OPTN | UNOS Public Comment Proposal

OPTN/UNOS Kidney Transplantation Committee

Simultaneous Liver Kidney (SLK) Allocation

Prepared by:
Gena Boyle, MPA
UNOS Executive Department

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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 medical criteria assessing the kidney function of the candidate. 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 to a *regional* SLK candidate, although they have the discretion to do so.

The Kidney Transplantation Committee ("the Committee"), has identified several problems with this current policy:

- The current policy for SLK allocation is counter to requirements in the OPTN Final Rule ("Final Rule") specifying 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 or Pediatric End Stage Liver Disease (PELD) 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 proposing a second round of public comment on this proposal which consists of the following:

- 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 as an added element to address concerns about limitations associated with the SLK medical eligibility criteria.

This proposal is the result of two consensus conferences and two rounds of public comment and 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. The proposal is intended to 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 Period: January 25 - March 25, 2016

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.

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 A, page 4**), which are kidneys prioritized for local pediatric candidates in kidney alone allocation. Recent

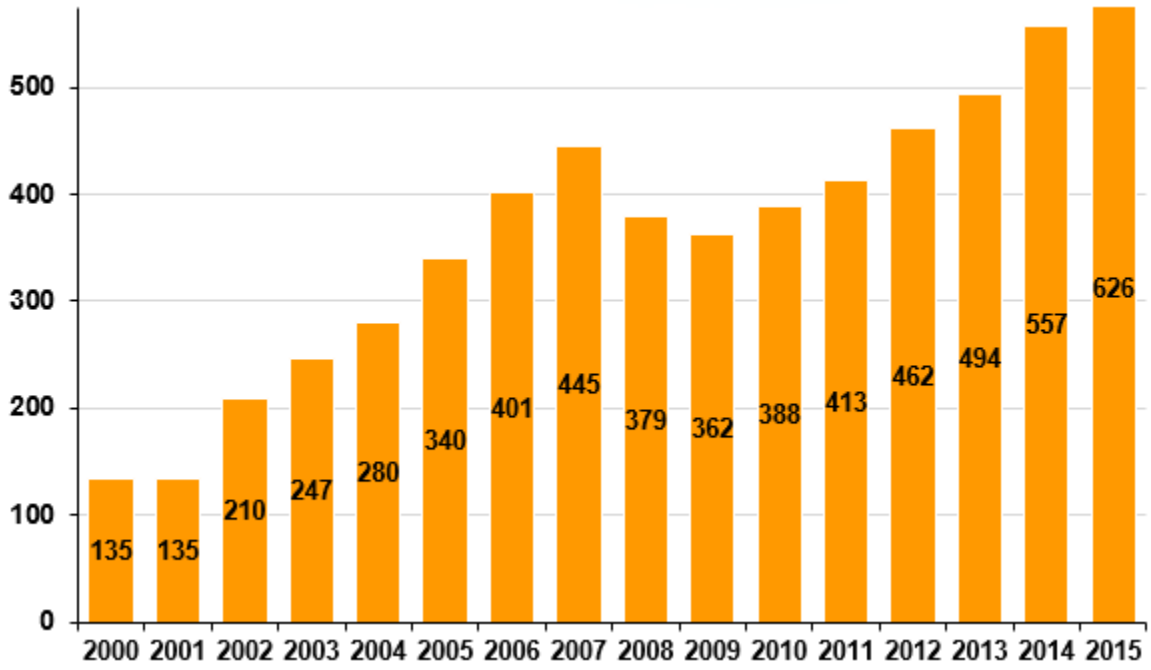
[1] OPTN policy 5.8 *Allocation of Multi-Organ Combinations*. http://optn.transplant.hrsa.gov/governance/policies/

[2] 42 CFR §121.8, available at: http://www.ecfr.gov/cgi-bin/text-idx?SID=e3fd0c2a70bb895235e55fac41f87701&mc=true&node=se42.1.121_18&rgn=div8

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 transplants[3] because survival outcomes for these liver recipients can be dependent on also receiving a kidney transplant (Figure 2). 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] Nadim, at 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 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 *one* of the following: 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	At least *one* of the following, or a combination of both of the following, for the last 6 weeks: 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. 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.
Metabolic disease	A diagnosis of at least *one* of the following: 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 well 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, 8.5K, 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 is 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 candidate 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. The candidate will be eligible 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 three consecutive 30-day periods after the initial qualifying date, the candidate will remain eligible for safety net priority indefinitely 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, UNet℠ (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 as 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 UNet℠ 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 be programming new fields in order to implement this new match classification priority and the new fields will be available well 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 in the future. 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 in the beginning of these efforts. The MPSC will be seeking feedback from the transplant community throughout 2015-2016 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 long 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. 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. The Policy Oversight Committee (POC) and Organ Procurement Organization (OPO) Committee plan to begin a comprehensive review of the multi-organ allocation policies later this year.

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 and attempt to combine the most commonly discussed solutions for addressing the problems with the current policy. The Kidney Committee has solicited and responded to feedback from many different stakeholder groups in the development of this policy and has achieved a high level of consensus. 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**) 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 adjustments in response to the pre-public comment feedback and sponsored another public comment proposal in the fall 2015[4].

[4] http://optn.transplant.hrsa.gov/governance/public-comment/simultaneous-liver-kidney-allocation/

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 to each element of the new policy. In an attached document (**Exhibit C**), the Committee has provided an individual response to each of the comments received during the Fall 2015 public comment period.

Overview of Changes Made to Medical Eligibility Criteria

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 30 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 prior to the SLK transplant.	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 7 days.	In the sustained acute kidney injury category, the transplant program must report that the medical criteria is met at least once every 7 days (the report does not have to take place on the 7th 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.	Only adult SLK candidates will be required to meet medical criteria. Pediatric SLK candidates (those registered on the liver waiting list prior to their 18th 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.
It was not contemplated 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.
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, 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

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 only 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 or status 1A.	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 are eligible if they meet medical eligibility criteria. 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 permissible 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.
Pediatric candidates receive local/regional priority when meeting the medical eligibility criteria.	Pediatric candidates will receive local, regional, and national priority regardless of whether they meet the medical eligibility criteria.	Liver Committee

Fall 2015 Public Comment Proposal	Spring 2016 Public Comment Proposal	Who requested the change?
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

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 ≤ 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 ≤ 20 mL/min in the 60-365 day period to qualify for the safety net. In order to remain qualified, the transplant program must confirm at least once a month that the GFR ≤ 20 mL/min. Once this has been confirmed for 3 consecutive months after the candidate's first qualifying month, the priority will apply indefinitely.	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 ≤ 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 ≤ 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. 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 3 consecutive months after the candidate's first qualifying month, the priority will apply indefinitely.	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.
The Committee did not describe how existing candidates would be treated once new policy has been implemented.	Upon implementation, all liver recipients who meet the medical criteria will be eligible for safety net priority.	The question was raised by UNOS staff in the process of developing an implementation plan for the proposal.

Changes considered but not adopted

The Committee considered but ultimately did not adopt other modifications to the proposed safety net.

First, the Committee considered whether to require that the liver recipient show some level of kidney dysfunction prior to liver transplant for safety net eligibility. The working group and Committee agreed that such a requirement would be counter to the ultimate goal of the safety net, which is to increase the survival of liver recipients who also need a kidney transplant. As is discussed further in this document, the Committee reviewed data showing those liver recipients 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.

The working group and Committee also discussed whether safety net priority should be removed from Sequence B (kidney allocation sequence when the KDPI is 21-34%) altogether. However, when the Committee considered that all local adults fall into the category that now resides in the match classification where the safety net is proposed in the sequence, they decided that this level of prioritization is appropriate because these candidates are likely going to appear in the local adult category currently; this is only a slight increase in prioritization.

At the Liver Committee's request, the Committee also discussed whether to shorten the timeframe for eligibility in the safety net to 30 days post liver transplant. The Committee did not support shortening the timeframe, stating that the current proposal is already a compromise and a shorter timeframe than the 2009 proposal.

The Committee did consider concerns that establishment of the safety net could act as a disincentive for a liver recipient to find a living kidney donor. The Committee reviewed data showing that about 1/3 of the kidney transplants received by liver recipients were living donor transplants (**Exhibit A,** page 15**)**. The Committee did not make any changes to address this concern, mostly because any new policy requirement could potentially disadvantage candidates who may have a harder time finding a living donor than others and would be very difficult for the OPTN to monitor. Since outcome measures for living donor transplants are not risk adjusted for prior liver transplants, there is also not consensus regarding the efficacy of living kidney donation for liver recipients. The Committee is considering whether to develop some OPTN guidance on this issue.

How well does this proposal address the problem statement?

To support the development of the proposal, the committee examined a variety of data analyses (**Exhibits A and D**), including:

- Survival advantage of receiving a kidney vs. liver alone;
- 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.

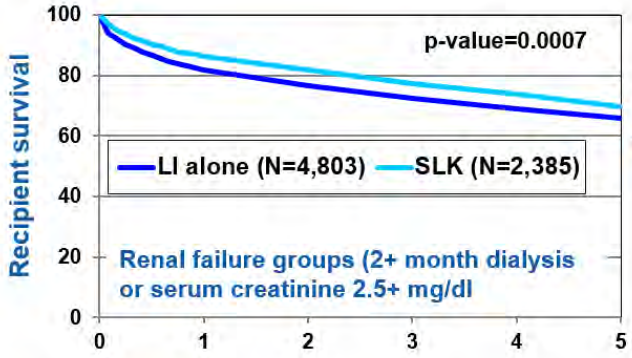
Survival advantage of receiving a kidney vs. liver alone

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

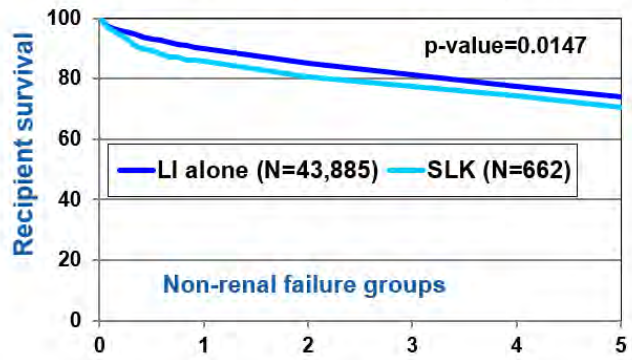
Figure 2 compares recipient survival for those who received a kidney along with the liver vs. those who received a liver alone transplant for those with strong evidence of renal failure prior to transplant (top portion) and those without strong evidence of renal failure (bottom). Strong evidence of renal 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.



	LI Alone	SLK
White	70%	62%
Diabetes	27%	41%
MELD*	36	27
KDPI%	46	35
Age*	55	56
LI CIT*	6.9	6.4



	LI Alone	SLK
White	73%	65%
Diabetes	23%	38%
MELD*	17	28
KDPI%	52	37
Age*	55	57
LI CIT*	6.7	6.5

* 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≥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[5]. 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 D** 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[6] [7].

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.

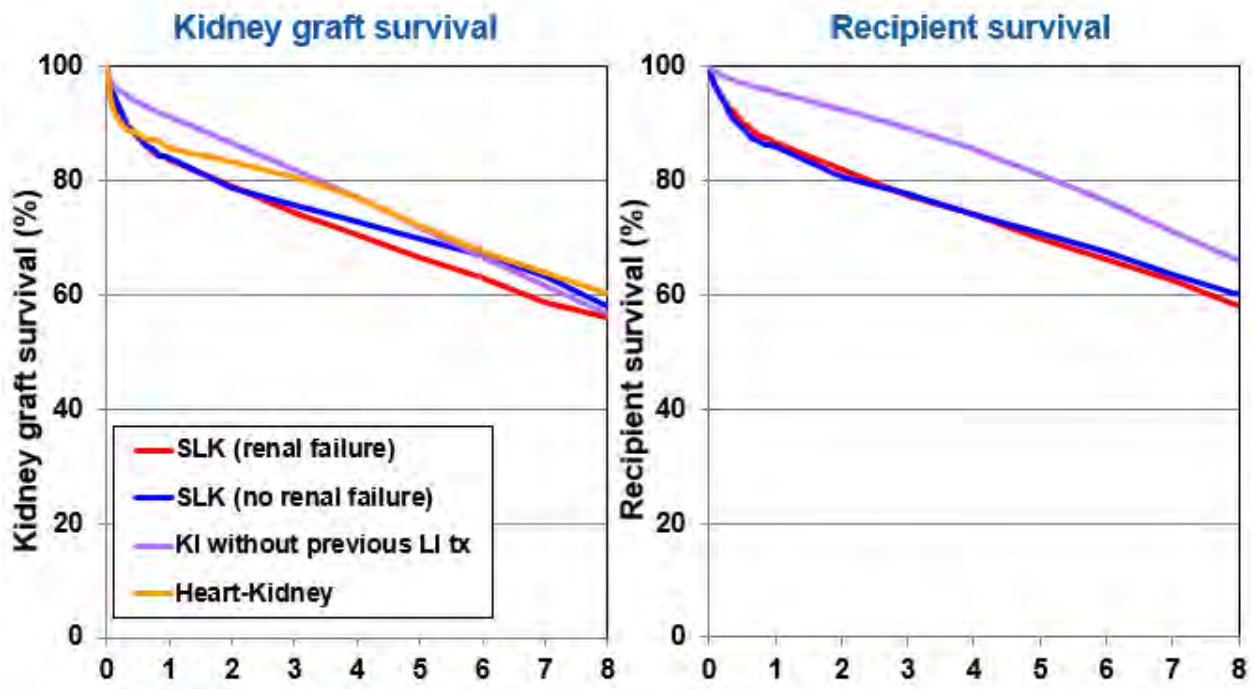
[5] Fong, et al. *Transplantation. 94(4):411-416, Aug 27, 2012*

[6] 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.

[7] 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.



	SLK (renal failure)	SLK (no renal failure)	KI
White	62%	65%	45%
Age (median)	56	57	54

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.

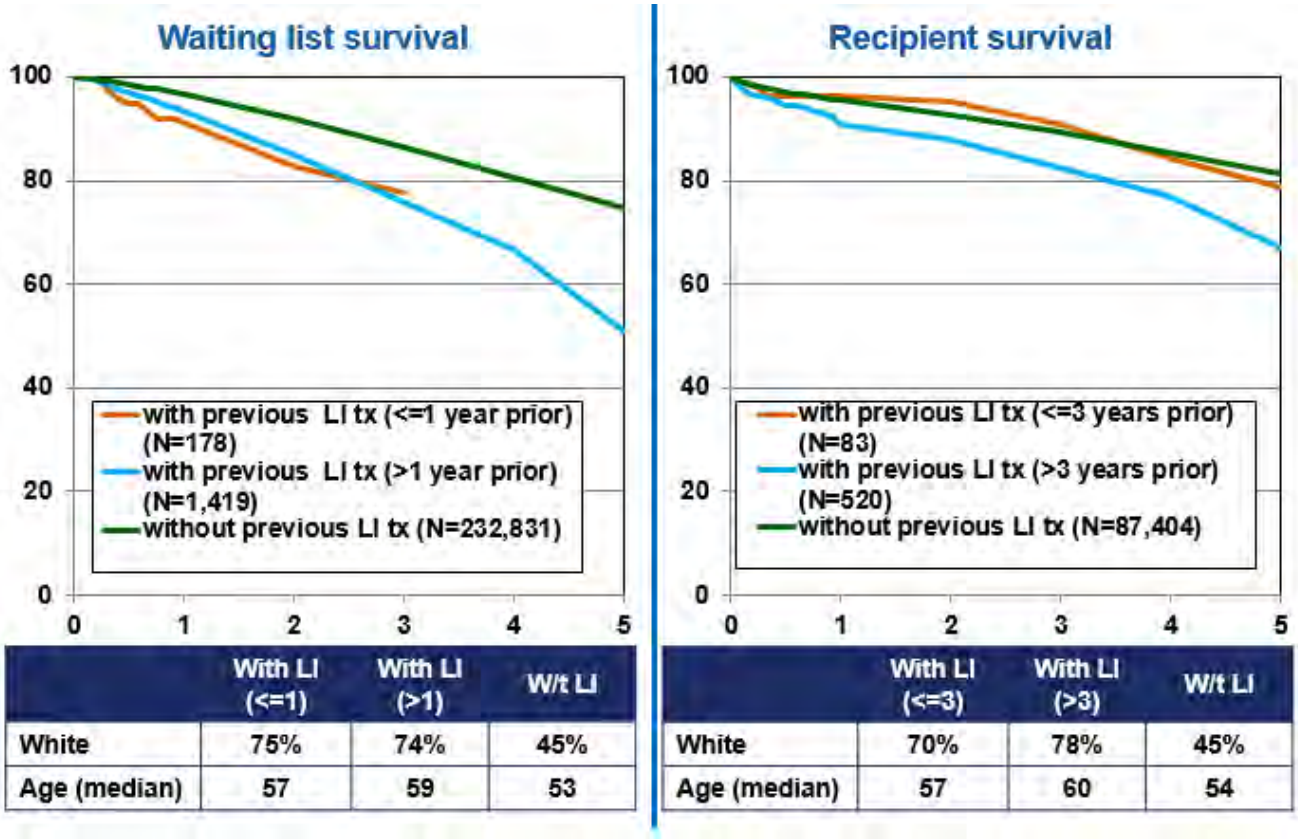
Differences in patient characteristics may have contributed to differences in survival. SLK recipients were more likely to be white compared to kidney alone. All groups had similar median ages.

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.



	With LI (<=1)	With LI (>1)	W/t LI
White	75%	74%	45%
Age (median)	57	59	53

	With LI (<=3)	With LI (>3)	W/t LI
White	70%	78%	45%
Age (median)	57	60	54

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?

To the extent that this proposal reduces the number of SLK transplants, it could increase access to transplants for pediatric, highly sensitized, and prior living donor kidney alone candidates who are highly prioritized in kidney alone allocation but are currently prioritized *after* local (and sometimes regional) liver-kidney candidates. There were around 600-650 SLK transplants performed in 2015 (**Figure 1**). OPTN data show that about 50-65 of these SLK recipients had no pre-transplant dialysis. Approximately 110-120 recipients had spent less than two months on dialysis (see **Exhibit A**).

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 ≤ 60 mL/min for greater than 90 consecutive days -- dialysis vs. GFR/CrCl<=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 large 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 a very large 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 a significant level of effort to prepare for implementation of these new rules. Members will be required to document new information in their candidates' medical record and obtain new medical information related to candidate eligibility.

Will this proposal require members to submit additional data?

Yes, liver and kidney transplant programs will be required to submit additional data in UNet^{SM}. 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 GFR ≤ 60 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 liver candidate's registration record in Waitlist[SM].
    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 seven days (dialysis status and dates)
        b. Measured or calculated CrCl or GFR ≤ 25 mL/min at least once every seven 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 hospitals 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 eGFR/CrCl<=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 check 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 UNet℠ 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, with a dialysis start date prior to the date of eligibility for SLK (come back to this)
- 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 between registration on the kidney waiting list and listing for SLK priority

For recipients receiving a liver-kidney transplant based on a diagnosis of sustained acute kidney, UNOS staff will verify one of the following in the 7 days 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 UNet℠ 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~~).

5.10 Allocation of Multi-Organ Combinations

5.10.A Allocation of Heart-Lungs

Heart-lung combinations are allocated according to *Policy 6.5.F: Allocation of Heart-Lungs*.

5.10.B Allocation of Liver-Kidneys

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

5.10.~~B~~C Other Multi-Organ Combinations

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

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

Policy 9.6: Liver Allocation, Classifications, and Rankings

9.7 ~~Administrative Rules~~ Allocation of Liver-Kidneys

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

- *Policy 5.10.B: Allocation of Multi-Organ Combinations*
- *Policy 9.7: Allocation of Liver-Kidneys*
- *Policy 11.4.A: Kidney-Pancreas Allocation Order*

If a host OPO is offering a kidney and a liver from the same deceased donor, then the host OPO offers the kidney and liver according to the following:

1. Before allocating the kidney to kidney alone candidates, the host OPO must offer the kidney with the liver to local candidates who meet eligibility according to *Table 9-6: Medical Eligibility Criteria for Liver-Kidney Allocation* and regional candidates who meet eligibility according to Table 9-6 and have MELD at least 35 or status 1A.

2. The host OPO may do *either* of the following:

    - The host OPO may offer the kidney and liver to any candidates who meet eligibility in Table 9-6: *Medical Eligibility Criteria for Liver-Kidney Allocation*.
    - After completing step 1 above, the host OPO may offer the liver to liver alone candidates according to Policy 9: *Allocation of Livers and Liver-Intestines* and offer the kidney to kidney candidates according to Policy 8: *Allocation of Kidneys*.

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

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

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

In order for a candidate who is 18 years or older to receive both a liver and a kidney from the same deceased donor, the candidate must be registered on the waiting list for both organs and meet at least *one* of the criteria according to Table 9-6 below.

Table 9-6: Medical Eligibility Criteria for Liver-Kidney Allocation

If the candidate's transplant nephrologist confirms a diagnosis of:	**Then the transplant program must report to the OPTN Contractor 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 *one* of the following: • 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 calculated CrCl or GFR is less than or equal to 30 mL/min.
Sustained acute kidney injury	At least *one* of the following, or a combination of both of the following, for the last 6 weeks: • 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. 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.
Metabolic disease	A diagnosis of at least *one* of the following: • Hyperoxaluria • Atypical HUS from mutations in factor H or factor I • Familial non-neuropathic systemic amyloidosis • Methylmalonic aciduria

9.~~7~~8 Administrative Rules

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

8.5 Kidney Allocation Classifications and Rankings

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

If a kidney candidate received a liver transplant, but not a liver and kidney transplant from the same deceased donor, the candidate will be classified as a prior liver recipient. This classification gives priority to a kidney candidate if the candidate is registered on the kidney waiting list prior to the one-year anniversary of the candidate's most recent liver transplant date and at least *one* of the following criteria is met:

- On a date that is at least 60 days but not more than 365 days after the candidate's liver transplant date, the candidate has a measured or calculated creatinine clearance (CrCl) or glomerular filtration rate (GFR) less than or equal to 20 mL/min.
- On a date that is at least 60 days but not more than 365 days after the candidate's liver transplant date, the candidate is on regularly administered dialysis.

In order for a candidate to retain this classification, the transplant hospital must report the qualifying criteria as required above to the OPTN Contractor at least once every 30 days for the first 90 days after the candidate initially qualifies for this priority. A candidate whose priority is confirmed as required for 90 days after initial qualification will continue to receive this priority indefinitely.

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

If a kidney candidate received a liver and kidney transplant from the same deceased donor, the candidate will only be classified as a prior liver recipient that qualifies for priority if the candidate qualifies for kidney waiting time reinstatement according to *Policy 3.6.B.i: Non-function of a Transplanted Kidney.*

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

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

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

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

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
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, 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

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
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 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	OPO's DSA	Prior liver recipients that meet the medical criteria according to *Policy 8.5.H*, blood type permissible or identical	Any
~~42~~43	OPO's DSA	Blood type B	A2 or A2B

Classification	Candidates that are within the:	And are:	When the donor is this blood type:
~~43~~4	OPO's DSA	All remaining candidates, blood type permissible or identical	Any
~~44~~5	OPO's region	Registered prior to 18 years old, blood type permissible or identical	Any
~~45~~6	OPO's region	Blood type B	A2 or A2B
~~46~~7	OPO's region	All remaining candidates, blood type permissible or identical	Any
~~47~~8	Nation	Registered prior to 18 years old, blood type permissible or identical	Any
~~48~~9	Nation	Blood type B	A2 or A2B
~~59~~0	Nation	All remaining candidates, blood type permissible or identical	Any

8.5.J~~K~~ 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

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
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
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	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

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
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
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	Prior liver recipients that meet the medical criteria according to *Policy 8.5.H*, blood type permissible or identical	Any
~~41~~2	OPO's DSA	Blood type B	A2 or A2B
~~42~~3	OPO's DSA	All remaining candidates, blood type permissible or identical	Any
~~43~~4	OPO's region	Blood type B	A2 or A2B
~~44~~5	OPO's region	All remaining candidates, blood type permissible or identical	Any

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
~~45~~6	Nation	Blood type B	A2 or A2B
~~46~~7	Nation	All remaining candidates, blood type permissible or identical	Any

8.5.~~K~~L 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	Prior liver recipients that meet the medical criteria according to *Policy 8.5.H*, blood type permissible or identical	Any
~~28~~9	OPO's region	Blood type B	A2 or A2B
29~~30~~	OPO's region	All remaining candidates, blood type permissible or identical	Any
~~30~~1	Nation	Blood type B	A2 or A2B
3~~1~~2	Nation	All remaining candidates, blood type permissible or identical	Any

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FINAL REPORT

OPTN Kidney Transplantation Committee *Descriptive Data Request*

Simultaneous Liver-Kidney (SLK): Waiting List and Transplant Data

Prepared for:
OPTN Kidney Transplantation Committee Meeting
April 7, 2014

By:
Darren Stewart, M.S.
Anna Kucheryavaya, M.S.
Yulin Cheng
Wida Cherikh, Ph.D.
UNOS Research Department

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BACKGROUND/PURPOSE

The current system for SLK allocation does not account for liver candidates who may regain renal function after liver transplant. Some candidates may unnecessarily receive a kidney that could have benefitted someone else. Liver candidates who forgo receiving a kidney have little recourse if they remain in renal failure following transplant; they can either continue to wait for a deceased donor kidney, which may take years, or pursue a living kidney donor transplant. This reality provides a strong disincentive for liver patients with renal insufficiency to wait and see if native kidney function returns after solitary liver transplant.

