

Briefing Paper

Improving Allocation of En Bloc Kidneys

OPTN/UNOS Kidney Transplantation Committee

*Prepared by: Kimberly Uccellini, MS, MPH
UNOS Policy Department*

Contents

| | |
|--|----|
| Executive Summary | 1 |
| What problem will this proposal solve? | 2 |
| Why should you support this proposal? | 4 |
| How was this proposal developed? | 5 |
| How well does this proposal address the problem statement? | 11 |
| Was this proposal changed in response to public comment? | 15 |
| Which populations are impacted by this proposal? | 19 |
| How does this proposal impact the OPTN Strategic Plan? | 20 |
| How will the OPTN implement this proposal? | 21 |
| How will members implement this proposal? | 21 |
| Transplant Hospitals | 21 |
| OPOs | 22 |
| Will this proposal require members to submit additional data? | 22 |
| How will members be evaluated for compliance with this proposal? | 22 |
| How will the sponsoring Committee evaluate whether this proposal was successful post implementation? | 22 |
| Policy or Bylaws Language | 24 |

Improving Allocation of En Bloc Kidneys

| | |
|-------------------------------|--|
| <i>Affected Policies:</i> | <i>Policy 2.11.A: Required Information for Deceased Kidney Donors, Policy 8.6 Double Kidney Allocation</i> |
| <i>Sponsoring Committee:</i> | <i>Kidney Transplantation Committee</i> |
| <i>Public Comment Period:</i> | <i>January 23, 2017 – March 24, 2017</i> |
| <i>BOD Meeting Date:</i> | <i>June 5-6, 2017</i> |

Executive Summary

Kidney transplantation is the preferred treatment for end stage renal disease (ESRD), yet demand for kidneys far exceeds supply. One strategy to increase the donor pool is to use kidneys from small, pediatric donors. However, programs may be reluctant to transplant single kidneys from small pediatric donors due to technical challenges, which may result in inferior outcomes.

To mitigate the complications associated with transplanting kidneys from small pediatric donors singly, both kidneys, including the vena cava and aorta, can be transplanted en bloc into a single recipient. However, there are currently several challenges to allocating en bloc kidneys:

- There is currently no OPTN policy regarding allocation of en bloc kidneys
- The KDPI programmed into DonorNet[®] doesn't consider how kidneys will be used (en bloc or single) or acknowledge the improved function of en bloc kidneys, which could screen medically suitable candidates off the match run. In addition, there are other programming limitations that make en bloc kidney allocation a challenge

The proposed policy resolves these problems by providing explicit direction to organ procurement organizations (OPOs) on when to allocate en bloc kidneys. The policy includes donor criteria regarding the type of kidneys that can be allocated en bloc and mandates that programs must indicate in DonorNet that they accept en bloc kidneys, thus expediting placement of en bloc kidneys to programs that will transplant them. In addition, the Kidney Transplantation Committee (Committee) proposes masking the KDPI score for en bloc kidney offers to prevent potentially eligible candidates from being screened off the match run for kidneys from high KDPI donors.

This proposal aligns with three OPTN strategic goals. First, it should increase the number of transplants by utilizing kidneys previously left unrecovered or discarded. Second, it should improve outcomes for waitlisted kidney candidates and transplant recipients as studies indicate when kidneys from a small pediatric donor are transplanted into a recipient en bloc versus singly, they confer comparable to superior outcomes. In addition, accepting kidneys en bloc may shorten a candidate's time on the waitlist, conferring not only a survival advantage, but also several other additional benefits. Finally, this proposal should increase efficiency in management of the OPTN as OPOs should no longer have to contact the Organ Center for guidance or assistance in allocating en bloc kidneys.

What problem will this proposal solve?

Kidney transplantation is the preferred treatment for end stage renal disease (ESRD), yet demand for kidneys far exceeds supply. At the conclusion of 2016, there were 98,962 candidates waiting for a kidney transplant, but only 12,245 deceased donor kidney transplants occurred.^{1,2} One strategy to increase the donor pool is to utilize kidneys from small pediatric donors (≤ 20 kg). However, programs may be reluctant to transplant kidneys from very small donors singly due to technical challenges which may result in inferior outcomes.^{3,4,5,6,7,8,9,10}

To mitigate the complications associated with transplanting kidneys from small pediatric donors singly, both kidneys, including the vena cava and aorta, can be transplanted en bloc into a single recipient. However, there are currently several challenges to allocating en bloc kidneys:

