</i> meet medical eligibility criteria.	This request originated from the Liver Committee. Many regions supported the proposal with this change. Regions 7 and 10 specifically requested this in the comments.
Before allocating to the kidney alone list, OPOs are required to offer to regional SLK candidates who meet medical eligibility criteria and have MELD at least 35.	Before allocating to the kidney alone list, OPOs are required to offer to regional SLK candidates who meet medical eligibility criteria and have MELD at least 35 <i>or status 1A</i> .	This was an issue that was raised in the working group/Committee after public comment. Since liver-kidney offers will still be made off of the liver match run, the groups noticed that Status 1A candidates are prioritized on the liver match run ahead of "Share 35" candidates.
Regional candidates with MELD score below 35 are not eligible for SLK allocation.	Regional candidates with MELD score below 35 <i>are eligible if they meet medical eligibility criteria</i> . The OPO is not required to allocate the kidney with the liver to these candidates but allocation is permissible.	This was an issue that was raised in the working group/Committee after public comment. The working group/Committee wanted to ensure that the OPO still has flexibility in the allocation process if trying to avoid discards.
National SLK allocation is prohibited.	National SLK allocation is <i>permissible</i> and OPO will decide whether to allocate as national SLK or to a kidney alone candidate once required offers have been completed.	This was an issue that was raised in the working group/Committee after public comment. The working group/Committee wanted to ensure that the OPO still has flexibility in the allocation process if trying to avoid discards.

Fall 2015 Public Comment Proposal	Spring 2016 Public Comment Proposal	Who requested the change?
Pediatric candidates receive local/regional priority when meeting the medical eligibility criteria.	Pediatric candidates will receive local, regional, and <i>national priority regardless of whether they meet the medical eligibility criteria.</i>	Liver Committee
Proposed language is silent in directing OPOs for regional SLK allocation.	Proposed language makes clear that OPO must offer kidney to eligible regional SLK candidates before offering to the kidney alone waiting list.	The change originated from the Liver Committee. Many regions supported the proposal with this change. Regions 5, 7, and 10 specifically requested this change. The OPO Committee requested the clarification that the requirement applies before allocating to the kidney alone list, not other multi-organ candidates.

Overview of Changes Made to the Safety Net for 2016 Spring Public Comment

Fall 2015 Public Comment Proposal	Spring 2016 Public Comment Proposal	Who requested the change?
If not on dialysis, the liver recipient must have one GFR \leq 20 mL/min in the 60-365 day period to qualify for safety net. Once qualified, the candidate maintains safety net priority.	If not on dialysis, the liver recipient must have one GFR \leq 20 mL/min in the 60-365 day period to qualify for the safety net. <i>In order to remain qualified, the transplant program must confirm at least once every 30 days that the GFR \leq 20 mL/min. Once this has been confirmed for a 90 consecutive day period after the candidate's first qualifying test date or treatment, the priority will apply until candidate is removed from the kidney waiting list.</i>	The Kidney Committee requested this change in response to comments that the safety net requirements were too lax and programs should be required to show there is continued kidney dysfunction.
If no GFR \leq 20 mL/min, transplant program must report that the candidate is on dialysis in the timeframe that is 60-365 days after the liver transplant to qualify for the safety net.	If no GFR \leq 20 mL/min, transplant program must report that the candidate is on dialysis in the timeframe that is 60-365 days after the liver transplant to qualify. <i>To remain qualified, the transplant program must confirm at least once every 30 days that the candidate is still on dialysis. Once this has been confirmed for a 90 consecutive day period after the candidate's first qualifying test date or treatment, the priority will apply until candidate is removed from the kidney waiting list.</i>	The Kidney Committee requested this change in response to comments that the safety net requirements were too lax and programs should be required to show there is continued kidney dysfunction.

Fall 2015 Public Comment Proposal	Spring 2016 Public Comment Proposal	Who requested the change?
The Committee did not describe how existing candidates would be treated once new policy has been implemented.	Upon implementation, <i>all liver recipients who meet the medical criteria will be eligible for safety net priority.</i>	The question was raised by UNOS staff in the process of developing an implementation plan for the proposal.

The Committee then distributed the updated proposal for Spring 2016 public comment.

Was this proposal changed in response to the most recent public comment?

Because the proposal represents over 10 years of work and compromises from groups representing the many different perspectives and received overwhelming support from the OPTN regions in the Spring 2016 public comment cycle, the SLK working group and the Kidney Committee voted unanimously to recommend that the proposal move forward to the Board with no post-public comment changes.

However, the Committee did consider and discuss changes based on public comment.

Changes considered but not adopted: SLK medical eligibility criteria

The SLK medical eligibility criteria being recommended to the Board of Directors enjoys wide ranging support from the 11 OPTN regions, the AUA, NKF, and the many OPTN/UNOS committees that reviewed and provided comment on the proposal. However, a review of the comments from the American Society of Nephrology (ASN) and ASTS highlight the difficulty the working group faced in achieving wide ranging clinical consensus on these criteria. The ASN suggests that the medical criteria for CKD and sustained acute kidney injury are too liberal, while the ASTS suggests they are too conservative.

The ASTS and Region 9 suggested that the Committee consider revising the duration of time (from 6 weeks to 4 weeks) that a liver-kidney candidate must be on dialysis or have continued GFR ≤ 25 to meet the SLK eligibility standard for sustained acute kidney injury. The ASTS comments reflect that there were differing opinions and practices among their own membership about the appropriate duration. During policy development, the working group and Committee actively debated the duration of dialysis. It was generally, although not universally, felt that 12 weeks was too long. Much of the debate centered around 6 versus 8 weeks. In the end, the Kidney Committee representatives compromised and agreed to 6 weeks because of concerns that candidates for SLK have MELD scores that portend a poor 3 month survival and 6 weeks duration was more favorable to the patient. In the end, the Committee decided on the six week duration as a reasonable compromise, since there were strong voices arguing for both more and less dialysis time prior to SLK eligibility. The Committee discussed that the implementation of the safety net should address concerns expressed about the duration being too strict.

There were also comments debating whether the GFR threshold (30 mL/min) for the CKD criteria is too liberal. These comments were received from the American Society of Nephrology (ASN) and an individual commenter. The Committee, along with the working group, has debated this point at length. The Committee believes it has arrived at the medical criteria that is well supported by the transplant community and the best evidence that exists at this time.

