Current Transplantation Reports (2018) 5:130–138
https://doi.org/10.1007/s40472-018-0190-0

OPTN POLICY (K ANDREONI, SECTION EDITOR)

Simultaneous Liver-Kidney Transplantation: Policy Update and the Challenges Ahead

Mark I. Aeder[1]

Published online: 10 April 2018

Abstract

Purpose of the Review Institution of a Simultaneous Liver Kidney (SLK) policy by the OPTN in 2016 represented the culmination of more than a decade of consensus conferences, public comments, and inter-society cooperation. The debates produced a multi-tiered proposal that established medical eligibility criteria for kidney allocation, a requirement for the regional sharing of a kidney to a MELD 35 medical eligible candidate and creation of a safety net for patients receiving a liver-alone transplant with subsequent kidney failure within the first post transplant year.

Recent Interventions The stratifications and alterations represented the first time that eligibility requirements have been instituted for allocating a multi-organ combination that is not tracked by the Scientific Registry of Transplant Recipients (SRTR). The provisions for reporting and follow-up of the allocation alteration have been identified and will be reported at regular intervals to the OPTN for public release. Although there are multiple interventions to limit the kidney utilization to those candidates with true medical necessity, it is unknown how this will impact the overall distribution of the kidneys, especially with the safety net now being offered to candidates that would not have met medical eligibility at the time of their transplant. As SLK comprises over 10% of all liver transplants, the requirement change may be significant and would hopefully result in the more efficient use of kidneys without a negative impact on patient survival. Although utilization would be much better monitored, the outcome measures would still be lacking.

Summary Even with this landmark change, review of the allocation process that presently favors allocating a kidney to a multi-organ transplant before allocation to a kidney-alone recipient is examined, especially as the prioritization affects pediatric candidates. It is hoped that advancements in this area would bring allocation policies into greater alignment with the intentions of the Final Rule legislation.

Keywords Simultaneous liver-kidney transplantation · Multi-organ transplantation · UNOS medical eligibility policy · Kidney allocation · Kidney safety net · Liver-kidney transplant outcomes

Introduction and Background

After more than 10 years of study, public comment, and policy modifications, a national OPTN/UNOS simultaneous liver kidney (SLK) transplantation took effect on August 10, 2017. This followed a national consensus conference, multiple society-sponsored conferences, two distinct policy proposals, and three rounds of public comment. Beyond a simultaneous kidney-pancreas transplant, it represented the first time, for any multi-organ transplant allocation, that a candidate had to satisfy defined medical eligibility criteria before they could receive a simultaneous second organ for which they had not been previously listed. The policy development required the collaborative participation of key OPTN/UNOS Committees with personnel representing the kidney and liver transplantation communities, with ethics, minority affairs, and operation and safety representatives as well as the organ procurement organizations. The new ground afforded by this collaboration will be studied for outcome analysis in the coming years but the project represented the need for multidisciplinary participation in policy development especially as transplant numbers increase, candidate pools expand and therapies evolve.

This article is part of the Topical Collection on *OPTN Policy*

✉ Mark I. Aeder
mark.aeder@uhhospitals.org

[1] Division of Transplantation, Department of Surgery, Case Western Reserve University, University Hospitals Cleveland Medical Center, 11100 Euclid Ave., Cleveland, OH 44106, USA

To better understand the issues defining SLK, a brief historical review is warranted. The OPTN/UNOS policy had noted that any candidate who would be requiring multiple organs must be registered on the heart, lung, or liver match run to have initial eligibility. The policy went on to note, "When multi-organ candidates other than heart-lung candidates are eligible to receive a heart, lung or liver, the second required organ will be allocated to the multi-organ candidate from the same donor if the donor's donor service area (DSA) is the same DSA where the multi-organ candidate is registered." [1]. The policy was written with no mention as to any medical criteria for using a kidney (or any second organ) from the same donor, thus the kidney utilization was variable, dependent on the individual criteria of the transplant programs and without national standardization.

The Model for End-Stage Liver Disease (MELD), originally used as a predictor for 3-month survival for liver disease patients following transjugular intrahepatic portosystemic shunt (TIPS) procedures, [2] was introduced into the national liver allocation policy in 2002 [3, 4]. This created a priority algorithm within each local DSA and by subsequent policy modifications, extension to the region. The MELD score, which has been accepted as a prognostic scoring tool for end-stage liver failure (ESLD) patients, is driven by four crucial laboratory values including creatinine and the need for dialysis. As a result, many of the patients with the highest MELD scores were afforded the increased priority for transplantation due to renal insufficiency or end-stage renal disease (ESRD). The MELD score could be recalculated as the clinical situation and laboratory values changed and a liver transplant candidate with progressive renal insufficiency, especially acute kidney injury (AKI), could rapidly rise up the priority list. The result was that a significant proportion of the higher MELD patients had a component of associated renal disease when the donor liver was offered. As the ordering within the liver allocation list contained a heavily weighted variable favoring the candidate with renal compromise, the result was a rapid rise in the numbers of SLK transplants (UNOS data). The rates of SLK increased from 2.8% of all liver transplants in 2001 (last pre-MELD year) to 4.2% in 2002 and then climbed dramatically in the following years, 7.2% in 2007 and 9.4% of all deceased donor (DD) liver transplants in 2016 [5].