- There is currently no OPTN policy regarding allocation of en bloc kidneys
- The KDPI programmed into DonorNet doesn't consider how kidneys will be used (en bloc or single) or acknowledge the improved function of en bloc kidneys, which could screen medically suitable candidates off the match run. In addition, there are other programming limitations that make en bloc kidney allocation a challenge

Absence of an OPTN en bloc allocation policy

OPTN policy has never included provisions on how an OPO should allocate kidneys en bloc, or which kidneys qualify for en bloc allocation. *Policy 8.6. Double Kidney Allocation* does not cover en bloc kidneys, because although they fit the general definition of double kidneys, in that en bloc describes utilization of two kidneys from the same donor, clinically, en bloc kidneys do not meet the criteria in that policy. For example, en bloc kidney donors would not meet the age threshold or history of longstanding diabetes mellitus or hypertension currently outlined in *Policy 8.6*. Less than two percent of all kidney transplants are en bloc kidney transplants.¹¹ However, frequent requests to define an allocation algorithm for en bloc kidneys prompted the Committee to develop a policy.

KDPI score is overestimated for en bloc kidneys and other programming challenges

When the OPTN developed the Kidney Donor Risk Index model (KDRI) for deceased donor kidneys, the authors identified HLA match, cold ischemic time, en bloc, and dual kidney coefficients in addition to the 10 variables that were ultimately included in the Kidney Donor Profile Index (KDPI) score.¹² When the OPTN implemented KDPI into DonorNet in 2012, it omitted the aforementioned variables without recalculating the model because at the time of the match run, it may not be known whether the kidneys will be offered en bloc or as singles. The match run needs KDPI to determine which allocation sequence to use and how screening will be done. DonorNet currently does not require OPOs to indicate in real time

¹ "Data – OPTN," *United Network for Organ Sharing*, <https://optn.transplant.hrsa.gov/data/>. Accessed December 14, 2016.

² "View Data Reports - National Data -," *United Network for Organ Sharing*, <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#>. Accessed December 14, 2016.

³ Pelletier, S. J., M. K. Guidinger, R. M. Merion, M. J. Englesbe, R. A. Wolfe, J. C. Magee, and H. W. Sollinger. "Recovery and Utilization of Deceased Donor Kidneys from Small Pediatric Donors." *American Journal of Transplantation* 6, no. 7 (2006): 1646-652. doi:10.1111/j.1600-6143.2006.01353.x.

⁴ Sureshkumar, Kalathil K., Chandana S. Reddy, Dai D. Nghiem, Stephen E. Sandroni, and Barbara J. Carpenter. "Superiority of Pediatric En Bloc Renal Allografts over Living Donor Kidneys: A Long-term Functional Study." *Transplantation* 82, no. 3 (2006): 348-53. doi:10.1097/01.tp.0000228872.89572.d3.

⁵ Mohanka, Ravi, Amit Basu, Ron Shapiro, and Liise K. Kayler. "Single Versus En Bloc Kidney Transplantation from Pediatric Donors Less Than or Equal to 15 kg." *Transplantation* 86, no. 2 (2008): 264-68. doi:10.1097/tp.0b013e318177894e.

⁶ Kayler, L. K., J. Magliocco, R. D. Kim, R. Howard, and J. D. Schold. "Single Kidney Transplantation from Young Pediatric Donors in the United States." *American Journal of Transplantation* 9, no. 12 (2009): 2745-751. doi:10.1111/j.1600-6143.2009.02809.x.

⁷ Beltrán, S., J. Kanter, A. Plaza, T. Pastor, E. Gavela, A. Ávila, A. Sancho, J. Crespo, and L. Pallardó. "One-Year Follow-up of En Bloc Renal Transplants from Pediatric Donors in Adult Recipients." *Transplantation Proceedings* 42, no. 8 (2010): 2841-844. doi:10.1016/j.transproceed.2010.07.070.

⁸ Sharma, Amit, Robert A. Fisher, Adrian H. Cotterell, Anne L. King, Daniel G. Maluf, and Marc P. Posner. "En Bloc Kidney Transplantation from Pediatric Donors: Comparable Outcomes with Living Donor Kidney Transplantation." *Transplantation* 92, no. 5 (2011): 564-69. doi:10.1097/tp.0b013e3182279107.