The Policy Oversight Committee has tasked the organ specific committees with developing (a) a "safety net" to protect patients who have undergone an isolated liver transplant then subsequently have renal dysfunction that does not recover and (b) medical criteria to determine eligibility for receiving a kidney allograft at the time of liver transplantation. The Kidney Committee discussed these issues during the August 26, 2013 meeting and requested descriptive data for future discussions.

WORK PLAN ITEM ADDRESSED

Increase access to transplant.

COMMITTEE REQUEST

Provide the following data:

1. Clinical information for SLK recipients at time of transplant for transplants performed since 2005, including percent on dialysis, time on dialysis (<6 months, 6+ months), creatinine values, primary diagnoses for kidney and liver transplants, donor quality (KDPI), MELD by creatinine, and sensitization level (PRA/CPRA).

2. Number of listings for kidney after liver transplant for each year since 2005 by Region and DSA; and distribution of time between the liver and subsequent kidney listings including the proportion with kidney listings within certain time period (e.g., within one and three years) after the liver transplants, stratified by primary kidney diagnosis (CNI nephrotoxicity, hepatorenal syndrome, hypertensive nehrosclerosis, type 2 diabetes, other) and exposure to dialysis prior to the liver transplants.

3. Number of kidney transplants after liver transplants each year since 2005 by Region and DSA; and distribution of time between the liver and subsequent kidney transplant including the proportion with kidney transplants within certain time period (e.g., one and three years) after the liver transplants, separately for deceased and living donor transplants, and stratified by primary kidney diagnosis (CNI nephrotoxicity, hepatorenal syndrome, hypertensive nehrosclerosis, type 2 diabetes, other) and exposure to dialysis prior to the liver transplants.

4. 25th and 50th percentiles of times to transplant for registrations waiting for kidney after liver and for registrations waiting for kidney with no previous liver transplants by blood type. Explore the feasibility of computing percentiles of time to transplant for each blood type, by Region and DSA (feasibility may be limited by sample size).

DATA AND METHODS

Data Sources

Information provided in this report is based on OPTN data as of October 25, 2013. Data are subject to change based on future data submission or correction.

Cohort and Methods

1. *Clinical characteristics of SLK transplants*. The following clinical characteristics of deceased donor (DD) SLK transplants performed during 1/1/05-6/30/13 were tabulated:
   - Pre-transplant dialysis and if on dialysis, time on dialysis (<6 months, 6+ months)
   - Serum creatinine at transplant as reported on liver waiting list transplant removal records
   - Primary diagnoses for kidney and liver transplants
   - Kidney donor profile index (KDPI)
   - MELD by creatinine at transplant as reported on liver waiting list transplant removal records
   - Sensitization level (PRA/CPRA) (CPRA was used for records on or after 10/1/09. Missing PRA values were categorized under 0%. CPRA is computed based on unacceptable antigens reported on the waiting list. If no unacceptable antigens are reported, CPRA value defaults to 0%.)

   SLK transplants with other organ(s) were excluded from the tabulation.

2. *Kidney listings after liver transplants*. The number of listings during 1/1/05-6/30/13 for a kidney transplant subsequent to a liver transplant was tabulated for each year by Region and DSA; and the distribution of time between liver transplant and subsequent kidney listing was summarized by kidney diagnosis (CNI nephrotoxicity, hepatorenal syndrome, hypertensive nehrosclerosis, type 2 diabetes, other) and exposure to dialysis prior to liver transplant. This analysis included registrations added to the kidney alone waiting list for the first time during the study period after a liver alone transplant that was still functioning at the time of the subsequent kidney listing.

3. *Kidney transplants after liver transplants.* The number of first kidney transplants performed during 1/1/05-6/30/13 subsequent to the liver transplants was tabulated each year by Region and DSA; and the distribution of time between the liver and subsequent kidney transplants was tabulated for each kidney donor type (deceased vs. living) by primary kidney diagnosis (CNI nephrotoxicity, hepatorenal syndrome, hypertensive nehrosclerosis, type 2 diabetes, other) and exposure to dialysis prior to the liver transplants. This analysis included first deceased and living donor kidney alone transplants that occurred during the study period and followed a liver alone transplant that was still functioning at the time of the subsequent kidney transplant.

4. *Percentiles of times to deceased donor transplant*. Percentiles of time to a deceased donor kidney transplant were computed among registrations added to the kidney alone waiting list during 2003-2008 subsequent to a functioning liver transplant using a competing risk method. For comparison, registrations added to the kidney alone waiting list during 2003-2008 without a prior liver transplant were analyzed separately. The competing risk method accounts for other competing outcomes on the waiting list beside a deceased donor transplant. The current analysis considers the following waiting list outcomes: 1) deceased donor transplant; 2) living donor transplant; 3) removal for other reason such as patient death; and those still waiting are considered censored data points.

Median time to transplant is a time point at which half of the registrations have received a deceased donor transplant (also known as 50th percentile of time to transplant). Because median waiting time or the 50th percentile of time to transplant could not be estimated for most of the ABO blood groups, the 25th and 35th percentiles of times to deceased donor kidney transplants were also calculated for each ABO blood group. Stratification by Region and DSA in addition to ABO blood group was not feasible due to limited sample size.

RESULTS

Clinical Characteristics of SLK Transplants

Table 1 shows basic characteristics of DD SLK transplants during 1/1/05-6/30/13:

- Among the 3,431 recipients (approximately 400 per year) of SLK transplants during 1/1/05-6/30/13, almost 60% were on dialysis at transplant, among which more than half were on dialysis for less than 6 months.
- Almost half (48%) of SLK recipients received transplants from donors with a KDPI of less than 35% and the majority (84%) were non-sensitized (PRA/CPRA 0%).

Table 1. Characteristics of DD SLK transplants during 01/01/05 - 06/30/13

Notes: PRA was used for transplants prior to 10/1/09, and calculated PRA (CPRA) was used for transplants on or after 10/1/09; Missing PRA values were categorized under 0%. If no unacceptable antigens are reported on the waiting list, CPRA value defaults to 0%.

Characteristic		N	%
Pre-transplant Dialysis:	Yes	2,045	59.6
	No	1,284	37.4
	Unknown	102	3.0
	Total	3,431	100.0
Pre-transplant Dialysis Time:	<6 months	1,118	54.7
	6+ months	787	38.5
	Unknown	140	6.8
	Total	2,045	100.0
KDPI:	0 - 20%	1,056	30.8
	21 - 34%	600	17.5
	35 - 85%	1,547	45.1
	86+%	205	6.0
	Missing	23	0.7
	Total	3,431	100.0
PRA/CPRA at Transplant:	0%	2,890	84.2
	1 - 79%	387	11.3
	80 - 97%	89	2.6
	98 - 100%	65	1.9
	Total	3,431	100.0

Table 2 shows the distribution of serum creatinine values at transplant as reported on the liver waiting list removal records among DD SLK recipients during 1/1/05-6/30/13, by pre-transplant dialysis status:

- Median serum creatinine was higher for those on dialysis prior to the SLK transplants compared to those not on dialysis (4.2 vs. 2.8 mg/dl, respectively).
- Those with unknown pre-transplant dialysis status had a median serum creatinine that was similar to those with no pre-transplant dialysis (2.7 vs. 2.8 mg/dl, respectively).

Table 2. Distribution of serum creatinine at transplant for DD SLK transplants performed during 01/01/05 - 06/30/13

	N	Mean	Std Dev	5th PCTL	25th PCTL	Median	75th PCTL	95th PCTL
Pre-transplant Dialysis								
Yes	2,045	4.6	2.6	1.1	2.8	**4.2**	5.9	9.4
No	1,284	3.2	1.6	1.3	2.1	**2.8**	4.0	6.5
Unknown	102	3.5	2.1	1.3	2.1	**2.7**	4.8	7.5
Total	3,431	4.0	2.4	1.2	2.3	**3.5**	5.2	8.5

Table 3 summarizes MELD/PELD score or status and serum creatinine values at transplant (<1.5 vs. 1.5+ mg/dl) by pre-transplant dialysis status for DD SLK transplants during 1/1/05-6/30/13:

- The vast majority of recipients (99.6%) had a MELD/PELD score of 15+ regardless of pre-transplant dialysis status.
- Over half (54%) of recipients who received pre-transplant dialysis had a MELD/PELD score of 30+, whereas over half (55%) of those who did not receive a pre-transplant dialysis had a score of 15-29. In other words, SLK recipients previously on dialysis tended to have higher MELD/PELD scores than those without prior dialysis.
- The majority of recipients had a serum creatinine of 1.5+ mg/dl at transplant, regardless of pre-transplant dialysis status.

Table 3. MELD/PELD score or status at transplant and serum creatinine at transplant by pre-transplant dialysis status for DD SLK transplants during 01/01/05 - 06/30/13

	Pre-transplant Dialysis						Total	
	Yes		No		Unknown			
	N	%	N	%	N	%	N	%
--M/P Score/Status								
M/P <15	7	0.3	7	0.5	0	0.0	14	0.4
M/P 15 – 29	899	44.0	706	55.0	45	44.1	1,650	48.1
M/P 30+	1,111	54.3	545	42.4	56	54.9	1,712	49.9
Status 1B	8	0.4	13	1.0	0	0.0	21	0.6
Status 1	4	0.2	4	0.3	0	0.0	8	0.2
Status 1A	16	0.8	9	0.7	1	1.0	26	0.8
Total	2,045	100	1,284	100	102	100	3,431	100
--Creatinine at Transplant (on liver waiting list removal record)								
<1.5	168	8.2	91	7.1	12	11.8	271	7.9
1.5+	1,877	91.8	1,193	92.9	90	88.2	3,160	92.1
Total	2,045	100	1,284	100	102	100	3,431	100

Table 4 tabulates pre-transplant dialysis status data among DD SLK transplants during 1/1/05-6/30/13 by more granular categories of creatinine values and KDPI values:

- A total of 510 (15%) of 3,431 SLK recipients did not receive pre-transplant dialysis and had a serum creatinine of <2.5 mg/dl at transplant.
- Of the 510 SLK recipients with no pre-transplant dialysis and a serum creatinine of <2.5 mg/dl, 237 (46%) received a kidney with KDPI <35%.

Table 4. Serum creatinine and KDPI values by pre-transplant dialysis status for DD SLK transplants during 01/01/05 - 06/30/13

		Pre-transplant Dialysis						Total	
		Yes		No		Unknown			
		N	%	N	%	N	%	N	%
---Creatinine at Transplant (on liver waiting list removal record)	**KDPI**								
<1.5	**0 - 20%**	49	29.2	26	28.6	5	41.7	80	29.5
	21 - 34%	36	21.4	19	20.9	4	33.3	59	21.8
	35 - 85%	74	44.0	40	44.0	3	25.0	117	43.2
	86+%	7	4.2	6	6.6	0	0	13	4.8
	Missing	2	1.2	0	0	0	0	2	0.7
	Total	168	100.0	91	100.0	12	100.0	271	100.0

		Pre-transplant Dialysis						Total	
		Yes		No		Unknown			
		N	%	N	%	N	%	N	%
1.5 - <2.0	**KDPI**								
	0 - 20%	24	23.5	49	27.1	3	27.3	76	25.9
	21 - 34%	21	20.6	25	13.8	2	18.2	48	16.3
	35 - 85%	50	49.0	92	50.8	4	36.4	146	49.7
	86+%	5	4.9	15	8.3	1	9.1	21	7.1
	Missing	2	2.0	0	0	1	9.1	3	1.0
	Total	102	100.0	181	100.0	11	100.0	294	100.0
2.0 - <2.5	**KDPI**								
	0 - 20%	45	30.4	82	34.5	3	18.8	130	32.3
	21 - 34%	27	18.2	36	15.1	2	12.5	65	16.2
	35 - 85%	63	42.6	110	46.2	9	56.3	182	45.3
	86+%	13	8.8	8	3.4	2	12.5	23	5.7
	Missing	0	0	2	0.8	0	0	2	0.5
	Total	148	100.0	238	100.0	16	100.0	402	100.0
2.5 - <3	**KDPI**								
	0 - 20%	47	29.2	73	36.7	4	23.5	124	32.9
	21 - 34%	25	15.5	36	18.1	3	17.6	64	17.0
	35 - 85%	77	47.8	82	41.2	7	41.2	166	44.0
	86+%	11	6.8	6	3.0	2	11.8	19	5.0
	Missing	1	0.6	2	1.0	1	5.9	4	1.1
	Total	161	100.0	199	100.0	17	100.0	377	100.0
3+	**KDPI**								
	0 - 20%	462	31.5	171	29.7	13	28.3	646	31.0
	21 - 34%	249	17.0	103	17.9	12	26.1	364	17.4
	35 - 85%	657	44.8	261	45.4	18	39.1	936	44.8
	86+%	89	6.1	37	6.4	3	6.5	129	6.2
	Missing	9	0.6	3	0.5	0	0	12	0.6
	Total	1,466	100.0	575	100.0	46	100.0	2,087	100.0
Total	**KDPI**								
	0 - 20%	627	30.7	401	31.2	28	27.5	1,056	30.8
	21 - 34%	358	17.5	219	17.1	23	22.5	600	17.5
	35 - 85%	921	45.0	585	45.6	41	40.2	1,547	45.1
	86+%	125	6.1	72	5.6	8	7.8	205	6.0
	Missing	14	0.7	7	0.5	2	2.0	23	0.7
	Total	2,045	100.0	1,284	100.0	102	100.0	3,431	100.0

Table 5 lists kidney and liver diagnoses of recipients of DD SLK transplants during 1/1/05-6/30/13:

- Among 3,431 DD SLK transplants during the study period, 14% had a kidney diagnosis of type 2 diabetes, 7% had hypertensive nephrosclerosis, 6% had hepatorenal syndrome, and 4% had CNI nephrotoxicity diagnosis.
- Twenty-six percent of SLK recipients had a liver diagnosis of type C cirrhosis, followed by alcoholic cirrhosis (14%), NASH (9%), cryptogenic (idiopathic) cirrhosis (8%), and PLM (hepatoma and cirrhosis) (6%).

Table 5. Kidney and liver diagnoses for DD SLK transplants during 01/01/05 - 06/30/13

	N	%
---Kidney Diagnosis		
Not Reported	21	0.6
OTHER SPECIFY	1,255	36.6
IDIO/POST-INF CRESCENTIC GLOMERULONEPHRI	4	0.1
MEMBRANOUS GLOMERULONEPHRITIS	76	2.2
MESANGIO-CAPILLARY 1 GLOMERULONEPHRITIS	4	0.1
MESANGIO-CAPILLARY 2 GLOMERULONEPHRITIS	2	0.1
IGA NEPHROPATHY	67	2.0
FOCAL GLOMERULAR SCLEROSIS (FOCAL SEGMENTAL - FSG)	41	1.2
CHRONIC PYELONEPHRITIS/REFLUX NEPHROPATH	6	0.2
POLYCYSTIC KIDNEYS	174	5.1
NEPHRITIS	18	0.5
NEPHROPHTHISIS	3	0.1
OXALATE NEPHROPATHY (INCLUDES HEREDITARY OXALOSIS)	69	2.0
CYSTINOSIS	1	0.0
AMYLOIDOSIS	11	0.3
GOUT	1	0.0
SYSTEMIC LUPUS ERYTHEMATOSUS	9	0.3
PROGRESSIVE SYSTEMIC SCLEROSIS	2	0.1
RENAL CELL CARCINOMA	10	0.3
INCIDENTAL CARCINOMA	1	0.0
HEMOLYTIC UREMIC SYNDROME	9	0.3
CORTICAL NECROSIS	1	0.0
ACUTE TUBULAR NECROSIS	94	2.7
MEDULLARY CYSTIC DISEASE	2	0.1
SICKLE CELL ANEMIA	5	0.1
ACQUIRED OBSTRUCTIVE NEPHROPATHY	7	0.2
GOODPASTURE'S SYNDROME	1	0.0
MALIGNANT HYPERTENSION	19	0.6
RETRANSPLANT/GRAFT FAILURE	127	3.7
HYPERTENSIVE NEPHROSCLEROSIS	***256***	***7.5***

	N	%
CHRONIC GLOMERULONEPHRITIS UNSPECIFIED	71	2.1
MEMBRANOUS NEPHROPATHY	4	0.1
CHRONIC GLOMERULOSCLEROSIS UNSPECIFIED	25	0.7
ANALGESIC NEPHROPATHY	15	0.4
ANTIBIOTIC-INDUCED NEPHRITIS	2	0.1
CANCER CHEMOTHERAPY INDUCED NEPHRITIS	4	0.1
CALCINEURIN INHIBITOR NEPHROTOXICITY	***146***	***4.3***
HEROIN NEPHROTOXICITY	1	0.0
RENAL ARTERY THROMBOSIS	1	0.0
CHRONIC NEPHROSCLEROSIS-UNSPECIFIED	22	0.6
CONGENITAL OBSTRUCTIVE UROPATHY	1	0.0
WEGENERS GRANULOMATOSIS	1	0.0
POLYARTERITIS	1	0.0
RHEUMATOID ARTHRITIS	1	0.0
SARCOIDOSIS	14	0.4
NEPHROLITHIASIS	8	0.2
DRUG RELATED INTERSTITIAL NEPHRITIS	12	0.3
THIN BASEMENT MEMBRANE DISEASE	1	0.0
RAPID PROGRESSIVE GLOMERULONEPHRITIS (RPGN)	2	0.1
DIABETES MELLITUS - TYPE I	79	2.3
DIABETES MELLITUS - TYPE II	***490***	***14.3***
DIABETES MELLITUS - TYPE OTHER / UNKNOWN	40	1.2
HEPATORENAL SYNDROME	***193***	***5.6***
LITHIUM TOXICITY	1	0.0
Total	3,431	100.0
---Liver Diagnosis		
OTHER SPECIFY	188	5.5
AHN: DRUG OTHER SPECIFY	13	0.4
AHN: TYPE A	2	0.1
AHN: TYPE B- HBSAG+	6	0.2
AHN: TYPE C	20	0.6
AHN: TYPE B AND C	2	0.1
AHN: TYPE B AND D	1	0.0
AHN: ETIOLOGY UNKNOWN	13	0.4
AHN: OTHER, SPECIFY (E.G., ACUTE VIRAL INFECTION, AUTOIMMUNE HEPATITIS - FULMINANT)	23	0.7
CIRRHOSIS: DRUG/INDUST EXPOSURE OTHER SPECIFY	8	0.2
CIRRHOSIS: TYPE A	3	0.1
CIRRHOSIS: TYPE B- HBSAG+	69	2.0
CIRRHOSIS: TYPE C	***891***	***26.0***
CIRRHOSIS: TYPE D	3	0.1

	N	%
CIRRHOSIS: TYPE B AND C	14	0.4
CIRRHOSIS: CHRONIC ACTIVE HEPATITIS: ETIOLOGY UNKNOWN	15	0.4
CIRRHOSIS: OTHER, SPECIFY (E.G., HISTIOCYTOSIS, SARCOIDOSIS, GRANULOMATOUS)	69	2.0
CIRRHOSIS: AUTOIMMUNE	54	1.6
CIRRHOSIS: CRYPTOGENIC (IDIOPATHIC)	***265***	***7.7***
CIRRHOSIS: FATTY LIVER (NASH)	***292***	***8.5***
ALCOHOLIC CIRRHOSIS	***489***	***14.3***
ALCOHOLIC CIRRHOSIS WITH HEPATITIS C	147	4.3
ACUTE ALCOHOLIC HEPATITIS	9	0.3
PRIMARY BILIARY CIRRHOSIS (PBC)	77	2.2
SEC BILIARY CIRRHOSIS: CAROLI'S DISEASE	9	0.3
SEC BILIARY CIRRHOSIS: OTHER SPECIFY	6	0.2
PSC: CROHN'S DISEASE	14	0.4
PSC: ULCERATIVE COLITIS	26	0.8
PSC: NO BOWEL DISEASE	29	0.8
PSC: OTHER SPECIFY	13	0.4
FAMILIAL CHOLESTASIS: OTHER SPECIFY	5	0.1
CHOLES LIVER DISEASE: OTHER SPECIFY	16	0.5
NEONATAL CHOLESTATIC LIVER DISEASE	1	0.0
NEONATAL HEPATITIS OTHER SPECIFY	1	0.0
BILIARY ATRESIA: EXTRAHEPATIC	5	0.1
BILIARY HYPOPLASIA: NONSYNDROMIC PAUCITY OF INTRAHEPATIC BILE DUCT	1	0.0
BILIARY HYPOPLASIA: ALAGILLE'S SYNDROME (PAUCITY OF INTRAHEPATIC BILE DUCT)	3	0.1
CONGENITAL HEPATIC FIBROSIS	44	1.3
CYSTIC FIBROSIS	4	0.1
BUDD-CHIARI SYNDROME	13	0.4
METDIS: ALPHA-1-ANTITRYPSIN DEFIC A-1-A	28	0.8
METDIS: HEMOCHROMATOSIS - HEMOSIDEROSIS	13	0.4
METDIS: GLYC STOR DIS TYPE I (GSD-I)	6	0.2
METDIS: PRIMARY OXALOSIS/OXALURIA, HYPEROXALURIA	79	2.3
METDIS: OTHER SPECIFY	24	0.7
PLM: HEPATOMA - HEPATOCELLULAR CARCINOMA	54	1.6
PLM: HEPATOMA (HCC) AND CIRRHOSIS	***216***	***6.3***
PLM: CHOLANGIOCARCINOMA (CH-CA)	4	0.1
PLM: HEPATOBLASTOMA (HBL)	4	0.1
PLM: HEMANGIOENDOTHELIOMA, HEMANGIOSARCOMA, ANGIOSARCOMA	1	0.0
PLM: OTHER SPECIFY (I.E., KLATZKIN TUMOR, LEIOMYSARCOMA)	2	0.1
SECONDARY HEPATIC MALIGNANCY OTHER SPECIFY	3	0.1
BENIGN TUMOR: POLYCYSTIC LIVER DISEASE	106	3.1
BENIGN TUMOR: OTHER SPECIFY	2	0.1
TPN/HYPERALIMENTATION IND LIVER DISEASE	1	0.0

	N	%
GRAFT VS. HOST DIS SEC TO NON-LI TX	7	0.2
TRAUMA OTHER SPECIFY	1	0.0
GRAFT FAILURE	17	0.5
Total	3,431	100.0

Kidney Listings after Liver Transplants

Figure 1 illustrates the number of kidney listings during 1/1/05-6/30/13 after a previous liver transplant by Region of the listing center and **Figure 2** illustrates the number by DSA of the listing center. **Tables A.1 and A.2** in Appendix A show the number by Region and DSA for each listing year.

- During 1/1/05-6/30/13, the number of kidney registrations added to the waiting list after a liver transplant ranged widely from 54 in Region 6 to 322 in Region 5.
- Across DSAs, the number of kidney registrations added to the waiting list after a liver transplant also ranged substantially from 3 to 107.

Figure 1. Number of kidney registrations added during 1/1/05-6/30/13 after liver transplants by region (N=1,931)

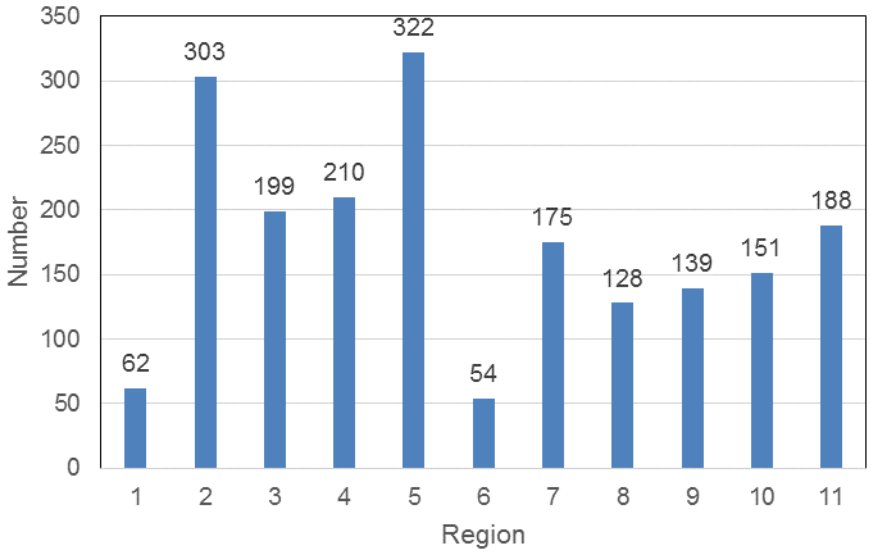

Figure 2. Number of kidney registrations added during 1/1/05-6/30/13 after liver transplants by DSA (N=1,931)

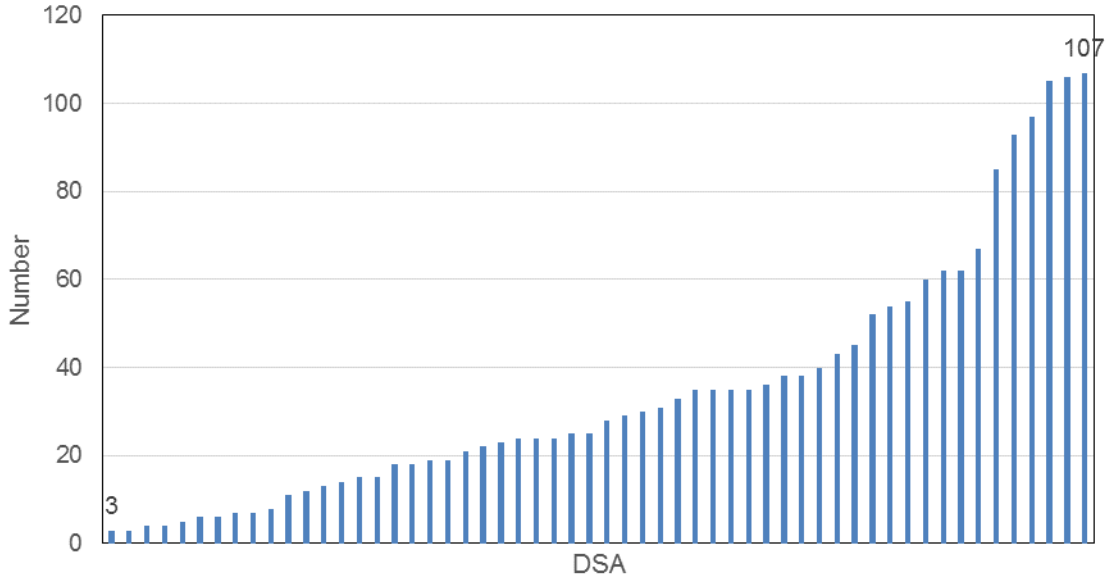

Table 6 summarizes the distribution of times (in months) from previous liver transplants to kidney listings during 1/1/05-6/30/13:

- Overall median time from previous liver transplants to kidney listings was 78 months (about 6.5 years), and it was the smallest for hepatorenal syndrome diagnosis (at 11 months) and the highest for CNI nephrotoxicity diagnosis (at 108 months or about 9 years).
- Only 5% of kidney listings occurred with 8 months of the liver transplant.
- Median time from liver transplants to kidney listings was substantially smaller for those on dialysis prior to the liver transplants compared to those not on dialysis prior to the liver transplants (19 vs. 70 months, respectively). However, only 7% (among those with known dialysis status) of liver-only recipients with a subsequent kidney listing were on dialysis prior to the liver transplant.