Board Amendment: SLK medical eligibility criteria

Subsequent to the committee's April 18, 2016 vote on the proposal, a Board member requested a draft amendment to be considered by the Board at the June meeting. The amendment would change the GFR threshold criteria for the CKD category from 30 mL/min to 20 mL/min in order to make SLK eligibility criteria for CKD consistent with the criteria used to assign waiting time points in kidney alone allocation. The leadership of the Kidney and Liver Committees discussed the amendment and are requesting that the Board *not* adopt the amendment. The Kidney Committee's regional representatives raised this specific question for feedback at the regional meetings. The feedback was overwhelmingly against lowering the GFR threshold for this category. The change would significantly restrict candidate eligibility

and the Committee is concerned that making such a change without the consensus of the transplant community will jeopardize the trust that the working group and Committee have gained in the development of this proposal.

Changes considered but not adopted: SLK allocation

The proposed new SLK allocation rules were also widely supported by the OPTN regions, the AUA, NKF, and other OPTN/UNOS committees (including the OPO and Liver and Intestinal Organ Committees). However, the ASTS and Region 7 expressed concerns about whether the expanded requirements for regional liver-kidney allocation go far enough. The ASTS suggested that the OPO should be required to allocate the kidney with the liver to regional candidates with MELD at least 30. Region 7 (the only region to vote to oppose the proposal) offered that the OPO should be required to share the kidney with the liver to all regional candidates, regardless of MELD. The working group and the Committee discussed these comments and agreed that it is not appropriate to make either of these changes for the below reasons:

- The proposal is designed to align the new liver-kidney allocation policy with the current liver alone allocation policy. The current liver-kidney allocation policy does not require sharing beyond the local DSA, although the current liver alone allocation policy mandates regional liver sharing for candidates with MELD score of at least 35. Making this rule consistent also decreases complexity in implementing any new rules by ensuring that liver-kidney offers will still be made using the liver match run and a consistent allocation scheme.
- Using the addition of MELD score for regional liver-kidney sharing acknowledges that there must be a balance in access for liver-kidney and kidney alone candidates and that kidney alone candidates face a large supply/demand mismatch for organs and additional time on dialysis results in worse outcomes.

Changes considered but not adopted: Safety net for liver recipients

The safety net element of this proposal enjoys the most support and consensus of any other element of the proposal. However, there was feedback concerning the placement of safety net priority among the deceased donor kidney allocation sequences. This is also an area where the Committee has received conflicting feedback throughout the public comment cycles. Some commenters have suggested that there should be no additional priority for liver recipients in sequence B (the allocation sequence when the donor's KDPI score is 20-34%), even though local adult liver recipients would only be prioritized within this sequence after the highly sensitized and local pediatric candidates.

Others (notably the ASTS and Region 9) expressed concern that there is no additional safety net priority in sequence A of kidney allocation. The working group and the Kidney Committee discussed this concern and decided against recommending additional priority in sequence A for the following reasons:

- While liver recipients will not receive additional safety net *priority* for kidneys in sequence A, they are not excluded from receiving these offers altogether. For instance, a liver recipient who is highly sensitized would still appear in the highly sensitized match classification in sequence A. A liver recipient with an EPTS in the top 20% would still appear in this classification within the sequence. And, liver recipients in the OPO's DSA will still appear in the "all local adults" match classification in sequence A.
- The main goal of sequence A is to provide more life years from kidney transplantation. In previous public comment periods, the regions and other commenters have expressed concern that the new safety net classification may act as a disincentive for a liver recipient to find a living kidney donor. The Committee contends that sequence A kidneys perform similar to living donor kidneys, and exempting a special classification for liver recipients in this sequence may provide incentives for liver recipients to seek a living kidney donor.

How well does this proposal address the problem statement?

To support the development of the proposal, the committee examined a variety of data analyses, including:

- Estimated percentage of prior SLK recipients that would not have qualified under new medical eligibility criteria;
- Survival advantage of receiving an SLK vs. liver alone transplant;
- Kidney graft survival for SLK vs. kidney alone and heart-kidney;
- The effect of a previous liver transplant on kidney waiting list and recipient survival.

Estimated percentage of prior SLK recipients that would not have qualified under new medical eligibility criteria

OPTN and CMS data were used to estimate that 42% of past SLK recipients were on dialysis for ESRD as reported on a CMS 2728 medical evidence form. 24% were not on chronic dialysis but had eGFR of 20 or less based on serum creatinine just before transplant. An additional 13% had eGFR between 21 and 30, while 2% were on dialysis at least 6 weeks before transplant, for a total of 81% estimated to have qualified. It is estimated that the remaining 19% of recipients, having eGFR's above 30, would not have qualified. (Table 1)

Estimated Number of Prior SLK Recipients (January 2005 – June 2015) that would have Met Medical Eligibility Criteria

Would SLK Recipient Have Met Proposed SLK Eligibility Criteria?*	Detailed criteria	N	%
Chronic kidney disease	On Dialysis for ESRD at Time of Transplant	1,874	41.6
	Not on Dialysis for ESRD, eGFR <21	1,081	24.0
	Not on Dialysis for ESRD, eGFR 21-25	328	7.3
	Not on Dialysis for ESRD, eGFR 26-30	267	5.9
Sustained acute kidney injury	On dialysis for 6+ weeks before transplant #	101	2.2
Would not qualify for SLK	No Dialysis for ESRD or temporary dialysis for 6+ weeks, eGFR 31-35	213	4.7
	No Dialysis for ESRD or temporary dialysis for 6+ weeks, eGFR > 35	636	14.1
Total		4,500	100.0

* OPTN and CMS data were used as proxies for determining whether recipient would have qualified under proposed criteria. These data were not collected for this purpose and are limited in their ability to determine whether each recipient would have qualified, so the results are only approximate.

#Dialysis date from TRR or in CMS CROWNWeb database, but not on CMS 2728 form.
(43 SLK transplants were excluded due to unknown eGFR.)

Given over 600 SLK transplants were performed in 2015, a 19% decrease translates into about 120 fewer SLK transplants per year due to not meeting the proposed eligibility criteria. However, the inclusion of a safety net in this proposal may further reduce the number of SLK transplants due to changes in clinician and patient decision-making. The degree to which this behavior may change is unknown.

In addition, the 19% estimate is very likely an underestimate, since many of the recipients assumed to have qualified based on a recent eGFR measurement of 30 or less may not have met the proposed criterion of eGFR≤60 for at least 90 days to qualify based on chronic kidney disease. In other words, more than 19% of patients currently receiving SLK transplants may not qualify under the proposed criteria. On the other hand, this analysis may underestimate the number of previous SLK recipients with sustained acute kidney injury and thus would have qualified, since serial creatinine measurements were not included in the analysis.

These limitations and assumptions must be taken into account when interpreting these findings.

