OPTN/UNOS Kidney Transplantation Committee

Simultaneous Liver Kidney (SLK) Allocation Policy

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Executive Summary

Current OPTN 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. 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.
- 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 SLK allocation is not required.

In order to provide more clarity and consistency in the rules for SLK allocation, the Committee is proposing the following new policies:

- Establish medical eligibility criteria for candidates seeking an SLK transplant. Because 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.
- Establish a "safety net" (some 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 reflects feedback from the 11 OPTN 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."

Because there is a tremendous amount of transplant community interest in the development of this policy and a need to ensure a high level of consensus for the final product, the Committee may utilize the Fall 2015 and Spring 2016 public comment periods to receive input on these changes, with an expectation that the OPTN/UNOS Board of Directors will consider final adoption at the June 2016 Board meeting.

Simultaneous Liver Kidney (SLK) Allocation Policy

Affected Policies: Policy 5.8 *Allocation of Multi-Organ Combinations;* Policy 8.5 *Kidney Allocation Classifications and Rankings;* Policy 9.6 *Liver Allocation, Classifications, and Rankings*

Sponsoring Committee: Kidney Transplantation Committee

Public Comment Period: August–October, 2015

What problem will this proposal solve?

Current OPTN 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)[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 the discretion to do so.

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

- The current allocation for SLK transplants 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.[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.
- 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**), which are kidneys prioritized for local pediatric candidates in kidney alone 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 status or Model End Stage Liver Disease Score (MELD) score or Pediatric End Stage Liver Disease (PELD) score for regional allocation but regional SLK allocation is not required. The Liver and Intestinal Transplantation Committee ("the Liver Committee") is concerned with the

[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

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).

In order to provide more clarity and consistency in the rules for SLK allocation, the Committee is proposing the following new policies.

SLK Medical Eligibility Criteria

The Committee is proposing that liver-kidney candidates 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 a 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 a liver-kidney candidate 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 candidate to receive this priority, the candidate must meet one of the following criteria.

The table below is to be read from left to right. The diagnosis confirmed in the left column must be accompanied by certain medical record documentation in the right column. The left column will be operationalized through IT programming in UNet℠ (see sections "How will the OPTN implement this proposal?" and "How will members implement this proposal" for additional details). The right column would be monitored by UNOS staff analysis (see section "How will members be monitored for compliance with this proposal?").

[3] Nadim, at al. "Simultaneous Liver-Kidney Transplantation: A Survey of US Transplant Centers" *Am J Transplantation* 2012; 12: 3119-3127

If the candidate's transplant nephrologist confirms a diagnosis of:	Then the transplant program must 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. • That the candidate's most recent measured or calculated creatinine clearance (CrCl) or glomerular filtration rate (GFR) is less than or equal to 35 mL/min at the time of registration on the kidney waiting list.
Sustained acute kidney injury	*At least one* of the following: 1. That the candidate has been on dialysis for at least 6 consecutive weeks. 2. That the candidate has a measured or calculated CrCl or GFR less than or equal to 25 mL/min for at least 6 consecutive weeks and this is documented in the candidate's medical record every 7 days beginning with the date of the first test with this value. 3. That the candidate has any combination of #1 and #2 above for six consecutive weeks.
Metabolic disease	An additional diagnosis of *at least one* of the following: 1. Hyperoxaluria 2. Atypical HUS from mutations in factor H and possibly factor I 3. Familial non-neuropathic systemic amyloid 4. Methylmalonic aciduria

If the candidate meets the SLK medical eligibility criteria, the candidate would be eligible for liver-kidney allocation from a donor in the same DSA. If the candidate meets the SLK medical eligibility criteria *and*, due to status or MELD/PELD score, is also eligible for regional liver allocation, then the candidate will be eligible for regional SLK allocation. The candidate's SLK eligibility status would be displayed for OPOs, so that the eligibility status will not be in question in the allocation process. If the candidate does not meet the SLK eligibility criteria, the candidate would not be prioritized for SLK allocation.

See the section "How was this proposal developed?" for a complete history of the selection of this medical eligibility criteria.

"Safety net" for liver recipients who continue to be on the kidney waiting list after liver transplant

There has been significant concern from the liver transplant community about establishing SLK medical eligibility criteria and, in particular, whether some liver-kidney candidates may "fall through the cracks" under the proposal because they would not meet the medical criteria and, therefore, would not be eligible to receive a kidney offer at the time of liver offer. In response to this concern, the Committee is recommending a change to OPTN policy that would provide some additional 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.

The Committee's proposal provides the kidney match classification priority 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 criteria in the period between two and twelve months after liver transplant. During this period, the candidate must be registered on the kidney waiting list *and* either on dialysis for ESRD or have a GFR at or below 20 mL/min in order to receive additional priority for kidney alone offers. 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 priority is limited within each KDPI sequence (see below table) and would apply to all liver recipients regardless of whether they met criteria before or after their liver transplant. The classification priority will apply until the candidate receives a kidney transplant or the candidate is removed from the kidney waiting list for other reasons.

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 status, 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 and form as the program currently uses to apply for kidney waiting time modifications under policy 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. The table below details the match classification priority for liver recipients by KDPI sequence.

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

Many in the transplant community have also 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 either of these issues, 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 at a later date. 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 general multi-organ policies. 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) plans to begin a comprehensive review of the multi-organ, allocation policies later this year. That work will build on the efforts of this proposal.

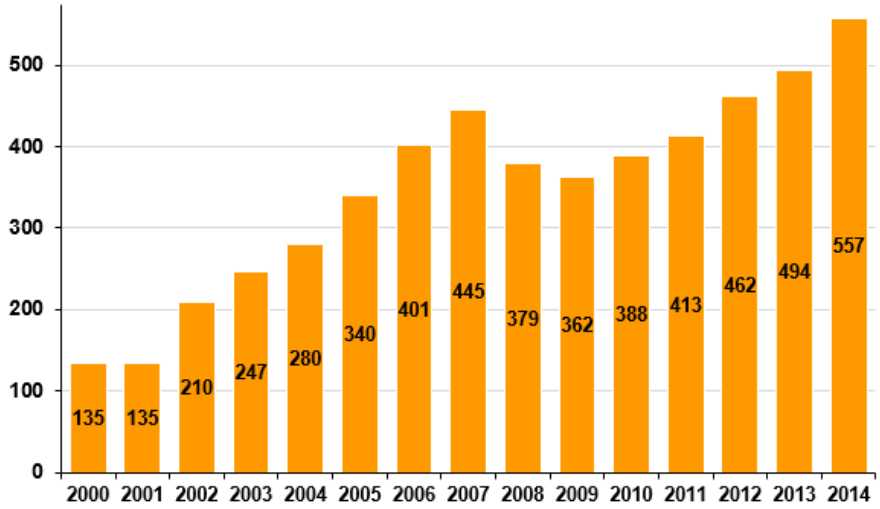
Why should you support this proposal?

For over a decade, the transplant community has discussed the need for clearer and more consistent SLK allocation policy. The two elements of this proposal (SLK medical eligibility criteria and a safety net for liver recipients with a continued need for kidney transplant) attempt to combine the two most commonly discussed policy solutions for addressing the problems with the current SLK allocation policy. While the working group and the Committee had limited data to review in selecting the solutions, both obtained a high level of clinical consensus on this proposal and garnered support from representatives of many different segments of the transplant community, including but not limited to the OPTN/UNOS Liver and Intestinal Transplantation, OPO, Ethics, and Minority Affairs Committees, as well as the American Society of Transplantation (AST) and the National Kidney Foundation (NKF). There was also a great deal of support for the recommendations among the 11 OPTN regions. The Committee feels that there is a strong basis of support for moving forward with the proposal and examining data after implementation to determine whether changes are needed in the future (see "How will the sponsoring committee evaluate whether this proposal was successful post-implementation?").