Table 6. Distribution of times (in months) from previous liver transplants to kidney listings during 1/1/05-6/30/13 by kidney diagnosis and dialysis status prior to liver transplants

Note: Dialysis information became optional for adults on 2/7/07 and for pediatrics on 3/8/08

			Months from Liver Tx to Subsequent Kidney Listing								
	N	%	Mean	Std Dev	Min	5th PCTL	25th PCTL	*Median*	75th PCTL	95th PCTL	Max
---Kidney Diagnosis at Listing											
CNI Nephrotoxicity	821	43	114	66	3	15	59	***108***	164	225	326
Hepatorenal Syndrome	61	3	15	13	0	3	7	***11***	18	33	78
Hypertensive Nephrosclerosis	118	6	90	69	0	7	24	***83***	145	223	232
Diabetes Type 2	277	14	82	60	2	11	34	***66***	121	205	279
Other	654	34	75	63	0	6	23	***56***	118	197	284
Total	1,931	100	91	67	0	8	34	***78***	142	215	326

			Months from Liver Tx to Subsequent Kidney Listing								
	N	%	Mean	Std Dev	Min	5th PCTL	25th PCTL	*Median*	75th PCTL	95th PCTL	Max
---Dialysis Prior to Previous Liver Tx											
Yes	112	6	40	48	0	3	9	***19***	55	152	210
No	1,404	73	78	53	0	9	34	***70***	117	175	263
Unknown	415	21	150	80	0	9	81	***173***	210	248	326
Total	1,931	100	91	67	0	8	34	***78***	142	215	326

Table 7 summarizes the number of years from previous liver transplants to kidney listings during 1/1/05-6/30/13:

- The majority (87%) of kidney registrations with hepatorenal syndrome diagnosis, but only 8% of those with CNI nephrotoxicity diagnosis, were added to the waiting list within one year of the liver transplant.
- Nearly half of kidney registrations with CNI nephrotoxicity diagnosis were added to the waiting list more than 9 years after the liver transplant.
- Over half of kidney registrations reported with dialysis prior to the liver transplant were added to the waiting list within one year of the liver transplant.

Table 7. Number of years from previous liver transplants to kidney listings during 1/1/05-6/30/13 by kidney diagnosis and dialysis status prior to liver transplants

Note: Dialysis information became optional for adults on 2/7/07 and for pediatrics on 3/8/08

	Years from Liver Transplants to Subsequent Kidney Listings												Total	
	<=1 year		>1-3 years		>3-5 years		>5-7 years		>7-9 years		>9 years			
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
---Kidney Diagnosis at Listing														
CNI Nephrotoxicity	65	7.9	100	12.2	89	10.8	104	12.7	98	11.9	365	44.5	821	100.0
Hepatorenal Syndrome	53	86.9	6	9.8	1	1.6	1	1.6	0	0	0	0	61	100.0
Hypertensive Nephrosclerosis	29	24.6	10	8.5	18	15.3	11	9.3	12	10.2	38	32.2	118	100.0
Diabetes Type 2	49	17.7	48	17.3	50	18.1	33	11.9	27	9.7	70	25.3	277	100.0
Other	165	25.2	130	19.9	98	15.0	54	8.3	46	7.0	161	24.6	654	100.0
Total	361	18.7	294	15.2	256	13.3	203	10.5	183	9.5	634	32.8	1,931	100.0
---Dialysis Prior to Previous Liver Tx														
Yes	64	57.1	17	15.2	9	8.0	6	5.4	7	6.3	9	8.0	112	100.0
No	246	17.5	245	17.5	231	16.5	186	13.2	165	11.8	331	23.6	1,404	100.0
Unknown	51	12.3	32	7.7	16	3.9	11	2.7	11	2.7	294	70.8	415	100.0
Total	361	18.7	294	15.2	256	13.3	203	10.5	183	9.5	634	32.8	1,931	100.0

Kidney after Liver Transplants

Figure 3 illustrates the number of first kidney alone deceased donor transplants during 1/1/05-6/30/13 after a previous liver transplant by Region of the listing center, and **Figure 4** illustrates the number by DSA of the listing center. **Tables A.3 and A.4** in Appendix A show the number by Region and DSA for each of the listing years:

- The number of transplants ranged widely from 36 in Region 6 to 175 in Region 2.
- The number of transplants also ranged substantially across DSAs from 1 to 65.

Figure 3. Number of first kidney alone transplants during 1/1/05-6/30/13 after liver transplants by region (N=1,016)

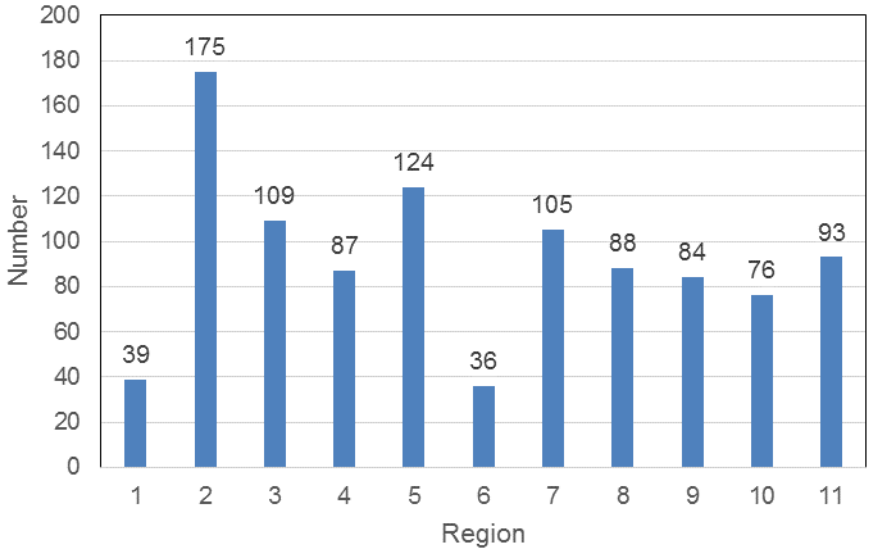

Figure 4. Number of first kidney alone transplants during 1/1/05-6/30/13 after liver transplants by DSA (N=1,016)

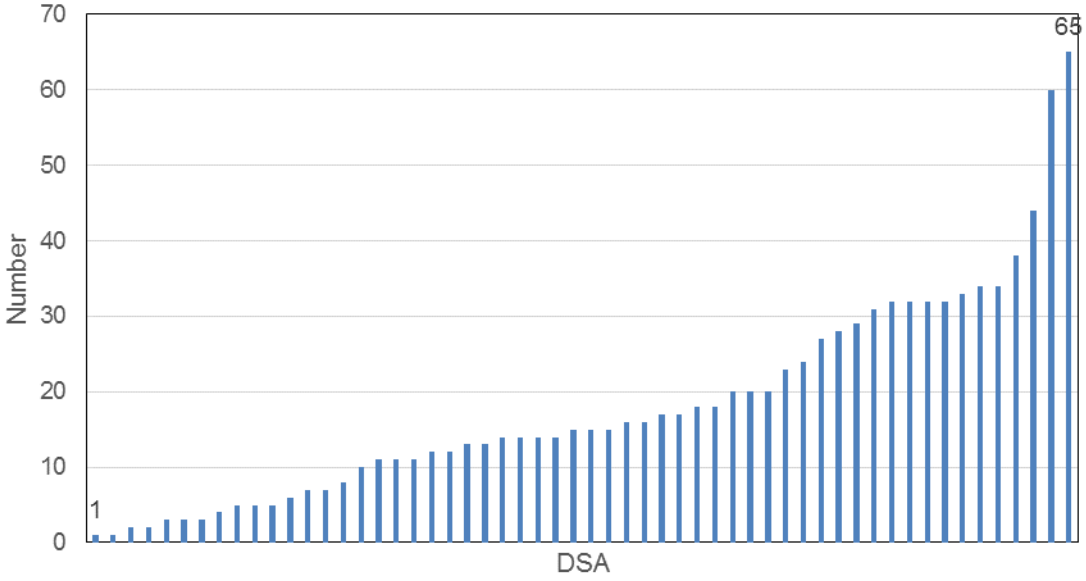

Table 8 summarizes the distribution of times from previous liver transplants to first kidney transplants during 1/1/05-6/30/13:

- Overall median time from liver to deceased donor kidney transplants was 8 years and it was 7 years for those receiving living donor kidneys.
- Median time from liver to kidney transplants was the smallest for hepatorenal syndrome diagnosis (3 years for deceased donor kidney transplants and 1 year for living donor kidney transplants) and the longest for CNI nephrotoxicity diagnosis (10 years for deceased or living donor kidney transplants).
- Overall median time from liver to kidney transplants was much smaller for those on dialysis prior to the liver transplants compared to those not on dialysis prior to the liver transplants (2 vs. 7 years, respectively).

Table 8. Distribution of years between previous liver transplants to kidney transplants during 1/1/05-6/30/13 by kidney diagnosis and dialysis status prior to liver transplants

Note: Dialysis information became optional for adults on 2/7/07 and for pediatrics on 3/8/08

		Years from Liver Transplants to Subsequent Kidney Transplants									
		N	Mean	Std Dev	Min	5th PCTL	25th PCTL	Median	75th PCTL	95th PCTL	Max
---Kidney Diagnosis at Tx	**Kidney Donor Type**										
CNI Nephrotoxicity	**Deceased Donor**	331	10.6	5.4	0.0	2.0	6.0	***10.0***	15.0	19.0	28.0
	Living Donor	162	10.0	5.5	1.0	2.0	5.0	***10.0***	14.0	19.0	23.0
	Total	493	10.4	5.4	0.0	2.0	6.0	***10.0***	15.0	19.0	28.0
Hepatorenal Syndrome	**Deceased Donor**	14	2.6	1.9	0.0	0.0	2.0	***3.0***	3.0	6.0	6.0
	Living Donor	9	1.1	1.3	0.0	0.0	0.0	***1.0***	1.0	4.0	4.0
	Total	23	2.0	1.8	0.0	0.0	0.0	***2.0***	3.0	6.0	6.0
Hypertensive Nephrosclerosis	**Deceased Donor**	51	7.8	5.3	0.0	1.0	3.0	***7.0***	12.0	18.0	19.0
	Living Donor	21	7.9	5.7	0.0	1.0	3.0	***6.0***	12.0	16.0	19.0
	Total	72	7.8	5.4	0.0	1.0	3.0	***7.0***	12.0	18.0	19.0
Diabetes Type 2	**Deceased Donor**	86	6.5	4.1	0.0	1.0	4.0	***5.0***	9.0	14.0	18.0
	Living Donor	32	6.6	3.4	0.0	1.0	4.5	***6.0***	9.0	13.0	14.0
	Total	118	6.5	3.9	0.0	1.0	4.0	***6.0***	9.0	14.0	18.0
Other	**Deceased Donor**	205	6.7	4.9	0.0	1.0	3.0	***5.0***	10.0	16.0	21.0
	Living Donor	105	6.6	5.9	0.0	0.0	1.0	***5.0***	11.0	18.0	22.0
	Total	310	6.7	5.3	0.0	0.0	3.0	***5.0***	10.0	17.0	22.0
Total	**Deceased Donor**	687	8.5	5.5	0.0	1.0	4.0	***8.0***	13.0	18.0	28.0
	Living Donor	329	8.2	5.8	0.0	0.0	3.0	***7.0***	12.0	18.0	23.0
	Total	1,016	8.4	5.6	0.0	1.0	4.0	***8.0***	13.0	18.0	28.0
---Dialysis Prior to Liver Tx											
Yes	**Deceased Donor**	36	3.4	4.1	0.0	0.0	1.0	***2.0***	4.5	13.0	17.0
	Living Donor	14	1.2	1.8	0.0	0.0	0.0	***0.0***	2.0	6.0	6.0
	Total	50	2.8	3.7	0.0	0.0	0.0	***2.0***	3.0	13.0	17.0

		Years from Liver Transplants to Subsequent Kidney Transplants									
		N	Mean	Std Dev	Min	5th PCTL	25th PCTL	Median	75th PCTL	95th PCTL	Max
No	**Deceased Donor**	489	7.2	4.0	0.0	1.0	4.0	***7.0***	10.0	14.0	17.0
	Living Donor	229	6.7	4.1	0.0	1.0	3.0	***6.0***	10.0	13.0	17.0
	Total	718	7.0	4.1	0.0	1.0	4.0	***7.0***	10.0	14.0	17.0
Unknown	**Deceased Donor**	162	13.8	5.9	0.0	2.0	11.0	***16.0***	18.0	20.0	28.0
	Living Donor	86	13.4	6.4	0.0	1.0	12.0	***15.0***	18.0	21.0	23.0
	Total	248	13.6	6.1	0.0	1.0	11.0	***15.0***	18.0	21.0	28.0
Total	**Deceased Donor**	687	8.5	5.5	0.0	1.0	4.0	***8.0***	13.0	18.0	28.0
	Living Donor	329	8.2	5.8	0.0	0.0	3.0	***7.0***	12.0	18.0	23.0
	Total	1,016	8.4	5.6	0.0	1.0	4.0	***8.0***	13.0	18.0	28.0

Table 9 summarizes the number of years between previous liver to kidney transplants during 1/1/05-6/30/13:

- About half (54%) of recipients with CNI nephrotoxicity diagnosis received the kidney transplant beyond 9 years after the liver transplant.
- The majority (78%) of living donor recipients with hepatorenal syndrome diagnosis received kidney transplants within one year of the liver transplants and 79% of deceased donor recipients received the kidney transplant within 3 years of the liver transplant. It's worth noting that there were only 23 kidney recipients after liver transplants with hepatorenal syndrome.
- Approximately three fourth of recipients (76%) who were on dialysis prior to the liver transplants received kidney transplants within 3 years after the liver transplants compared to less than one fourth (23%) of those who were not on dialysis.

Table 9. Number of years from previous liver to kidney transplants during 1/1/05-6/30/13 by kidney diagnosis and dialysis status prior to liver transplants

Note: Dialysis information became optional for adults on 2/7/07 and for pediatrics on 3/8/08

		Years from Liver Transplants to Subsequent Kidney Transplants												Total	
		<=1 year		>1-3 years		>3-5 years		>5-7 years		>7-9 years		>9 years			
		N	%	N	%	N	%	N	%	N	%	N	%	N	%
---Kidney Diagnosis at Transplant															
CNI Nephrotoxicity	**Deceased Donor**	9	2.7	32	9.7	22	6.6	40	12.1	44	13.3	184	55.6	331	100.0
	Living Donor	6	3.7	16	9.9	22	13.6	19	11.7	16	9.9	83	51.2	162	100.0
	Total	15	3.0	48	9.7	44	8.9	59	12.0	60	12.2	267	54.2	493	100.0
Hepatorenal Syndrome	**Deceased Donor**	3	21.4	8	57.1	1	7.1	2	14.3	0	0	0	0	14	100.0
	Living Donor	7	77.8	1	11.1	1	11.1	0	0	0	0	0	0	9	100.0
	Total	10	43.5	9	39.1	2	8.7	2	8.7	0	0	0	0	23	100.0
Hypertensive Nephrosclerosis	**Deceased Donor**	5	9.8	8	15.7	10	19.6	4	7.8	4	7.8	20	39.2	51	100.0
	Living Donor	3	14.3	4	19.0	3	14.3	1	4.8	1	4.8	9	42.9	21	100.0
	Total	8	11.1	12	16.7	13	18.1	5	6.9	5	6.9	29	40.3	72	100.0
Diabetes Type 2	**Deceased Donor**	6	7.0	14	16.3	25	29.1	11	12.8	10	11.6	20	23.3	86	100.0
	Living Donor	2	6.3	4	12.5	4	12.5	11	34.4	3	9.4	8	25.0	32	100.0
	Total	8	6.8	18	15.3	29	24.6	22	18.6	13	11.0	28	23.7	118	100.0
Other	**Deceased Donor**	24	11.7	40	19.5	44	21.5	26	12.7	19	9.3	52	25.4	205	100.0
	Living Donor	28	26.7	17	16.2	9	8.6	10	9.5	7	6.7	34	32.4	105	100.0
	Total	52	16.8	57	18.4	53	17.1	36	11.6	26	8.4	86	27.7	310	100.0
Total	**Deceased Donor**	47	6.8	102	14.8	102	14.8	83	12.1	77	11.2	276	40.2	687	100.0
	Living Donor	46	14.0	42	12.8	39	11.9	41	12.5	27	8.2	134	40.7	329	100.0
	Total	93	9.2	144	14.2	141	13.9	124	12.2	104	10.2	410	40.4	1,016	100.0
---Dialysis Prior to Previous Liver Tx															
Yes	**Deceased Donor**	14	38.9	12	33.3	3	8.3	2	5.6	1	2.8	4	11.1	36	100.0
	Living Donor	9	64.3	3	21.4	1	7.1	1	7.1	0	0	0	0	14	100.0
	Total	23	46.0	15	30.0	4	8.0	3	6.0	1	2.0	4	8.0	50	100.0
No	**Deceased Donor**	26	5.3	79	16.2	92	18.8	77	15.7	74	15.1	141	28.8	489	100.0
	Living Donor	28	12.2	34	14.8	36	15.7	39	17.0	26	11.4	66	28.8	229	100.0
	Total	54	7.5	113	15.7	128	17.8	116	16.2	100	13.9	207	28.8	718	100.0
Unknown	**Deceased Donor**	7	4.3	11	6.8	7	4.3	4	2.5	2	1.2	131	80.9	162	100.0
	Living Donor	9	10.5	5	5.8	2	2.3	1	1.2	1	1.2	68	79.1	86	100.0
	Total	16	6.5	16	6.5	9	3.6	5	2.0	3	1.2	199	80.2	248	100.0

		Years from Liver Transplants to Subsequent Kidney Transplants												Total	
		<=1 year		>1-3 years		>3-5 years		>5-7 years		>7-9 years		>9 years			
		N	%	N	%	N	%	N	%	N	%	N	%	N	%
Total	**Deceased Donor**	47	6.8	102	14.8	102	14.8	83	12.1	77	11.2	276	40.2	687	100.0
	Living Donor	46	14.0	42	12.8	39	11.9	41	12.5	27	8.2	134	40.7	329	100.0
	Total	93	9.2	144	14.2	141	13.9	124	12.2	104	10.2	410	40.4	1,016	100.0

Percentiles of Times to Deceased Donor Kidney Transplants

Figures 5 and 6 illustrate the 25th and 35th percentiles of times to deceased donor kidney alone transplants for registrations waiting for kidney alone transplants during 2003-2008 after a previous liver transplant; and for comparison, the 25th and 35th percentiles of times to deceased donor transplants for registrations waiting for kidney alone transplants during 2003-2008 without a previous liver transplant. **Table 10** tabulates the 25th, 35th, and 50th percentiles of times to deceased donor kidney alone transplants. Note that 50th percentile of times to transplant or median waiting time could not be estimated for most of the ABO blood groups because less than half of registrations had received a deceased donor kidney alone transplant or due to the presence competing risks such as death on the waitlist or removal for another reason besides deceased donor kidney transplant.

- For all ABO blood groups combined, the 25th percentile of times to transplant was substantially lower for kidney registrations added to the list after a liver transplant as compared to those without a previous liver transplant (646 days vs. 1,081 days).
- For each of the ABO blood groups, the 25th percentile of times to transplant was lower for kidney registrations added to the list after a liver transplant as compared to those without a previous liver transplant, and the difference reached statistical significance for A, B and O blood group, as suggested by the non-overlapping confidence intervals.
- Overall, the 35th percentile of times to transplant was much lower for kidney registrations added to the list after a liver transplant as compared to those without a previous liver transplant (1,217 days vs. 2,205 days).

Figure 5. Competing risk method 25th percentiles of times to deceased donor kidney alone transplants for registrations added to the waiting list during 2003-2006 with and without a previous liver transplant

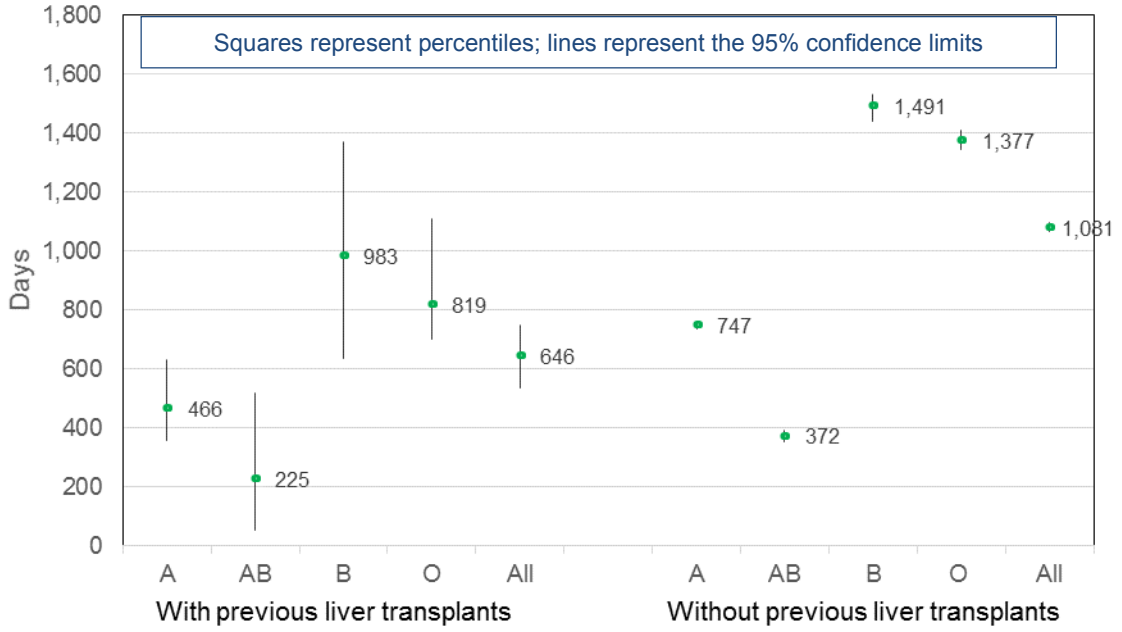

Figure 6. Competing risk method 35th percentiles of times to deceased donor kidney alone transplants for registrations added to the waiting list during 2003-2006 with and without a previous liver transplant

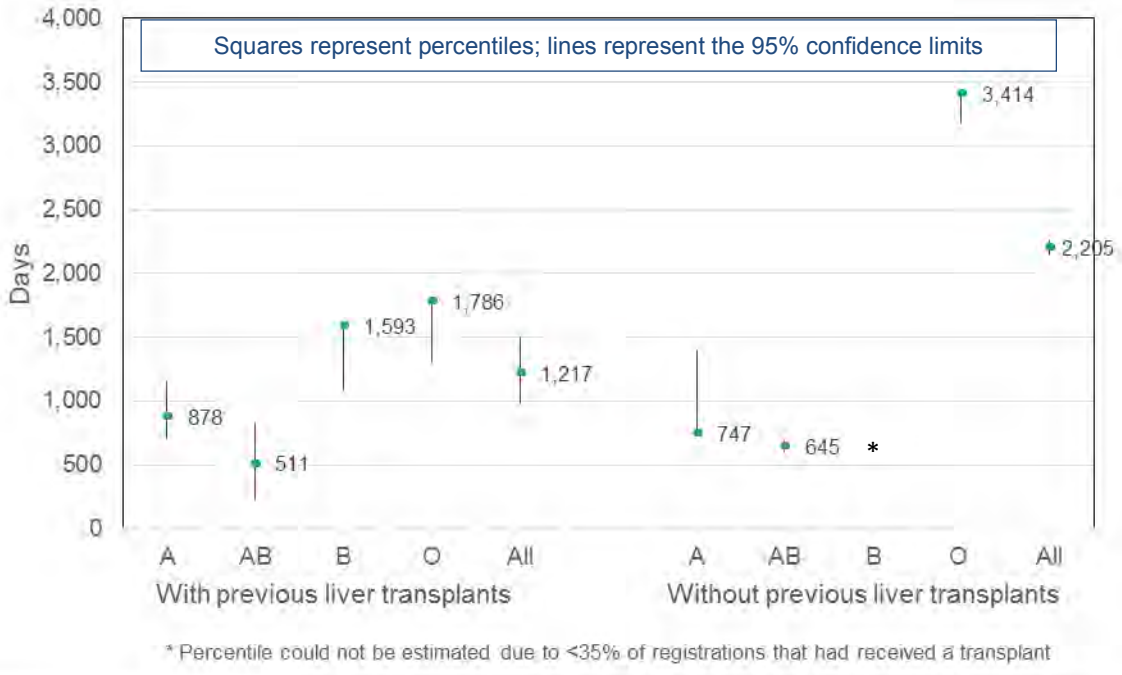

Table 10. Competing risks method percentiles of times to transplants for kidney alone registrations added to the waiting list during 2003-2008 by listing type and ABO blood group

Note: '.' denotes percentile could not be estimated

Listing Type	ABO	No. of Regs	Percentiles	Waiting Time (Days)	95% Lower Confidence Limit	95% Upper Confidence Limit
Kidney with Previous Liver Transplants	A	457	25.0%	466	357	631
			35.0%	878	705	1159
			50.0%	.	.	.
	AB	64	25.0%	225	54	516
			35.0%	511	225	832
			50.0%	921	531	.
	B	149	25.0%	983	635	1370
			35.0%	1593	1090	.
			50.0%	.	.	.
	O	530	25.0%	819	701	1111
			35.0%	1786	1299	.
			50.0%	.	.	.
	Total	1,200	25.0%	646	534	749
			35.0%	1217	993	1502
			50.0%	.	.	.
Kidney without Previous Liver Transplants	A	48,102	25.0%	747	735	761
			35.0%	1349	1312	1396
			50.0%	.	.	.
	AB	5,649	25.0%	372	351	393
			35.0%	645	603	690
			50.0%	2624	1748	.
	B	22,126	25.0%	1491	1442	1532
			35.0%	.	.	.
			50.0%	.	.	.
	O	72,785	25.0%	1377	1347	1408
			35.0%	3414	3178	.
			50.0%	.	.	.
	Total	148,662	25.0%	1081	1065	1098
			35.0%	2205	2146	2259
			50.0%	.	.	.