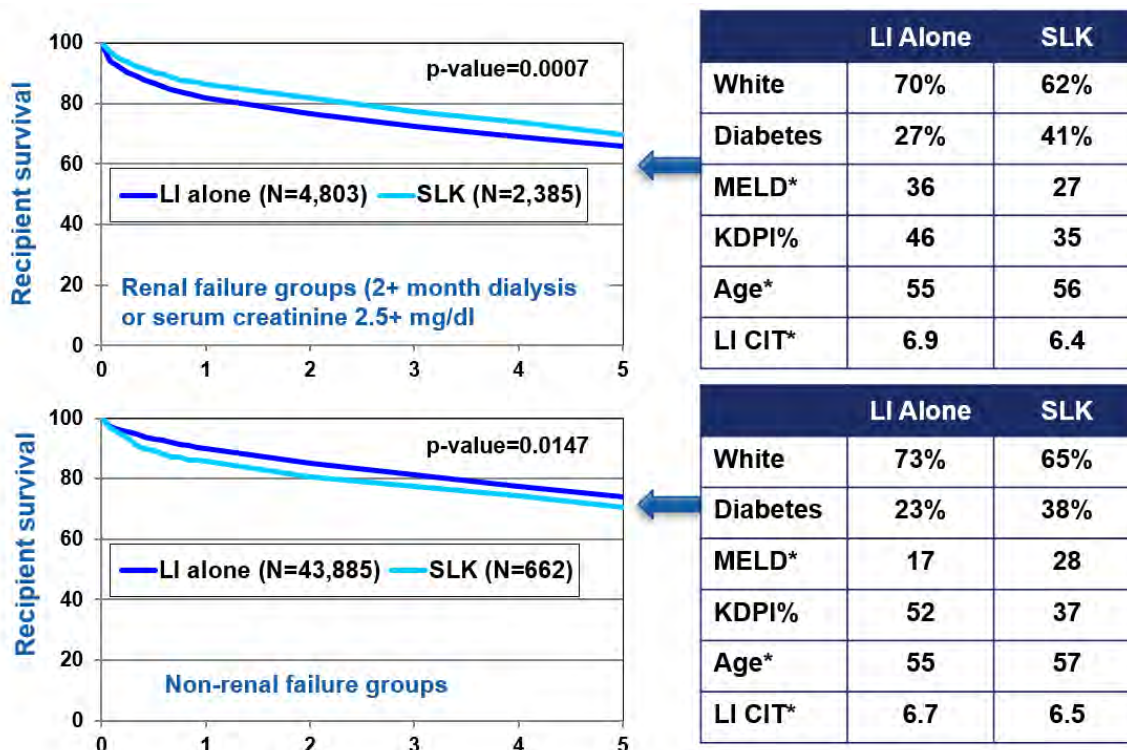
Survival advantage of receiving a kidney vs. liver alone

The committee examined the survival advantage of receiving a kidney along with the liver vs. receiving a liver alone transplant to provide evidence supporting SLK eligibility criteria.

Figure 2 compares recipient survival for those who received a kidney along with the liver vs. those who received a liver alone transplant for those with strong evidence of renal failure prior to transplant (top portion), and those without strong evidence of renal failure (bottom). Strong evidence of renal failure was defined as 2+ months or dialysis or serum creatinine of 2.5 mg/dl or greater prior to transplant. Donor, recipient and transplant characteristics are displayed on the left.

Figure 2. Crude (non-risk adjusted) survival advantage of receiving an SLK vs. liver alone transplant

Kaplan-Meier survival for transplants performed from March 1, 2002 through December 31, 2012. Unless specified otherwise, multi-organ transplants and prior transplant recipients were excluded from analyses.



* Medians are shown

Figure 2 suggests that a patient survival advantage exists for liver recipients who also received a kidney, but only among liver patients with strong evidence of renal failure (top graph). In fact, for patients not on

dialysis for 2+ months or with Cr \geq 2.5 prior to transplant, a survival decrement was associated with receiving a kidney (bottom graph).

However, it is important to recognize that differences in survival rates for liver-alone versus SLK recipients may not be attributable to receiving the liver, but rather may be at least partially explained by differences in recipient characteristics. Liver alone patients were more likely to be white and non-diabetic, but their donors tended to have higher KDPI score. Liver alone patients had higher MELD scores for renal failure groups and lower scores for non-renal failure groups. Liver alone and SLK recipients had similar median ages and liver cold ischemia time (CIT).

To account for these differences and avoid providing the Committee with potentially misleading results, a rudimentary risk-adjusted analysis (using Cox regression with ethnicity, diabetes, era, recipient age, MELD, and KDPI as covariates) was performed. This supplementary analysis confirmed that a statistically significant survival advantage of receiving the kidney for the renal-failure group, and a slight survival detriment for the non-renal-failure group, were both still evident even after accounting for a variety of key patient and donor characteristics.

These findings are consistent with a study by Fong, et al.⁷ The study also analyzed differences in survival for renal failure group adjusting for patient characteristics (age, MELD, ICU at time of transplant, donor quality, etc.) and, even after accounting for differences in patient characteristics, there was a survival benefit of receiving a kidney along with the liver.

Based on **Figure 2**, there seems to be a survival advantage of receiving a kidney along with the liver over receiving a liver alone, but only for those with renal failure. This could be considered as evidence supporting a restriction of SLK transplants to those liver candidates with renal failure. Whether a liver patient should be afforded the advantage associated with an SLK versus liver alone transplantation must also be considered in light of the substantial survival advantage for a kidney-alone patient of receiving a kidney transplant compared to remaining on the waitlist (or on dialysis), since each kidney used in an SLK leaves one less kidney for a kidney alone transplant. Table A.1 in **Exhibit C**⁸ shows that kidney patients remaining on the waitlist have an estimated 74.7% five-year survival rate (measured from the date of listing), while Table A.3 reveals an 81.1% five-year post-transplant survival rate after transplant for kidney recipients. The survival advantage associated with receiving a solitary kidney transplant has been widely published.^{9 10}

Kidney graft survival for SLK vs. kidney alone and heart-kidney

To assess the degree of decrease in kidney graft survival in multi-organ transplants, the Committee compared kidney graft survival for SLK vs. kidney alone recipients and also compared those with heart-kidney recipients.

Figure 3 shows kidney graft survival rates (left panel) and recipient survival (right panel) for SLK recipients with and without renal failure and kidney alone recipients without previous liver transplant. The left panel also includes kidney graft survival for heart-kidney transplants. The table shows the percentage of white recipients and median age for each of those groups.

⁷ Fong, et al. *Transplantation*. 94(4):411-416, Aug 27, 2012

⁸ This exhibit can be accessed in the public comment document at https://optn.transplant.hrsa.gov/media/1240/05_slk_allocation.pdf

⁹ Wolfe, Robert A., et al. "Comparison of mortality in all patients on dialysis, patients on dialysis awaiting transplantation, and recipients of a first cadaveric transplant." *New England Journal of Medicine* 341.23 (1999): 1725-1730.

¹⁰ Merion, Robert M., et al. "Deceased-donor characteristics and the survival benefit of kidney transplantation." *Jama* 294.21 (2005): 2726-2733.