How was this proposal developed?

Since the introduction of the Model End-Stage Liver Disease (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.

Figure 1. Number of SLK transplants by year
SLK transplants with other organs were excluded from the tabulation.



The 2009 policy proposal contained two main elements:

- Proposed medical listing criteria for allocating a kidney with the liver from the same donor in the candidate's donation service area (DSA)
- Increased priority on the kidney waiting list for liver recipients with continued kidney disease or dysfunction (often referred to as a 'safety net')

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 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. Once the new KAS was approved by the OPTN/UNOS 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 monthly over a period of a year and a half 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. Below is a description of the working group's recommendation and the feedback the Committee considered in finalizing this proposal.

Development of new SLK medical eligibility criteria

Similar to the 2009 policy proposal, the working group recommended that the OPTN establish medical *eligibility* criteria that liver-kidney candidates would have to meet in order to receive a kidney and liver from the same deceased donor. This is different from the 2009 medical listing criteria in that, under the current proposal, a liver candidate could still be registered on the kidney waiting list and would be eligible to receive kidney offers if active. However, the candidate would not receive the enhanced priority for an SLK transplant at the time of their liver offer unless the candidate met certain medical eligibility criteria associated with kidney failure or dysfunction. The criteria recommended by the working group amended somewhat the medical criteria originally proposed in 2009.

The working group's draft medical eligibility criteria as presented to regions and groups for early feedback:

The candidate's transplant nephrologist must confirm a diagnosis of:	**And the transplant program must document in the candidate's medical record:**
Chronic kidney disease (CKD)	*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. That the candidate has a measured or calculated creatinine clearance (CrCl) or glomerular filtration rate (GFR) less than or equal to 35 mL/min.
Sustained acute kidney failure	*One* of the following: That the candidate has been on dialysis for at least 6 consecutive weeks. That the candidate has a measured or calculated CrCl or GFR less than or equal to 25 mL/min for at least 6 consecutive weeks and this is documented in the candidate's medical record every 7 days beginning with the date of the first test with this value. That the candidate has any combination of #1 and #2 above for six consecutive weeks.
Metabolic disease	An additional diagnosis of *one* of the following: Hyperoxaluria Atypical HUS from mutations in factor H and possibly factor I Familial non-neuropathic systemic amyloid Methylmalonic aciduria

For the “chronic kidney disease category”, the working group chose the eGFR at 35 mL/min simply as a compromise made to accommodate opposing views from the 2009 public comment proposal. In that proposal, the GFR requirement for the chronic kidney disease category was at or below 30 mL/min. The ASTS opposed the criteria because of a concern that it was too strict and several individual commenters said the standard criteria at their center was eGFR 40 mL/min. The working group decided to meet in the middle. Many of the working group members were more comfortable with this compromise because of the recommended safety net for liver recipients who do not regain kidney function.

The “acute kidney failure” criteria was largely unchanged from the 2009 proposal, except that the previous proposal required that the candidate have dialysis at least twice a week. The working group did not want to require a specific frequency of dialysis. For the “metabolic disease” category, the working group added methylmalonic aciduria upon recommendation from the chair of the OPTN/UNOS Pediatric Transplantation Committee.

The Committee presented the working group recommendations for SLK medical eligibility to the 11 OPTN regions and circulated these draft recommendations in a memo to the following groups who had commented on the 2009 proposal:

- ASTS
- AST
- NKF
- AUA

The Committee received feedback from all 11 OPTN regions, AST, NKF, and AUA. In general, most of the regions and groups were in favor of new medical criteria for SLK allocation. The AUA generally rejected the notion that SLK transplants should be occurring because of the outcomes data associated with these transplants and suggested encouraging liver recipients to find a living kidney donor instead. However, the Committee decided at the outset of the SLK project that the focus of the discussion was going to be on developing the most appropriate medical eligibility criteria, not debating whether any SLK transplants should occur at all. Therefore, the Committee made no changes in response to the AUA feedback. The NKF was generally supportive of the proposal and strongly in favor of having the candidate’s transplant nephrologist confirm the candidate diagnosis, which was not proposed in the 2009 proposal.

There were also some common themes among all of the feedback in terms of requests for changes:

- There was a suggestion that the policy needed to be more explicit about the definition of chronic kidney disease and the Committee should consider adopting the NKF’s Kidney Disease Outcomes Quality Initiative (KDOQI) criteria to further define CKD.--several OPTN regions and AST
- There was a suggestion that the policy require more than one GFR measurement to show a duration of GFR score in the chronic kidney disease category. --several OPTN regions
- There was a suggestion that the policy require a uniform method of measuring and calculating GFR--several OPTN regions and AST
- There was a request that the Committee consider a different label of diagnosis for category #2, because the medical documentation required does not describe what is typically considered kidney “failure”--NKF

In response to this feedback, the Committee made some adjustments to the final proposal:

- The final proposal includes a definition of chronic kidney disease using the KDOQI criteria (including that the GFR duration be for 90 consecutive days)
- The final proposal includes a requirement that the most recent GFR measurement be used at the time of registration on the kidney waiting list

- The final proposal includes a different label for category #2 (acute kidney "injury").

The Committee considered but did not adopt a requirement for a uniform method for measuring and calculating GFR. The majority of the Committee was concerned with requiring a uniform measurement because programs use different tools, there is sufficient debate about the accuracy of differing measurements, and such a new requirement would be very difficult and complex to monitor for compliance.

Development of the "safety net"

Because there is still significant concern from the liver transplant community about establishing SLK medical eligibility criteria and, in particular whether some liver-kidney candidates may "fall through the cracks" under such a new policy, the working group again recommended a safety net policy. Unlike the 2009 proposal, however, the working group decided to limit safety net priority to certain categories of kidneys based on KDPI. The working group agreed to this after reviewing comments from the 2009 proposal, in which the NKF and AUA expressed significant concern that liver recipients would receive kidney match classification priority before other classes of kidney alone candidates. Their concern was mostly focused on priority for highly sensitized and pediatric candidates.

The working group also wanted to ensure some period of waiting after liver transplant and cap it beyond the period of time that would be tied to the need for a kidney related to liver disease. In determining the time period for the safety net prioritization, the Committee looked at the following data:

- Of those liver recipients listed for a kidney, 19% of them were listed in the first year after their liver transplant.
- Of those liver recipients who later received a kidney transplant, 93% of them received their kidney transplant more than a year after their liver transplant. 40-41% of them received their kidney transplant more than 9 years after their liver transplant.
- A 2013 AJT publication, which found that the risk of *newly developed* ESRD is at its highest in the 6 months after liver transplant.[4]

The working group's updated safety net priority differed from the 2009 proposal in two key ways:

- In the 2009 proposal, the liver recipient must have been listed for the kidney between 90-180 days (instead of the current 60-365 days) after liver transplant in order to get priority on the kidney alone waiting list.
- The required documented medical criteria for the candidate was different based on whether or not the candidate met the criteria before or after liver transplant. In particular, the GFR criteria was significantly higher (between 30 and 40 mL/min) for candidates who did not initially qualify for SLK allocation.