SUMMARY

- Among 3,431 SLK recipients during 1/1/05-6/30/13, 510 (15%) did not receive pre-transplant dialysis and had a serum creatinine of <2.5 mg/dl at transplant, which would suggest that some of these patients may not have needed a kidney.
  - Of the 510 SLK recipients with no pre-transplant dialysis and a serum creatinine of <2.5 mg/dl, 237 (46%) received a KDPI <35% kidney, which suggests that kidneys utilized in SLK transplants also tended to have a lower KDPI scores.
  - Since pediatric kidney candidates are prioritized to receive kidneys from donors with age<35 (KDPI<35 in the new allocation system), SLK transplants in which the kidney was not needed may disproportionately affect pediatric access to kidneys.

- On average, 200 patients were listed per year for a kidney transplant during 1/1/05-6/30/13 after a solitary liver transplant; the median time to listing for these patients was about 9 years for those with a kidney diagnosis of CNI nephrotoxicity, 6.5 years for hypertensive nephrosclerosis, 5 years for type 2 diabetes, and 11 months for hepatorenal syndrome; additionally, only 19% were listed within a year of the liver transplant.

- On average, there were 120 kidney transplants (including both deceased and living donor) performed per year during 1/1/05-6/30/13 after a solitary liver transplant; the median time to kidney transplant was 10 years for those with a kidney diagnosis of CNI nephrotoxicity, 7 years for hypertensive nephrosclerosis, 6 years for type 2 diabetes, and 2 years for hepatorenal syndrome; additionally, only 9% were transplanted within a year of the liver transplant.

- The 25th percentile of times to deceased donor kidney transplant tended to be lower for registrations added to the waiting list during 2003-2008 after a previous liver transplant as compared to those added to the waiting list during the same time period without a previous liver transplant.

APPENDIX A

Table A.1. Number of kidney alone registrations added to the waiting list during 1/1/05-6/30/13 after a previous liver transplant by region and listing year

Listing Region	Year of Listing																		Total	
	2005		2006		2007		2008		2009		2010		2011		2012		2013			
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
1	5	2.6	4	2.0	4	1.7	5	2.6	11	5.1	8	3.2	12	5.0	9	3.5	4	2.8	62	3.2
2	30	15.4	39	19.2	28	12.1	33	16.8	39	18.1	41	16.2	31	13.0	32	12.4	30	21.3	303	15.7
3	25	12.8	20	9.9	28	12.1	30	15.3	18	8.4	23	9.1	16	6.7	28	10.8	11	7.8	199	10.3
4	20	10.3	16	7.9	30	13.0	25	12.8	24	11.2	35	13.8	26	10.9	24	9.3	10	7.1	210	10.9
5	36	18.5	31	15.3	40	17.3	30	15.3	35	16.3	38	15.0	37	15.5	48	18.5	27	19.1	322	16.7
6	6	3.1	4	2.0	7	3.0	6	3.1	10	4.7	4	1.6	6	2.5	7	2.7	4	2.8	54	2.8
7	19	9.7	22	10.8	18	7.8	10	5.1	19	8.8	18	7.1	24	10.1	29	11.2	16	11.3	175	9.1
8	9	4.6	16	7.9	19	8.2	18	9.2	8	3.7	19	7.5	17	7.1	15	5.8	7	5.0	128	6.6
9	10	5.1	13	6.4	13	5.6	20	10.2	13	6.0	23	9.1	23	9.7	15	5.8	9	6.4	139	7.2
10	22	11.3	21	10.3	18	7.8	10	5.1	15	7.0	16	6.3	17	7.1	22	8.5	10	7.1	151	7.8
11	13	6.7	17	8.4	26	11.3	9	4.6	23	10.7	28	11.1	29	12.2	30	11.6	13	9.2	188	9.7
Total	195	100.0	203	100.0	231	100.0	196	100.0	215	100.0	253	100.0	238	100.0	259	100.0	141	100.0	1,931	100.0

Table A.2. Number of kidney alone registrations added to the waiting list during 1/1/05-6/30/13 after a previous liver transplant by DSA and listing year

Listing DSA	Year of Listing																		Total	
	2005		2006		2007		2008		2009		2010		2011		2012		2013			
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
ALOB-OP1	4	2.1	4	2.0	4	1.7	5	2.6	4	1.9	3	1.2	3	1.3	6	2.3	2	1.4	35	1.8
AROR-OP1	0	0	1	0.5	0	0	1	0.5	0	0	1	0.4	1	0.4	2	0.8	0	0	6	0.3
AZOB-OP1	5	2.6	6	3.0	4	1.7	4	2.0	4	1.9	4	1.6	2	0.8	11	4.2	5	3.5	45	2.3
CADN-OP1	11	5.6	12	5.9	14	6.1	7	3.6	9	4.2	12	4.7	14	5.9	9	3.5	9	6.4	97	5.0
CAGS-OP1	1	0.5	2	1.0	1	0.4	3	1.5	1	0.5	1	0.4	3	1.3	2	0.8	0	0	14	0.7
CAOP-OP1	15	7.7	9	4.4	11	4.8	8	4.1	15	7.0	19	7.5	8	3.4	13	5.0	7	5.0	105	5.4
CASD-IO1	1	0.5	1	0.5	7	3.0	4	2.0	3	1.4	1	0.4	6	2.5	4	1.5	2	1.4	29	1.5
CORS-OP1	5	2.6	4	2.0	9	3.9	3	1.5	2	0.9	5	2.0	5	2.1	3	1.2	2	1.4	38	2.0
CTOP-OP1	2	1.0	0	0	1	0.4	0	0	0	0	1	0.4	1	0.4	1	0.4	1	0.7	7	0.4
DCTC-OP1	8	4.1	6	3.0	6	2.6	3	1.5	6	2.8	2	0.8	1	0.4	2	0.8	1	0.7	35	1.8
FLFH-IO1	2	1.0	0	0	0	0	1	0.5	1	0.5	1	0.4	1	0.4	1	0.4	1	0.7	8	0.4
FLMP-OP1	7	3.6	3	1.5	9	3.9	4	2.0	5	2.3	2	0.8	2	0.8	2	0.8	4	2.8	38	2.0
FLUF-IO1	4	2.1	4	2.0	6	2.6	8	4.1	0	0	4	1.6	1	0.4	3	1.2	0	0	30	1.6
FLWC-OP1	3	1.5	2	1.0	2	0.9	4	2.0	1	0.5	6	2.4	2	0.8	2	0.8	0	0	22	1.1
GALL-OP1	3	1.5	6	3.0	3	1.3	3	1.5	4	1.9	3	1.2	6	2.5	6	2.3	2	1.4	36	1.9
HIOP-OP1	0	0	0	0	0	0	1	0.5	1	0.5	0	0	0	0	0	0	1	0.7	3	0.2
IAOP-OP1	2	1.0	0	0	4	1.7	5	2.6	2	0.9	3	1.2	2	0.8	4	1.5	1	0.7	23	1.2
ILIP-OP1	2	1.0	8	3.9	8	3.5	4	2.0	9	4.2	6	2.4	6	2.5	15	5.8	4	2.8	62	3.2
INOP-OP1	3	1.5	9	4.4	4	1.7	3	1.5	5	2.3	1	0.4	4	1.7	4	1.5	2	1.4	35	1.8
KYDA-OP1	1	0.5	0	0	1	0.4	1	0.5	1	0.5	3	1.2	5	2.1	4	1.5	2	1.4	18	0.9
LAOP-OP1	1	0.5	0	0	4	1.7	4	2.0	3	1.4	3	1.2	0	0	5	1.9	1	0.7	21	1.1
MAOB-OP1	3	1.5	4	2.0	3	1.3	5	2.6	11	5.1	7	2.8	11	4.6	8	3.1	3	2.1	55	2.8

Listing DSA	Year of Listing																		Total	
	2005		2006		2007		2008		2009		2010		2011		2012		2013			
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
MDPC-OP1	2	1.0	7	3.4	4	1.7	4	2.0	5	2.3	3	1.2	6	2.5	6	2.3	6	4.3	43	2.2
MIOP-OP1	7	3.6	5	2.5	8	3.5	3	1.5	10	4.7	6	2.4	4	1.7	14	5.4	3	2.1	60	3.1
MNOP-OP1	11	5.6	8	3.9	6	2.6	6	3.1	6	2.8	5	2.0	9	3.8	9	3.5	7	5.0	67	3.5
MOMA-OP1	1	0.5	7	3.4	1	0.4	3	1.5	1	0.5	4	1.6	3	1.3	3	1.2	1	0.7	24	1.2
MWOB-OP1	1	0.5	1	0.5	3	1.3	4	2.0	1	0.5	5	2.0	3	1.3	3	1.2	3	2.1	24	1.2
NCCM-IO1	0	0	1	0.5	3	1.3	0	0	4	1.9	0	0	4	1.7	0	0	1	0.7	13	0.7
NCNC-OP1	2	1.0	6	3.0	7	3.0	2	1.0	4	1.9	8	3.2	5	2.1	4	1.5	2	1.4	40	2.1
NEOR-OP1	0	0	4	2.0	2	0.9	3	1.5	2	0.9	2	0.8	4	1.7	2	0.8	0	0	19	1.0
NJTO-OP1	1	0.5	3	1.5	3	1.3	4	2.0	4	1.9	6	2.4	2	0.8	2	0.8	0	0	25	1.3
NMOP-OP1	0	0	0	0	0	0	1	0.5	0	0	0	0	1	0.4	2	0.8	3	2.1	7	0.4
NYAP-OP1	0	0	0	0	0	0	1	0.5	0	0	1	0.4	1	0.4	1	0.4	0	0	4	0.2
NYFL-IO1	2	1.0	3	1.5	1	0.4	3	1.5	2	0.9	3	1.2	6	2.5	2	0.8	2	1.4	24	1.2
NYRT-OP1	8	4.1	8	3.9	12	5.2	16	8.2	11	5.1	17	6.7	16	6.7	12	4.6	6	4.3	106	5.5
NYWN-OP1	0	0	2	1.0	0	0	0	0	0	0	2	0.8	0	0	0	0	1	0.7	5	0.3
OHLB-OP1	6	3.1	3	1.5	4	1.7	2	1.0	0	0	6	2.4	4	1.7	3	1.2	3	2.1	31	1.6
OHLC-OP1	0	0	0	0	0	0	1	0.5	0	0	1	0.4	2	0.8	0	0	0	0	4	0.2
OHLP-OP1	1	0.5	2	1.0	1	0.4	0	0	0	0	0	0	0	0	1	0.4	1	0.7	6	0.3
OHOV-OP1	5	2.6	2	1.0	1	0.4	1	0.5	0	0	2	0.8	3	1.3	0	0	1	0.7	15	0.8
OKOP-OP1	1	0.5	1	0.5	2	0.9	4	2.0	1	0.5	6	2.4	1	0.4	2	0.8	1	0.7	19	1.0
ORUO-IO1	3	1.5	1	0.5	2	0.9	0	0	4	1.9	2	0.8	3	1.3	3	1.2	0	0	18	0.9
PADV-OP1	9	4.6	13	6.4	7	3.0	18	9.2	9	4.2	17	6.7	13	5.5	12	4.6	9	6.4	107	5.5
PATF-OP1	10	5.1	10	4.9	8	3.5	4	2.0	15	7.0	13	5.1	9	3.8	10	3.9	14	9.9	93	4.8
PRLL-OP1	1	0.5	0	0	0	0	0	0	0	0	0	0	0	0	1	0.4	1	0.7	3	0.2
SCOP-OP1	0	0	1	0.5	1	0.4	1	0.5	0	0	2	0.8	2	0.8	5	1.9	0	0	12	0.6
TNDS-OP1	2	1.0	0	0	6	2.6	2	1.0	7	3.3	3	1.2	2	0.8	2	0.8	4	2.8	28	1.5
TNMS-OP1	1	0.5	0	0	1	0.4	2	1.0	1	0.5	2	0.8	0	0	7	2.7	1	0.7	15	0.8

Listing DSA	Year of Listing																		Total	
	2005		2006		2007		2008		2009		2010		2011		2012		2013			
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
TXGC-OP1	7	3.6	7	3.4	10	4.3	9	4.6	11	5.1	14	5.5	15	6.3	7	2.7	5	3.5	85	4.4
TXSA-OP1	5	2.6	5	2.5	8	3.5	6	3.1	6	2.8	6	2.4	5	2.1	11	4.2	2	1.4	54	2.8
TXSB-OP1	7	3.6	3	1.5	10	4.3	6	3.1	6	2.8	9	3.6	5	2.1	4	1.5	2	1.4	52	2.7
UTOP-OP1	3	1.5	1	0.5	3	1.3	3	1.5	3	1.4	1	0.4	3	1.3	7	2.7	1	0.7	25	1.3
VATB-OP1	7	3.6	9	4.4	7	3.0	1	0.5	6	2.8	10	4.0	11	4.6	8	3.1	3	2.1	62	3.2
WALC-OP1	3	1.5	3	1.5	5	2.2	5	2.6	5	2.3	2	0.8	3	1.3	4	1.5	3	2.1	33	1.7
WIDN-OP1	1	0.5	0	0	0	0	0	0	3	1.4	1	0.4	4	1.7	0	0	2	1.4	11	0.6
WIUW-IO1	5	2.6	6	3.0	4	1.7	0	0	1	0.5	6	2.4	5	2.1	5	1.9	3	2.1	35	1.8
Total	195	100.0	203	100.0	231	100.0	196	100.0	215	100.0	253	100.0	238	100.0	259	100.0	141	100.0	1,931	100.0

Table A.3. Number of first kidney alone transplants during 1/1/05-6/30/13 after a previous liver transplant by region and listing year

Tx Region	Year of Kidney Transplant																		Total	
	2005		2006		2007		2008		2009		2010		2011		2012		2013			
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
1	5	3.9	3	2.5	1	0.9	4	3.2	3	2.5	7	6.6	5	3.9	8	6.6	3	4.9	39	3.8
2	26	20.3	28	23.3	20	18.9	13	10.5	25	20.5	14	13.2	27	21.1	9	7.4	13	21.3	175	17.2
3	19	14.8	12	10.0	15	14.2	15	12.1	15	12.3	5	4.7	13	10.2	9	7.4	6	9.8	109	10.7
4	12	9.4	5	4.2	14	13.2	13	10.5	9	7.4	8	7.5	11	8.6	13	10.7	2	3.3	87	8.6
5	13	10.2	15	12.5	11	10.4	14	11.3	18	14.8	14	13.2	17	13.3	16	13.2	6	9.8	124	12.2
6	1	0.8	6	5.0	4	3.8	4	3.2	4	3.3	5	4.7	2	1.6	8	6.6	2	3.3	36	3.5
7	14	10.9	14	11.7	9	8.5	16	12.9	13	10.7	14	13.2	10	7.8	9	7.4	6	9.8	105	10.3
8	12	9.4	6	5.0	8	7.5	12	9.7	11	9.0	5	4.7	16	12.5	15	12.4	3	4.9	88	8.7
9	12	9.4	9	7.5	9	8.5	10	8.1	8	6.6	9	8.5	9	7.0	12	9.9	6	9.8	84	8.3
10	8	6.3	13	10.8	7	6.6	11	8.9	8	6.6	11	10.4	6	4.7	7	5.8	5	8.2	76	7.5
11	6	4.7	9	7.5	8	7.5	12	9.7	8	6.6	14	13.2	12	9.4	15	12.4	9	14.8	93	9.2
Total	128	100.0	120	100.0	106	100.0	124	100.0	122	100.0	106	100.0	128	100.0	121	100.0	61	100.0	1,016	100.0

Table A.4. Number of first kidney alone transplants during 1/1/05-6/30/13 after a previous liver transplant by DSA and listing year

Transplant DSA	Year of Kidney Transplant																		Total	
	2005		2006		2007		2008		2009		2010		2011		2012		2013			
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
ALOB-OP1	3	2.3	2	1.7	1	0.9	1	0.8	2	1.6	2	1.9	2	1.6	2	1.7	0	0	15	1.5
AROR-OP1	0	0	1	0.8	1	0.9	0	0	1	0.8	0	0	0	0	2	1.7	0	0	5	0.5
AZOB-OP1	2	1.6	2	1.7	2	1.9	2	1.6	1	0.8	3	2.8	0	0	4	3.3	1	1.6	17	1.7
CADN-OP1	1	0.8	4	3.3	4	3.8	4	3.2	6	4.9	2	1.9	6	4.7	4	3.3	1	1.6	32	3.1
CAGS-OP1	1	0.8	1	0.8	0	0	1	0.8	2	1.6	0	0	1	0.8	1	0.8	0	0	7	0.7
CAOP-OP1	6	4.7	2	1.7	1	0.9	3	2.4	5	4.1	4	3.8	7	5.5	3	2.5	1	1.6	32	3.1
CASD-IO1	0	0	1	0.8	2	1.9	3	2.4	1	0.8	3	2.8	0	0	2	1.7	1	1.6	13	1.3
CORS-OP1	3	2.3	0	0	4	3.8	3	2.4	3	2.5	1	0.9	5	3.9	4	3.3	1	1.6	24	2.4
CTOP-OP1	0	0	1	0.8	1	0.9	2	1.6	0	0	0	0	1	0.8	0	0	0	0	5	0.5
DCTC-OP1	3	2.3	5	4.2	2	1.9	3	2.4	4	3.3	0	0	0	0	2	1.7	1	1.6	20	2.0
FLFH-IO1	1	0.8	0	0	0	0	1	0.8	0	0	0	0	1	0.8	0	0	0	0	3	0.3
FLMP-OP1	6	4.7	4	3.3	4	3.8	2	1.6	4	3.3	0	0	3	2.3	3	2.5	2	3.3	28	2.8
FLUF-IO1	1	0.8	1	0.8	4	3.8	4	3.2	3	2.5	1	0.9	0	0	0	0	1	1.6	15	1.5
FLWC-OP1	3	2.3	2	1.7	1	0.9	3	2.4	3	2.5	1	0.9	3	2.3	0	0	2	3.3	18	1.8
GALL-OP1	2	1.6	2	1.7	3	2.8	0	0	0	0	0	0	3	2.3	1	0.8	0	0	11	1.1
HIOP-OP1	0	0	0	0	1	0.9	0	0	0	0	0	0	0	0	1	0.8	0	0	2	0.2
IAOP-OP1	3	2.3	0	0	1	0.9	3	2.4	1	0.8	0	0	3	2.3	2	1.7	1	1.6	14	1.4
ILIP-OP1	3	2.3	3	2.5	6	5.7	4	3.2	9	7.4	4	3.8	2	1.6	1	0.8	1	1.6	33	3.2
INOP-OP1	3	2.3	1	0.8	1	0.9	3	2.4	2	1.6	1	0.9	2	1.6	1	0.8	0	0	14	1.4
KYDA-OP1	0	0	0	0	1	0.9	1	0.8	0	0	1	0.9	5	3.9	0	0	0	0	8	0.8
LAOP-OP1	3	2.3	0	0	1	0.9	4	3.2	2	1.6	1	0.9	1	0.8	1	0.8	1	1.6	14	1.4
MAOB-OP1	5	3.9	2	1.7	0	0	2	1.6	3	2.5	7	6.6	4	3.1	8	6.6	3	4.9	34	3.3

Transplant DSA	Year of Kidney Transplant																		Total	
	2005		2006		2007		2008		2009		2010		2011		2012		2013			
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
MDPC-OP1	3	2.3	4	3.3	7	6.6	1	0.8	7	5.7	1	0.9	7	5.5	1	0.8	3	4.9	34	3.3
MIOP-OP1	1	0.8	7	5.8	4	3.8	2	1.6	3	2.5	3	2.8	3	2.3	5	4.1	3	4.9	31	3.1
MNOP-OP1	6	4.7	4	3.3	2	1.9	7	5.6	1	0.8	8	7.5	4	3.1	5	4.1	1	1.6	38	3.7
MOMA-OP1	2	1.6	4	3.3	1	0.9	2	1.6	1	0.8	1	0.9	1	0.8	3	2.5	1	1.6	16	1.6
MWOB-OP1	2	1.6	1	0.8	1	0.9	1	0.8	3	2.5	2	1.9	6	4.7	2	1.7	0	0	18	1.8
NCCM-IO1	0	0	2	1.7	1	0.9	0	0	0	0	2	1.9	0	0	1	0.8	0	0	6	0.6
NCNC-OP1	2	1.6	1	0.8	2	1.9	1	0.8	4	3.3	0	0	1	0.8	4	3.3	2	3.3	17	1.7
NEOR-OP1	2	1.6	1	0.8	1	0.9	3	2.4	3	2.5	1	0.9	1	0.8	4	3.3	0	0	16	1.6
NJTO-OP1	2	1.6	1	0.8	1	0.9	0	0	2	1.6	2	1.9	2	1.6	1	0.8	1	1.6	12	1.2
NMOP-OP1	0	0	1	0.8	0	0	0	0	1	0.8	0	0	0	0	0	0	0	0	2	0.2
NVLV-OP1	1	0.8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0.1
NYAP-OP1	2	1.6	0	0	0	0	0	0	0	0	1	0.9	0	0	0	0	0	0	3	0.3
NYFL-IO1	4	3.1	1	0.8	2	1.9	2	1.6	1	0.8	3	2.8	2	1.6	3	2.5	2	3.3	20	2.0
NYRT-OP1	6	4.7	8	6.7	7	6.6	8	6.5	7	5.7	5	4.7	6	4.7	9	7.4	4	6.6	60	5.9
NYWN-OP1	0	0	0	0	0	0	0	0	0	0	0	0	1	0.8	0	0	0	0	1	0.1
OHLB-OP1	2	1.6	2	1.7	0	0	2	1.6	2	1.6	2	1.9	1	0.8	0	0	0	0	11	1.1
OHLC-OP1	1	0.8	0	0	0	0	0	0	0	0	1	0.9	0	0	0	0	1	1.6	3	0.3
OHLP-OP1	0	0	1	0.8	1	0.9	2	1.6	1	0.8	2	1.9	0	0	0	0	0	0	7	0.7
OHOV-OP1	1	0.8	2	1.7	1	0.9	2	1.6	0	0	2	1.9	0	0	1	0.8	1	1.6	10	1.0
OKOP-OP1	2	1.6	0	0	1	0.9	1	0.8	2	1.6	3	2.8	0	0	4	3.3	0	0	13	1.3
ORUO-IO1	1	0.8	1	0.8	2	1.9	0	0	2	1.6	0	0	0	0	3	2.5	2	3.3	11	1.1
PADV-OP1	7	5.5	6	5.0	2	1.9	5	4.0	4	3.3	6	5.7	8	6.3	3	2.5	3	4.9	44	4.3
PATF-OP1	11	8.6	12	10.0	8	7.5	4	3.2	8	6.6	5	4.7	10	7.8	2	1.7	5	8.2	65	6.4
SCOP-OP1	0	0	0	0	0	0	1	0.8	0	0	0	0	1	0.8	2	1.7	0	0	4	0.4
TNDS-OP1	0	0	0	0	1	0.9	2	1.6	1	0.8	5	4.7	1	0.8	1	0.8	3	4.9	14	1.4
TNMS-OP1	0	0	2	1.7	1	0.9	2	1.6	0	0	3	2.8	0	0	3	2.5	1	1.6	12	1.2

Transplant DSA	Year of Kidney Transplant																		Total	
	2005		2006		2007		2008		2009		2010		2011		2012		2013			
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
TXGC-OP1	2	1.6	2	1.7	7	6.6	4	3.2	4	3.3	1	0.9	7	5.5	4	3.3	1	1.6	32	3.1
TXSA-OP1	5	3.9	2	1.7	2	1.9	3	2.4	0	0	1	0.9	0	0	2	1.7	0	0	15	1.5
TXSB-OP1	3	2.3	1	0.8	4	3.8	5	4.0	3	2.5	3	2.8	4	3.1	3	2.5	1	1.6	27	2.7
UTOP-OP1	2	1.6	4	3.3	2	1.9	1	0.8	2	1.6	2	1.9	3	2.3	2	1.7	2	3.3	20	2.0
VATB-OP1	4	3.1	4	3.3	2	1.9	5	4.0	3	2.5	3	2.8	4	3.1	4	3.3	3	4.9	32	3.1
WALC-OP1	0	0	5	4.2	1	0.9	4	3.2	2	1.6	5	4.7	2	1.6	4	3.3	0	0	23	2.3
WIDN-OP1	2	1.6	1	0.8	0	0	0	0	0	0	1	0.9	0	0	1	0.8	0	0	5	0.5
WIUW-IO1	3	2.3	6	5.0	1	0.9	5	4.0	3	2.5	1	0.9	4	3.1	2	1.7	4	6.6	29	2.9
Total	128	100.0	120	100.0	106	100.0	124	100.0	122	100.0	106	100.0	128	100.0	121	100.0	61	100.0	1,016	100.0

2009 SLK Proposal

III. Policy Proposals

At-a-Glance

- **Proposed listing requirements for simultaneous liver-kidney transplant candidates**
- **Policy proposed: Policy 3.5.10 (Simultaneous Liver-Kidney Transplantation)**
- **The Kidney Transplantation Committee and the Liver and Intestinal Organ Transplantation Committee**
- This proposal would set minimum criteria for candidates listed for simultaneous liver-kidney (SLK) transplantation. The intent of this proposal is first to identify candidates who are unlikely to regain renal function following liver transplantation. Once identified, these proposed policy changes would provide priority for these candidates to receive a SLK transplant. The goal of this proposal is to improve patient and renal graft survival following SLK transplant.
- **Affected groups:** candidates listed for kidney-liver transplant, transplant surgeons, transplant physicians, transplant coordinators

Proposed listing requirements for simultaneous liver-kidney transplant candidates

Policy proposed: Policy 3.5.10 (Simultaneous Liver-Kidney Transplantation)

Kidney Transplantation Committee and Liver Intestinal Organ Transplantation Committee

Summary and Goals of the Proposal:

This poposal would set minimum criteria for candidates listed for simultaneous liver-kidney (SLK) transplantation. The intent of this proposal is first to identify candidates who are unlikely to regain renal function following liver transplantation. Once identified, these proposed policy changes would provide priority for these candidates to receive a SLK transplant. The goal of this proposal is to improve patient and renal graft survival following SLK transplant.