Figure 3. Kidney graft and recipient survival

Kaplan-Meier survival for transplants performed from March 1, 2002 through December 31, 2012. Unless specified otherwise, multi-organ transplants and prior transplant recipients were excluded from the analyses.

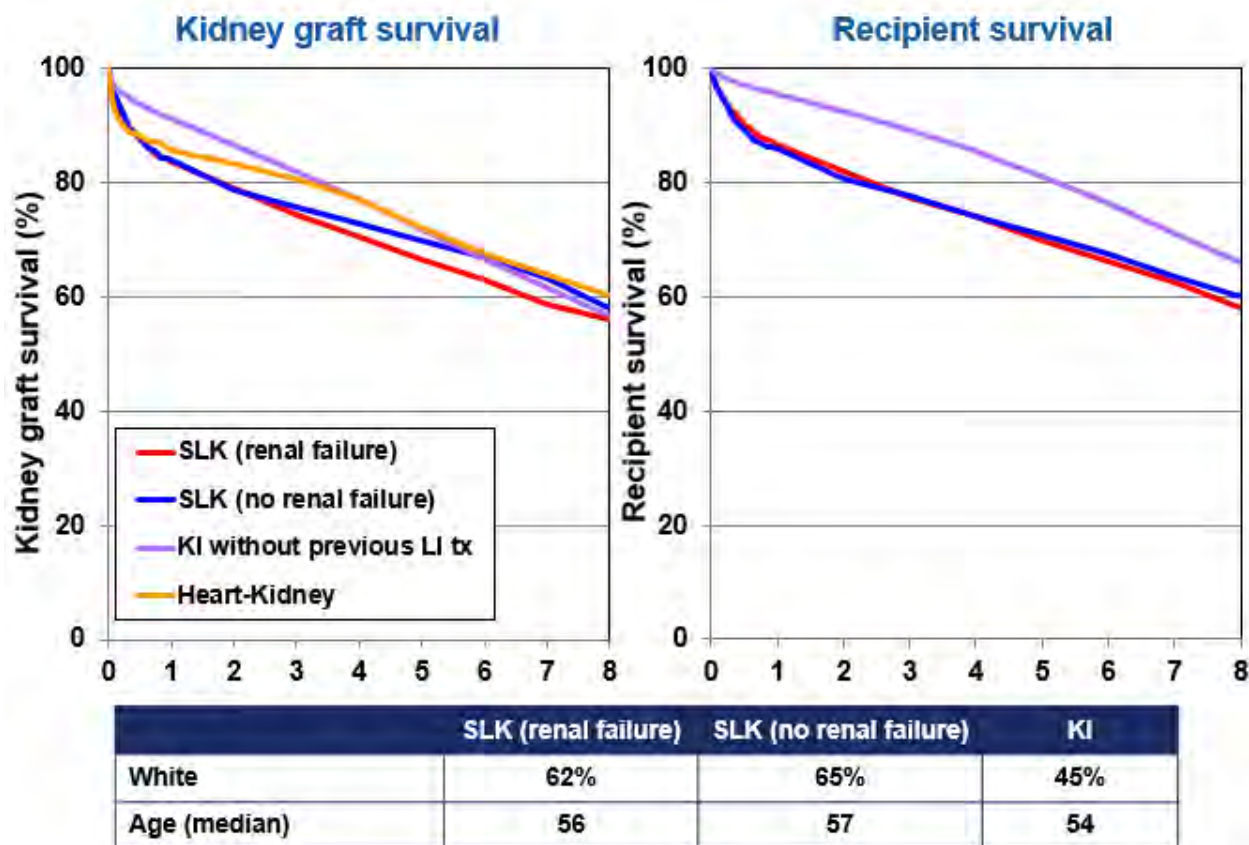


Figure 3 (left panel) shows that within the first several years after transplant, SLK recipients had a substantially worse kidney graft survival compared to the kidney alone group. This difference was primarily driven by high rates of kidney graft failure and recipient mortality within the first three months of transplant. However, the strikingly similar pattern observed in the two panels highlights the fact that higher recipient mortality in SLK transplants is the driving factor behind lower kidney graft survival rates in SLK recipients. When a recipient dies, a kidney is lost as well, so kidney graft status was considered failed at the time of recipient death even if a recipient died with the functioning graft. In fact, out of all kidney graft failures within the first year of transplant, about 60-70% of kidney graft failures in the SLK group (59% for those with renal failure and 70% for those with no renal failure) were because the patient died with a functioning kidney. This percentage was much lower for the kidney alone group, at 39%.

In the long term (5+ years after transplant), kidney graft survival rates appear to converge for SLK recipients and kidney alone recipients, and a relatively small number of SLK recipients surviving with the functioning kidney makes it harder to identify statistically significant differences in long-term graft survival.

Similar to SLK recipients, survival of the kidney is also initially worse in heart-kidney patients compared to kidney alone, but the curves converge even earlier, at around 3 years post-transplant.

Differences in patient characteristics may have contributed to differences in survival. SLK recipients were more likely to be white compared to kidney alone. All groups had similar median ages.