Pre-transplant kidney injury or increased serum creatinine had been identified as predictors of poor outcomes following liver-alone transplant [6, 7]. Renal failure requiring dialysis in the first year following liver transplantation correlates with reduced patient survival [8]. Once the liver was transplanted, a liver transplant alone (LTA) recipient with persistent renal failure and no readily available living donor would have to be listed separately for a kidney, a process that, in many DSAs, would require years of waiting. As a result, many programs had to decide at the time of the original liver offer whether their candidate had renal dysfunction which was unlikely to reverse following LTA transplant and whether simultaneously transplanting a kidney would be beneficial for their recipient's survival. There was wide variation (0–43% of all liver transplants at an individual center) in the last mid-decade as to utilization of SLK versus LTA [9]. There was limited reporting and no consensus regarding which pre-transplant situations were more likely to be benefitted by an SLK resulting in some programs adhering to more selective criteria than others. This resulted in the lack of a meaningful national database to define which candidates were more likely to benefit from the SLK transplants [10].

During the initial years after the introduction of the MELD allocation, there were a few studies that looked at the benefits of the SLK versus the LTA in those patients with underlying renal dysfunction [11, 12]. An additional issue was that there was no good way to predict which of the AKI ESLD patients would recover their kidney function following a LTA [13, 14]. Although some candidates were self-selected due to availability and urgency, only 2.4% of the LTA patients on dialysis at the time of transplant were listed for a kidney transplant in their first year [9]. Further, there was evidence that the short- and long-term patient survival was better in the transplant recipients after LTA compared to that of SLK, although this was affected by factoring in candidate pre-selection [9, 11, 15, 16]. The presence of an elevated serum creatinine (> 2.0 mg/dL) in a non-dialysis candidate treated with SLK and LTA yielded similar 3-year survival outcomes. [10] The assessment of each SLK recipient for the recovery of the native renal function with defined testing, such as renal scans, was limited at best, leaving the community with incomplete data from which to make an assessment.

Since there were no nationally accepted medical criteria regarding the use of the kidney in the ESLD candidate and no good data as to potential recovery of the native kidneys, a few studies tried to outline specific factors [17–20]. One feature that appeared to have an impact was the time length of pre-liver transplant renal dysfunction on post transplant recovery, with a difference noted at > 12 weeks. About a quarter of these patients did not recover function. So, even with the presence of the longer time of pre-transplant renal dysfunction, most of the LTA recipients did not progress to listing for a kidney transplant. At the shorter times (< 12 weeks), 95% of the patients had regained renal function with an eGFR > 20 mL/min. A large single-center study of patients without CKD but with > 2 weeks of renal replacement therapy or GFR of ≤ 25 mL/min found that in those receiving a LTA, 87% recovered renal function within 1 month [21]. Another single-center study found no predictive factors in the AKI population that reliably predicted the need for a kidney after a LTA [22]. As noted, if the need for a kidney transplant following the LTA arose, there was no conclusive data to show the deleterious effect on survival of the staged operations to that of the SLK transplant event [11].

A multi-society consensus conference in 2008 was convened to address the then recognized concerning rise in SLK transplants [9]. The conference recommended guidelines for SLK transplantation dependent on combination of factors including ESRD stage, creatinine, duration of dialysis in AKI, kidney biopsy, and high portal vein pressures. This was formulated into an OPTN policy proposal that, after a round of public comment, was never advanced. Despite calls for established medical guidelines by the conference attendees and the community at large, SLK transplants were still performed without defined criteria [23, 24]. Interestingly, even with such a large percentage of liver transplant recipients receiving a simultaneous kidney, there was no consistent reporting of the preoperative candidate data nor follow-up regarding risk stratification, return of native kidney function, or even patient outcomes. The Scientific Registry of Transplant Recipients (SRTR) has never had a mandate to record SLK recipients as a separate program outcomes measure (PSR), this despite requests from members of the transplant community. The end result is that in 2016, nearly 10% of the liver transplant recipients who received simultaneous kidneys, over 1400 donated organs, did not have their outcomes centrally recorded and analyzed.