The Committee presented the working group recommendations for the safety net priority to the 11 OPTN regions and circulated these draft recommendations in a memo to the following groups who had commented on the 2009 proposal:

- ASTS
- AST
- NKF

[4] Israni, at al. "Predicting End-Stage Renal Disease After Liver Transplant" *Am J Transplant* 2013; *13: 1782–1792*

- AUA

The Committee received feedback on the safety net priority from all 11 OPTN regions, AST, and NKF. Several OPTN regions noted support for the proposal solely because of the inclusion of some safety net for liver recipients. There were also some common themes among all of the feedback in terms of requests for changes:

- There was a suggestion that the policy allow for safety net priority only if the candidate met certain medical criteria *prior* to liver transplant.—several OPTN regions
- There was a suggestion that there should be no safety net priority for sequence B (donor KDPI greater than 20% but less than 35%)—several OPTN regions
- Some were concerned with whether this new priority would be a disincentive for the liver recipient to find a living kidney donor.–several OPTN regions

The working group and the Committee considered but did not adopt a requirement that the liver recipient have met certain medical criteria prior to the liver transplant in order to be eligible for safety net priority. 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 selection of a one year safety net window was, again, due to a balance and compromise of the many different perspectives on this issue.

The working group and Committee also discussed whether safety net priority should be removed from Sequence B 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 just a slight advancement in prioritization.

Finally, the Committee did consider concerns that establishment of the safety net could act as a disincentive for a liver recipient to find a living donor. The Committee reviewed data showing that about 1/3 of the kidney transplants received by liver recipients were living donor transplants (see **Exhibit A**). The Committee did not make any changes to accommodate this concern, mostly because any new 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.

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 C**), 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.

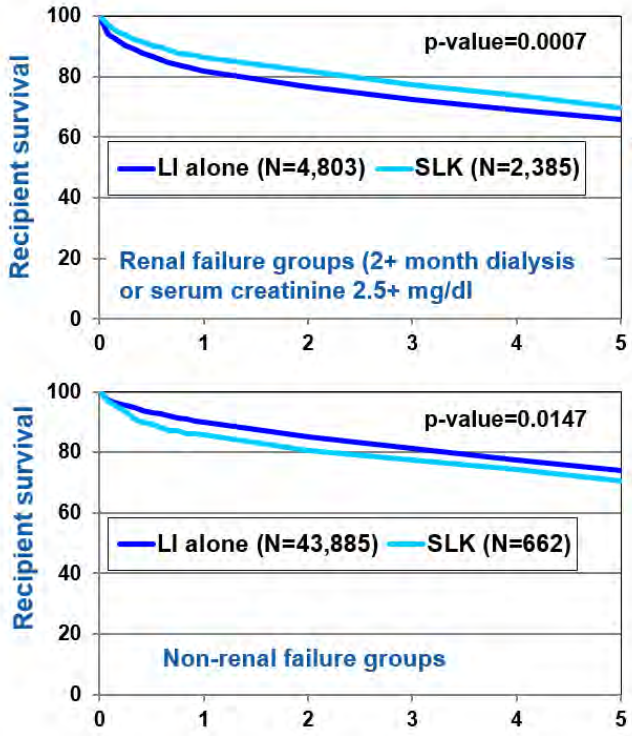
Survival advantage of receiving a kidney vs. liver alone

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]. Fong, et al, also analyzed differences in survival for renal failure group adjusting for patient characteristics (age, MELD, ICU at time of transplant,

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

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 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 in Exhibit C 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

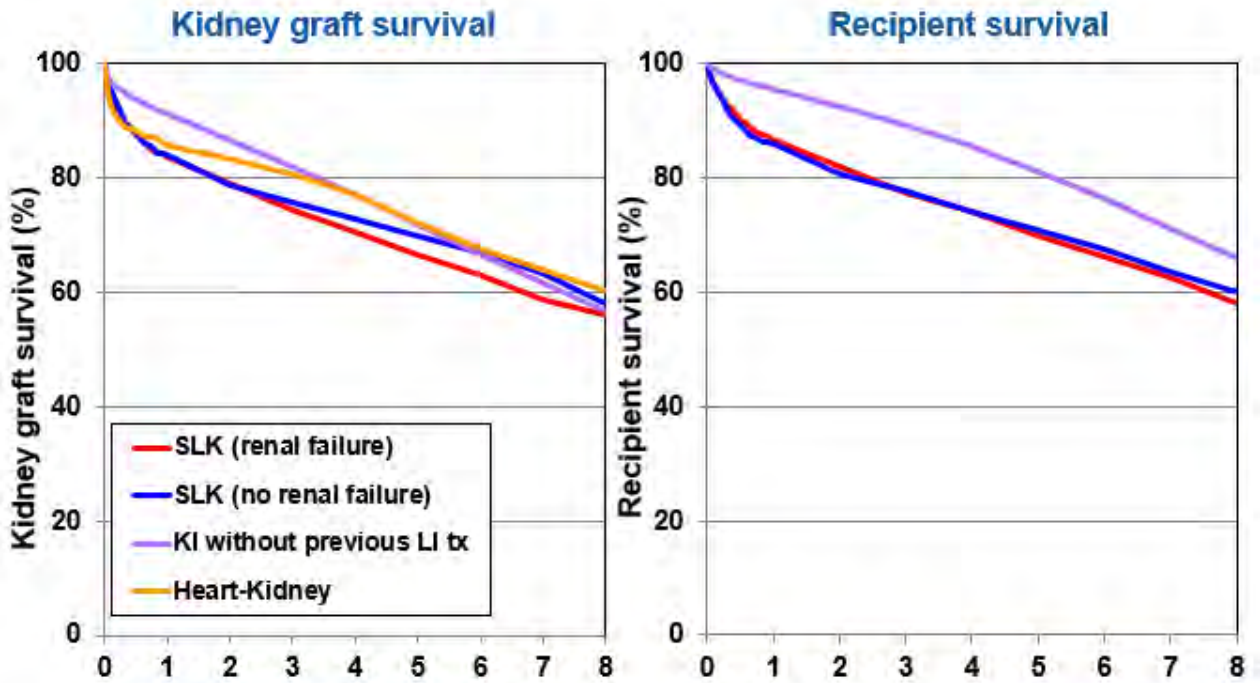
To assess the degree of decrease in kidney graft survival in multi-organ transplants, the committee compared kidney graft survival for SLK vs. kidney alone recipients and also compare those with heart-kidney recipients.

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.

[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 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.