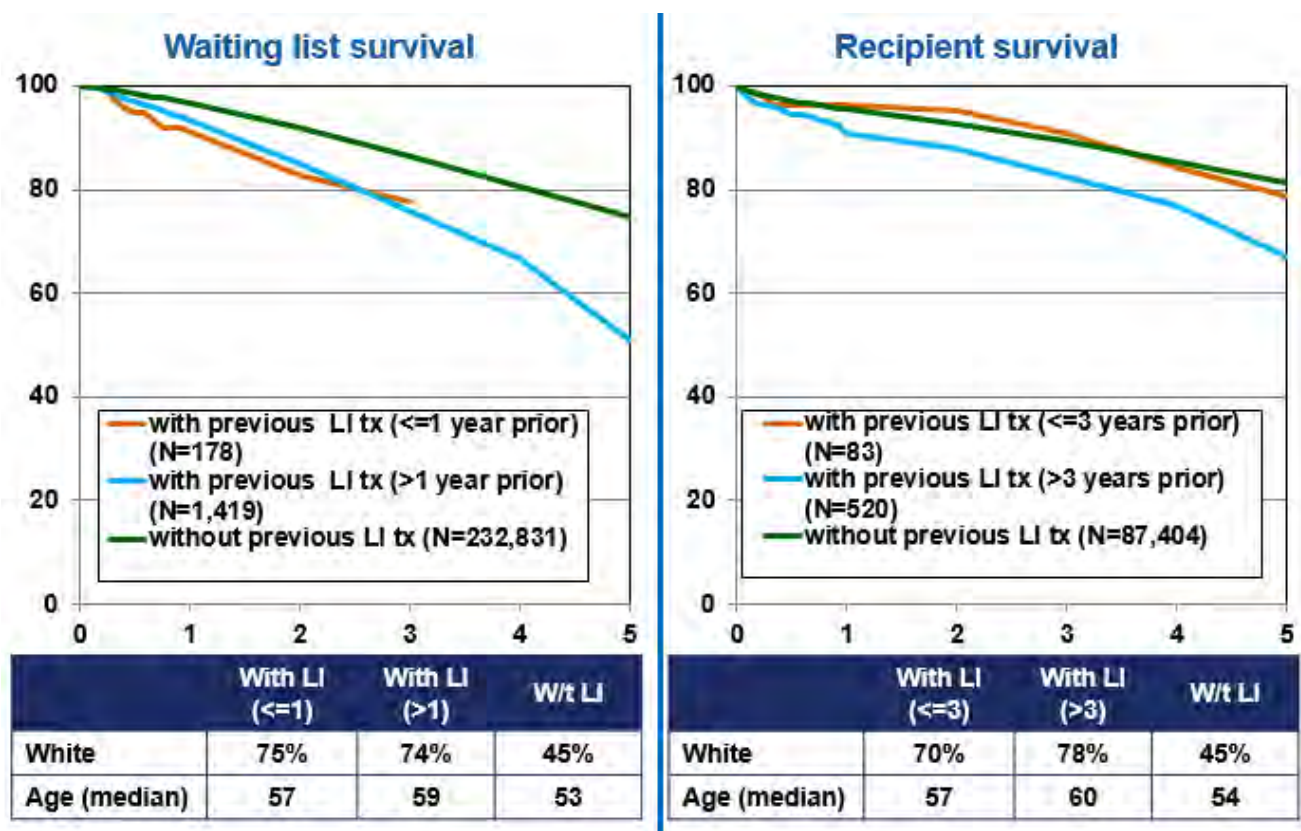
The effect of a previous liver transplant on kidney waiting list and recipient survival

The committee also examined the effect of a previous liver transplant on kidney waiting list and recipient survival to provide evidence supporting a “safety net” concept that would increase priority on the deceased donor kidney waitlist for previous liver alone recipients that later develop ESRD.

Figure 4 compares waiting list survival (left panel) and recipient survival (right panel) for kidney candidates and recipients with and without previous liver transplant. Those with previous liver transplant were stratified by duration of time from liver transplant to listing for kidney or kidney transplant, since the “safety net” concept is only intended to apply to patients that show evidence ESRD within a specified time period shortly after liver transplant. The table shows the percentage of white recipients and median age for each of those groups.

Figure 4. Waiting list and recipient survival for kidney patients: with vs. without a prior liver transplant

Kaplan-Meier survival for adult candidates added to the waiting list for from March 1, 2002 through December 31, 2012 and for transplants performed from March 1, 2002 through December 31, 2012. Deaths included removals for deaths and removals for reasons other than transplant with death dates within 30 days of removal. Unless specified otherwise, multi-organ transplants and prior transplant recipients were excluded from the analyses.



Kidney candidates without a previous liver transplant had the highest waiting list survival. Candidates with a previous liver transplant had a substantially lower waiting list survival, suggesting increased priority for those kidney candidates is warranted from a “sickest first” perspective. The right panel shows that those who receive a deceased donor kidney transplant shortly after liver transplant (within 3 years) seem to be doing as well post kidney transplant as those without previous liver transplant, supporting the concept of a

limited time window for the safety net. Differences in patient characteristics may have contributed to differences in survival.

Those listed for kidney within a year of the liver transplant had a substantially worse waiting list survival compared to the kidney alone group, but those who get a kidney transplant shortly after liver transplant have survival comparable with those without a prior liver transplant. This supports the concept of a “safety net” for liver alone recipients who end up needing a kidney shortly after transplant.

Which populations are impacted by this proposal?

The Committee reviewed data suggesting that approximately 19% of current SLK recipients would not have met the proposed medical eligibility criteria. To the extent that this proposal reduces the number of SLK transplants, it could mean an increase in access to kidney-pancreas candidates, heart-kidney candidates, lung-kidney candidates or for pediatric, highly sensitized, and prior living donor kidney alone candidates who are highly prioritized in kidney alone allocation.

If approved, this proposal has the potential to decrease access for liver-kidney candidates who do not meet the medical eligibility criteria specified. However, if a liver-kidney candidate is not eligible for an SLK at the time of liver transplant, the liver recipient would then receive additional priority for a kidney transplant during the year after their transplant if they have dialysis dependency or other evidence of kidney dysfunction.

How does this proposal support the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is some expectation that establishing medical eligibility criteria for SLK transplants will reduce the number of kidneys allocated with a liver and the kidney will be allocated to a kidney alone candidate, increasing the number of kidney alone candidates transplanted.
2. *Improve equity in access to transplants:* The primary goal of this proposal is to establish medical criteria for SLK allocation, so that all candidates on the waiting list for a kidney are assessed for medical need. This will create equitable, fair rules for allocation of kidneys whether to a multi-organ or single organ candidate. This is a specific initiative mentioned in the 2015 OPTN Strategic Plan.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* The Committee has reviewed data showing that transplant outcomes are better for SLK recipients when the recipient was experiencing ESRD prior to the kidney transplant.
4. *Promote living donor and transplant recipient safety:* There is no impact on this goal.
5. *Promote the efficient management of the OPTN:* OPTN members (particularly OPOs and kidney and liver transplant programs) have long requested clearer and more consistent rules around liver-kidney allocation. This proposal will provide more efficiency to the entire OPTN network.

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

This policy 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 SLK medical eligibility criteria affected the number of SLK transplants?

- Has the combination of SLK medical eligibility criteria and the “safety net” resulted in a net decrease, increase, or no change in the number of kidneys going to liver recipients?
- Has there been a change in the number of registrations for kidney within a year of a liver transplant?
- Has the policy increased access to transplants and decreased mortality rates for those registered for kidney within a year of a liver transplant?
- Has the number of living donor kidney transplants post liver transplants remained stable?

The following metrics, and any others subsequently requested by the Committee, will be evaluated to compare performance before vs. after the implementation of the new policy:

- The number of SLK transplants, overall, by geographic distribution (local, regional, national) and pediatric vs. adult
- The distribution of SLK transplants by diagnosis confirming SLK eligibility (CKD with GFR \leq 60 mL/min for greater than 90 consecutive days -- dialysis vs. GFR/CrCl \leq 30; sustained acute kidney injury; metabolic disease) and more granular GFR groups, where appropriate (post implementation only);
- The number of candidates registering for a kidney within a year of a liver transplant;
- The number of candidates registering for a kidney within a year of a liver transplant by candidate’s eligibility for kidney allocation “safety net” priority (post implementation only);
- The number of transplants for kidney candidates who were reported to be eligible for kidney allocation “safety net” priority;
- Waiting list mortality and transplant rates for kidney candidates added to the waiting list within a year of liver transplant;
- Number of living donor kidney transplants post liver transplants.