By 2014, 6 years after the original national consensus conference, there was still no reliable way to project which liver recipients with renal insufficiency or short-term renal failure would regain renal function and require a simultaneous kidney, and to understand the impact the simultaneous kidney had on the recipient outcome. The collaboration between the professionals representing the six committees noted above was convened under the direction of the OPTN/UNOS Kidney Committee and charged with developing national medical criteria that would standardize when the allocation of the kidney with the liver would be permitted. Additionally, the policy would define whether there would be mandatory regional sharing of a kidney for medically eligible SLK candidates. Finally, the policy would establish defined criteria for candidates who received a LTA to have a "safety net" should they have persistent renal failure in the first year after transplant [25•]. After more than a year of intensive committee preparatory work, followed by a subsequent year incorporating the salient points of two rounds of public comments, along with the input and support of the Joint Societies, the OPTN Board of Directors approved the SLK policy in June 2016.

Current Policy

The SLK policy passed and implemented is essentially three separate but interdependent policy components. The first part defines a medical eligibility component that must be satisfied before a kidney can be allocated with a liver to any candidate over 18 years. The medical eligibility requirement is further subdivided into three distinct aspects: chronic renal failure, acute renal failure, and underlying disease processes that may be associated with long-term kidney failure following transplantation. The second main component of the policy alleviated the regional kidney sharing difficulties associated with the MELD Share 35 rule. Previously, there was a "payback" that afforded the donor DSA when a kidney was shipped with the liver; however, the payback system was eliminated with the introduction of the new Kidney Allocation System (KAS) in December 2014. The kidney would now be required to be offered and shared with the liver to all medically eligible regional MELD Share 35 recipients. Finally, there was a safety net component inserted for the first postoperative year for all liver-alone recipients who had medically documented persistent renal failure.

Medical Eligibility Criteria—Table 1

To understand the basis of candidate medical eligibility, it is important to appreciate the background details of all three components. The greatest discussion, by far, was centered on the diagnosis of chronic kidney disease (CKD).

The liver candidate must first have documented CKD according to NKF criteria [26] which requires a measured or calculated glomerular filtration rate (GFR) of ≤ 60 mL/min for greater than 90 consecutive days. The transplant center has to then report and document that the candidate has at least one of the following: (1) is on regularly administered dialysis (had ESRD), or, (2) at the time of registration, has a GFR or creatinine clearance (CrCl) of ≤ 30 mL/min, or, (3) on a date after registration, the candidate's CrCl or GFR was ≤ 30 mL/min. The latter two of these criteria generated much discussion as the historically accepted kidney function value to accrue wait time listing points for kidney transplantation is ≤ 20 mL/min. Reviewing the 2008 OPTN/UNOS criteria, which never made it past the single round of public comment, it was evident that a more readily acceptable medical criterion of renal failure in ESLD patients was required. At that time, the proposed GFR was < 25 mL/min, and it required direct or MDRD6 measurement. The single-measurement criteria, in the absence of a previously established diagnosis of CKD, were not well received in the renal community. The two components which were eventually incorporated into the current policy were based on multiple studies which showed that the calculated or measured CrCl or GFR in patients with liver disease was generally elevated, resulting in a value higher than the true function [14, 27, 28], and the NKF defined 90-day history of CRF, indicating that there was already underlying renal disease.

The second potential pathway to determine medical eligibility was to specifically define the presence of sustained kidney injury, or AKI, and establish the requirements for

Table 1 Qualifications for medical eligibility

Transplant nephrologist (name recorded in UNet) must confirm and document one of the following diagnoses:	Transplant program must document in the patient's medical record and report supporting evidence to the OPTN:
Chronic kidney disease:	At least one of the following:
A measured or calculated GFR ≤ 60 mL/min for 90 consecutive days	a. Candidate has initiated regularly administered dialysis in an inpatient or outpatient setting, or
	b. At time of registration on the kidney list, the most recent measured or calculated CrCl or GFR is ≤ 30 mL/min, or
	c. On a date after registration on the kidney list, measured or calculated CrCl or GFR is ≤ 30 mL/min
Sustained kidney injury	Must be present in the most recent prior 6-week period and contain at least one of the following alone or in combination:
	a. Dialysis at least once every 7 days
	b. Measured or calculated CrCl or GFR ≤ 25 mL/min obtained at least once every 7 days
	Failure to have confirmatory documentation of either at least once every 7 days over prior 6 weeks negates kidney eligibility.
Metabolic disease	a. Hyperoxaluria
	b. Atypical hemolytic uremic syndrome
	c. Familial non-neuropathic amyloidosis
	d. Methylmalonic aciduria