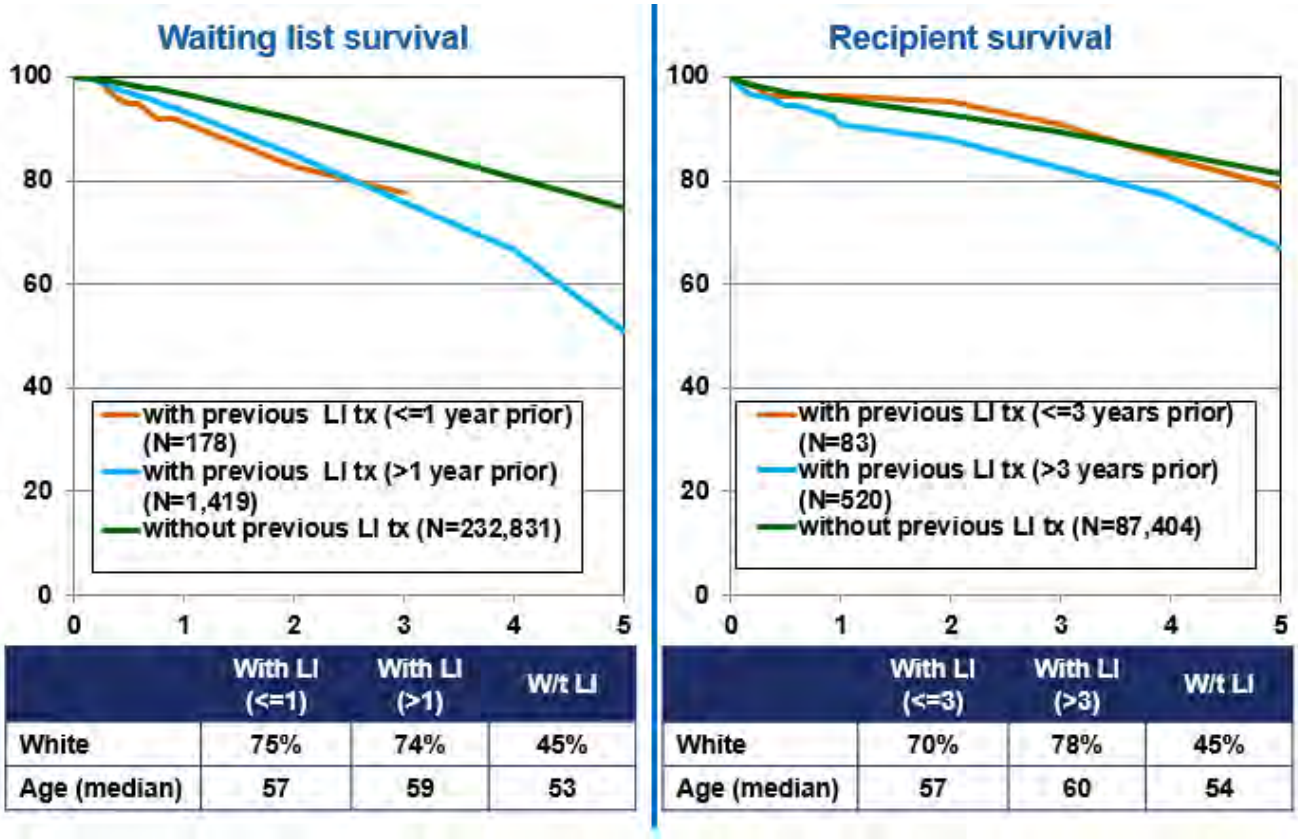
Differences in patient characteristics may have contributed to differences in survival. SLK recipients were more likely to be white compared to kidney alone. All groups had similar median ages.

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 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.

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 are currently around 500-550 SLK transplants performed each year (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.

There is also a possibility that these new rules could have an impact on kidney-pancreas candidates in cases where the OPO must decide whether to allocate a kidney to a liver-kidney candidate or a kidney-pancreas candidate.

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 this kidney will be allocated to a kidney alone candidate, increasing the number of kidney candidates transplanted.

2. *Improve equity in access to transplants:* The main 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.

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 resulted in decreasing number of SLK transplants?
- Has there been a change in the number of listings for kidney within a year of a liver transplant?
- Has the policy increased equity in access to transplants and decreased mortality rates for those listed 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 and by sharing type;
- The distribution of SLK transplants by diagnosis (CKD with GFR ≤ 60 mL/min for greater than 90 consecutive days, sustained acute kidney injury, metabolic disease) (post implementation only);
- The number of listing for kidney within a year of a liver transplant;
- The number of listing for kidney within a year of a liver transplant by candidate's eligibility for additional match classification priority (post implementation only);
- The number of transplants for kidney candidates who were reported to be eligible for additional match classification 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, minority) and geographic location (OPTN region, Donation Service Area).

How will the OPTN implement this proposal?

Depending on the level of consensus achieved from this proposal, the Committee may utilize a second public comment period in spring 2016 to finalize this proposal. If a high level of consensus is obtained in the transplant community, the Committee will recommend final approval of the proposal to the Board of Directors in June 2016. If the Board of Directors approves this proposal, the changes will require significant effort from the OPTN.

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). There will be a very large effort needed to program these changes into the UNOS computer system. 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? Will this proposal require members to submit additional data?

Yes. Liver and kidney transplant programs will be required to submit additional data in UNet℠ if this proposal is implemented. The data will be used for organ allocation (which supports the OPTN data collection principles).

For SLK medical eligibility criteria part of proposal, 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)

- The transplant nephrologist's name who confirms the diagnosis liver candidate's registration record in Waitlist.

For the safety net portion of proposal, kidney transplant programs will be required to fill in several additional fields on kidney candidate's registration in Waitlist to indicate candidate's eligibility for additional match classification priority.

OPOs 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?

The policy modifications outlined in this proposal may be monitored by OPTN staff following implementation of the proposed language. This monitoring plan is subject to change pending the outcome of public comment and further computer programming discussions.

Policy 9.6.L Allocation of Liver-Kidney

OPTN staff may request and review documentation in liver-kidney recipient medical records to verify that the recipients met the medical eligibility criteria for liver-kidney allocation prior to their transplant. These reviews will occur retrospectively.

Any transplant hospital that is unable to provide complete medical record documentation demonstrating that a liver-kidney recipient met the medical eligibility criteria prior to receiving the combined transplant may be referred to the MPSC for further review.

Recipients receiving a liver-kidney transplant based on a diagnosis of chronic kidney disease must have documentation of either:

- Evidence of regularly administered dialysis for End Stage Renal Disease such as a 2728 form, physician's note or dialysis center documentation, with a dialysis start date prior to the date of transplant
- A measured or calculated creatinine clearance (CrCl) or glomerular filtration rate (GFR) less than or equal to 35 mL/min prior to registration on the kidney waiting list, including:
    - The date of the recipient's registration on the kidney waiting list
    - The date of the CrCl or GFR calculation or measurement
    - The value of the CrCl or GFR calculation or measurement

Recipients receiving a liver-kidney transplant based on a diagnosis of sustained acute kidney injury must have documentation of one of the following:

- Physician notes or dialysis center documentation showing the dates of dialysis received
    - The dates of dialysis must occur over 6 consecutive weeks
    - 6 consecutive weeks of dialysis must have been completed prior to the date of transplant
- Measured or calculated CrCl or GFR values less than or equal to 25 mL/min, including
    - The value of each CrCl or GFR calculation or measurement
    - The date of each CrCl or GFR calculation or measurement
    - That each of these values was measured or calculated every 7 days for 6 consecutive 7-day periods
    - That the 6 consecutive 7-day periods were completed prior to the date of transplant
- Evidence of a combination of dialysis and measured or calculated CrCl or GFR values less than or equal to 25 mL/min over 6 consecutive weeks, including
    - 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, including
  - The value of each CrCl or GFR calculation or measurement
  - The date of each CrCl or GFR calculation or measurement
- That a dialysis date or a CrCl or GFR calculation or measurement has been recorded during each of 6 consecutive 7-day periods
- That the 6 consecutive 7-day periods were completed prior to the date of transplant

Recipients receiving a liver-kidney transplant based on a diagnosis of metabolic disease must have documentation via a physician's note dated before transplant date of a diagnosis of one of the following:

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

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

OPTN staff may request and review documentation to verify that kidney recipients who reported that they qualified for increased priority to receive a kidney due to a prior liver transplant met one of the qualifying criteria for the increased priority. The review may include review of medical record documentation to verify that the recipient:

- Had a measured or calculated CrCl or GFR less than or equal to 20 mL/min on a date that is 60 to 365 days after the recipient's liver transplant
- Was receiving regularly administered dialysis for ESRD on a date that is 60 to 365 days after the recipient's liver transplant
- Previously received a liver-kidney transplant and qualifies for kidney waiting time reinstatement due to non-function of the transplanted kidney

Policy or Bylaw Language

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

5.8 Allocation of Multi-Organ Combinations

Candidates registered for multiple organs must appear on the heart, lung, or liver match run to be eligible to receive a heart, lung, or liver.