The Committee will also evaluate the effect of the policy on specific patient populations (pediatric, racial and ethnic minority) and geographic location (OPTN region, DSA).

How will the OPTN implement this proposal?

If this proposal is approved, the OPTN will take on a significant level of effort to implement the proposal. UNOS IT provides cost estimates for each public comment proposal that will require programming to implement. The estimates can be small (108-419 hrs.), medium (420-749 hrs.), large (750-1,649 hrs.), very large (1,650-3,999), or enterprise (4,000-8,000). This proposal is an enterprise level project. In addition to the enterprise IT programming effort, there will also need to be a significant communication and education effort to help members prepare for implementation of the new policy. Since the new policy will require an enterprise IT programming effort, it would not become effective right away if approved.

How will members implement this proposal?

It is expected that liver and kidney transplant programs will also take on some effort to prepare for implementation of these new rules. As of April 1, 2016 there were 1,082 SLK candidates waiting for an SLK transplant. Liver and kidney transplant programs will be required to report new information on the liver and kidney waiting list and document new information in their candidates’ medical records. UNOS will release the new data fields at least two months in advance of the implementation date to allow members to input the new data.

OPOs will need to educate their staff on these new rules and to follow the eligibility requirements indicated in DonorNet®.

Will this proposal require members to submit additional data?

Yes, liver and kidney transplant programs will be required to submit additional data in UNetSM. This new data collection will be used to determine a candidate’s eligibility for SLK and safety net priority and to

ensure members are complying with the policy. As the Committee monitors this policy post-implementation, the data may prove useful for future policy development. Collecting data for these purposes is consistent with the OPTN Principles of Data Collection.

For the SLK medical eligibility criteria, liver transplant programs will need to enter:

- A confirmation of one of three medical diagnoses for receiving a kidney with a liver offer (CKD with $\text{GFR} \leq 60 \text{ mL/min}$ for greater than 90 consecutive days, sustained acute kidney injury, metabolic disease), along with the transplant nephrologist's name who confirms the diagnosis and the liver candidate's registration record in WaitlistSM.
 1. For CKD diagnosis, the dialysis status for the regularly administered dialysis and the dialysis start date or measured or calculated creatinine clearance (CrCl) or GFR value and date of the test.
 2. For sustained acute kidney injury, a confirmation of eligibility at least once **every 7 days** for the last 6 weeks by reporting one for the following or a combination of both:
 - a. Dialysis treatment at least once every 7 days (dialysis status and dates)
 - b. Measured or calculated CrCl or $\text{GFR} \leq 25 \text{ mL/min}$ at least once every 7 days (value, date and time of the test)
 3. For metabolic disease, an indication of the patient's diagnosis.

For the safety net portion of proposal, kidney transplant programs will be required to enter the following new data:

1. If the transplant program is registering a liver recipient on the kidney waiting list, additional fields will be required to indicate candidate's eligibility for additional match classification priority. This data entry only applies to candidates on the kidney waiting list between 60 and 365 days after a liver transplant.
2. To retain safety net eligibility, transplant hospitals must report qualifying criteria (dialysis treatment or $\text{eGFR/CrCl} \leq 20$) at least once every 30 days for the first 90 days after initial qualification.

OPOs will not have any additional data entry requirements but will need to confirm a liver candidate's SLK eligibility status in DonorNet[®] before allocating a kidney with the liver from the same deceased donor.

How will members be evaluated for compliance with this proposal?

Members will be expected to comply with requirements in the proposed language. In addition to the monitoring outlined below, all elements required by policy may be subject to OPTN review, and members are required to provide documentation as requested.

9.7.B Liver-Kidney Candidate Eligibility for Candidates 18 Years or Older

At transplant hospitals, OPTN staff will review a sample of medical records, and any material incorporated into the medical record by reference for documentation that data reported through UNetSM is consistent with source documentation.

For recipients receiving a liver-kidney transplant based on a diagnosis of CKD, OPTN staff will verify either:

- Evidence of regularly administered dialysis for ESRD (such as a 2728 form, physician's note or dialysis center documentation)
- A measured or calculated creatinine clearance (CrCl) or glomerular filtration rate (GFR) less than or equal to 30 mL/min on either:
 - The date of the most recent result before registration on the kidney waiting list
 - A date after registration on the kidney waiting list

For recipients receiving a liver-kidney transplant based on a diagnosis of sustained acute kidney, UNOS staff will verify the accuracy of the most recently reported one of the following before transplant:

- Physician notes or dialysis center documentation showing the dates of dialysis received
- Measured or calculated CrCl or GFR values less than or equal to 25 mL/min and the corresponding collection dates for each value

For recipients receiving a liver-kidney transplant based on a diagnosis of metabolic disease, UNOS staff will verify the presence and date of one of the following diagnoses:

- Hyperoxaluria
- Atypical HUS from mutations in factor H or factor I
- Familial non-neuropathic systemic amyloidosis
- Methylmalonic aciduria

Policy 8.5.H Prioritization for Liver Recipients on the Kidney Waiting List

At transplant hospitals, UNOS staff will review a sample of medical records, and any material incorporated into the medical record by reference, of kidney recipients who received priority for a kidney due to a prior liver transplant, for documentation that data reported through UNetSM is consistent with source documentation, including the most recent dates and results for any of the following:

- Measured or calculated creatinine clearance (CrCl)
- Glomerular filtration rate (GFR)
- Dialysis

Policy or Bylaw Language

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

1 **RESOLVED, that changes to Policies 5.10.B (Allocation of Liver-Kidneys), 5.10.C (Other Multi-**
2 **Organ Combinations), 9.7 (Administrative Rules), 8.5.H (Allocation of Kidneys from Deceased**
3 **Donors with KDPI Scores less than or equal to 20%), 8.5.I (Allocation of Kidneys from Deceased**
4 **Donors with KDPI Scores Greater Than 20% but Less Than 35%), 8.5.J (Allocation of Kidneys from**
5 **Deceased Donors with KDPI Scores Greater than or Equal to 35%), and 8.5.K (Allocation of**
6 **Kidneys from Deceased Donors with KDPI Scores Greater than 85%), as set forth below, are**
7 **hereby approved, effective pending implementation and notice to OPTN.**

8 **5.10.B. Allocation of Liver-Kidneys**

9 Liver-kidney combinations are allocated according to *Policy 9.7: Liver-Kidney Allocation*
10

11 **5.10.BC Other Multi-Organ Combinations**

12 When multi-organ candidates are registered on the heart, lung, or liver waiting list, the second required
13 organ will be allocated to the multi-organ candidate from the same donor if the donor's DSA is the same
14 DSA where the multi-organ candidate is registered.