documentation. As noted above, it was well established through multiple reports that many candidates with acute renal failure following a liver transplant regained native kidney function and never required renal long-term renal replacement therapy [21]. While it was well known that renal failure following liver transplant was associated with higher morbidity and mortality, the rates of native recovery were significant, exceeding 90% in some reports [18]. The OPTN reported that only 9% of all liver recipients (those with and without pre-transplant compromise) were listed for a kidney transplant within their first post transplant year [10]. The time range to be used to define sustained kidney injury was debated, with proponents advocating times from 4 to 12 weeks and, in the end, it was agreed that it should encompass 6 consecutive weeks. Concomitant within this timeframe was the requirement that renal failure (dialysis or CrCl/GFR ≤ 25 mL/min) has to be documented at least once every 7 days and the eligibility would be effective at the completion of 6 consecutive weeks. Medical eligibility had to be maintained by the continuous reporting until the time of transplant offer and would be lost if one of the criteria was not met or documented in the timeframe.

With the consensus reached on these first two components for medical eligibility, the least controversial component was the third, based on specific metabolic diseases. These underlying diseases, in the presence of CRF, were associated with irreversible poor long-term renal function. Although the disease categories were extended from the original 2008 proposal, the list was easily accepted.

Medical Eligibility Certification

The medical eligibility certification is a two-step process, the first part being the confirmation of renal disease by a transplant nephrologist and the reporting of supporting documentation by the transplant program.

OPO Responsibilities—Table 2

The organ procurement organization (OPO) is now required to assess the eligibility for a simultaneous kidney in DonorNet before allocating the kidney. For local allocation, the OPO would determine if the liver candidate met the medical eligibility criteria to receive a simultaneous kidney and, if so, would allocate the kidney regardless of the candidate's MELD score. If the liver is not allocated locally, then before allocation to the local kidney-alone list, the OPO must offer the kidney with the liver to any regional candidate with a MELD ≥ 35 and who meets the medical eligibility criteria. If the regionally shared liver candidate meets the medical eligibility criteria but their MELD is < 35, it is permissible, but not required, for the DSA to offer the kidney with the liver. It is also permissible for the OPO to offer the kidney with the liver nationally for a medically eligible liver candidate, generally

Table 2 OPO allocation of kidney with liver. OPO is required to assure potential recipient is medically eligible for kidney. Decision to accept kidney with liver rests with transplant program

Adult candidate does not meet medical eligibility for kidney with liver	No kidney allocated with the liver
Local liver candidate meets medical eligibility for kidney	OPO is required to offer kidney with the liver regardless of MELD
Regional Share 35/status 1 candidate meets medical criteria for kidney	OPO is required to offer kidney with the liver as MELD is ≥ 35 or status 1
Regional share candidate with MELD < 35 meets medical criteria for kidney	OPO is not required but allowed to offer kidney with liver
National candidate meets medical eligibility criteria for kidney	OPO is not required but allowed to offer kidney with liver
Pediatric liver candidate—local, regional, or national	OPO is required to offer kidney with liver regardless of PELD

after the local list has been exhausted. In all cases, pediatric liver recipients may receive a priority for a kidney with the liver regardless of medical criteria.

Safety Net—Table 3

By tightening access to the simultaneous kidney allocation through the medical eligibility criteria, especially for the patients with sustained AKI, a post transplant remedy was needed. Furthermore, there were patients who could not wait the 6 weeks for the liver replacement therapy due to the severity of their failure, and would only be eligible for a LTA. It was also speculated that another subgroup of CRF patients would progress to ESRD with the stresses of the surgery and other procedures, as well as the nephrotoxic effects of some of the immunotherapy. A safety net policy was developed which would provide the opportunity for post transplant prioritization within the first year. After much discussion and review of the results of previous studies regarding the timing of renal recovery, criteria for safety net eligibility were established to be 60–365 days following the LTA. Similar to candidates awaiting a kidney-alone transplant, the liver postoperative recipient would have to demonstrate the lack of native kidney recovery by maintenance dialysis or a measured or calculated CrCl or GFR of ≤ 20 mL/. The candidate would then have a prioritization for a kidney for 30 days or if not transplanted, would have to meet criteria every 30 days for at least 90 consecutive days after which the priority would remain intact until the patient is removed by the transplant center. A final aspect of the safety net is that there would be no prioritization for these patients for the sequence A kidneys, those with a KDPI ≤ 20. For KDPI 21 to 85%, these patients would be in a category below highly sensitized kidney alone candidates, 0-ABDR mismatches, prior living donors, local pediatrics (for 20 to 35 KDPI), but above local DSA kidney only adults.

Outcomes

As with any new allocation policy, it is imperative to monitor the impact of the modification and be ready to intervene should there be significant untoward ramifications. As there was not optimal data going into this policy iteration due to lack of risk stratification and required follow-up of the prior SLK recipients, the data collected following the policy implementation will be vital to direct future modifications in eligibility, both for SLK and the safety net.