⁹ Maluf, D. G., R. J. Carrico, J. D. Rosendale, R. V. Perez, and S. Feng. "Optimizing Recovery, Utilization and Transplantation Outcomes for Kidneys from Small, ≤ 20 kg, Pediatric Donors." *American Journal of Transplantation* 13, no. 10 (2013): 2703-712. doi:10.1111/ajt.12410.

¹⁰ Al-Shraideh, Yousef, Umar Farooq, Hany El-Hennawy, Alan C. Farney, Amudha Palanisamy, Jeffrey Rogers, Giuseppe Orlando, Muhammad Khan, Amber Reeves-Daniel, William Doares, Scott Kaczowski, Michael D. Gautreaux, Samy S. Iskandar, Gloria Hairston, Elizabeth Brim, Margaret Mangus, and Robert J. Stratta. "Single vs dual (en bloc) kidney transplants from donors ≤ 5 years of age: A single center experience." *World Journal of Transplantation* 6, no. 1 (March 24, 2016): 239-48. doi:10.5500/wjt.v6.i1.239.

¹¹ Stewart, Darren. *Double and En Bloc Kidney Data*. OPTN/UNOS Descriptive Data Analyses. Prepared for Double and En Bloc Kidney Workgroup Conference Call, February 19, 2016.

¹² Rao, Panduranga S., Douglas E. Schaubel, Mary K. Guidinger, Kenneth A. Andreoni, Robert A. Wolfe, Robert M. Merion, Friedrich K. Port, and Randall S. Sung. "A Comprehensive Risk Quantification Score for Deceased Donor Kidneys: The Kidney Donor Risk Index." *Transplantation* 88, no. 2 (July 27, 2009): 231-36. doi:10.1097/tp.0b013e3181ac620b.

when allocation has shifted from single to en bloc. After KDPI was implemented in DonorNet in March 2012, several members asked about whether and how KDPI accounts for en bloc use of kidneys.

Table 1 illustrates the vast majority (84 percent) of en bloc transplants between January 2010 and December 2015 had KDPI scores (retrospectively calculated) between 51-90 percent.¹³ Among kidneys recovered for transplantation, kidneys with KDPI above 50 percent are at increased risk of discard, and kidneys with KDPI above 85 percent have particularly high discard rates, exceeding 50 percent.¹⁴ Further, these scores are not reflective of true graft failure risk for kidneys transplanted en bloc. Since the implemented KDPI score assumes each kidney will be transplanted singly, it does not account for the survival advantage associated with en bloc usage.¹⁵ Furthermore, recent studies have found that en bloc kidneys have short-, medium- and long-term graft survival outcomes comparable to an ideal deceased or living donor.^{16, 17, 18, 19, 20, 21, 22, 23, 24} Therefore, candidate populations who might benefit from en bloc kidney transplant may be screened off the match run because DonorNet inflates the KDPI, sometimes to a value over 85 percent, by assuming single-kidney transplantation.^{25, 26} Many candidates on the waiting list have a maximum acceptable KDPI value of 85 percent, and policy requires transplant programs to obtain additional consent from candidates to receive kidneys with a KDPI value over 85 percent.²⁷

¹³ Stewart, Darren. *Analysis of Dual (double) and En Bloc Kidney Transplants, 2010-2015*. OPTN/UNOS Descriptive Data Analyses. Prepared for Double and En Bloc Kidney Workgroup Conference Call, April 15, 2016.

¹⁴ Stewart, *Double and En Bloc Kidney Data*.

¹⁵ Rao et al, 232.

¹⁶ Pelletier et al, 1649-1651.

¹⁷ Sureshkumar et al, 351-352.

¹⁸ Mohanka et al, 266-267.

¹⁹ Kayler et al, 2745-2749.

²⁰ Beltrán et al, 2842-2843.

²¹ Sharma et al, 565-568.

²² Maluf et al, 2705-2708, 2710-2711.

²³ Al-Shraideh et al, 243-245.

²⁴ Preczewski, L., K. Howes, N. Lovenette, A. Needham, and B. Gallay. "UNOS KDPI Score Is Significantly Overestimated for Pediatric En-Bloc Kidneys." *American Journal of Transplantation* 15 (2015).

²⁵ Al-Shraideh, 245.

²⁶ Preczewski et al.