15
16 If the multi-organ candidate is on a waiting list outside the donor's DSA, it is permissible to allocate the
17 second organ to the multi-organ candidate receiving the first organ.

18 **9.7 Administrative Rules Liver-Kidney Allocation**

19 If a host OPO procures a kidney along with other organs, the host OPO must first offer the kidney
20 according to *one* of the following policies before allocating the kidney to kidney alone candidates
21 according to *Policy 8: Allocation of Kidneys*:
22

- 23 • *Policy 5.10.C: Other Multi-Organ Combinations*
- 24 • *Policy 9.7: Liver-Kidney Allocation*
- 25 • *Policy 11.4.A: Kidney-Pancreas Allocation Order*

26
27 If a host OPO is offering a kidney and a liver from the same deceased donor, then the host OPO must
28 offer the kidney and liver according to *both* of the following:
29

- 30 1. Before allocating the kidney to kidney alone candidates, the host OPO must offer the kidney with the
31 liver to local candidates who meet eligibility according to *Table 9-11: Medical Eligibility Criteria for*
32 *Liver-Kidney Allocation* and regional candidates who meet eligibility according to *Table 9-11* and have
33 a MELD score of at least 35 or status 1A.
- 34
35 2. The host OPO may then do *either* of the following:
 - 36 a. The host OPO may offer the kidney and liver to any candidates who meet eligibility in *Table 9-11:*
37 *Medical Eligibility Criteria for Liver-Kidney Allocation.*
 - 38 b. After completing #1 above, the host OPO may offer the liver to liver alone candidates according
39 to *Policy 9: Allocation of Livers and Liver-Intestines* and offer the kidney to kidney alone
40 candidates according to *Policy 8: Allocation of Kidneys.*

41

42 **9.7.A Liver-Kidney Candidate Eligibility for Candidates Less than 18 Years Old**

43 Candidates who are less than 18 years old when registered on the liver waiting list are eligible to receive
 44 a liver and kidney from the same deceased donor when the candidate is registered on the waiting list for
 45 both organs. Before allocating the kidney to kidney alone candidates, the host OPO must offer the kidney
 46 with the liver to all local, regional, and national candidates less than 18 years old at the time of
 47 registration.

48 **9.7.B Liver-Kidney Candidate Eligibility for Candidates 18 Years or Older**

50 Candidates who are 18 years or older when registered on the liver waiting list are eligible to receive both
 51 a liver and a kidney from the same deceased donor when the candidate is registered on the waiting list
 52 for both organs and meets at least one of the criteria according to Table 9-11 below.

53 **Table 9-11: Medical Eligibility Criteria for Liver-Kidney Allocation**

<u>If the candidate's transplant nephrologist confirms a diagnosis of:</u>	<u>Then the transplant program must report to the OPTN Contractor and document in the candidate's medical record:</u>
<u>Chronic kidney disease (CKD) with a measured or calculated glomerular filtration rate (GFR) less than or equal to 60 mL/min for greater than 90 consecutive days</u>	<p><u>At least one of the following:</u></p> <ul style="list-style-type: none"> • <u>That the candidate has begun regularly administered dialysis as an end-stage renal disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting.</u> • <u>At the time of registration on the kidney waiting list, that the candidate's most recent measured or calculated creatinine clearance (CrCl) or GFR is less than or equal to 30 mL/min.</u> • <u>On a date after registration on the kidney waiting list, that the candidate's measured or calculated CrCl or GFR is less than or equal to 30 mL/min.</u>
<u>Sustained acute kidney injury</u>	<p><u>At least one of the following, or a combination of both of the following, for the last 6 weeks:</u></p> <ul style="list-style-type: none"> • <u>That the candidate has been on dialysis at least once every 7 days.</u> • <u>That the candidate has a measured or calculated CrCl or GFR less than or equal to 25 mL/min at least once every 7 days.</u> <p><u>If the candidate's eligibility is not confirmed at least once every seven days for the last 6 weeks, the candidate is not eligible to receive a liver and a kidney from the same donor.</u></p>
<u>Metabolic disease</u>	<p><u>A diagnosis of at least one of the following:</u></p> <ul style="list-style-type: none"> • <u>Hyperoxaluria</u> • <u>Atypical hemolytic uremic syndrome (HUS) from mutations in factor H or factor I</u> • <u>Familial non-neuropathic systemic amyloidosis</u> • <u>Methylmalonic aciduria</u>

55

56 **9.78 Administrative Rules**

57 [Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

58

59 **8.5.H Allocation of Kidneys from Deceased Donors with KDPI Scores less than or**
60 **equal to 20% Prioritization for Liver Recipients on the Kidney Waiting List**

61 If a kidney candidate received a liver transplant, but not a liver and kidney transplant from the same
62 deceased donor, the candidate will be classified as a prior liver recipient. This classification gives priority
63 to a kidney candidate if both of the following criteria are met:

- 64 1. The candidate is registered on the kidney waiting list prior to the one-year anniversary of the
65 candidate's most recent liver transplant date
- 66 2. On a date that is at least 60 days but not more than 365 days after the candidate's liver transplant
67 date, at least one of the following criteria is met:
 - 68 • The candidate has a measured or calculated creatinine clearance (CrCl) or glomerular filtration
69 rate (GFR) less than or equal to 20 mL/min.
 - 70 • The candidate is on dialysis.

71

72 When the transplant program reports that the candidate meets the criteria for this classification, the
73 candidate will remain at this classification for 30 days from the date of the qualifying test or treatment. If
74 the transplant program reports additional qualifying tests or treatments, then the candidate will remain at
75 this classification for 30 days from the most recent date of the test or treatment. If the transplant program
76 reports that the candidate meets the criteria for 90 consecutive days, the candidate will remain at this
77 classification until the candidate is removed from the kidney waiting list.

78 If a liver recipient receives a kidney using this priority classification and returns to the kidney waiting list
79 after the most recent kidney transplant, the candidate must again meet the criteria for this classification,
80 unless the candidate qualifies for kidney waiting time reinstatement according to Policy 3.6.B.i: Non-
81 function of a Transplanted Kidney. If the candidate qualifies for kidney waiting time reinstatement, the
82 candidate will be classified as qualifying for the classification.

83 If a kidney candidate received a liver and kidney transplant from the same deceased donor, the candidate
84 will only qualify for this classification if the candidate qualifies for kidney waiting time reinstatement
85 according to Policy 3.6.B.i: Non-function of a Transplanted Kidney.