The policy data and results are scheduled to be formally evaluated at three time points following implementation; 6 months, 1 year, and 2 years. The metrics will be compared to a time period prior to implementation as a baseline and assess the policy's impact following the August 2017 implementation date. Although the Kidney Committee requested the following metrics, others may be subsequently requested for further examination. The established metrics are as follows:

Table 3 Qualification for the safety net: prioritization for liver recipients on the kidney waiting list (Policy 8.5.G)

Inclusion criteria	Timeframe	Qualification for kidney priority
Liver transplant alone	Day 60–365 post-liver transplant	Either one of the below, alone or in combination: (1) On dialysis (2) Calculated or measured creatinine clearance ≤ 20 mL/min Documented at least once every 30 days with reset at each documentation. Once documented for 90 consecutive days, qualification remains effective until removed by transplant program.

Eligibility would be for kidneys with KDPI > 20 and priority established for local DSA allocation after highly sensitized, pediatric, and prior living donor candidates

1. Number of overall SLK transplants by:
    a. Geographic distribution (local, regional, national)
    b. Pediatric vs. adult
2. Distribution by eligibility diagnosis: (with more granular assessment of renal function)
    a. CKD with calculated or measured GFR or CrCl ≤ 60 mL/min with:
        i. Dialysis
        ii. GFR/CrCl ≤ 30 mL/min
    b. Sustained acute kidney injury
    c. Metabolic disease
3. Candidates registering on the kidney list in their first year post-liver transplant:
    a. By "safety net" criteria
    b. By other criteria
4. Number of kidney transplants allocated to "safety net" candidates

A more global assessment of the policy will evaluate the following:

1. Effect of the medical eligibility criteria on the number of SLK transplants
2. Whether the number of SLK transplants plus the number of "safety net" registrants exceeds the total SLK transplants prior to policy implementation
3. Actual number of qualified candidates registered for a kidney in the first post transplant year and correlation with eligibility criteria pre-liver transplant
4. Effect on the number of living donor renal transplants to liver recipients within their first post-transplant year
5. Waiting time and wait-list mortality changes for kidney candidates
6. Waiting time and wait list mortality changes for liver recipients in their first post-transplant year

The Kidney Committee will lead the data review based on the data reports. As there was a cooperative multi-committee development of the policy, significant modifications would, in all likelihood, be a collaborative effort. Since granular historic data in many of the nuanced areas was not readily available, nor was any modeling, the projections were extrapolated from the available reported metrics. As such, a significant deviation from these projections, although not expected, would necessitate a more rapid committee response.

There are also other factors that can potentially impact the long-term work of this policy development. Prior to the implementation of KAS, if a kidney was shared outside the local DSA with a liver, a payback kidney was expected in return. With the elimination of the payback system in KAS, there was a local reluctance to share the kidney with the mandated MELD 35 regional liver share. A concession made by the Kidney Committee was to have the kidney follow the liver on a regional basis if the candidate was medically eligible. This requirement did not apply to any national sharing of the livers. The OPTN Board of Directors recently passed a new liver allocation policy, championed by the OPTN Liver Committee outlining mandatory liver sharing. Although it is not clear at this time, it may markedly alter the baseline at which livers are mandated to be shared by adding a 150 mile geographic parameter that ignores the current regional borders and by lowering the MELD threshold for non-local sharing. The current SLK policy is clear on the parameters for the mandatory sharing of a kidney outside the local DSA, 1. and adheres to the regional boundaries for the MELD ≥ 35 candidates. The Kidney Committee has not proposed or advocated for any modifications based on the new liver sharing parameters.

Discussion

In summary, the recently introduced SLK policy addresses some of the overriding concerns of the transplant community. By incorporating a medical necessity for allocation of the kidney with the liver, it established a precedent that each organ must have a nationally recognized set of medical criteria that justifies its use for a particular recipient. It will also allow for the critical examination of parameters associated with the disease process of renal failure, such as patients with ESLD. Which native kidneys will recover with a functioning liver following transplantation has never been reliably defined, and which recipients that require both organs simultaneously is still unknown. The institution of a safety net for those patients that never regain native renal function may be a worthy component to avoid the overuse of SLK, even in medically eligible candidates. Although this currently applies to all liver recipients with sustained renal failure 2–12 months following transplant, the historic data seemed to indicate that these numbers should be relatively low. If so, we should see a significant reduction in the liver failure patients needing a kidney allograft. As with any new allocation policy with uncertain outcomes, there is an underlying concern that the overall use of kidneys under this policy may actually increase [29••].