Background and Significance of Proposal:

Currently OPTN/UNOS Policy does not contain listing requirements for candidates who require a simultaneous liver-kidney transplant (SLK). Reports in the peer-reviewed literature and from national consensus conferences suggest that SLK transplantation rates vary greatly among transplant centers, even among similar patient populations.[1] When the liver allocation system was changed to the current Model for End Stage Liver Disease (MELD) in 2002, a substantial amount of priority was given to liver transplantation candidates with renal insuffiency. [2] An unintended consequence of the MELD policy change may have been a rapid increase in the number of SLK transplants performed.

The increase in SLK transplants since the introduction of the MELD in 2002 prompted a joint review by the Kidney Transplantation Committee and the Liver Intestinal Organ Transplantation Committee. Findings from this review indicate that the number of SLK transplants has increased four fold from 82 in 1995 to 400 in 2006 (Figure 1).

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[1] Davis CL, Feng S, Sung R, Wong F, Goodrich NP, Melton LB, Reddy KR, Guidinger MK, Wilkinson A, Lake J. Simultaneous liver-kidney transplantation: evaluation to decision making. Am J Transplant. 2007 Jul;7(7):1702-9.

[2] Locke JE, Warren DS, Singer AL, Segev DL, Simpkins CE, Maley WR, Montgomery RA, Danovitch G, Cameron AM. Declining outcomes in simultaneous liver-kidney transplantation in the MELD era: ineffective usage of renal allografts. Transplantation. 2008 Apr 15;85(7):935-42.

Figure 1: Number of SLK Transplants pre/post MELD implementation in 2002

While the number of SLK transplants has increased steadily since 2002, patient survival, as well as kidney graft survival following SLK transplantation has declined. In a retrospective study of adult recipients of deceased donor liver transplants, kidney transplants, and SLK transplants, Locke, et al, found that patient survival for SLK recipients dimished from 87% in 2002 to 76.1% in 2005.[3] [4]

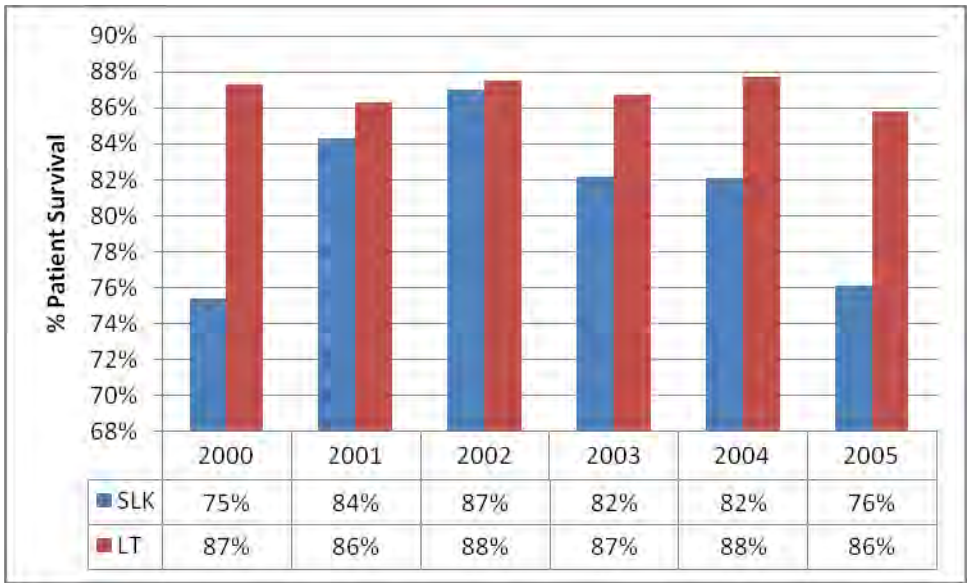

Figure 2: Patient survival following simultaneous liver kidney (SLK) transplant versus liver transplant (LT)

[3] ibid.

[4] ibid.

Current allocation for SLK or heart-kidney transplantation is based primarily on the life-saving organ. While candidates must be registered on the waiting list for each organ, the allocation is determined by the heart or liver match run. If the candidate is in the same donor service area (DSA) as the donor, then the kidney must be shared with the life-saving organ. If the candidate is in a different DSA than the donor, then sharing of the kidney is recommended but not mandatory (see OPTN/UNOS Policy 3.9.3).

Supporting Evidence and/or Modeling:

The transplant community discussed trends in SLK transplantation data in March 2006 and September 2007 during consensus conferences to review data related to SLK transplantation including incidence and outcomes. Based on the recommendations from these conferences, the Liver and Kidney Transplantation Committees evaluated the thresholds for dialysis time and glomerular fitration rate (GFR) to determine how many candidates would meet the following criteria for a liver-kidney transplant:

a. If a patient is on chronic maintenance dialysis, documentation of initation of dialysis with the chronic dialysis provider's name included. If available, a copy of the CMS Form 2728 should be provided; OR

b. Documentation of GFR<= 25 ml/min for 6 weeks or more by MDRD6 or direct measurement (iothalamate or iohexol); OR

c. Dialysis for 6 weeks or more (defined as dialysis at least twice per week for 6 consecutive weeks); OR

d. Metabolic disease requiring liver-kidney transplantation (such as hyperoxaluria, etc) with documentation from a nephrologist stating that the patient requires a combined liver-kidney transplant and the specific reason for the kidney graft listing (hyperoxaluria, dialysis for >6weeks, etc); OR

e. Documentation of GFR <=30 ml/min by MDRD6 or direct measurement (iothalamate or iohexol), with proteinuria (>3 grams protein per day with 24 hour protein measurement or urine protein/creatinine ration >3.0)

A snapshot of the liver waiting list on January 31, 2008 was analyzed to determine the number of candidates who would meet at least one of the above criteria. Pediatric (0-11 years) candidates were excluded. In addition, a cohort of liver transplants (> 11 years) from March 1, 2002- through September 30, 2007 was analyzed to determine the number of recipients who would have met at least one of the proposed criteria for a combined liver-kidney transplant at the time of the transplant. GFR was estimated using the abbreviated MDRD formula:

Abbreviated MDRD (aMDRD) = 186 ×[serum creatinine(mg/dL)]−1.154×[age]−0.203×[0.742 if patient is female]×[1.21 if patient is African-American]

Serum creatinine values were available from the laboratory values required for determining the MELD score of the liver candidate. Dialysis status (defined as dialyzed twice within the prior week) is another required component of MELD, and for candidates listed for both organs, current dialysis status is also collected on the kidney waiting list, along with date of first dialysis. However, unless the MELD labs are updated on a weekly basis, it is not possible to determine precisely if the candidate has had dialysis twice per week for six consecutive weeks or if the candidate's GFR was less than 25 ml/min for six consecutive weeks. As such, we can provide only a very crude estimate of the number of candidates or recipients who met these criteria. Primary oxalosis was the only metabolic disease that was considered as a criterion for a kidney transplant.

Based on data collected on the OPTN Liver waiting list, it is feasible to determine if the candidate or recipient qualified according to criteria b), c), and d). Because protein concentration data are not collected on the waiting list, it was not possible to evaluate criterion e). Additionally, at this time, the OPTN can not ascertain if a candidate is on chronic maintenance dialysis via CMS form 2728.

In order to be considered for the dialysis/GFR criteria in this analysis, the candidate must have had at least one MELD update no greater than eight weeks prior to the snapshot date (for the waiting list analysis) or the transplant date (for the transplant analysis). For example, a candidate with an estimated GFR < 25 ml/min or who was on dialysis based on one MELD update eight weeks prior to the date of interest (but no later updates) was assumed to have met the criteria. It is of course possible that the candidate later had a higher GFR and/or did not require further dialysis and therefore would not have satisfied the criteria. On the other hand, a candidate with one MELD update nine weeks prior to the date of interest would not meet the criteria, even if the candidate was reported to be on dialysis or to have an estimated GFR < 25 ml/min.

In addition, a candidate with any combination of dialysis or GFR < 25 ml/min for at least six consecutive weeks was considered to have met the dialysis/GFR requirement. For example, if a candidate was on dialysis for three weeks followed by three weeks of GFR < 25 ml/min prior to the date of interest, then that candidate met the criteria.

All analyses were based on OPTN data as of March 8, 2008. The results appear in Table 1 and Table 2.

Table 1. Number of Candidates on the OPTN Liver Waiting List on 1/31/08. Pediatric (0-11) candidates excluded. Dialysis and GFR estimates obtained from MELD components.

Active on Liver WL?	On Kidney WL?	Oxalosis?	6+ Weeks of GFR < 25 or Dialysis?	Frequency	Percent
N	**N**	**N**	**N**	3463	22.19
N	**N**	**N**	**Y**	7	0.04
N	**N**	**Y**	**N**	2	0.01
N	**Y**	**N**	**N**	63	0.40
N	**Y**	**N**	**Y**	15	0.10
N	**Y**	**Y**	**N**	1	0.01
Y	**N**	**N**	**N**	11776	75.45
Y	**N**	**N**	**Y**	13	0.08
Y	**N**	**Y**	**N**	1	0.01
Y	**Y**	**N**	**N**	185	1.19
Y	**Y**	**N**	**Y**	76	0.49
Y	**Y**	**Y**	**N**	4	0.03
Y	**Y**	**Y**	**Y**	1	0.01
TOTAL				15607	100.0

Table 2. Deceased donor liver transplants, 3/1/02 – 9/30/07. Pediatric (0-11) recipients excluded. Dialysis and GFR estimates obtained from MELD components.

Liver-Kidney Transplant?	Oxalosis?	6+ Weeks of GFR <25 or Dialysis?	Frequency	Percent
N	**N**	**N**	28407	93.67
N	**N**	**Y**	120	0.40
N	**Y**	**N**	6	0.02
N	**Y**	**Y**	3	0.01
Y	**N**	**N**	1364	4.50
Y	**N**	**Y**	394	1.30
Y	**Y**	**N**	20	0.07
Y	**Y**	**Y**	12	0.04
TOTAL			30326	100.0

Table 1 provides data based on a snapshot of the liver waiting list. Pediatric (0-11 years) candidates were excluded. Dialysis data and GFR estimates were obtained from the available MELD information prior to the snapshot date. Of 15,607 candidates on the 1/31/08 snapshot, 345 (2.2%) candidates were simultaneously listed for a kidney transplant. Of these candidates, 97 (28.1%) met at least one of the proposed criteria for a combined liver-kidney transplant at the time of the snapshot. Of the remaining liver candidates who were not simultaneously listed for a kidney transplant, 23 (0.15%) met at least one of the proposed criteria for a combined liver-kidney transplant at the time of the snapshot.

Table 2 provides data on deceased donor liver transplants from 3/1/02 – 9/30/07. Pediatric (0-11 years) recipients were excluded. Dialysis data and GFR estimates were obtained from the available MELD information prior to transplant. There were 30,326 liver transplants during the period, 1790 of which (5.9%) were combined liver-kidney transplants. Of the liver-kidney transplants, 426 (23.8%) recipients met at least one of the proposed criteria for a combined liver-kidney transplant. Of the other liver transplants, 129 (0.45%) met at least one of the proposed criteria for a combined liver-kidney transplant at the time of the transplant.

This proposal does not adopt the recommendations from the 2007 consensus conference wholesale. Due to practical limitations of organ allocation, two recommendations are not being included in this proposal. The first, that patients with end stage liver disease who also have evidence of chronic kidney disease undergo kidney biopsy at the time of OLT, was excluded for several reasons. For one, estimated GFR is an acceptable measure of kidney function and is less invasive than biopsy which may pose a risk to patients due to their coagulopathy. Some centers may not be equipped to perform biopsies in this patient population. Finally, due to the timing of organ allocation, it is impractical to perform the biopsy

at the time of OLT to determine the need for a kidney as recommended.[5] The second recommendation, that patients with Child's A cirrhosis must have a hepatic vein wedge pressure gradient pf less than 10 mm Hg, was intended to ensure that candidates listed for a CLK qualifies for a liver transplant. Because listing criteria for liver allocation belongs in Policy 3.6 (Allocation of Livers), separate language can be developed for this purpose for inclusion in the liver policy. The Liver Committee may also consider a more inclusive statement mentioning other legitimate reasons for liver transplantation (e.g., a candidate with HCC who is a Child's A cirrhotic). This proposal may result in unintended consequences such as candidates who do not regain renal function following OLT returning to the kidney waiting list. For this reason, a safety-net provision has been established so that these candidates receive additional priority (**Error! Reference source not found.**)

[5] Eason 2008.

Donors <35	
Kidney-Pancreas (according to pancreas allocation rules)	
Pediatric	0-MM local 0MM pediatric, ABO identical
Pediatric	0-MM Regional with CPRA >=80%, ABO identical
Pediatric	0-MM National with CPRA >=80%, ABO identical
Pediatric	0-MM Regional with CPRA <80%, ABO identical
Pediatric	0-MM National with CPRA <80%, ABO identical
Pediatric	0-MM local 0MM pediatric, ABO compatible[6]
Pediatric	0-MM Regional with CPRA >=80%, ABO compatible
Pediatric	0-MM National with CPRA >=80%, ABO compatible
Pediatric	0-MM Regional with CPRA <80%, ABO compatible
Pediatric	0-MM National with CPRA <80%, ABO compatible
Pediatric	Prior Living Organ Donors
Adult	Prior Living Organ Donors
Pediatric	Local, non 0-MM, ABO identical or A2→B[7]
Adult	Local, Liver-Recipients with Continued Kidney Nonfunction
Adult	Local or (CPRA >=80% and 0MM), ABO identical or A2→B
Pediatric	Regional, non 0-MM, ABO identical or A2→B
Adult	Regional, ABO identical or A2→B
Pediatric	National, non 0-MM, ABO identical or A2→B
Adult	National, ABO identical or A2→B
Donors ≥35	
Kidney-Pancreas (according to pancreas allocation rules)	
Adult	Prior Living Organ Donors
Adult	Local, Liver-Recipients with Continued Kidney Nonfunction
Adult	Local or (CPRA >=80% and 0MM), ABO identical or A2→B
Adult	Regional, ABO identical or A2→B
Adult	National, ABO identical or A2→B

Figure 3: Allocation sequence for liver-recipients with continued renal dysfunction

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

This policy proposal addresses the program goal to increase the average number of life-years gained following kidney transplant.

Plan for Evaluating the Proposal:

Overall, this proposal should reduce the number of SLK transplants for candidates who could regain renal function following OLT. The following metrics will be used to evaluate this policy proposal:

- The number/characteristics of candidates listed for simultaneous liver-kidney transplant pre and post policy change
- The number/characteristics of candidates who require a kidney transplant following a liver transplant
- Patient and graft survival following SLK and OLT followed by kidney transplant
- The overall number of SLK transplants and number by transplant center

This evaluation would begin at six months following policy implementation and continue at six month intervals. If the number of candidates requiring a kidney transplant following a liver transplant increases, then the Committees will evaluate the characteristics of these candidates to determine if the requirements should be loosened.

Additional data collection:

Recommendations resulting from consensus conferences included the collection of additional data, specifically dialysis duration, to better identify reversible renal insufficiency.[8] The Committees agreed with this recommendation; as part of this proposal, additional documentation to ascertain duration of dialysis, as well as GFR and proteinuria would be required.

Communication/Education Plan:

The following table proposes how and to whom these policy changes would be communicated if they are approved.

[8] Davis 2007

Type of Communication	Audience(s)	Delivery Method(s)	Timeframe
Policy Notice	Transplant Administrators, Coordinators, Program Directors, Surgeons, Physicians, Social Workers, Data Coordinators	Email	Distributed 30 days after Board approval
UNet^{SM} System Notice	Transplant Coordinators, Administrators, Directors, and Data Coordinators	Email	4 weeks before implementation
UNet^{SM} System Notice	Transplant Coordinators, Administrators, Directors, and Data Coordinators	Email	Date of implementation

Monitoring and Evaluation:

The UNOS Department of Evaluation and Quality (DEQ) staff conducts routine site surveys of transplant centers to evaluate member compliance with OPTN/UNOS Policies and Bylaws. More specific details about OPTN/UNOS monitoring efforts will be available in the OPTN Evaluation Plan[9] following approval and implementation of these policy changes.

If this change is approved, UNet^{SM} would be modified to collect the information described in the proposal. UNOS staff would modify monitoring efforts to incorporate a review of this data into the routine site survey process for liver transplant programs.

Policy Proposal:

3.5.10 Simultaneous Liver-Kidney Transplantation

This policy details the minimum criteria that candidates must meet for mandatory sharing of a donor kidney with the donor liver at the local level of allocation. At the regional and national levels of allocation, sharing is recommended but is not mandatory (see policy 3.9.3 Organ Allocation to Multiple Organ Transplant Candidates). This policy includes a description of the criteria and the documentation required to be maintained by the candidate transplant center.

[9] To read the OPTN Evaluation Plans, please visit the following website: http://www.optn.org/content/policiesAndBylaws/evaluation_plan.asp

3.5.10.1 Documentation Required for Simultaneous Liver-Kidney (SLK) Allocation

Candidates with chronic renal failure, sustained acute renal failure, and metabolic disease meet the requirements for SLK allocation with the following documentation:

a. Chronic Renal Failure Requiring Dialysis: For patients on chronic maintenance dialysis for End-Stage Renal Disease (ESRD), transplant centers must document the date of initiation of dialysis and the cause of ESRD.

b. Chronic Renal Failure Not requiring Dialysis: Documentation of both GFR <=30 ml/min (by MDRD6 or direct measurement (iothalamate or iohexol)) and proteinuria (> 3gms protein per day with 24 hr protein measurement or Urine Protein/Creatinine ratio >3.0) is required.

c. Sustained Acute Renal Failure Requiring Dialysis: Documentation of dialysis for 6 weeks or more (defined as dialysis at least twice per week for 6 consecutive weeks) is required.

d. **Sustained Acute Renal Failure (ARF) not Requiring Dialysis**: Documentation of a GFR <=25 ml/min for 6 weeks or more by MDRD6 or direct measurement (iothalamate or iohexol) is required. An acceptable test must be reported at least once a week (every 7 days). [10]

e. Sustained Acute Renal Failure: Patients may also qualify for SLK listing with a combination of time in categories (c) and (d) above for a total of six weeks.

f. Metabolic Disease: Metabolic disease requiring liver-kidney transplantation qualifies with documentation from a nephrologist specifying a diagnosis of hyperoxaluria, atypical HUS from mutations in factor H (and possibly factor I), familial non neuropathyic systemic amyloid (arising from amyloidogenic autosmal dominant mutations in APO-A1 - OMIM#107680)

3.5.10.2 Documentations Requirements for Listing of Liver Recipients in Continued Renal Failure

[10] A measured GFR can be correlated to a serum Cr for that individual patient and will be acceptable as sustained ARF. For example, if an iothalamate scan is performed which results in a GFR of 20 ml/min, and the patient's serum Cr is measured at 3.0 mg/dl that same day, then that patient will be considered to have sustained ARF as long as the serum Cr is not below 3.0 mg/dl. If the serum Cr drops below 3.0 mg/dl, then another direct measurement test (such as a repeat iothalamate clearance) must be performed to consider that patient still in ARF. Once a patient's GFR rises above 25 ml/min, their time in ARF is restarted at time 0.

Liver transplant recipients who had renal dysfunction pre-liver transplant, but did *not* receive a kidney graft and remain on hemodialysis (HD) or peritoneal dialysis (at least twice per week) for at least 90 days after liver transplantation, fall into two categories: those who met the listing criteria prior to liver transplant and those who did not meet the listing criteria prior to liver transplant . For these candidates, additional considerations apply as described below:

i. **Candidates who *met listing criteria* for SLK, but did not receive a SLK.** Those who met the listing criteria for SLK and were listed for SLK pre-liver transplant as in 3.5.10.1 above, but were not transplanted with the renal allograft at the time of orthotopic liver transplantation (OLT) should remain on the kidney transplant list until transplanted or inactivated on the kidney list. Candidates must receive chronic maintenance dialysis for at least 90 days following liver transplantation. The transplant center must list the candidate for "kidney after liver transplant" in UNet[sm] between 90 days and 180 days after liver transplant. The transplant center must document that the candidate has unrecoverable native renal function and requires a kidney transplant.

ii. **Candidates who did not qualify initially for SLK.** Liver recipients who did not qualify for SLK under policy 3.5.10.1 prior to receiving a liver transplant (3.5.10.1), but who fulfill a less stringent set of criteria (Table 1) and who fail to regain native renal function by 90 days after liver transplant can be listed for kidney transplant.

1. Liver recipients who *did not qualif*y for SLK initially include those on dialysis pre-liver transplant for at least two weeks, and those with intrinsic kidney disease pre-liver transplant, but who had a GFR between 30 and 40 ml/min for at least 4 weeks pre-liver transplant. Also, a patient who has a combination of GFR measured below 40 ml/min and/or dialysis totaling 4 or more weeks is also acceptable (Table 1).

		Dialysis Required *pre-Liver Transplant*	**Time Duration**	**Documentation Requirement**
D. Liver Recipients who did not qualify for SLK initially	**1**	Yes	≥2 weeks	Documentation of dialysis pre-liver transplant
	2	No	≥4 weeks	Documentation of intrinsic kidney disease pre-liver transplant **and** GFR between 30 and 40 ml/min for at least 4 weeks pre-liver transplant
	3	Yes	≥4 weeks	Combination of D1 and D2 documentation for at least 4 weeks

Table 1: Requirements for Liver Recipients who did not qualify for SLK initially who remain in renal failure post liver-transplant

3.5.10.3 Deceased Donor Waiting List Priority for Liver Recipients in Continued Renal Failure

Liver Recipients in continued renal failure who fulfill the requirements in Table 1 as well as the requirements below (all requirements must be met) will be prioritized locally after prior living organ donors and before payback obligations.

1. Chronic Maintenance Dialysis for at least 90 days after liver transplantation.
    a. In order to receive additional consideration, the liver recipient must be identified as a candidate for "Kidney after Liver Transplant" in UNet[sm] between 90 days and 180 days of last liver transplant.
    b. The transplant program must document that a nephrologist believes the candidate has unrecoverable native renal function and requires a kidney transplant. This documentation must be maintained and provided upon request.

Public Comments Received

Simultaneous Liver-Kidney (SLK) Allocation Project

Distributed for Public Comment August 17-October 14, 2015

Comments can be seen online at:
http://optn.transplant.hrsa.gov/governance/public-comment/simultaneous-liver-kidney-allocation/

OPTN/UNOS Region 1:

Region 1 approved this proposal with the following vote: 13 yes, 2 no, 1 abstention.