When multi-organ candidates other than heart-lung and liver-kidney candidates are eligible to receive a heart, lung, or liver, the second required organ from the same donor will be allocated to the multi-organ candidate if the donor's DSA is the same DSA where the multi-organ candidate is registered.

Policy 9.6: Liver Allocation, Classifications, and Rankings

9.6.K Allocation of Liver-Kidney

In order for a candidate to receive a liver and a kidney from the same deceased donor, the candidate must meet *both* of the following criteria:

1. The candidate must be in the host OPO's region and in *one* of the following classifications:
   - Classifications 1-34 in Table 9.7 *Allocation from Livers from Deceased Donors At Least 18 Years Old*
   - Classifications 1-6 in Table 9.8 *Allocation of Livers from Deceased Donors 11 to 17 Years Old*
   - Classifications 1-5 in Table 9.9 *Allocation of Livers from Deceased Donors Less Than 11 Years Old*

2. The candidate's transplant nephrologist must confirm at least *one* of the diagnoses according to Table 9-6: *Eligibility Criteria for Allocation of Liver-Kidney* below.

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

If the candidate's transplant nephrologist confirms a diagnosis of:	**Then the transplant program must 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. • That the candidate's most recent measured or calculated creatinine clearance (CrCl) or glomerular filtration rate (GFR) is less than or equal to 35 mL/min at the time of registration on the kidney waiting list.
Sustained acute kidney injury	At least *one* of the following: • That the candidate has been on dialysis for at least 6 consecutive weeks. • That the candidate has a measured or calculated CrCl or GFR less than or equal to 25 mL/min for at least 6 consecutive weeks and this is documented in the

	candidate's medical record every 7 days beginning with the date of the first test with this value. • That the candidate has any combination of #1 and #2 above for six consecutive weeks.
Metabolic disease	An additional diagnosis of at least *one* of the following: • Hyperoxaluria • Atypical HUS from mutations in factor H and possibly factor I • Familial non-neuropathic systemic amyloid • Methylmalonic aciduria

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 that qualifies for priority if the candidate is registered on the kidney waiting list prior to the one-year anniversary of the candidate's liver transplant and at least *one* of the following criteria are 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 as an end stage renal disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting.

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.Bi: Non-function of a Transplanted Kidney.*

Once a candidate qualifies for this classification, the candidate will remain at this classification until the candidate is removed from the kidney waiting list. If a kidney recipient returns to the kidney waiting list, this classification will only be applied if the candidate meets the criteria for this classification after the most recent kidney transplant, unless the candidate qualifies for kidney waiting time reinstatement according to *Policy 3.6.Bi: Non-function of a Transplanted Kidney.* If the candidate qualifies for kidney waiting time reinstatement, the candidate will also qualify for reinstatement of this classification.

8.5.~~H~~I Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%

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

Classification	Candidates that are within the:	And are:	When 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%, 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, 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:	When 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 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

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

8.5.~~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

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

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

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
41	OPO's DSA	Prior liver recipients that meet the medical criteria according to *Policy 8.5.H*, blood type permissible or identical	Any
42	OPO's DSA	Blood type B	A2 or A2B
43	OPO's DSA	All remaining candidates, blood type permissible or identical	Any
44	OPO's region	Blood type B	A2 or A2B
45	OPO's region	All remaining candidates, blood type permissible or identical	Any
46	Nation	Blood type B	A2 or A2B
47	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

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 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
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
29	OPO's region	Blood type B	A2 or A2B
30	OPO's region	All remaining candidates, blood type permissible or identical	Any
31	Nation	Blood type B	A2 or A2B

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
32	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

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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)

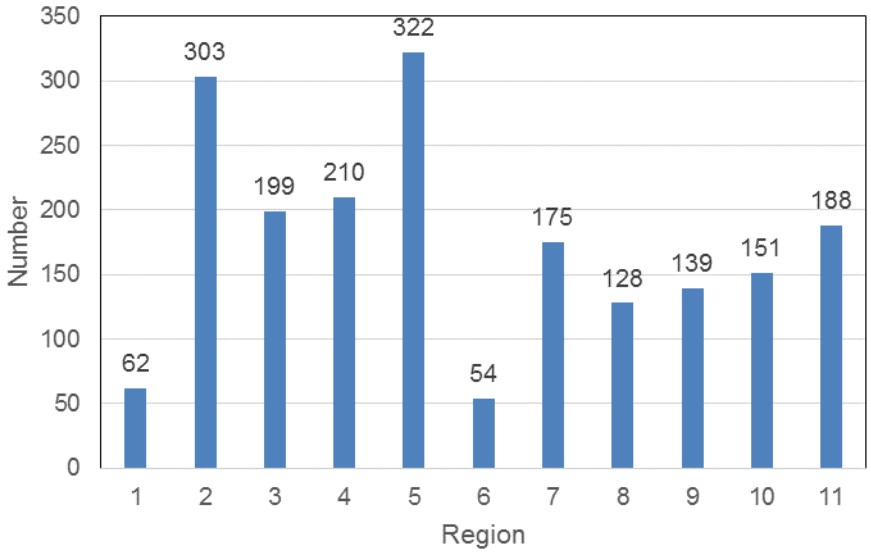

Figure 2. Number of kidney registrations added during 1/1/05-6/30/13 after liver transplants by DSA (N=1,931)

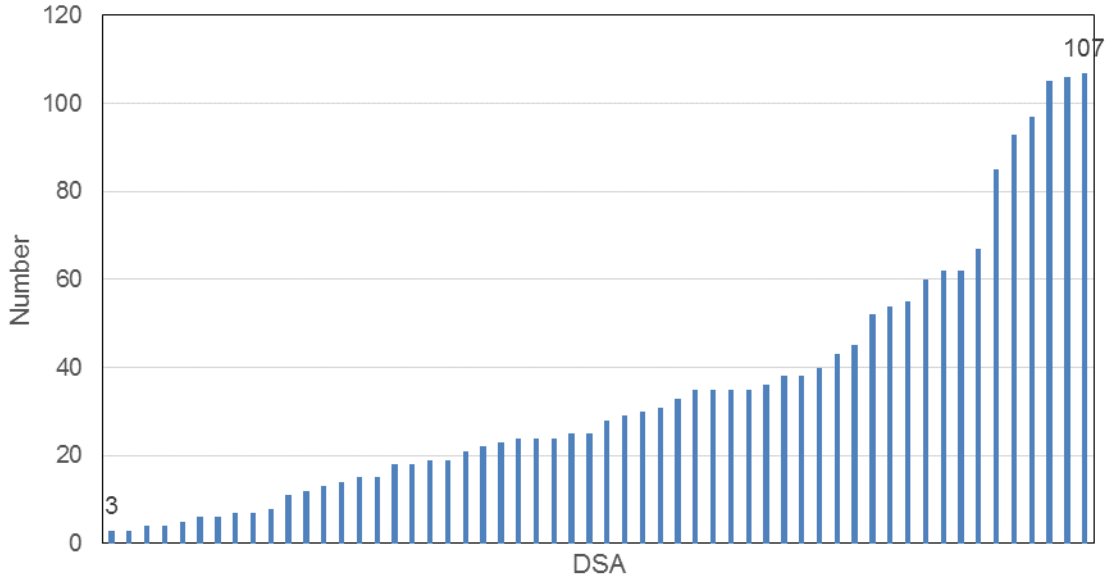

Table 6 summarizes the distribution of times (in months) from previous liver transplants to kidney listings during 1/1/05-6/30/13:

- 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		6									
Yes	112		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)