The monitoring parameters described above are well defined to answer these questions. They will note any early trends that may impact organ availability and jeopardize patient safety. Although this was a policy 10 years in the making during which time over a hundred dedicated individuals tried and finally succeeded in creating what was thought to be as ideal a policy as possible, there is still the potential for unintended consequences. Aggressive monitoring by the OPTN through the Kidney Committee with public disclosure and presentation is the optimal way to examine the nuances of

the policy, especially to modify early inconsistencies and adjust the parameters.

While this is a model for the simultaneous distribution of the kidney with a liver, it is only one aspect of the organ allocation system's ever evolving discrepancies as the ability to expand the envelope of services increases. SLK transplantation comprised less than 42.8 % of the record 1651 multi-organ (M-O) transplants involving a kidney in 2016. The precedent of establishing medical eligibility criteria is an important step that needs to be adapted for all organ combinations. 2. Even after removing the simultaneous pancreas kidneys (SPK) transplants, the SLK transplants were 82.8% of the remainder. This still avoids the basic issue as to why the M-O transplants receive priority for the kidneys ahead of the particularly vulnerable populations of kidney-alone candidates.

The use of kidneys in the M-O recipient requires further consideration within the perspective of the OPTN Final Rule (NOTA) [30]. The Final Rule which established and provides governance for our considerations in transplantation is that all organs be allocated based on sound medical judgment and according to standardized criteria, two key elements within liver-kidney allocation that were addressed with the passage of SLK policy. It is difficult to realize that the transplant community, a progressive and patient-oriented collaboration, took well over a decade to finally agree on this implementation. More troubling is that there are other organ combinations, including heart-kidney, that still have no governance as to kidney medical eligibility.

Of greater concern to many in the nephrology community is the current OPTN policy of prioritizing the allocation of kidneys to M-O candidates before those patients awaiting a kidney-alone transplant. There are currently over 100,000 candidates awaiting a kidney in the USA and it is well known that many will die before the opportunity for transplant arrives for them. The OPTN implemented the revised KAS in 2014 to address issues of fairness and equity and at the 1-year post-KAS data review, there was marked success noted in both these goals [31]. The primary issue limiting full compliance with the Final Rule is not that there is failure to fairly assure kidney-alone allocation but a legacy policy within the OPTN that prioritizes the M-O candidates ahead of all the kidney-alone recipients.

These policies to favor the M-O recipients will become more of an issue as M-O transplants continue to increase. In 2016, 11.7% of all kidneys retrieved were allocated to the M-O patients even before there was any allocation to the kidney-alone candidates. This is coupled with the fact that many M-O recipients have poorer 1-year and long-term survival than the kidney-alone recipients, again in contrast to the Final Rule's dictum to achieve the best use of the organs and to avoid futile transplants [32, 33]. As OPTN policy directs that a DSA must allocate a kidney to a M-O candidate before moving to the kidney list, those DSAs with very active M-O programs may disadvantage their kidney-alone patients by increasing their waiting times and the possibility that some candidates will never receive a transplant. Kidney recipients in some DSAs are, in effect, geographically disadvantaged in their ability to receive a kidney, again contrary to the Final Rule's comment that a candidate's geographic location should not alone dictate their access to transplantation.

Analysis of M-O kidney transplants has shown that the overwhelming majority of these donor organs are considered the most optimal for long-term post-transplant survival [5, 34]. The 2015 distribution data found that over 50% of these kidneys directed to multi-organ recipients came from sequence A (KDPI 0-20) and sequence B (KDPI 21–35) donors, comprising almost 20% of all these most ideal donor organs. The prioritization of the sequence A kidneys under KAS was designated to promote organ longevity, that those kidneys expected to have the longest potential life spans would be allocated to the candidates with the greatest post-transplant survival (EPTS). The fact that so many of these most ideal organs are being used in patients that do not share the same estimated post-transplant survival probabilities is inconsistent with the goals of KAS.

A fourth point regarding the current allocation to the M-O candidates before the kidney-alone patients is the marked effect on the most vulnerable segments of our kidney waiting list. KAS prioritized the children (0–18) to receive access to the better available kidneys, those having a KDPI of 0–35%. Additionally, every sequence in KAS primarily prioritizes the very highly sensitized 99 and 100% PRA candidates on a regional or national basis creating an equitable access to the optimally matched kidney. These patients may otherwise never receive a compatible kidney offer. Finally, the prior living donors who have donated an organ and now need a kidney may possibly have to wait longer with their renal failure as the M-O candidates are prioritized at the front of the line.

A further point is that, with the exception of kidney-pancreas recipients, none of the other M-O recipients receiving a kidney have their outcomes tracked by the SRTR. This is a continued deficiency in the system that has resulted in thousands of transplant recipients and at least twice as many transplanted organs having no data as to the risk adjustment and benefits of the M-O transplants. The current system has permitted the participating transplant programs the freedom to use these organs in their candidates without concern for their own program-specific outcome measures (PSRs). Thus, there could be the loss of two organs in a patient without the accountability that a program would face if the two organs were transplanted at two separate times.