Comments:

It is important that the OPTN track and monitor outcomes of liver recipients receiving kidney transplants, versus receiving a simultaneous liver-kidney transplant.

Several members of the region do not support including the safety net priority in sequence B of kidney allocation. The priority should be limited to sequences C and D.

Kidney Committee response: Analyses performed during development of this proposal showed that survival rates of kidney after liver (KAL) recipients were moderately higher than SLK recipients. Further, survival rates was notably superior for those KAL recipients that received the kidney relatively quickly compared to those with a long wait (>3 years) for a kidney; the committee felt these findings supported the safety net aspect of the proposal, which is expected to result in prior liver recipients with renal insufficiency receiving a kidney relatively quickly.

The Committee considered whether to remove priority in sequence B but elected not to do so. Data show the majority of all kidneys are allocated through sequences B and C and removing sequence B priority would reduce access.

OPTN/UNOS Region 2:

Region 2 approved this proposal with the following vote: 29 yes, 0 no, 2 abstentions

Comments:

Question: How many recipients will be eligible for the safety net? There may be more KI pulled for these recipients than anticipated. Will the safety net eventually be applied to HR and LU candidates? Will the safety net apply only to recipients transplanted post implementation?

Kidney Committee response: Analyses performed for the committee showed that approximately 50 candidates are currently added to the kidney waiting list per year within one year of receiving a liver transplant. Not all of these patients would meet safety net eligibility criteria, however (data unavailable). Under this proposal, additional candidates beyond the current ~50 per year may end up needing a kidney shortly after liver transplant, for example liver recipients that did not medically qualify to receive an SLK transplant, as well as qualifying liver recipients that opted not to receive an SLK because of the protection afforded by the safety

net. Since the number of patients/clinicians that will opt for a liver-alone transplants instead of SLK is dictated by changes in behavior that cannot be predicted from historical data, simulation modeling could not provide a reliable estimate of the number of candidates that would utilize the safety net; hence, such modeling was not performed for this proposal. Furthermore, though published literature suggests that at most 10% of liver recipients will develop de novo renal failure shortly after transplant, reliable estimates of the percentage of liver recipients with renal dysfunction at time of transplant that will not have renal function restored due to the liver transplant are not available.

This proposal requires that transplant centers document sustained renal failure for liver recipients added to the kidney waiting list in order to be awarded safety net priority. For example, one transient low GFR measurement (<=20) measurement will be insufficient for maintaining safety net priority indefinitely. The committee believed this was an essential aspect of the safety net in order to avoid liver recipients whose renal function begins to return sometime during the 2-12 month post-transplant eligibility period unnecessarily receiving safety net priority.

If implemented, the impact of this proposal will be monitored closely and extensively, as described in the public comment document. In particular, analyses will be performed to answer the question, “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?” These results will be reviewed periodically by the committees to determine whether future policy refinements are needed.

In answer to the second question, the safety net proposal only applies to liver recipients in need of a kidney shortly after liver transplant. The OPTN will also be evaluating the potential need for similar policies for recipients of other organs that may require a second organ, however these possibilities are outside the scope of this proposal.

In answer to the third question, at the time of implementation of this 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, even those that received the liver prior to implementation.

Question: Will centers have to get a new GFR from recipients every 7 days? The policy says that the center must document the GFR but it is not clear if the center has to actually do a new test every 7 days or once per week or an average of once per week. A narrow testing window will be burdensome given that these recipients are not always admitted to the hospital during this time.

Kidney Committee response: If the transplant nephrologist is reporting a diagnosis of sustained acute kidney injury, the transplant program must report in the UNOS computer system that the candidate is on dialysis or has a GFR at or below 25 mL/min at least once every seven days. They must both test and report within this timeframe. The intent of the requirement is that the liver transplant program demonstrate that the candidate has consistent kidney dysfunction over the period of six weeks prior to the SLK transplant.

The Liver Committee representatives on the working group offered that this shouldn’t be burdensome to liver programs because liver policy requires the program to update MELD status every 7 days (for patients with MELD at least 25). The working group and Kidney Committee discussed whether to change the requirement for candidates with MELD less than 25, but the

groups came to the conclusion that it would be rare when a liver candidate with sustained acute kidney injury and a MELD < 25 will be a liver-kidney candidate because the CrCl is a part of the MELD criteria. In those rare cases where a candidate does exist, the Kidney Committee representatives felt the liver transplant program needed to bear the burden to report kidney transplant eligibility for the candidate. The proposal does include a slight change to the wording to make it clear that the GFR/CrCl must be reported once a week for six consecutive weeks, not on the 7th day of each of those weeks.

OPTN/UNOS Region 3:

Region 3 approved this proposal with the following vote: 30 yes, 0 no, 0 abstentions.

OPTN/UNOS Region 4:

Region 4 approved this proposal with the following vote: 18 yes, 0 no, 0 abstentions.

Comments:

The region supports the proposal and asked the following question:

Does the safety net apply to recipients of living donor liver transplants? The region is in favor of this and the policy language seems to support it.

Kidney Committee response: Yes, the safety priority net applies to living donor liver transplant recipients who meet the medical criteria outlined.

OPTN/UNOS Region 5:

Region 5 opposed the proposal, 0 yes, 32 no, 0 abstentions. The region approved the proposal with amendments, 31 yes, 0-no, 1 abstention.

Amendment:

The region amended the proposal to exclude pediatrics and to require mandatory sharing of the kidney with regional candidate with a MELD greater or equal to 35.

Kidney Committee response: The Committee agreed with these amendments and the updated proposal includes both.

OPTN/UNOS Region 6:

Region 6 approved this proposal with the following vote: 48 yes, 11 no, 0 abstentions.

Comments:

The group was opposed to having the safety net apply to liver recipients who have no evidence of renal insufficiency prior to their liver transplant. The program should have to identify some KI disease prior to the LI transplant and only those recipients should get priority after transplant.

Listing criteria for KI with LI is too liberal and needs to be more restrictive.

There was concern about prioritizing SLK candidates regionally for high MELD candidates since these candidates don’t do well with SLK transplants.

Additional criteria is needed for candidates with KI injury.

Nuclear medicine scans on SLK recipients should be required to determine how many have 3 functioning KI's.

Kidney Committee response: The Committee has discussed at length whether or not to require some evidence of renal insufficiency prior to liver transplant. This was proposed in 2009 and found to be substantially difficult to program and monitor. The Committee also considered that there is a need to protect the liver recipient once the transplant has occurred and data show a survival advantage associated with receiving a kidney shortly after liver transplant exists. The criteria for the SLK medical eligibility criteria and the safety net were constructed through clinical consensus and the Committee feels there is strong support for these criteria.

Due to the increased data burden on members, the committee decided not to require reporting of nuclear scans to determine if SLK recipients have three functioning kidneys. Single or multi-center studies may be a more appropriate venue for collecting and reporting findings from such scans, as opposed to collection through the national (OPTN) registry.

OPTN/UNOS Region 7:

Region 7 opposed the proposal as written (0-yes, 21 no, 0 abstentions) but approved the proposal with amendments (21 yes, 0 no, 0 abstentions).

Amendments:

Inclusion of mandatory regional kidney sharing with liver candidates who meet medical eligibility and have a MELD > or equal to 35

Exclusion of pediatric candidates

Inclusion of mandatory local kidney sharing with liver candidates who meet medical eligibility

Kidney Committee response: The committee has made all of the changes requested above.

Comments:

The region requests clarification on the following:

Question: Does the verification of eligibility have to be completed by the Primary Transplant Physician (Nephrologist) or can any Transplant Nephrologist associated with the program complete the verification requirement?

Kidney Committee response: Any transplant nephrologist may complete the confirmation requirement. It does not have to be the primary transplant nephrologist.

Question: Under the safety net, proposed policy states that the candidate must meet the GFR standard prior to kidney listing. This language may preclude currently registered candidates from using the safety net unless they are removed from the waitlist and relisted. Was this the intention of the committee?

Kidney Committee response: It was not the intention of the committee and the language has been amended to address this concern.

Concern: In regards to the safety net requirement the proposal has a huge data burden. The region requests that the committee review the proposal and provide clear guidance as to how often and when a test must be performed in order to qualify.

Kidney Committee response: Please see the updated version of the public comment document. The policy language has also been updated to make data reporting requirements clearer.

Request: The region requests that UNOS committees continue to work on better defining multiple organ placement. Current policy language does not provide clear direction as to order of allocation priority and therefore this is left up to each OPO to determine. Nationally there is no consistency on how this is done.

Kidney Committee response: The committee agrees that changes are needed and will be working with the OPO and other committees on this effort going forward.

OPTN/UNOS Region 8:

Region 8 voted to support this proposal, 19 yes, 2 no, 2 abstentions

Multi-organ policy is still a problem for OPOs and needs to be clarified. This policy does nothing to take OPOs out of the position of having to choose the criteria to use when allocating kidneys with extra renal organs.

The committee should consider how quickly this policy can be modified given new treatments for liver disease, particularly Hepatitis C and subsequently have lower MELD scores.

Since the new policy proposes that any liver transplant recipient with significant decline in renal function post-transplant, regardless of pre-transplant renal function can get prioritization over local waitlisted kidney candidates, heart and lung recipients will likely want to get the same priority if they need a kidney after getting their heart or lung transplant.

Kidney Committee response: This policy does take OPOs out of the position of making the decision of whether a liver-kidney candidate is medically suitable for receiving priority for liver-kidney allocation. An eligibility status will display for all liver-kidney candidates that will signal to the OPO whether the candidate is eligible for liver-kidney allocation. The system will also indicate whether the OPO is required to share the kidney with the liver (based on medical eligibility criteria and also the MELD score or status 1A for regional liver-kidney candidates). OPOs will be prohibited from allocating the kidney with the liver if an adult SLK candidate does not meet eligibility criteria. With this proposal, the Kidney Committee has taken the incremental step of addressing problems with one of the most common types of multi-organ allocation—liver-kidney allocation. The Committee believes this is an important step forward and that future work to clarify order of allocation for multi-organ allocation will build on this work. This proposal needs to move forward in order for the rest of the work to follow.

The Committee will be monitoring the new policy closely to determine when/how the medical criteria need to be adjusted.

The safety net priority is being implemented in part due to the fact that there is new medical criteria for liver-kidney allocation and the committee would like to monitor whether the criteria chosen is appropriate or needs to be adjusted. There is an expectation that the elements of this proposal (medical eligibility criteria and safety net) will be used as a model to amend allocation policies for other multi-organ combinations as well.

OPTN/UNOS Region 9

The region approved the proposal with a friendly amendment to request that UNOS address the bigger issue of multi-organ allocation and provide the OPOs with direction regarding allocation priority. The region commented that modeling should be done to ensure that the proposed policy will decrease the number of SLK transplants performed. There was concern that a significant number of good kidneys will continue to go to SLK candidates and kidney alone candidates will be disadvantaged. A member also commented that the time on dialysis for the acute kidney injury criteria should be shortened to 4 weeks.

Kidney Committee response: The Committee understands the region's desire to improve OPTN policy regarding allocation order for multi-organ and single organ candidates. The Policy Oversight Committee (POC) and Organ Procurement Organization (OPO) Committees are working on a project to address this issue in a more comprehensive way. With this proposal, the Kidney Committee has taken the incremental step of addressing problems with one of the most common types of multi-organ allocation—liver-kidney allocation. The Committee believes this is an important step forward and that future work to clarify order of allocation for multi-organ allocation will build on this work. This proposal needs to move forward in order for the rest of the work to follow.

Although data isn't available that allows us an "apples to apples" comparison on how many SLK recipients would have met the medical eligibility criteria (some of the newly proposed criteria is not currently collected on liver recipients), we used a working definition of ESRD (dialysis <2 months or creatinine <2.5) to model the medical eligibility criteria. Using that definition, it was found that 15-30% of current SLK recipients would not have met medical criteria. The committee expects the number of SLK transplants to decrease due to the introduction of renal medical eligibility criteria as well as behavior changes that may cause some patients/clinicians to opt for the liver-alone transplant with expectation of renal recovery, knowing that a safety net is in place.

The Committee considered but decided not to change the dialysis duration for the acute kidney injury criteria. These criteria were developed based on clinical consensus of a large working group that consists of liver and kidney surgeons and physicians and the group felt that four weeks is too short a duration.

OPTN/UNOS Region 10:

Region 10 opposed this proposal as written with the following vote: 0 yes, 18 no, 4 abstentions. The Region approved the proposal with amendments with the following vote: 15 yes, 0 no, 8 abstentions.

Amendments:

1. That pediatric candidates be excluded from the proposal. The committee needs to collaborate with the Pediatric and Liver committee to develop policy for when a pediatric patient receives a local, regional or national SLK offer.
2. The addition of policy language requiring the OPO to offer the kidney to a regional candidate with a MELD over 35 who meets medical eligibility.

3. The addition of policy language requiring the OPO to offer the kidney to a local candidate who meets medical eligibility.

Kidney Committee response: The Committee has adopted all of the above amendments in the updated proposal.

Comments:

The region request that the committee consider including guidance to encourage programs to consider living donation as an option prior to listing for the safety net. The committee needs to collaborate with the MPSC to develop an alternate approach for how kidney outcomes would be monitored in this patient population. Under the current review process, centers hesitate to perform a living kidney transplant post liver transplant because of the potential negative impact on their living donor graft rates and subsequent MPSC scrutiny.

Kidney Committee response: The Committee is currently discussing whether to recommend guidance on living donation after liver transplant. One of the reasons the safety net priority does not apply in sequence A (donors with KDPI less than 20%), is to avoid reducing incentives to pursue living donor kidney transplantation, which has expected longevity similar to the deceased donor kidneys in this allocation sequence.

OPTN/UNOS Region 11:

Region 11 approved this proposal with the following votes:

Proposed Policy 9.6.K-Allocation of Liver/KI: 17 yes, 1 no, 0 abstentions.

Proposed Policy 8.5 Safety Net for Liver Recipients on the KI Waiting List: 15 yes, 3 no, 0 abstentions.

Concerns were raised about the impact this proposal could have on the other kidney candidates, since this could lead to safety nets for other multi organ recipients that needed a kidney but did not receive one.

Kidney Committee response: The Committee will be closely monitoring the impact that the safety net priority has on other kidney candidates. Safety nets for recipients of organs other than livers are outside the scope of this proposal; however, if other kidney safety nets are developed for recipients of other organs the impact of these proposals on kidney-alone candidates will be monitored for unintended consequences.

OPTN/UNOS Liver and Intestinal Organ Transplantation Committee:

After a presentation, the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee voted unanimously to support the proposal with the amendments proposed by the leadership from both the Liver and Kidney Committees (13-Yes, 0-No, 0-Abstentions).

These amendments include:

- A requirement that local SLK candidates meet the kidney medical eligibility criteria only and that regional SLK priority be contingent on both medical eligibility and Liver "Share 35" priority.
- If an OPO chooses to allocate the kidney as an SLK combination, the OPO must offer to eligible local and regional SLK candidates before offering the kidney alternatively.
- The medical eligibility criteria does not apply to pediatric SLK candidates.

While there is not consensus about national allocation, out-of-region SLK offers should not be expressly prohibited, as is implied by the proposed language.

Several members were in favor that a program should be able to register a candidate within 30 days post-liver transplant, instead of the proposed minimum of 60 days post-transplant. They believe surgeons will make a determination about whether a candidate will recover renal function within a 30-day timeframe, especially if the candidate showed signs of renal failure prior to the transplant.

Kidney Committee response: The Kidney Committee has adopted all of the changes requested above, with the exception of shortening the timeframe for the safety net. In this updated proposal, local candidates are only required to meet SLK medical eligibility criteria, the language includes OPO direction, pediatric candidates do not have to meet medical eligibility criteria, and national SLK allocation will be permissible (although not required).

The Committee did not agree that it is appropriate to shorten the timeframe (after liver transplant) for which a liver recipient can be eligible to receive the safety net classification. The Committee believes that 60 days is more than a reasonable timeframe and is itself a compromise from the more strict 2009 proposal (which included a 90-180 day timeframe post-liver transplant). To be clear, programs will be able to register the candidate on the kidney waiting list as soon after the liver transplant as the transplant program decides it is appropriate. However, the liver recipient will not be eligible for the additional safety net criteria until 60 days post-liver transplant.

OPTN/UNOS Membership and Professional Standards Committee:

The OPTN/UNOS Membership and Professional Standards Committee (MPSC) reviewed this proposal, and raised the following questions and concerns:

Referencing the proposed SLK chronic kidney disease eligibility criteria of a GFR threshold of 35 mL/min or less, what are the expectations if a patient's condition improves and GFR increases? The Kidney Committee chair responded that it is critical that this proposal include an eligibility threshold, and the Kidney Committee spent a lot of time discussing the appropriate balance for determining this value. The Kidney Committee agreed to a GFR of 35 mL/min or less, and once someone meets this SLK eligibility threshold they indefinitely remain eligible. This threshold defines eligibility to obtain liver and kidney offers simultaneously, but the

transplant program is not obligated to accept that offer. Ultimately, if a patient's condition improves such that a kidney transplant may not be necessary at the same time as the liver transplant, then the transplant hospital is not required to accept the kidney offer. Kidney transplant programs will be expected to use discretion and their medical judgment to determine what is necessary and appropriate.

What are the expectations if the patient is suffering from chronic kidney disease, but the transplant program does not have an extended relationship with this patient and cannot validate that their GFR was 60 mL/min or less for 90 days or more? The Kidney Committee Chair replied that the transplant program could see if their new patient meets any of the other eligibility criteria. If none of those criteria can be met, this scenario is not something that has been addressed in this proposal. The Kidney Committee Chair encouraged the MPSC to include this question in its public comment feedback so that the Kidney Committee could discuss this during its review of public comment feedback.

In response to requests for feedback about the possibility of national SLK sharing, the MPSC stated it is increasingly seeing more sensitized candidates in need of a liver and kidney transplant. This patient population would seem to benefit from national SLK sharing considerations, and is something worth exploring further.

Some concerns were expressed about patients who do not receive an SLK transplant, and rely on the "safety net" provided for in the proposal. Receiving the liver transplant has the potential to increase the patient's sensitization, which may further complicate, and extend the time for, obtaining an appropriate isolated kidney offer. The MPSC member was concerned that this extended period may negatively impact outcomes. The Kidney Committee chair reminded the Committee that if these patients become highly sensitized, then they will also obtain the regional and national priority that is currently provided in policy for highly sensitized kidney candidates.

The MPSC and Kidney Committee Chairs encouraged the committee to keep thinking about this proposal, and to email any additional questions or concerns that they may have.

Kidney Committee response: The Committee has addressed many of these comments in the attached public comment document. The Committee has amended the proposal so that national SLK sharing is permissible (though not required) if the liver-kidney candidate meets medical eligibility criteria.

OPTN/UNOS Minority Affairs Committee:

The Minority Affairs Committee (MAC) reviewed this proposal on 09/15/2015. Generally, the Committee felt this would increase fairness and equity in organ allocation in that it addresses a much needed provision for those recipients who have post OLT kidney failure. There was consensus in support for the proposed medical eligibility criteria and most members were on board with the safety net component. One member, a transplant hepatologist, felt the requirement to use the safety net option seems too restrictive and does not allow for any other opportunity for those patients with significant renal dysfunction affecting management of the liver allograft to be considered for priority. For example, someone may have been a recent transplant with a GFR <30 which is low but not low enough for the safety net, yet this GFR affects the hepatologist's ability to use immunosuppression and can place the graft at risk. Another member, a transplant nephrologist, raised the concern that the safety net in effect prioritizes the liver transplant recipient over any other solid organ transplant recipient who has

also developed renal failure after their transplant in the first year of transplant. She felt this group, though they may be a minority, will be disadvantaged with this part of the proposal. The Committee is interested in viewing outcomes data to see whether this benefits or disadvantages minorities.

MAC consensus: Support

Kidney Committee response: The Committee thanks MAC for being a partner in the development of this proposal. The Committee has been careful to balance additional priority for liver recipients with access to other kidney alone candidates. The Committee felt it was important to keep the GFR criteria consistent with other types of kidney allocation priority (i.e. GFR to begin accruing waiting time priority points is GFR at or below 20 mL/min). And, the safety net classification is appropriately positioned after local pediatric and highly sensitized candidates. The safety net criteria does not prevent a prior liver recipient from being listed on the kidney waiting list, accruing waiting time, being eligible for other types of kidney allocation priority (e.g., high CPRA priority), or pursuing a living donor transplant. It is simply an additional type of priority.

In response to the comment about the safety net creating priority over other solid organ transplant recipients, the Committee would like to point out that these other recipients receive priority for a local heart-kidney or lung-kidney transplant over all kidney alone candidates. There are no medical criteria related to the candidate's kidney function. The reason this classification is being created for liver recipients is that additional restrictions are being put in place for allocating the kidney to liver-kidney candidates. Under the new scenario, local heart-kidney and lung-kidney candidates will have an advantage over liver-kidney candidates because there is still no medical criteria that they are required to meet.

OPTN/UNOS Operations and Safety Committee

OPTN/UNOS Operations and Safety Committee members did not reach consensus on this proposal but all agreed that something needs to address the issue. It was expressed that the kidney community has concerns about these organs being siphoned off without justification while those on the kidney-alone list who have legitimate needs are passed over. One member opined that the kidneys in SLKs are often given to those with adequate kidney function. There was concern that in some sequences the SLK safety net would get any priority over kidney-alone candidates who might have greater needs and actually be on dialysis.

It was noted that there are no current guidelines and that keeping the status quo will continue perpetuating the issue. It seems as though there were over 600 SLKs this year.

There was discussion over whether the proposal would increase or decrease the number of SLKs. One member indicated it could increase unnecessary SLKs because if someone meets medical criteria they may feel entitled. The diagnosis of chronic kidney failure can vary greatly by transplant nephrologists. On the other hand the proposal will address situations where SLK is done to avoid being counted in SRTR calculated outcomes data or those done without any justification. It will also challenge the liver community as the evidence reviewed did not support common beliefs. Mortality due to renal insufficiency was not as high as many might believe. Overall the Committee desires to see a reduction in unnecessary SLKs although some may not agree with all of the points proposed.

Kidney Committee response: The Committee thanks the Ops and Safety Committee for being a partner in the development of this proposal.

Based on the data available, the Committee is of the firm opinion that the new medical criteria and availability of the safety net will result in a decrease of SLK transplants. Although data isn't available that allows us an "apples to apples" comparison on how many SLK recipients would have met the medical eligibility criteria (some of the newly proposed criteria is not currently collected on liver recipients), we used a working definition of ESRD (dialysis <2 months or creatinine <2.5) to model the medical eligibility criteria. Using that definition, it was found that 15-30% of current SLK recipients would not have met medical criteria.

OPTN/UNOS Organ Procurement Organization (OPO) Committee:

The OPO Committee supports the proposal but remains concerned about the variability of practice for sharing kidneys regionally.

This variability in practice is not always OPO-driven and can be influenced by local transplant programs.

Kidney Committee response: One of the Committee's main goals with this proposal is to address the variability in practice for sharing liver-kidneys regionally and increase fairness for kidney candidates. This proposal will increase equity for all kidney candidates by having a policy that allocates kidneys (whether alone or with a liver) based on a candidate's level of kidney dysfunction. The Committee feels that a candidate's medical need for a kidney should be the basis upon which kidney allocation is based across the country.

OPTN/UNOS Pancreas Transplantation Committee:

The Pancreas Transplantation Committee reviewed this proposal on 10/08/2015 and raised the following comments and concerns:

The committee fully supports the medical eligibility criteria and believes that it will reduce the number of kidneys being transplanted to individuals who do not need a kidney with a liver.

The committee suggested that the safety net might disincentivize living donation. The committee member stated that if a candidate would likely receive a deceased donor kidney shortly after liver transplant through the safety net, then it could potentially dissuade living donation following the liver transplant. Although, the committee acknowledges that liver living donor kidney after liver transplant has be an infrequently used alternative.

The committee raised several concerns and expressed confusion pertaining to the idea of mandating regional sharing of kidneys with SLK candidates. The Kidney Committee Chair explained to the committee that the allocation of the kidney was still up to the OPO's discretion. However, several committee members were confused on how the policy would interact with mandatory Share 35 allocation. It was the consensus of the committee that this proposal would suggest to OPOs that the kidney would follow the liver regionally, thus prioritizing SLK over other multi-organ allocations. Additionally, the committee suggests that the entire multi-organ order project be addressed holistically, rather than the SLK piece move forward initially and the rest being worked on later.

The committee is concerned that this proposal may lead to a further decline in volume of pancreas transplants. A deceased donor pancreas is most likely to get transplanted if it is placed as a simultaneous pancreas-kidney (SPK) transplant. If a regional SLK were to be prioritized above the SPK, the pancreas may never get transplanted. The committee is not convinced that the marginal benefit of a SLK over a liver-alone, for similar meld score patient, warrants prioritization above the SPK list, particularly at the regional level. It is important to note that candidates are required to qualify for kidney-alone waiting time as part of qualifying for SPK waiting time, thus meeting criteria that is more restrictive compared to the eligibility criteria for SLK in this proposal. This fact concerns the committee, as they conjectured that SPK candidates have the highest mortality on the wait list of all kidney candidates.

Kidney Committee response: In the public comment document, the committee addresses concerns about the safety net possibly being a disincentive to living donation. As you point out, living donor kidney transplants following a liver transplant are infrequently used today. One of the motivations for excluding KDPI 0-20% kidneys – those with the longest expected graft longevity, comparable to some living donor kidney transplants, in fact – from safety net priority it to preserve incentives for pursuing a living donor kidney transplant. There is no way to fully address this concern through a policy change, but the committee has discussed developing guidance for transplant programs on this issue.