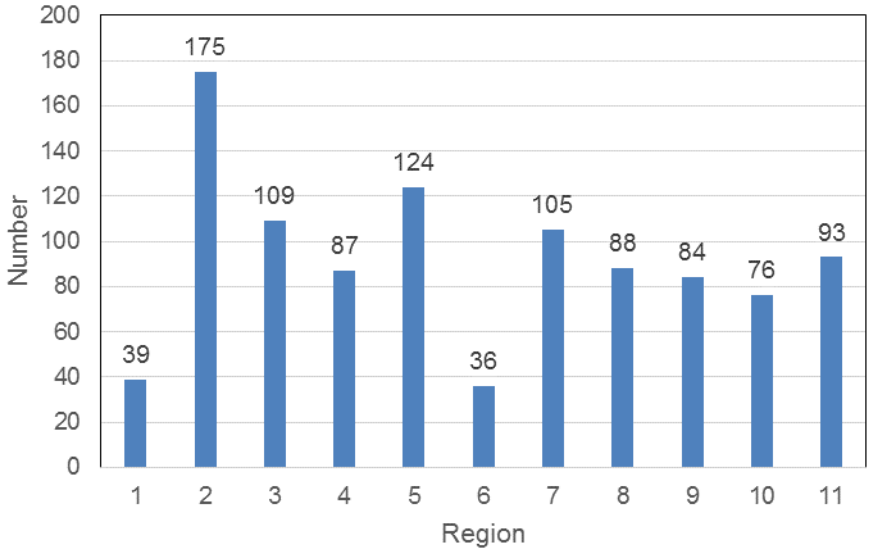

Figure 4. Number of first kidney alone transplants during 1/1/05-6/30/13 after liver transplants by DSA (N=1,016)

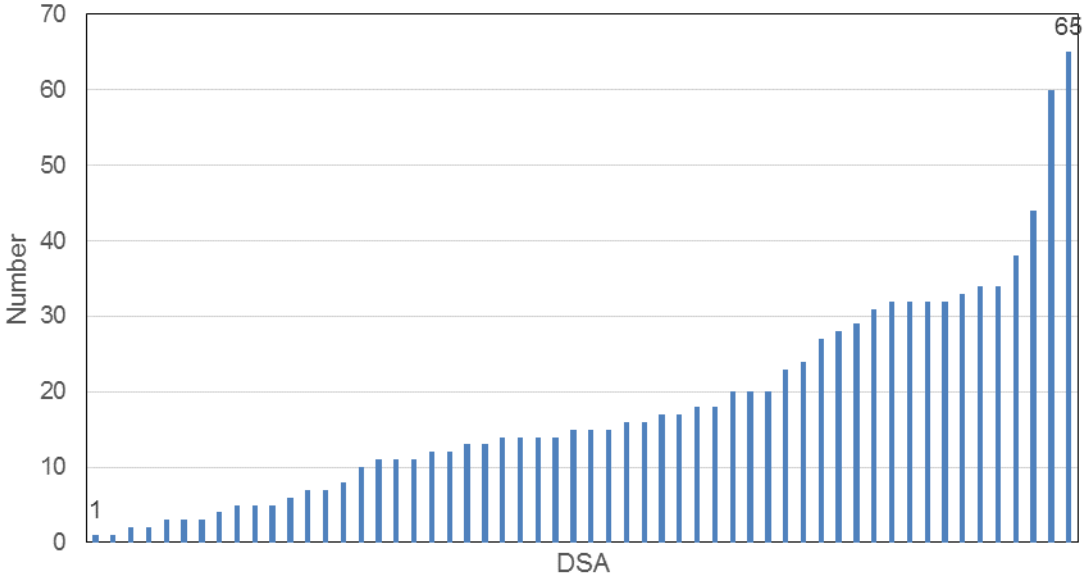

Table 8 summarizes the distribution of times from previous liver transplants to first kidney transplants during 1/1/05-6/30/13:

- 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

		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	%
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
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

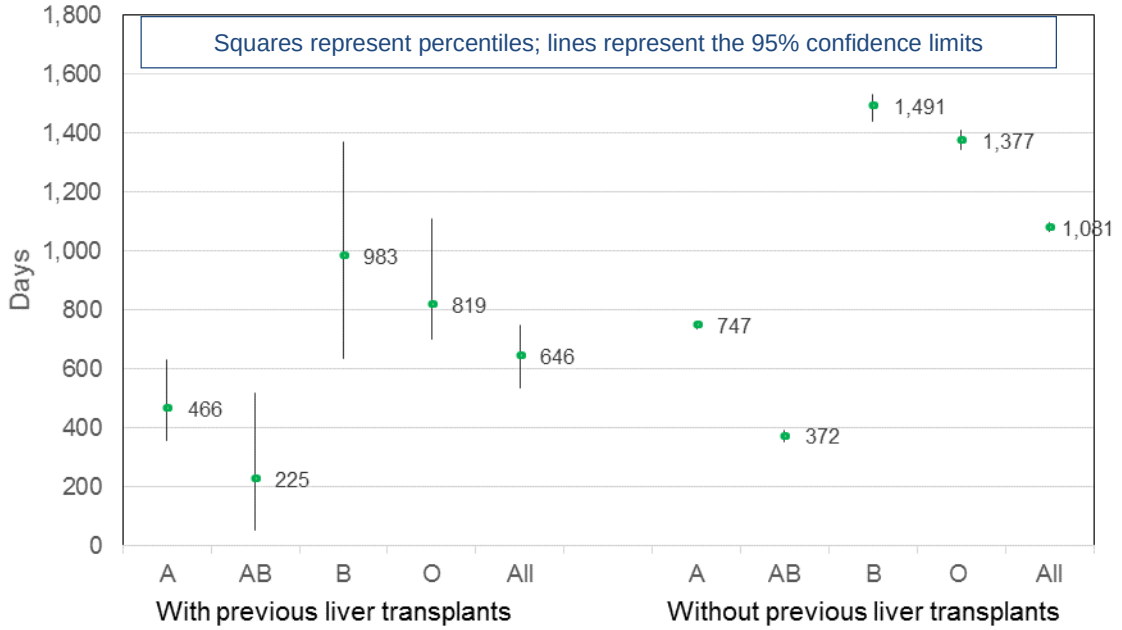

Figure 6. Competing risk method 35th percentiles of times to deceased donor kidney alone transplants for registrations added to the waiting list during 2003-2006 with and without a previous liver transplant