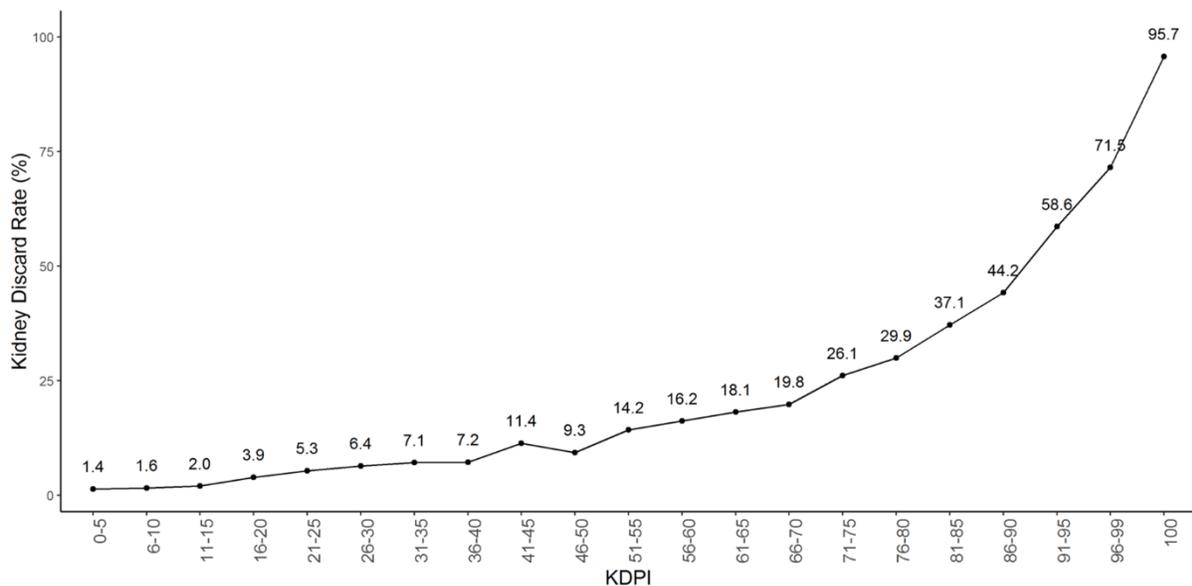
²⁷ Stewart, D., A. Kucheryavaya, G. Boyle, R. Metzger, M. Aeder, R. Formica. "Emerging Strategies to Screen Kidney Offers Based on the Kidney Donor Profile Index (KDPI)." *American Journal of Transplantation* 15 (2015).

Table 1: En bloc Kidney Transplants by KDPI, January 1, 2010 – December 31, 2015

| | N | % |
|-------------------|-------|------|
| All | 1,264 | 100% |
| KDPI Unknown | 1 | 0% |
| 0% - 25% | 6 | 0% |
| 26% - 50% | 49 | 4% |
| 51% - 60% | 162 | 13% |
| 61% - 70% | 269 | 21% |
| 71% - 80% | 337 | 27% |
| 81% - 90% | 292 | 23% |
| 91% - 100% | 148 | 12% |

Source: Stewart, "Double and En Bloc Kidney Data," 2016.

Figure 1: Discard Rates among Recovered Kidneys, by KDPI, December 4, 2014 – May 31, 2016



Source: Stewart, "Double and En Bloc Kidney Data," 2016.

Why should you support this proposal?

The proposed policy resolves the problems outlined above by providing explicit direction to OPOs on how to allocate en bloc kidneys. The policy includes criteria regarding which kidneys must be allocated en bloc and mandates that programs must indicate in WaitlistSM that they are willing to accept en bloc kidneys. The proposed policy will facilitate placement of en bloc kidneys to programs that will utilize them, thereby potentially increasing the use of kidneys previously discarded or unrecovered due to the real or perceived technical difficulties reluctance to transplant of transplanting small donor kidneys singly. In addition, the Committee proposes masking the KDPI score for en bloc kidney offers, which will prevent potentially eligible candidates from being screened off the match run for kidneys that convey a high KDPI that assumes single-kidney transplantation.

Transplanting two kidneys into a single recipient versus transplanting two kidneys into two recipients may negatively impact the total number of transplants. To mitigate the risk of potentially reducing the number of transplants, the policy includes a provision that allows the transplanting surgeon, based on medical judgment, to split the en bloc kidneys so they may be transplanted into two recipients.