As with any new OPTN/UNOS policy, the data will be carefully collected, analyzed, and disseminated. There will be early reviews to assess whether the primary goals of the policy are being met as well as to rapidly identify any unintended consequences. In the absence of a significant allocation disruption, the OPTN/UNOS Kidney Committee does not plan to offer any

modification to the current policy, including altering the mandatory sharing outside of the historic regional boundaries. Any policy alterations would have to be data driven and have the necessary modeling evaluated to show benefit to all candidates.

Summary

Establishing defined medical criteria for allocating a kidney with a liver provides uniform practice for SLK. The parameters in the policy were determined by the best analysis of available data and agreement of six separate UNOS Committees. The close follow-up and frequent reporting over the first 2 years of implementation will assess the impact of the kidney utilization and guide any future modifications of the criteria. While this new policy is expected to have a relatively low impact on the total numbers of kidneys transplanted into ESLD patients compared to the total kidney pool, there will be a reduction in the total allocation of the most optimal donated kidneys, those with a KDPI ≤ 35, to the SLK candidates currently not meeting medical eligibility criteria. This should allow more of these ideal kidneys to pass to the kidney-alone list to be prioritized according to the recently implemented KAS.

A major task ahead for the transplant community is to implement a policy for all kidney allocation that recognizes the needs of all potential kidney recipients, kidney-alone and M-O, and based on the Final Rule's principles of utility, equity, and fairness. By stratifying allocation prioritization to the best use of each organ with protection for the children and prior living donors, while also enhancing survival opportunities for the medically eligible M-O recipients, we can achieve fairness and allocation equity.

Compliance with Ethical Standards

Conflict of Interest The author declares that he has no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

References

Papers of particular interest, published recently, have been highlighted as:
- • Of importance
- •• Of major importance

1. OPTN Policy 5.10.C: optn.transplant.hrsa.org.
2. Malinchoc M, Kamath P, Gordon F, et al. A model to predict poor survival in patients undergoing transjugular intrahepatic portosystemic shunts. Hepatology. 2000;31(4):864–71.
3. Freeman RB Jr, Wiesner RH, Harper A, et al. The new liver allocation system: moving towards evidence-based transplantation policy. Liver Transpl. 2002;8:851–8.
4. Wiesner R, Edwards E, Freeman R, Harper A, Kim R, Kamath P, et al. Model for end-stage liver disease (MELD) and allocation of donor livers. Gastroenterology. 2003;124:91–6.
5. Formica RN. Simultaneous liver kidney transplantation. Curr Opin Nephrol Hypertens. 2016;25:577–82.
6. Nair S, Verma S, Thuluvath PJ. Pretransplant renal function predicts survival in patients undergoing orthotopic liver transplantation. Hepatology. 2002;35:1179–85.
7. Davis CL, Feng S, Sung R, Wong F, Goodrich NP, Melton LB, et al. Simultaneous liver-kidney transplantation: evaluation to decision making. Am J Transplant. 2007;7:1702–9.
8. Fong TL, Khemichian S, Shah T, Hutchinson IV, Chou YW. Combined liver kidney transplant is preferable to liver transplant alone for cirrhotic patients with renal failure. Transplantation. 2012;94:411–6.
9. Eason JD, Gonwa TA, Davis CL, Sung RS, Gerber D, Bloom RD. Proceedings of consensus conference on simultaneous liver kidney transplantation (SLK). Am J Transprant. 2008;8:2243–51.
10. Gonwa TA, McBride MA, Anderson K, Mai ML, Wadei H, Ahsan N. Continued influence of preoperative renal function on outcome of orthotopic liver transplant (OLTX) in the US: where will MELD lead us? Am J Transplant. 2006;6:2651–9.
11. Simpson N, Chou YW, Cicciarelli JC, Selby RR, Fonf TL. Comparison of renal graft outcomes in combined liver-kidney transplantation versus subsequent kidney transplantation in liver transplant recipients: analysis of UNOS database. Transplantation. 2006;82:1298–303.
12. Schmitt TM, Kumer SC, Al-Osaimi A, et al. Combined liver-kidney transplantation in patients with renal failure outcomes in the MELD era. Eur Soc Organ Transplant. 2009;22:876–83.
13. Israni AK, Xiong H, Liu J, Salkowski N, Trotter JF, Snyder JJ, et al. Predicting end-stage renal disease after liver transplant. Am J Transplant. 2013;13:1782–92.
14. Ruebner R, Goldberg D, Abt PL, Bahirwani R, Levine M, Sawinski D, et al. Risk of end-stage renal disease among liver transplant recipients with pretransplant renal dysfunction. Am J Transplant. 2012;12:2958–65.
15. Locke JL, Warren DS, Singer AL, et al. Declining outcomes in simultaneous liver-kidney transplantation in the MELD era: ineffective use of renal allografts. Transplantation. 2008;85:935–42.
16. Sharma P, Shu X, Schaubel DE, Sung RS, Magee JC. Propensity score based survival benefit of simultaneous liver-kidney transplant over liver transplant alone for recipients with pretransplant renal dysfunction. Liver Transpl. 2016;22:71–9.
17. Campbell MS, Kotyar DS, Brensinger CM, et al. Renal function after orthotopic liver transplantation is predicted by duration of pretransplantation creatinine elevation. Liver Transpl. 2005;11(9):1022–5.
18. Bahirwani R, Campbell MS, Siropaides T, Markmann J, Olthoff K, Shaked A, et al. Transplantation: impact of pretransplant renal insufficiency. Lever Transpl. 2008;14:665–71.
19. Hmoud B, Yong-Fang K, Wiesner RH, Singal AK. Outcomes of liver transplantation alone after listing for simultaneous kidney: comparison to simultaneous liver kidney transplantation. Transplantation. 2015;99:823–8.
20. Sharma P, Goodrich NP, Zhang M, Guidinger MK, Schaubel DE, Merion RM. Short-term pretransplant renal replacement therapy and renal nonrecovery after liver transplantation alone. Clin J Am Soc Nephrol. 2013;8(7):1135–42.
21. Brennan TV, Lunsford KE, Vagefi PA, Bostrom A, Ma M, Feng S. Renal outcomes of simultaneous liver-kidney transplantation compared to liver transplant alone for candidates with renal dysfunction. Clin Transpl. 2015 Jan;29(1):34–43.