The committee is releasing an FAQ document with this proposal that addresses the questions and concerns raised with regard to how this proposal impacts multi-organ allocation order. Please reference that document for more information. Put simply, though, this proposal does not prioritize regional SLK allocation over SPK allocation. The Committee has made some changes to the policy language to help clarify this point.

OPTN/UNOS Patient Affairs Committee:

After a presentation of the proposal, Patient Affairs Committee members expressed appreciation for the Kidney Committee's work on this difficult issue. The Committee believes this policy will improve the overall equity and utility of the allocation system, since kidneys used in SLK transplants are among some of the highest quality and for which pediatric candidates also receive priority.

One member asked about the eventual impact of liver redistricting on this policy. Another member expressed discomfort that this policy allows for OPO discretion and voiced continued support for a comprehensive multi-organ policy that ensures fairness for all candidates.

Kidney Committee response: The Committee will be monitoring this policy closely and will adjust as changes are needed. It isn't clear yet if any changes would be needed if livers were allocated according to different regions.

This policy actually begins to address the issue of OPO discretion. While it would be out of scope for this project to address OPO discretion to allocate kidneys with any other organs, the Committee is addressing OPO discretion when it comes to one of the most common types of multi-organ allocation involving kidneys—liver-kidney allocation. Under the new policy, OPOs would not have the discretion to allocate a kidney with a liver to any candidate who does not meet SLK medical eligibility criteria. The new policy does leave the OPOs some discretion in terms of allocating kidneys with livers to regional candidates with MELD scores 34 or below and

national SLK candidates, but that was done at the advice of OPO representatives and is intended to avoid discards.

OPTN/UNOS Pediatric Transplantation Committee:

The Pediatrics Committee reviewed the proposal during a conference call on September 16, 2015. As written, the proposal outlined medical eligibility criteria for all transplant candidates in need of a liver and kidney. Communication from the Kidney Committee shared that discussions on the medical eligibility criteria have occurred since the beginning of the public comment period, and Committee was amendable to removing the medical eligibility criteria for pediatric SLK candidates. The Kidney Committee sought feedback from the Pediatrics Committee on the matter.

The Pediatrics Committee members noted this proposal addressed the concern that dual organ candidates may “take away” organs, when not clinically appropriate, from candidates in need of a single organ. Further, this proposal is a step in the right direction to establish medical criteria for patients who need a kidney and liver, and identify those patients who do not need a kidney with a liver.

The Pediatrics Committee supports the proposal with the removal of medical eligibility criteria for pediatric SLK candidates.

Kidney Committee response: The Committee thanks the Pediatric Committee for providing consultation on the issue of medical criteria for pediatric SLK candidates. In the updated proposal, pediatric candidates do not have to meet medical eligibility criteria in order to receive liver-kidney offers.

OPTN/UNOS Policy Oversight Committee:

The Policy Oversight Committee (POC) reviewed this proposal on September 29, 2015 and voted unanimously in support of the proposal. The committee believes it is important to establish criteria for SLK transplants, as well as for multi-organ transplants in general, and supports this proposal as an important step in having clearer policies for multi-organ transplants.

Kidney Committee response: Thank you for your guidance and partnership in the development of this proposal.

OPTN/UNOS Transplant Administrators Committee (TAC):

The Transplant Administrators Committee (TAC) reviewed this proposal and had the following questions and concerns:

In terms of medical criteria that has to be met, there is no disagreement with the premise of having consistent criteria to follow. However, a committee member had some concerns about the following operational issues. This proposal would require the center to document every 7 days that the GFR is at a certain level and if the patient is not hospitalized or being dialyzed in your unit, then they would be required to come in to the clinic or local lab every 7 days. This requirement is difficult to meet if patients are non-compliant. The member questioned if there was any leeway in this requirement.

The following scenario was posed and questioned if the cost impact on centers was considered for this proposal. A center has a patient who received a liver transplant and it was decided that

the patient does not need a kidney right away. The patient does not do well afterward the transplant, ends up in renal failure, requires dialysis, has an increased length of stay, and placement issues arise.

The region 9 representative asked how this proposal would affect region 9 being as they have a region wide list for liver transplant.

The Committee generally supported the proposal after receiving responses to the above questions.

Kidney Committee response: The particular GFR criteria referenced applies only to candidates with sustained acute kidney injury. The intent of the requirement is that the liver transplant program demonstrate that the candidate has consistent kidney dysfunction over the period of six weeks prior to the SLK transplant. The Liver Committee representatives on the working group offered that this shouldn't be burdensome to liver programs because liver policy requires the program to update MELD status every 7 days (for patients with MELD at least 25). The working group and Kidney Committee discussed whether to change the requirement for candidates with MELD less than 25, but the groups came to the conclusion that it would be rare when a liver candidate with sustained acute kidney injury and a MELD < 25 will be a liver-kidney candidate because the CrCl is a part of the MELD criteria. In those rare cases where a candidate does exist, the Kidney Committee representatives felt the liver transplant program needed to bear the burden to report kidney transplant eligibility for the candidate. The proposal does include a slight change to the wording to make it clear that the GFR/CrCl must be reported once a week for six consecutive weeks, not on the 7th day of each of those weeks.

The Committee did discuss and acknowledge that liver transplant programs will endure additional costs in order to implement this proposal. This was weighed against the benefit of addressing the inequities of the current system and the recognition that there could be cost savings for the health care system as a whole as more kidneys are made available to kidney alone patients. The Committee has come to the conclusion that the benefit outweighs the cost in this proposal.

Even in cases such as Region 9 where there are different rules for liver allocation, the liver-kidney allocation rules will be the same. Liver-kidney allocation will be required for local candidates who meet medical eligibility criteria and regional candidates who meet medical eligibility criteria and have MELD at least 35 or status 1A. Liver-kidney allocation will be permissible (though not required) for any other candidates (within or outside of the region) who meet medical eligibility criteria.

OPTN/UNOS Transplant Coordinators Committee (TCC):

The Transplant Coordinators Committee reviewed and support this proposal. Some committee members had the following questions/comments:

TCC question: If a patient receives a SLK, and a kidney fails on day 95 and they are relisted for a kidney, are they considered in the safety net?

Kidney Committee response: No, SLK recipients are only eligible for the safety net if they meet the definition of having immediate and permanent non-function of a transplanted kidney (this is a definition that is used for reinstatement of waiting time for kidney alone candidates). Under that definition, the candidate will be eligible for the safety net if they experience kidney

graft failure within 90 days of transplant. SLK recipients received priority above all other kidney candidates, and this is a way to provide a consistent benchmark for applying/reinstating priority for different types of kidney candidates.

TCC Question: Please clarify why a center would provide a kidney transplant to a patient with only a moderate GFR and then for the safety net, the patient has to have a GFR of 20. If you at the CRD breakdown for GFRs, it does not make sense that it would be modified.

Most patients would not receive a kidney with a GFR of 30, why allow it with an SLK

Kidney Committee response: The SLK medical eligibility criteria are based on clinical consensus from kidney and liver surgeons/physicians. Members of the SLK working group stated that there is a difference when the candidate needs a liver transplant and there is also a strong indication that the candidate kidney function is rapidly declining and likely will not recover. The level of kidney dysfunction may not be at or below 20 mL/min at the time of the liver offer, so it is reasonable to establish a less strict standard for this medical criteria.

TCC Question: Has the new KAS and Liver Share 35 changed some of this? Are you seeing sicker Liver patients with worsening renal function showing up on these lists?

Kidney Committee response: The number of SLK transplants has increased substantially since the Liver Share 35 policy was implemented in 2012. The new KAS is focused on rules for kidney alone allocation and changed little with regard to liver-kidney allocation, except for the fact that kidney paybacks no longer apply when an OPO allocates a kidney with a liver beyond the local level. Despite this incentive going away, the number of SLK transplants has continued to increase since the implementation of KAS.

TCC Question: This seems to greatly affect the kidney-only candidates. We have already been affected by the KAS. Have you done models looking at kidney only candidates?

Kidney Committee response: The Committee is currently working to determine whether we can use current data to determine how many liver recipients would have met the medical criteria outlined in the proposal.

The impact of this proposal on the kidney-alone waiting list is expected to be small. More kidneys would be available for kidney-alone candidates if fewer SLK transplants are performed. However, this could be offset if more liver recipients than expected receive kidneys via the new safety net. Since the net effect of this proposal is driven, in part, by unpredictable behavior changes, the net impact on kidney-alone patients cannot be definitively estimated. In turn, the committee will be closely monitoring the impact of the proposal – number of SLK transplants and number of safety net transplants – to assess unintended consequences and whether policy refinements are needed.

TCC Question: If we are going down the liver match, we would be mandated to offer the kidney if it was available, but the OPO would still have the choice with multi-visceral it chooses? It was one committee member's understanding that if an OPO offers for an SLK locally, then the Share 35 must be offered regionally as well, but it was not said that they had to allocate an SLK at all. If chosen to allocate to a local SLK, then we must also allocate to a regional SLK.

Kidney Committee response: This policy does *not* mandate that an OPO offer the kidney with the liver before offering the kidney as part of a different multi-organ combinations. The OPO will

still follow the match run and determine whether to allocate as a local heart-kidney, liver-kidney, lung-kidney, or kidney-pancreas before allocating the kidney to the kidney-alone list. This policy adds one additional class of liver-kidney candidates that the OPO is required to offer to *before allocating the kidney to the kidney alone list*—regional liver-kidney candidates who meet medical eligibility criteria and have a MELD of at least 35 or status 1A. These are candidates who are prioritized for regional liver shares according to the deceased donor liver policy. This requirement simply makes the liver-kidney policy consistent with deceased donor liver policy in terms of priority for regional sharing.

TCC Question: One concern is that the policy always references a "transplant nephrologist". Not all transplant centers have a designated transplant nephrologist. Should that reference be removed or changed? Will it cause problems for transplant centers as currently worded? Also, is it the designated nephrologist that has to follow the patient and document the results or can the transplant team manage the patient and get confirmation from the designated nephrologist of the results meeting the criteria?

Kidney Committee response: In order to be approved to transplant kidneys (whether with other organs or in kidney alone patients) a transplant hospital must have an approved kidney transplant program. In order to have an approved transplant program, there must be a primary kidney surgeon and physician. So, any transplant program performing kidney transplants has a transplant nephrologist.

This element of the policy is of tremendous importance to the Committee and the kidney community, because any patient who is registered for a kidney transplant should have been diagnosed by a transplant nephrologist. The diagnosing nephrologist does not have to be the primary transplant nephrologist at the hospital. However, the nephrologist must provide documentation in the medical record that they have provided one of the three diagnoses specified in the policy. The coordinator or other staff may then enter into the UNOS computer system that this has been confirmed, indicating the nephrologist's name as well.

TCC Question: A concern from some regions that have kidney only programs, transplant centers are seeing a decline in local kidney transplants because a large number of kidneys are being exported out of the local area. One of the issues is the effect of hepatic-renal syndrome and where the line is. If a liver is transplanted, and there is some return of kidney function, should the liver center return the kidney? If function does not return then do they go into the safety net?

Kidney Committee response: The Committee's hope is that the new medical eligibility criteria will decrease the number of SLK transplants that go to liver candidates who will regain kidney function after liver transplant. If a candidate receives an SLK transplant, the candidate will not be eligible for the safety net priority unless they experience kidney graft failure within 90 days of the SLK transplant.

American Society of Transplantation (AST):

The American Society of Transplantation (AST) strongly supports the use of simultaneous liver kidney transplantation in patients with liver failure who have established chronic kidney disease that will not improve with liver transplantation alone. We recognize the difficulty in identifying such patients prior to transplantation and encourage the development of objective criteria to identify such patients.

The AST supports elements of the proposal, including the concept of a safety net to allow patients who underwent liver transplantation alone but failed to recover kidney function to receive priority for a kidney after liver transplant if they would benefit from kidney transplantation.

However, in the absence of sufficient data, the AST found the proposed criteria to identify SLK candidates to be arbitrary and recommends detailed prospective data collection and analysis of patients with advanced renal impairment requiring liver transplantation to better inform these criteria. Given the provision of the safety net, the proposed criteria for combined SLK were considered too inclusive and may result in unnecessary kidney transplantation. To facilitate prospective data collection and the optimal use of SLK transplantation, the AST recommends that the outcomes of SLK transplants be included in center specific liver outcomes.

The AST also suggests that a transplant nephrologist's input in the evaluation of potential SLK listing, recognizing the great variability in transplant nephrology input from center to center. We recommend that SLK listings should require approval from both the transplant hospital's liver and kidney committees or the hospital's medical review board.

Kidney Committee response: The Committee thanks the AST for the response and also for providing early feedback that the Committee was able to incorporate into the proposal prior to Fall 2015 public comment.

Unfortunately, definitive data does not exist to tell us whether the medical eligibility criteria closely aligns with those receiving SLK transplants today. This is because most of the data that could answer this question (related to kidney function) is not collected on liver candidates. However, the Committee created some working definitions to try to predict whether the number of SLK transplants may increase or decrease under the new rules. Using a working definition of ESRD (dialysis <2 months or creatinine <2.5) to model the medical eligibility criteria, we found that 15-30% of current SLK recipients would not have met medical criteria.

The Committee agrees with the AST that the outcomes of SLK transplants should be included in program specific outcomes reports. That particular action is out of scope for our committee to propose (what is included in these reports is not determined by OPTN policy). Therefore, that particular change is not included in this proposal. However, the SRTR has informed us that SLK transplants will be included in the PSRs in the near future.

This proposal includes a requirement that the transplant nephrologist confirm the diagnosis that (along with certain documentation) will allow candidates to qualify for liver-kidney allocation. We are of the opinion that this is sufficient to address the concerns about variability in transplant nephrologist input. Because OPTN policy does not specify requirements that must be met prior to registration on the kidney waiting list (but instead specifies how candidates will be ordered once registered on the waiting list), we feel it may be an inappropriate and inconsistent interference with medical practice to specify any requirements prior to registration.

American Urological Association (Suzanne Pope):

The American Urological Association would like to thank OPTN/UNOS for the opportunity to submit comments. The AUA acknowledges that these standards are critical for dual organ listing and will give more priority to kidney alone recipients with long term survival.

Kidney Committee response: The committee thanks the AUA for being so responsive in the pre-public comment phase of this proposal.

National Kidney Foundation:

The National Kidney Foundation (NKF) supports this policy position. This policy allows for better organ allocation by diminishing the disadvantages to kidney alone recipients. NKF appreciates the incorporation of our preliminary comments. Specifically we appreciate that the policy is consistent with the Kidney Disease Improving Quality Outcomes (KDOQI) definitions of chronic kidney disease, kidney failure, and acute kidney injury as well as consistent with these guidelines for diagnosing chronic kidney disease by requiring the measurement of eGFR be below the threshold to qualify or SLK for 90 consecutive days. We also agree that the most recent GFR measurement be used at the time of registration on the kidney waiting list.

We are also particularly supportive of the safety net provisions to ensure that kidneys are not unnecessarily given to an individual that may recover kidney function post liver transplant, but that also prioritize, under the kidney allocation system, Orthotropic Liver Transplantation (OLT) recipients who have prior ESRD and do not recover renal function. In addition, we highlight our support that documentation on the need for the kidney be fulfilled by the nephrologist rather than the hepatologist or transplant surgeon. Nephrologists have a vested interest in assuring the best use of the valuable resource in kidneys for transplantation.

Kidney Committee response: The Committee thanks the NKF for their responsiveness and for being a partner in the development of this new policy.

FINAL REPORT

OPTN Simultaneous Liver Kidney (SLK) Work Group of the Kidney Transplantation and Liver and Intestinal Organ Transplantation Committees Descriptive Data Request

Providing Evidence Supporting SLK Eligibility Criteria and a "Safety Net"

Analyses Prepared for:
SLK Work Group Conference Call,
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Report finalized: February 24, 2015

By:
Anna Y. Kucheryavaya
Darren E. Stewart
Erick B. Edwards
Ann M. Harper
UNOS Research Department

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BACKGROUND/PURPOSE

The Simultaneous Liver Kidney (SLK) Work Group (Work Group) was formed to review current OPTN policy on SLK allocation and make final recommendations to the Kidney Transplantation Committee (Kidney Committee) and Liver and Intestinal Organ Transplantation Committee (Liver Committee). The Work Group is made up representatives from the Kidney, Liver, OPO, Minority Affairs and Ethics Committees.

On the August 18, 2014 call, the Work Group agreed that there should be more well defined rules around SLK allocation and that the lack of rules and consistency is counter to the Final Rule principles regarding policies being based on medical criteria and medical urgency. The Work Group agreed on the following problem statement, amending problem statement previously developed by the Kidney Committee:

There are minimal rules for SLK allocation. There is a need for more consistency for these transplants, especially when a liver is being shared (non-local). The lack of allocation rules is counter to the Final Rule principles regarding the best use of organs and allocation policies being based on medical urgency.

On the September 22, 2014 call, the Work Group reviewed the summary of the data previously presented to the Kidney Committee along with highlights of several articles published on the topic:

- Number of SLK transplants by year and clinical characteristics of SLK recipients.
- Time to listing for kidney after liver transplant.
- Time to kidney transplant after liver transplant.
- Time to deceased donor kidney transplant for those with and without previous liver transplant.
- Published outcomes data comparing liver graft survival and patient survival for SLK recipients vs. liver alone recipients (for cirrhotic adult patients with renal failure prior to transplant).
- Published literature on predicting end stage renal disease (ESRD) post liver alone transplant.

The Work Group members discussed the data and agreed that kidney graft outcomes, recipient outcomes (patient survival) as well as waiting list mortality data for different groups of patients need to be taken into account when making recommendations on policy changes.

These data will help to address the following research hypotheses:

- For different groups of patients, what is the survival advantage of receiving a kidney vs. remaining on the waiting list?
- Between different groups of patients, what is the difference in outcomes?
- What are kidney graft survival rates for multi-organ recipients (SLK, heart-kidney) compared to kidney alone recipients?

STRATEGIC PLAN GOAL OR COMMITTEE PROJECT ADDRESSED

SLK Allocation

COMMITTEE REQUEST

The work group requested the following analyses in post-MELD era:

1. Waiting list survival rates with half-lives/median survival times (if estimable) for:

- SLK candidates (those who qualified for kidney waiting time based on dialysis or GFR)
- SLK candidates (those who didn't qualify for kidney waiting time based on dialysis or GFR)
- Kidney alone candidates with previous liver transplant
- Kidney alone candidates without previous liver transplant

2. Kidney graft survival rates with half-lives/median survival times (if estimable) for:

- SLK recipients (those on dialysis for two or more months or serum creatinine 2.5+ mg/dl)
- SLK recipients (those not on dialysis with serum creatinine <2.5 mg/dl or on dialysis for less than two months)
- Kidney alone recipients with previous liver transplant
- Kidney alone recipients without previous liver transplant
- Heart-kidney recipients

3. Recipient survival rates with half-lives/median survival times (if estimable):

- SLK recipients (those on dialysis for two or more months or serum creatinine 2.5+ mg/dl)
- Liver alone recipients (those on dialysis for two or more months or serum creatinine 2.5+ mg/dl)
- SLK recipients (those not on dialysis with serum creatinine <2.5 mg/dl or on dialysis for less than two months)
- Liver alone recipients (those not on dialysis with serum creatinine <2.5 mg/dl or on dialysis for less than two months)
- Kidney alone recipients with previous liver transplant
- Kidney alone recipients without previous liver transplant
- Heart-kidney recipients

The outcomes listed above will be compared for the following groups, where applicable.

Analysis will be limited to adult patients, excluding multi-organ transplants and registrations and previous transplant recipient unless specified above.

Cohorts will be chosen such as 1, 3 and 5 year survival rates are estimable.

Analyses will be based on the Kaplan-Meier method. For waitlist survival analyses, we will consider the potential need to account for informative censoring due to competing risks, as well as time-dependent covariates.

DATA AND METHODS

Data Sources:

All kidney graft and recipient survival results are based on OPTN data as of January 3, 2015. OPTN data were supplemented with alternative sources of death data including SSDMF data as of December 19, 2014 and dialysis data from the CMS database as of March 31, 2014. Data are subject to change based on future data submission or correction.

Waiting list survival rates:

Analysis was performed for adult kidney and SLK candidates added to the waiting list from March 1, 2002 through December 31, 2012. Unless specified otherwise, prior transplant recipients and candidates that had other registrations (for the same or different organs) added to the waiting list prior to March 1, 2002 were excluded.

Kidney candidates with a previous liver transplant were limited to those with liver functioning at the time of listing for kidney.

In order to be considered an SLK candidate, a patient needed to have a kidney and a liver registration on the waiting list at the same center. SLK candidates group included:

- All candidates with liver and kidney registrations that had the same start and end dates.

- All candidates with a liver registration added to the waiting list first and then kidney registration added within 30 days of the liver registration and both registrations ending on the same day.

Note that those listed for kidney first and later for liver were excluded from the analyses.

SLK were stratified into two groups depending on whether they qualified for kidney waiting time per OPTN policy based on dialysis or creatinine clearance/glomerular filtration rate (GFR). A small number of candidates (N=78), who didn't qualify at the beginning date of kidney registration but later qualified, were excluded.

Analyses were performed on a patient level with all multiple registrations for the same organ (either kidney alone or both kidney and liver) for the same patient combined into one:

- The earliest date was taken as the start date.
- For each registration, the latest end date and the latest removal reason were taken. If there was a registration ending in transplant and the same patient was added on the list after the transplant, post-transplant registration was excluded.

For some SLK registrations, end dates were recoded:

- If SLK registration ended with a liver and a kidney transplant from the same donor but transplant procedures were performed on different dates, the earliest date was taken as the end date of the registration.
- If a kidney or a liver registration for an SLK candidate was removed from the waiting list for death, but the other registration for that candidate had a later end date, the death date was used as the end date for that SLK candidate.

For SLK candidates, kidney and liver removal reasons were combined into one as follows:

- If both registrations had the same removal reason, than that reason was used as a removal reason for the SLK candidate.
- If one removal reason was for transplant (a kidney alone or a liver alone transplant) and another one for reasons other than death or transplant, removal reason was set to transplant.
- If one registration was removed for transplant and other registration was removed for death, death during transplant procedure was used as a removal reason.

Each SLK candidate was identified by having one of the following waitlist outcomes:

- Received SLK transplant;
- Death after listing (does not include death after transplant but may include death after waitlist removal if death was identified from other sources);
- Death during transplant procedure;
- Other;
- Still waiting.

Death dates were based on death dates provided by OPTN members and supplemented with alternative sources of deaths, including SSDMF. If a death date found was prior to removal from the waiting list, candidate's end date was set to the death date and removal reason was set to death.

Waiting list survival time was computed as time between the start day (date when the patient was added to the waiting list) and waiting list death date or the date survival time was censored.

Waiting list deaths include:

- All waiting list removals for death (not including deaths during transplant procedure);
- All removals for reasons other than transplant or death during transplant procedure, if death within 30 days of removal was found.

Waiting list survival time was censored:

- At the time of removal from the waiting list, for patients removed for transplant (also includes 17 (0.01%) candidates removed for death during transplant procedure);
- 30 days after removal from the waiting list, for patients removed for reasons other than transplant or death (only for those with no death date found within 30 days of removal);
- On January 3, 2015 (database copy date) for patients still waiting on that date.

Given the presence of censoring, the Kaplan-Meier method was used to generate waiting list survival curves. Survival curves were compared using the log-rank test statistic.

Kidney graft survival and recipient survival rates:

Deceased donor adult transplants (liver, kidney, SLK, or heart-kidney) performed between March 1, 2002 and December 31, 2012 were included in kidney graft survival and recipient survival analyses. Multi-organ transplants other than SLK and heart-kidney were excluded from the analyses. Unless specified otherwise, pediatric and prior transplant recipients were excluded. Liver Status 1A recipients were excluded as well.

Kidney recipients with a previous liver transplant were limited to those with liver functioning at the time of kidney transplant.

SLK and liver alone recipients were stratified into two groups:

- Those on dialysis for 2+ months or 2.5+ mg/dl serum creatinine;
- Those not on dialysis with <2.5 mg/dl serum creatinine or on dialysis for <2 months.

Two months were defined as 60 days.

Serum creatinine data were based on the most recent pre-transplant data reported:

- On the Kidney Transplant Recipient Registration (TRR) form for kidney alone, SLK and heart-kidney recipients;
- On the waiting list for liver alone recipients. (Serum creatinine is not collected on Liver TRR form, but it is required for liver candidates at waiting list removal.)

Dialysis status and dialysis start date were based on kidney TRR form data. If dialysis status and/or date wasn't reported on the form, but the information was provided on the waiting list for kidney registrations, waiting list data were used. Missing data were supplemented with CMS dialysis data from Medical Evidence Form 2728. Use of the CMS dialysis date was based on linking to the CMS database by patient social security number (SSN).

Due to differences in OPTN data collection between organs, for liver alone recipients dialysis status and date were based solely on CMS database.

A graft was considered to have failed if graft failure, return to chronic maintenance dialysis, or patient death was reported to the OPTN contractor. Otherwise, graft survival time was considered to be censored as of the last date for which the graft was reported as still functioning.

Given the presence of censoring (e.g. some patients still have a functioning graft and the time of graft failure is not known for all patients), the Kaplan-Meier method was used to generate graft and patient survival curves and to estimate the median graft half-lives (the time at which 50% of grafts are expected to have failed). If less than 50% of grafts are expected to have failed within the analysis timeframe, half-lives are not estimable.