Finally, studies have shown that en bloc kidney transplants offer comparable to superior graft survival and outcomes as compared to single kidney transplants from donors of the same weight.^{28,29,30,31,32,33,34,35}

How was this proposal developed?

Policy is currently silent about when en bloc transplantation is permissible and what type of kidneys are suitable. OPOs have asked UNOS which donor characteristics should be considered and at what point can they allocate kidneys en bloc. The implemented KDPI programmed into DonorNet currently overestimates KDPI scores for en bloc kidneys, subsequently impacting which candidates are screened off the match run. A workgroup comprised of members from the Kidney Transplantation, OPO, Pediatric Transplantation, Transplant Coordinator and Transplant Administrator Committees, in addition to several external members representing programs who transplant a high volume of en bloc kidneys, collaborated to develop this policy proposal.

The workgroup considered several solutions. They quickly dismissed developing an educational program or guidance document because, although those options would provide some direction to OPOs regarding when to allocate kidneys en bloc, these interventions would not address the lack of a policy, nor would they address the current challenges with DonorNet functionality in areas such as KDPI exclusions. It is difficult to assess the impact of a guidance document or an education program on behavior, as the implementation may not be consistent nor enforceable. Similarly, a DonorNet programming enhancement in the absence of a policy would not inform OPOs how to allocate.

The workgroup discussed whether policy is warranted for the small number of kidneys transplanted en bloc. In a comparison of the one year pre- and one year post-revision of the kidney allocation system (KAS), en bloc kidney transplants remained stable at approximately at just under 2 percent of all transplants.³⁶ En bloc kidney transplantation is a complex procedure and many programs may lack technical expertise; of the 264 kidney transplant programs in the United States, 89 programs performed at least one en bloc kidney transplants during the year pre-and year post-KAS.³⁷ Of those 89 programs, 10 percent performed 10 or more en bloc kidney transplants, 26 percent performed between 5 and 9 en bloc kidney transplants, and 64 percent performed between 1 and 4 en bloc kidney transplants.³⁸ However, the workgroup felt that creation of an en bloc policy was appropriate and consistent with the OPTN strategic plan emphasis on increasing the number of transplants.³⁹ The OPTN's Deceased Donor Potential Study recently estimated a gap that may be as high as about 800 unrealized potential donors per year within the 5 and under age range.⁴⁰

Once the workgroup determined it would propose an en bloc policy, it considered whether a single policy could effectively inform how to allocate both en bloc and double kidneys, as both entail transplanting two kidneys from a single donor into a single recipient. The workgroup felt that because the donor populations were distinctly different, there should be two separate policies developed by two different workgroups.

²⁸ Pelletier et al, 1649-1651.

²⁹ Sureshkumar et al, 351-352.

³⁰ Mohanka et al, 266-267.

³¹ Kayler et al, 2745-2749.

³² Beltrán et al, 2842-2843.

³³ Sharma et al, 565-568.

³⁴ Maluf et al, 2705-2708, 2710-2711.

³⁵ Preczewski et al.

³⁶ Stewart, *Double and En Bloc Kidney Data*.

³⁷ "US Hospitals with Kidney Transplant Centers." Scientific Registry of Transplant Recipients.

<http://www.srtr.org/csr/current/Centers/TransplantCenters.aspx?organcode=KI>. Accessed December 14, 2016.

³⁸ Stewart, Darren. *Dual and en bloc volume by center pre- and post- KAS*. OPTN/UNOS Descriptive Data Analyses. Prepared for Kidney Committee leadership in preparation for the April 15, 2015 Double and En Bloc Kidney Workgroup Conference Call, sent via email March 15, 2016.

³⁹ Klassen, D. K., L. B. Edwards, D. E. Stewart, A. K. Glazier, J. P. Orlowski, and C. L. Berg. "The OPTN Deceased Donor Potential Study: Implications for Policy and Practice." *American Journal of Transplantation* 16, no. 6 (2016): 1707-714. doi:10.1111/ajt.13731.

⁴⁰ Ibid.