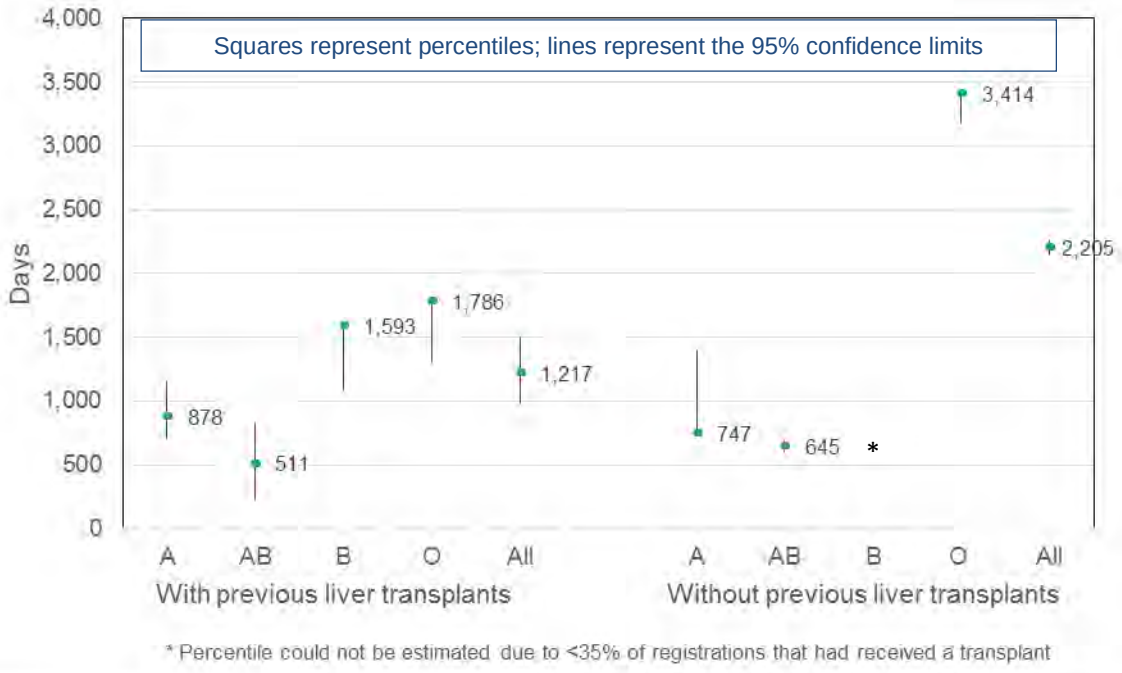

Table 10. Competing risks method percentiles of times to transplants for kidney alone registrations added to the waiting list during 2003-2008 by listing type and ABO blood group

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.

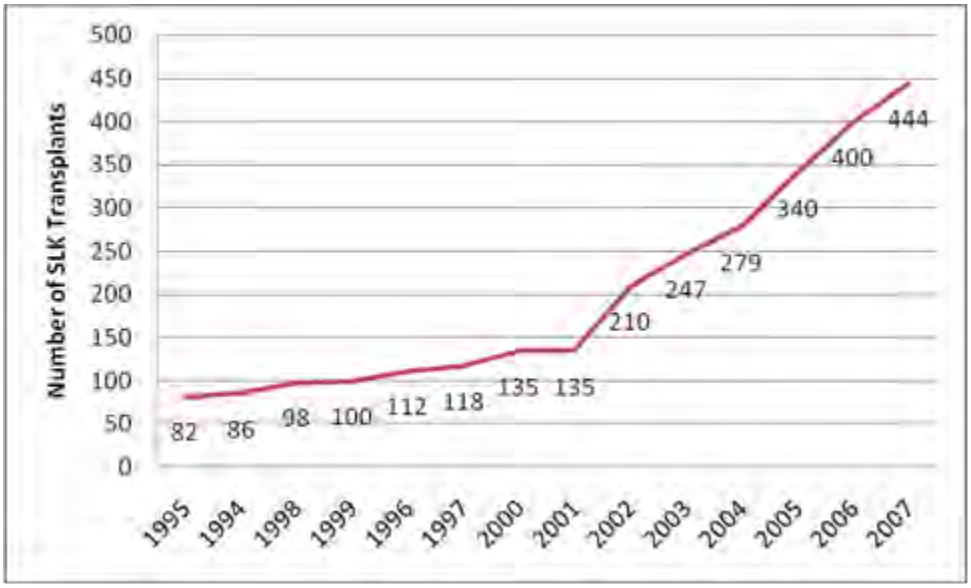
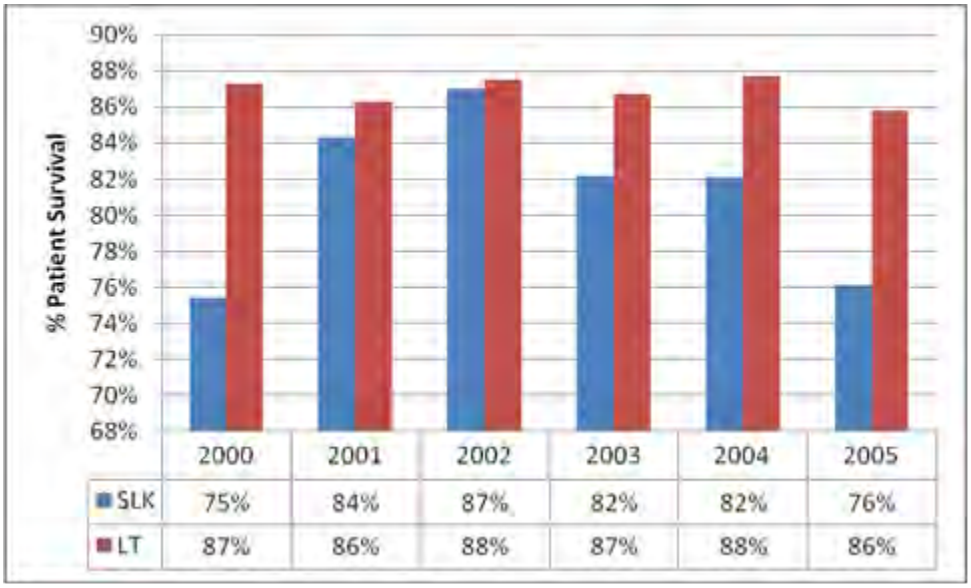


Figure 1: Number of SLK Transplants pre/post MELD implementation in 2002

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]



	2000	2001	2002	2003	2004	2005
SLK	75%	84%	87%	82%	82%	76%
LT	87%	86%	88%	87%	88%	86%

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.

[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 qualify* 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.

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,
January 12, 2015
Report finalized: February 24, 2015

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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

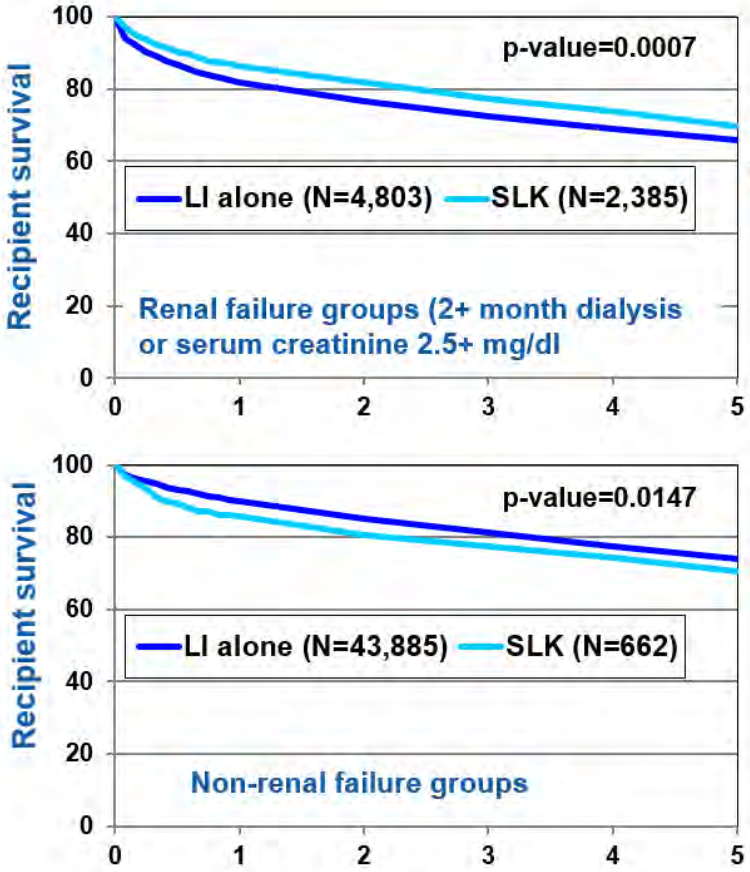
Tables A.1 – A.5 located in Appendix A show waiting list survival, kidney graft survival and recipient survival rates (with median half-lives), as well as donor, recipient and transplant characteristics.

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].