Graft and recipient survival curves were compared using the log-rank test statistic. Comparisons of characteristics of recipients were made using the chi-square statistic for categorical variables and Kruskal-Wallis test for continuous variables.

RESULTS

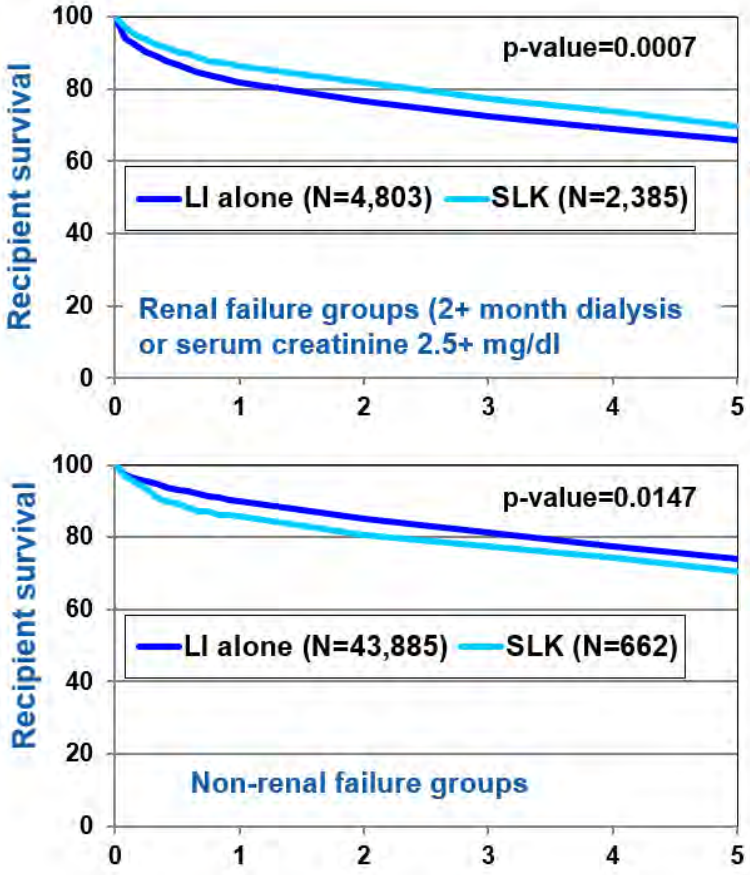
Tables A.1 – A.5 located in Appendix A show waiting list survival, kidney graft survival and recipient survival rates (with median half-lives), as well as donor, recipient and transplant characteristics.

Survival advantage of receiving a kidney vs. liver alone

The work group asked to examine survival advantage of receiving a kidney along with the liver vs. receiving a liver alone transplant to provide evidence supporting SLK eligibility criteria.

Figure 1 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 1. 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.



	LI Alone	SLK
White	70%	62%
Diabetes	27%	41%
MELD*	36	27
KDPI%	46	35
Age*	55	56
LI CIT*	6.9	6.4

	LI Alone	SLK
White	73%	65%
Diabetes	23%	38%
MELD*	17	28
KDPI%	52	37
Age*	55	57
LI CIT*	6.7	6.5

* Medians are shown

Figure 1 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>=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, in fact, 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[1] (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[2]. Fong, et al, 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 1, 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 potential proposal to restrict SLK transplants to those liver candidates with renal failure, as is being discussed. 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 solitary kidney transplant. Table A.1 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[3,4].

[1] If requested by the committee, a more thorough, multivariable analysis to isolate the effect of receiving a kidney among liver recipients would fall under the purview of the SRTR contractor.

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

[3] 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.

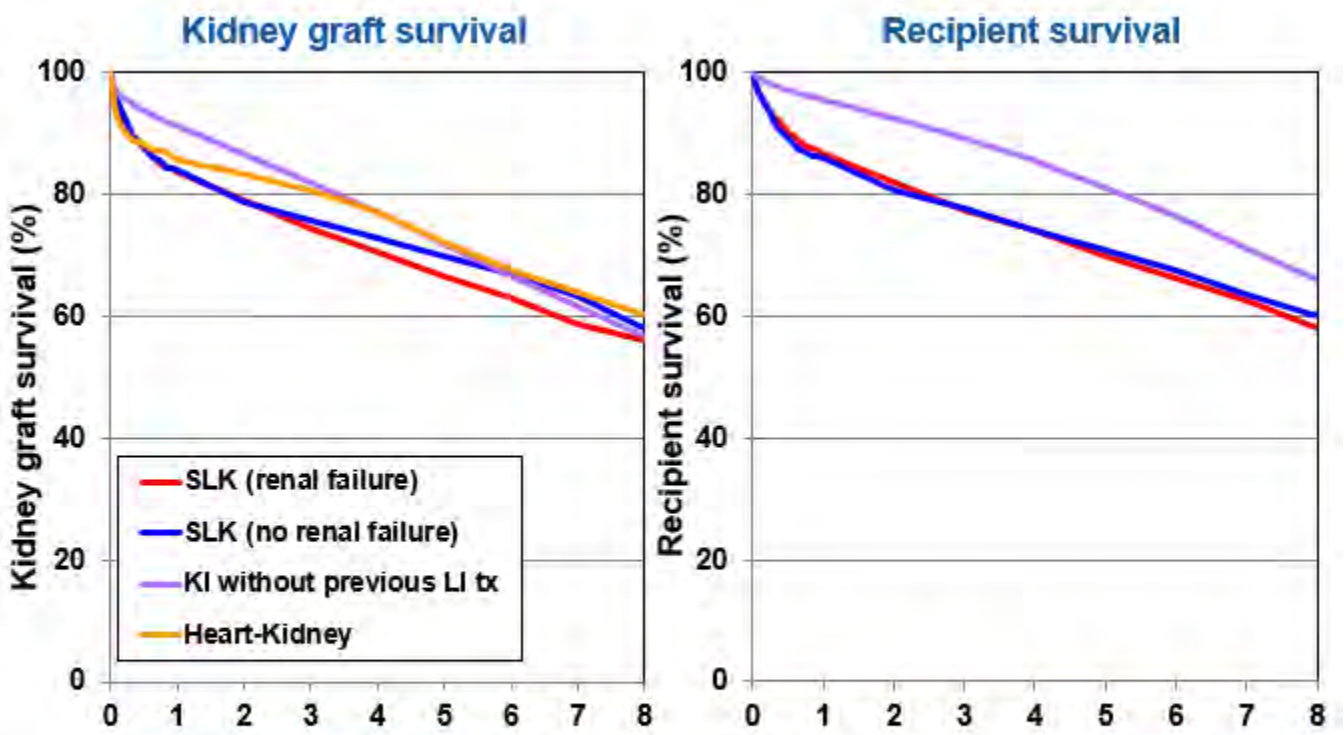
[4] Merion, Robert M., et al. "Deceased-donor characteristics and the survival benefit of kidney transplantation." *Jama* 294.21 (2005): 2726-2733.

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 work group asked to compare kidney graft survival for SLK vs. kidney alone recipients and also compare those with heart-kidney recipients.

Figure 2 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.

Figure 2. 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.



	SLK (renal failure)	SLK (no renal failure)	KI
White	62%	65%	45%
Age (median)	56	57	54

Figure 2 (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 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.

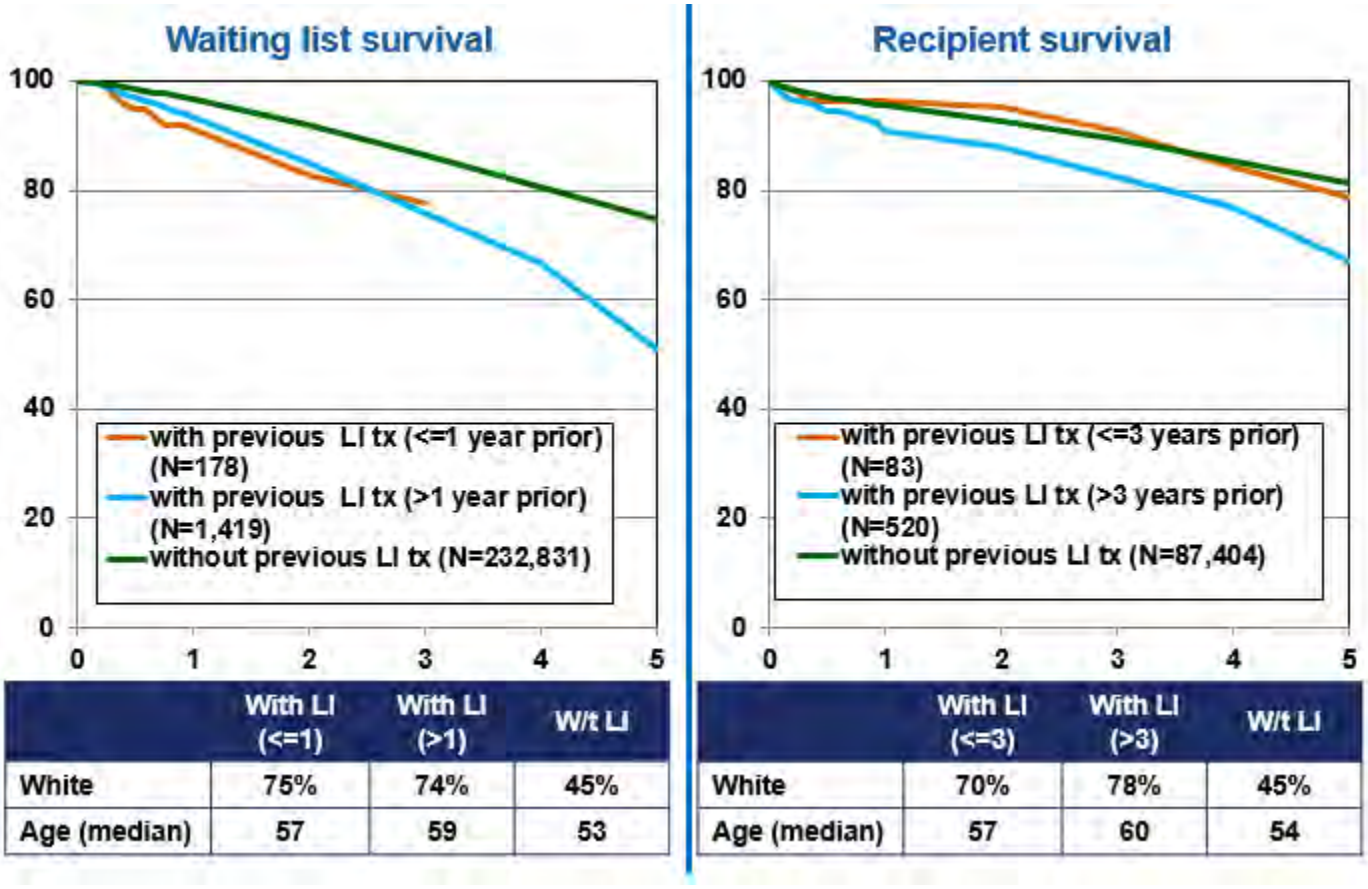
Differences in patient characteristics may have contributed to differences in survival. SLK recipients were more likely to be white compared to kidney alone. All groups had similar median ages.

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

The work group also asked to examine 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 3 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 3. 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. See *Data and methods* section for more information.



	With LI (<=1)	With LI (>1)	W/t LI
White	75%	74%	45%
Age (median)	57	59	53

	With LI (<=3)	With LI (>3)	W/t LI
White	70%	78%	45%
Age (median)	57	60	54

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 seem to 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.

SUMMARY

- There appears to be a survival advantage of receiving a kidney along with the liver over receiving a liver alone transplant, but only for those with renal failure. This could be considered an evidence supporting a potential proposal to restrict SLK transplants to those liver candidates with renal failure.
- SLK recipients had a substantially lower kidney graft survival compared to kidney alone recipients, primarily due to high mortality rates within the first year of transplant.
- Those listed for kidney within a year of the liver transplant had a substantially worse waiting list survival compared to kidney candidates without a prior liver transplant, but those who received a kidney transplant shortly after liver transplant seem to have survival comparable with those without a prior liver transplant. This supports the concept of a “safety net” for liver-alone recipients that need a kidney shortly after transplant.

Note that differences in patient characteristics may have contributed to differences in survival. Relatively small numbers of patients in some groups make it harder to detect differences in survival.

APPENDIX A

Table A.1. Estimated waiting list survival rates by recipient group

Kaplan-Meier survival for adult candidates added to the waiting list from March 1, 2002 through December 31, 2012. Unless specified otherwise, prior transplant recipients and candidates that had other registrations (for the same or different organs) added to the waiting list prior to March 1, 2002 were excluded. Deaths included removals for deaths and removals for reasons other than transplant with death dates within 30 days of removal. See *Data and methods* section for more information.

Candidate Type	Years	Waiting list survival (%)		
		Lower 95% CL	Estimated survival rate	Upper 95% CL
SLK (qualified for KI waiting time based on dialysis or GFR) (N=2,260)	0.5	64.9	67.5	70.1
	1	56.4	59.4	62.5
	2	44.9	48.5	52.2
	3	34.9	39.3	43.6
	4	26.9	32.0	37.1
	5	23.8	29.3	34.9
SLK (didn't qualified for KI waiting time based on dialysis or GFR) (N=744)	0.5	71.9	75.9	80.0
	1	62.2	67.2	72.2
	2	48.8	55.0	61.3
	3	37.4	44.9	52.4
	4	34.7	42.9	51.0
KI alone candidates with a previous LI transplant (N=1,597)	0.5	95.7	96.7	97.7
	1	91.8	93.2	94.7
	2	82.6	84.7	86.9
	3	73.1	76.0	78.8
	4	63.9	67.6	71.2
	5	47.5	52.4	57.3
KI alone candidates without a previous LI transplant (N=232,831)	0.5	98.5	98.5	98.6
	1	96.5	96.6	96.7
	2	91.7	91.9	92.0
	3	86.3	86.5	86.7
	4	80.3	80.6	80.8
	5	74.4	74.7	75.0

Table A.2. Estimated waiting list survival rates by recipient group and time since liver transplant

Kaplan-Meier survival for adult candidates added to the waiting list for from March 1, 2002 through December 31, 2012. Unless specified otherwise, prior transplant recipients and candidates that had other registrations (for the same or different organs) added to the waiting list prior to March 1, 2002 were excluded. Deaths included removals for deaths and removals for reasons other than transplant with death dates within 30 days of removal. See *Data and methods* section for more information.

Candidate Type	Years	Waiting list survival (%)		
		Lower 95% CL	Estimated survival rate	Upper 95% CL
KI alone candidates with a previous LI transplant – listed for kidney ≤1 year of liver transplant (N=178)	0.5	90.6	94.9	99.2
	1	86.0	91.3	96.7
	2	75.6	82.9	90.1
	3	68.7	77.5	86.3
	4	68.7	77.5	86.3
	5	53.0	67.2	81.3
KI alone candidates with a previous LI transplant – listed for kidney more than 1 year after liver transplant (N=1,419)	0.5	95.8	96.9	97.9
	1	92.0	93.5	95.0
	2	82.7	85.0	87.3
	3	72.8	75.8	78.9
	4	62.6	66.5	70.4
	5	45.6	50.8	56.0
KI alone candidates without a previous LI transplant (N=232,831)	0.5	98.5	98.5	98.6
	1	96.5	96.6	96.7
	2	91.7	91.9	92.0
	3	86.3	86.5	86.7
	4	80.3	80.6	80.8
	5	74.4	74.7	75.0

Table A.3. Estimated kidney graft and recipient survival rates by recipient group

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

Transplant Type	Years	Kidney graft survival (%)			Recipient survival (%)		
		Lower 95% CL	Estimated survival rate	Upper 95% CL	Lower 95% CL	Estimated survival rate	Upper 95% CL
SLK (2+ months of dialysis or 2.5+ mg/dl serum creatinine) (N=2,385)	0.5	86.2	87.6	89.0	89.0	90.2	91.5
	1	82.0	83.5	85.1	85.0	86.4	87.8
	2	77.5	79.2	80.9	80.2	81.8	83.4
	3	72.8	74.6	76.5	75.6	77.3	79.1
	4	68.7	70.7	72.6	72.0	73.9	75.8
	5	64.6	66.7	68.9	67.6	69.7	71.8
	6	60.8	63.1	65.4	63.9	66.2	68.5
	7	56.3	58.8	61.3	60.0	62.4	64.9
	8	53.2	55.9	58.6	55.2	58.0	60.8
	9	48.7	51.7	54.8	50.2	53.4	56.6
	10	44.0	47.5	51.1	44.3	48.1	51.8
	11	40.3	44.4	48.6	39.9	44.3	48.7
LI alone (2+ months of dialysis or 2.5+ mg/dl serum creatinine) (N=4,803)	0.5	NA			85.7	86.7	87.7
	1				80.7	81.9	83.0
	2				75.2	76.4	77.7
	3				71.3	72.6	73.9
	4				67.7	69.1	70.5
	5				64.4	65.9	67.4
	6				60.3	61.9	63.5
	7				57.1	58.9	60.6
	8				52.6	54.5	56.4
	9				50.7	52.7	54.7
	10				47.2	49.5	51.7
	11				43.8	46.4	49.1
SLK (not on dialysis with <2.5 mg/dl serum creatinine or on dialysis for <2 months) (N=662)	0.5	85.2	87.9	90.5	86.6	89.2	91.7
	1	81.0	84.0	87.0	82.9	85.8	88.6
	2	75.5	78.8	82.1	77.5	80.7	83.9
	3	72.2	75.7	79.2	74.1	77.6	81.0
	4	69.1	72.8	76.5	70.5	74.2	77.9

Transplant Type	Years	Kidney graft survival (%)			Recipient survival (%)		
		Lower 95% CL	Estimated survival rate	Upper 95% CL	Lower 95% CL	Estimated survival rate	Upper 95% CL
	5	65.8	69.8	73.7	66.7	70.7	74.6
	6	62.6	66.8	71.0	63.2	67.4	71.7
	7	58.8	63.3	67.9	59.0	63.6	68.2
	8	53.0	58.1	63.3	55.0	60.0	65.0
	9	48.3	54.2	60.1	50.0	55.8	61.7
	10	39.6	47.7	55.7	43.5	51.0	58.6
LI alone (not on dialysis with <2.5 mg/dl serum creatinine or on dialysis for <2 months) (N=43,885)	0.5				93.0	93.2	93.5
	1				89.6	89.9	90.2
	2				84.7	85.0	85.3
	3				80.7	81.1	81.5
	4				77.2	77.6	78.0
	5				73.6	74.0	74.5
	6				70.0	70.5	71.0
	7				66.7	67.3	67.8
	8				63.6	64.2	64.8
	9				60.3	60.9	61.5
	10				56.6	57.4	58.1
	11				52.6	53.4	54.3
KI alone with previous LI transplant (N=603)	0.5	91.3	93.5	95.7	92.9	94.8	96.8
	1	87.8	90.3	92.9	89.3	91.7	94.1
	2	82.3	85.3	88.4	86.0	88.7	91.5
	3	76.2	79.7	83.2	80.2	83.5	86.7
	4	70.1	74.0	78.0	74.3	78.0	81.8
	5	59.7	64.2	68.7	64.0	68.4	72.8
	6	53.1	57.9	62.7	57.1	61.9	66.6
	7	46.1	51.3	56.4	49.7	54.9	60.1
	8	41.6	47.1	52.5	45.1	50.6	56.1
	9	37.5	43.2	49.0	40.1	46.0	52.0
	10	25.0	32.4	39.8	27.8	35.2	42.7
	11	*	*	*	18.3	27.4	36.6
	0.5	93.6	93.8	94.0	96.9	97.1	97.2

Transplant Type	Years	Kidney graft survival (%)			Recipient survival (%)		
		Lower 95% CL	Estimated survival rate	Upper 95% CL	Lower 95% CL	Estimated survival rate	Upper 95% CL
KI alone without previous LI transplant (N=87,404)	1	91.1	91.3	91.4	95.3	95.4	95.6
	2	86.5	86.7	86.9	92.4	92.6	92.7
	3	81.8	82.0	82.3	89.1	89.3	89.5
	4	76.7	77.0	77.3	85.2	85.5	85.7
	5	71.5	71.9	72.2	80.8	81.1	81.4
	6	66.3	66.7	67.1	75.9	76.3	76.6
	7	61.3	61.7	62.1	70.8	71.2	71.6
	8	56.4	56.8	57.3	65.4	65.9	66.3
	9	51.6	52.1	52.7	59.7	60.2	60.8
	10	46.9	47.5	48.1	54.1	54.8	55.4
	11	42.2	42.9	43.5	47.7	48.5	49.2
Heart-Kidney (N=460)	0.5	85.1	88.3	91.4	87.0	90.0	93.0
	1	82.4	85.8	89.2	84.5	87.8	91.0
	2	79.6	83.3	86.9	81.2	84.8	88.3
	3	76.9	80.8	84.7	78.5	82.3	86.1
	4	73.0	77.3	81.6	76.3	80.4	84.4
	5	67.4	72.2	77.1	71.5	76.1	80.7
	6	62.3	67.6	73.0	64.4	69.8	75.1
	7	58.2	64.1	69.9	63.2	68.7	74.2
	8	54.0	60.3	66.7	59.5	65.6	71.6

* N at risk < 10

Table A.4. Estimated kidney and recipient half-lives

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

Transplant Type	N	Kidney half-life (years)			Recipient half-life (years)		
		Lower 95% CL	Estimated half-life	Upper 95% CL	Lower 95% CL	Estimated half-life	Upper 95% CL
SLK (2+ months of dialysis or 2.5+ mg/dl serum creatinine)	2,385	8.8	9.5	10.4	9.0	9.7	10.6
LI alone (2+ months of dialysis or 2.5+ mg/dl serum creatinine)	4,803	NA			9.2	9.7	10.5
SLK (not on dialysis with <2.5 mg/dl serum creatinine or on dialysis for <2 months)	662	8.8	9.9	*	*	* (Greater than 10 years)	*
LI alone (not on dialysis with <2.5 mg/dl serum creatinine or on dialysis for <2 months)	43,885	NA			11.7	11.9	12.1
KI alone with previous LI transplant	603	6.4	7.3	8.8	7.0	8.5	9.1
KI alone without previous LI transplant	87,404	9.3	9.4	9.6	10.7	10.8	10.9
Heart-Kidney	460	*	* (Greater than 8 years)	*	*	* (Greater than 8 years)	*

* Not estimable

Table A.5. Donor, recipient and transplant characteristics of transplants performed from March 1, 2002 through December 31, 2012.

Unless specified otherwise, multi-organ transplants and repeat transplant recipients were excluded from analyses. Continuous factors are expressed as median (5^{th} – 95^{th} percentiles).

Characteristic	SLK (2+ months of dialysis or 2.5+ mg/dl serum creatinine)	LI alone (2+ months of dialysis or 2.5+ mg/dl serum creatinine)	SLK (not on dialysis with <2.5 mg/dl serum creatinine or on dialysis for <2 months)	LI alone (not on dialysis with <2.5 mg/dl serum creatinine or on dialysis for <2 months)	KI alone with previous LI transplant	KI alone without previous LI transplant	Heart-Kidney	p-value
Male	67.4%	71.7%	61.2%	69.0%	68.2%	60.5%	80.6%	<0.0001
White	62.1%	70.3%	64.7%	73.0%	76.9%	44.5%	62.6%	<0.0001
Black	16.1%	10.0%	10.3%	8.5%	8.1%	32.7%	25.5%	<0.0001
Diabetes at listing	40.6%	27.0%	38.4%	22.8%	45.4%	35.3%	36.8%	<0.0001
0ABDR Mismatch	0.1%	0.2%	0.0%	0.2%	12.1%	9.8%	0.0%	<0.0001
0ABDR Mismatch Unknown	17.5%	61.3%	24.2%	57.3%	0.0%	0.0%	1.7%	<0.0001
Recipient age	56.0 (37.0 - 67.0)	55.0 (39.0 - 67.0)	57.0 (41.0 - 68.0)	55.0 (37.0 - 68.0)	60.0 (44.0 - 72.0)	54.0 (29.0 - 72.0)	56.0 (32.0 - 67.0)	<0.0001
Donor age	36.0 (16.0 - 60.0)	42.0 (17.0 - 67.0)	36.0 (16.0 - 60.0)	43.0 (16.0 - 70.0)	42.0 (12.0 - 63.0)	41.0 (11.0 - 64.0)	29.5 (16.0 - 54.0)	<0.0001
Donor KDPI (%)*	35.0 (3.0 - 88.0)	46.0 (4.0 - 97.0)	37.0 (4.0 - 89.0)	52.0 (5.0 - 98.0)	50.5 (5.0 - 90.0)	48.0 (5.0 - 92.0)	24.0 (2.0 - 71.0)	<0.0001
Cold ischemia time (CIT) not reported	4.4%	6.1%	3.0%	5.7%	8.5%	6.1%	15.9%	<0.0001
KI CIT (hours)	9.6 (4.1 - 20.5)	NA	10.0 (4.5 - 24.6)	NA	17.3 (6.0 - 35.0)	17.0 (6.0 - 34.0)	12.0 (5.0 - 29.0)	<0.0001
LI CIT (hours)	6.4 (3.1 - 11.5)	6.9 (3.2 - 12.0)	6.5 (3.0 - 12.5)	6.7 (3.2 - 12.0)	NA	NA	NA	<0.0001
Most recent pre transplant MELD lab score	27.0 (20.0 - 43.0)	36.0 (22.0 - 46.0)	28.0 (14.0 - 45.0)	17.0 (7.0 - 35.0)	NA	NA	NA	<0.0001

* Reference population = 2013 donors