22. Sanchez EQ, Gonwa TA, Levy MF, Goldstein RM, Mai ML, Hays SR, et al. Preoperative and perioperative predictors of the need for renal replacement therapy after orthotopic liver transplantation. Transplantation. 2004;78:1048–54.
23. Levitsky J, Baker T, Ahya SN, Levin ML, Friedewald J, Gallon L, et al. Outcomes and native kidney recovery following simultaneous liver-kidney transplantation. Am J Transplant. 2012;12:2949–57.
24. Nadim MK, Sung RS, Davis CL, Andreoni KA, Biggins SW, Danovitch GM, et al. Simultaneous liver-kidney transplantation summit: current state and future directions. Am J Transplant. 2012;12:2901–8.
25.• Formica RN, Aeder M, Boyle G, Kucheryavaya A, Stewart D, Hirose R, et al. Simultaneous liver-kidney allocation policy: proposal to optimize appropriate utilization of scarce resources. Am J Transplant. 2016;16:758–66. **This paper describes the background and discussions of the initial policy proposal that was circulated in 2015. The final policy was based on this framework.**
26. Levey AS, Coresh J, Balk E, et al. National Kidney Foundation practice guidelines for chronic kidney disease: evaluation, classification and stratification. Ann Intrern Med. 2003;139:605.
27. Beben T, Rifkin DE. GFR estimating equations and liver disease. Adv Chronic Kidney Dis. 2015;22:337–42.
28. Sherman DS, Fish DN, Teitebaum I. Assessing renal function in cirrhotic patients: problems and pitfalls. Am J Kidney Dis. 2003;41:269–78.
29.•• Asch WS, Bia MJ. New organ allocation system for combined liver-kidney transplants and the availability of kidneys for transplant to patients with stage 4–5 CKD. Clin J Am Soc Nephrol. 2017;12:848–52. **Examines the potential implications of the new SLK policy. As there was no modeling data available from SRTR or within the UNOS database, the authors raise the issue of potential increases in SLK due to more medically eligible candidates or the increased utilization of the safety net.**
30. Final Rule National Organ Transplant Act (NOTA) of 1984 (42 U.S.C. 273, et seq).
31. Stewart DE, Kucheryavaya AY, Klassen DK, Turgeon NA Formica RN, Aeder MI. Changes in deceased donor kidney transplantation one year after KAS implementation. Am J Transplant. 2016;16:1834–47.
32. Choudhury RA, Reese PP, Goldberg DS, Bloom RD, Sawinski DL, Abt PL. A paired analysis of multi-organ transplantation: Implications for allograft survival. Transplantation. 2017;101(2):368–76.
33. Lunsford KE, Bodzin AS, Markovic D, Zarrinpar A, Kaldas FM, Gritsch HA, et al. Avoiding futility in simultaneous liver-kidney transplantation: analysis of 331 consecutive patients listed for dual organ replacement. Ann Surg. 2017;265(5):1016–24.
34. Aeder M, Stewart D, Kucheryavaya A. UNOS data: unpublished.