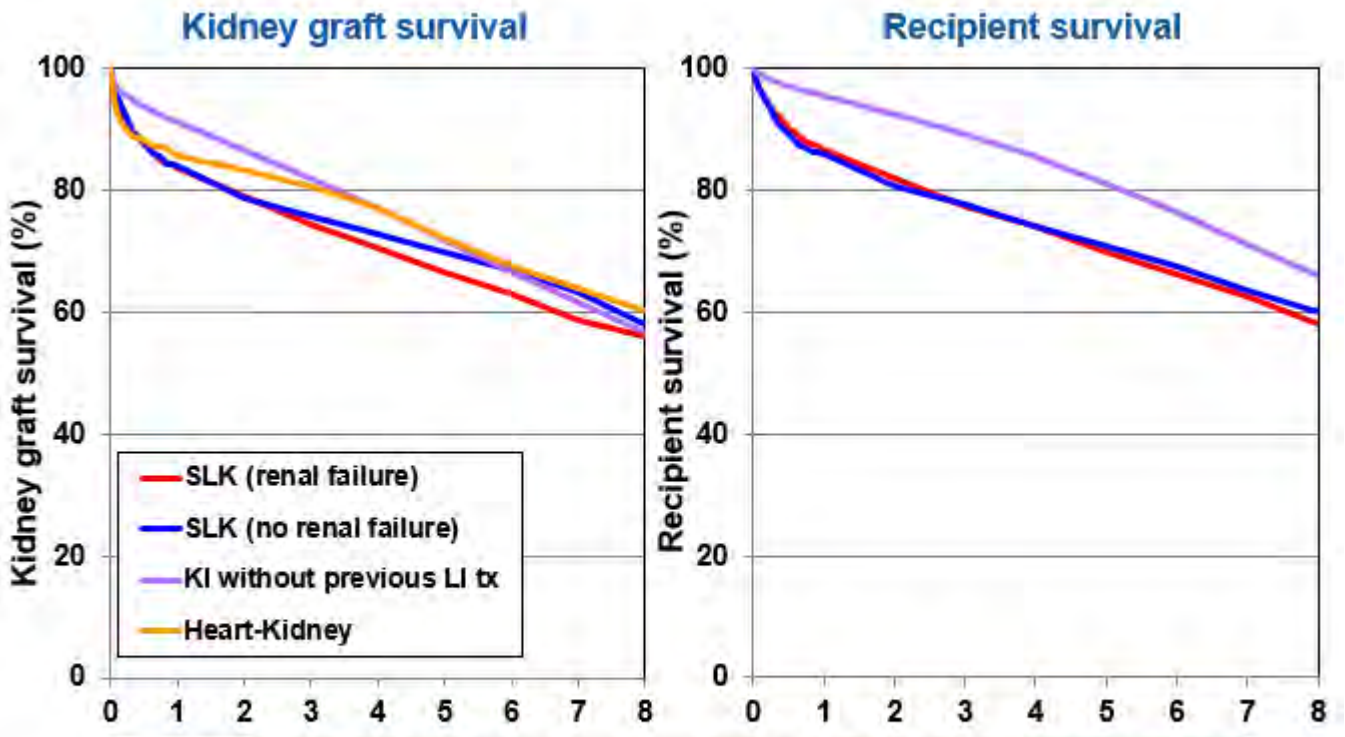
[1] If requested by the committee, a more thorough, multivariable analysis to isolate the effect of receiving a kidney among liver recipients would fall under the purview of the SRTR contractor.
[2] Fong, et al. *Transplantation. 94(4):411-416, Aug 27, 2012*
[3] Wolfe, Robert A., et al. "Comparison of 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.

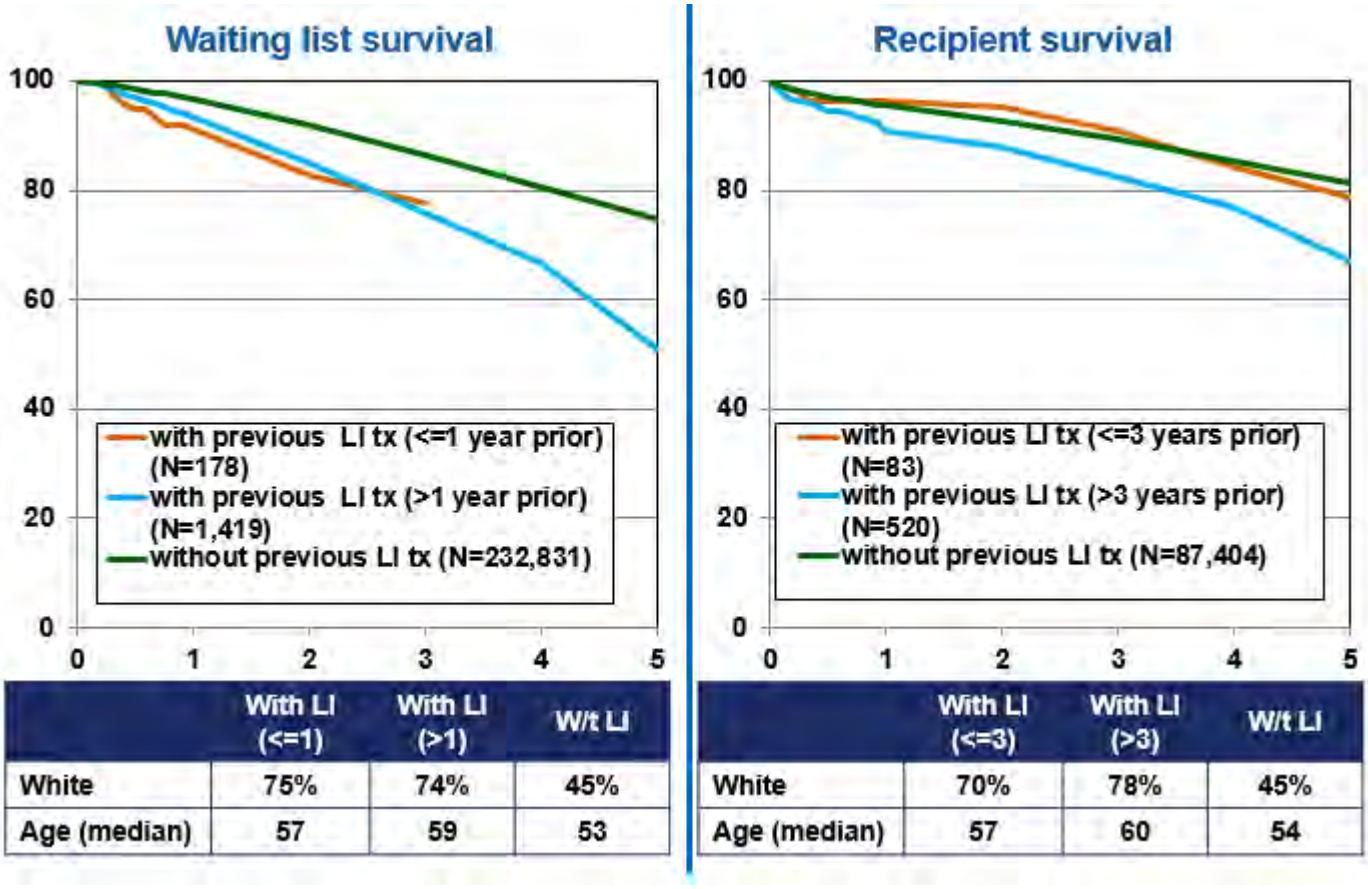
Differences in patient characteristics may have contributed to differences in survival. SLK recipients were more likely to be white compared to kidney alone. All groups had similar median ages.

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