86

87 [Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

88

89 **8.5.I.J Allocation of Kidneys from Deceased Donors with KDPI Scores Greater**
90 **Than 20% but Less Than 35%**

91 Kidneys from deceased donors with KDPI scores greater than 20% but less than 35% are allocated to
92 candidates according to Table 8-6 below.

93

94 **Table 8-6: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less Than**
95 **35%**

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
1	OPO's DSA	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
2	OPO's DSA	CPRA equal to 100%, blood type permissible or identical	Any
3	OPO's region	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
4	OPO's region	CPRA equal to 100%, blood type permissible or identical	Any
5	Nation	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
6	Nation	CPRA equal to 100%, blood type permissible or identical	Any
7	OPO's DSA	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
8	OPO's DSA	CPRA equal to 99%, blood type permissible or identical	Any
9	OPO's region	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
10	OPO's region	CPRA equal to 99%, blood type permissible or identical	Any
11	OPO's DSA	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	Any
12	OPO's DSA	CPRA equal to 98%, blood type permissible or identical	Any
13	OPO's DSA	0-ABDR mismatch, blood type identical	Any
14	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Any
15	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Any
16	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Any
17	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Any
18	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Any

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
19	Nation	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Any
20	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
21	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
22	OPO's DSA	0-ABDR mismatch, blood type B	O
23	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	O
24	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	O
25	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	O
26	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	O
27	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	O
28	Nation	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	O
29	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
30	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
31	OPO's DSA	0-ABDR mismatch, blood type permissible	Any

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
32	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Any
33	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Any
34	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type permissible	Any
35	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type permissible	Any
36	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type permissible	Any
37	Nation	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type permissible	Any
38	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
39	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
40	OPO's DSA	Prior living donor, blood type permissible or identical	Any
41	OPO's DSA	Registered prior to 18 years old, blood type permissible or identical	Any
42	<u>OPO's DSA</u>	<u>Prior liver recipients that meet the qualifying criteria according to Policy 8.5.H: Prioritization for Liver Recipients on the Kidney Waiting List, blood type permissible or identical</u>	<u>Any</u>
43	OPO's DSA	Blood type B	A2 or A2B
44	OPO's DSA	All remaining candidates, blood type permissible or identical	Any
45	OPO's region	Registered prior to 18 years old, blood type permissible or identical	Any

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
46	OPO's region	Blood type B	A2 or A2B
47	OPO's region	All remaining candidates, blood type permissible or identical	Any
48	Nation	Registered prior to 18 years old, blood type permissible or identical	Any
49	Nation	Blood type B	A2 or A2B
50	Nation	All remaining candidates, blood type permissible or identical	Any

8.5.JK Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than or Equal to 35% but Less than or Equal to 85%

Kidneys from donors with KDPI scores greater than or equal to 35% but less than or equal to 85% are allocated to candidates according to *Table 8-7* below.

Table 8-7: Allocation of Kidneys from Deceased Donors with KDPI Greater Than or Equal To 35% and Less Than or Equal To 85%

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
1	OPO's DSA	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
2	OPO's DSA	CPRA equal to 100%, blood type permissible or identical	Any
3	OPO's region	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
4	OPO's region	CPRA equal to 100%, blood type permissible or identical	Any
5	Nation	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
6	Nation	CPRA equal to 100%, blood type permissible or identical	Any
7	OPO's DSA	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
8	OPO's DSA	CPRA equal to 99%, blood type permissible or identical	Any
9	OPO's region	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
10	OPO's region	CPRA equal to 99%, blood type permissible or identical	Any
11	OPO's DSA	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	Any
12	OPO's DSA	CPRA equal to 98%, blood type permissible or identical	Any
13	OPO's DSA	0-ABDR mismatch, blood type identical	Any

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
14	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Any
15	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Any
16	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Any
17	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Any
18	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Any
19	Nation	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Any
20	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
21	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
22	OPO's DSA	0-ABDR mismatch, and blood type B	○
23	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	○
24	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	○
25	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	○
26	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	○
27	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	○
28	Nation	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	○

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
29	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
30	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
31	OPO's DSA	0-ABDR mismatch, blood type permissible	Any
32	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Any
33	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Any
34	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 years old at time of match, and blood type permissible	Any
35	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 years old at time of match, and blood type permissible	Any
36	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 years old at time of match, and blood type permissible	Any
37	Nation	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 years old at time of match, and blood type permissible	Any
38	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
39	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
40	OPO's DSA	Prior living donor, blood type permissible or identical	Any
41	OPO's DSA	<u>Prior liver recipients that meet the qualifying criteria according to <i>Policy 8.5.H: Prioritization for Liver Recipients on the Kidney Waiting List</i>, blood type permissible or identical</u>	Any
42	OPO's DSA	Blood type B	A2 or A2B
43	OPO's DSA	All remaining candidates, blood type permissible or identical	Any
44	OPO's region	Blood type B	A2 or A2B
45	OPO's region	All remaining candidates, blood type permissible or identical	Any
46	Nation	Blood type B	A2 or A2B

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
47	Nation	All remaining candidates, blood type permissible or identical	Any

8.5.KL Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%

With the exception of 0-ABDR mismatches, kidneys from deceased donors with KDPI scores greater than 85% will be allocated to adult candidates only.

Kidneys from deceased donors with KDPI scores greater than 85% are allocated to candidates according to *Table 8-8* below.

Table 8-8: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 85%

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
1	OPO's DSA	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
2	OPO's DSA	CPRA equal to 100%, blood type permissible or identical	Any
3	OPO's region	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
4	OPO's region	CPRA equal to 100%, blood type permissible or identical	Any
5	Nation	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
6	Nation	CPRA equal to 100%, blood type permissible or identical	Any
7	OPO's DSA	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
8	OPO's DSA	CPRA equal to 99%, blood type permissible or identical	Any
9	OPO's region	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
10	OPO's region	CPRA equal to 99%, blood type permissible or identical	Any
11	OPO's DSA	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	Any
12	OPO's DSA	CPRA equal to 98%, blood type permissible or identical	Any
13	OPO's DSA	0-ABDR mismatch, blood type permissible or identical	Any
14	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Any
15	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Any

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
16	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
17	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
18	OPO's DSA	0-ABDR mismatch, blood type B	O
19	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	O
20	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	O
21	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
22	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
23	OPO's DSA	0-ABDR mismatch, blood type permissible	Any
24	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Any
25	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% , and blood type permissible	Any
26	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
27	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
28	OPO's DSA	<u>Prior liver recipients that meet the qualifying criteria according to <i>Policy 8.5.H: Prioritization for Liver Recipients on the Kidney Waiting List</i>, blood type permissible or identical</u>	Any
29	OPO's region	Blood type B	A2 or A2B
30	OPO's region	All remaining candidates, blood type permissible or identical	Any
31	Nation	Blood type B	A2 or A2B
32	Nation	All remaining candidates, blood type permissible or identical	Any

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