The workgroup determined the overarching principles in developing the en bloc allocation policy are to:

1. Develop criteria targeting kidneys at risk of being unrecovered or discarded
2. Avoid decreasing the number of transplants
3. Facilitate placement of en bloc kidneys to programs who will use them
4. Create a policy that will accommodate, rather than change, current transplant program behavior

Development of en bloc kidney criteria

The workgroup began with identifying donor characteristics readily available prior to organ recovery to determine what criteria should be included in en bloc kidney allocation. There are currently no universally agreed upon donor characteristics to help programs determine which kidneys to transplant singly versus en bloc. Based on an initial literature review, the workgroup debated the following donor characteristics:

- Height
- Age
- Weight
- Height and weight in combination

It also considered KDPI, anatomy (kidney size) and donor type (donation after circulatory death (DCD) donor vs. brain dead (BD) donor). The workgroup eliminated donor height as a criterion, as clinicians do not tend to consider donor height in evaluation of kidney offers. Likewise, it dismissed age as a criterion, as donor weight and anatomy were deemed to be more critical characteristics in the evaluation process. There was consensus that donor type would not necessarily influence a center's decision whether or not to use kidneys en bloc versus singly. The OPO members of the workgroup favored criteria that were readily available pre-recovery, so OPOs would not have to rush to allocate after a visual inspection of kidney size in the operating room. The group felt strongly that donor weight was a critical factor programs consider when evaluating whether to use kidneys from small pediatric donors singly or en bloc.^{41, 42, 43, 44} Furthermore, several studies report that donor weight is a much more sensitive indicator of pediatric kidney graft survival than donor age.^{45, 46, 47}

Although there was consensus among the workgroup to include weight as a criterion, there was debate on what the weight range or threshold should be. The workgroup agreed that mandating allocation of kidneys from donors less than or equal to 5 kg en bloc should not be controversial, as that would not change current practice. Likewise, it felt comfortable expanding that mandate to donors between 5 to 10 kg, as a majority of those kidneys are currently transplanted en bloc. It acknowledged that mandating allocation of kidneys from donors less than 10 kg would have an impact in increasing utilization of kidneys at highest risk of discard or being left unrecovered. Studies confirm this recommendation.^{48, 49, 50}

Next, the workgroup debated whether the policy should extend to kidneys from donors between 10 to 20 kg. Some workgroup members felt that because en bloc transplants confer favorable outcomes, and approximately half of transplants from donors 10 to 15 kg were already performed en bloc, the weight threshold should be raised to 15 kg. This weight threshold aligns with protocols already in place at some

⁴¹ Pelletier, 1647.

⁴² Maluf, 2704, 2708-2709.

⁴³ Sureshkumar, K. K., A. A. Patel, S. Arora, and R. J. Marcus. "When Is It Reasonable to Split Pediatric En Bloc Kidneys for Transplantation Into Two Adults?" *Transplantation Proceedings* 42, no. 9 (2010): 3521-523. doi:10.1016/j.transproceed.2010.08.038.

⁴⁴ Al-Shraideh, 245.

⁴⁵ Kayler, 2750.

⁴⁶ Kayler, L. K., J. Magliocca, S. Fujita, R. D. Kim, I. Zendejas, A. W. Hemming, R. Howard, and J. D. Schold. "Recovery Factors Affecting Utilization of Small Pediatric Donor Kidneys." *American Journal of Transplantation* 9, no. 1 (2009): 210-16.

⁴⁷ Maluf, 2708.

⁴⁸ Pelletier, 1647-1648, 1651.

⁴⁹ Al-Shraideh, 245.

⁵⁰ Stewart, *Double and En Bloc Kidney Data*.

of the higher-volume en bloc transplant programs.⁵¹ Others felt this was too liberal and the threshold should be scaled back to 10 kg. Ultimately, workgroup members compromised that for donors less than 15 kg, OPOs *must* allocate kidneys en bloc, but requested feedback from the community on whether the community supports this weight threshold. Public comment predominantly favored this weight proposed threshold, although some advocated for a higher or lower threshold. The workgroup and Committee debated raising it to accommodate current practice in regions who transplant kidneys en bloc from donors greater than or equal to 15 kg. Ultimately, the Committee voted to increase the weight threshold (further details regarding this decision can be found in the “**Was this proposal changed in response to public comment?**” section below). As the workgroup proposes mandating en bloc allocation from this donor group, they felt strongly that they needed to include language permitting surgeons, based on their medical judgment, to split en bloc kidneys if they felt they could transplant into two recipients (see *Balancing utilization and outcomes* below).

The workgroup initially discussed keeping allocation of kidneys from donors greater than or equal to 15 kg unchanged, allocating as singles by KDPI first through one of the allocation sequences in *Policy 8.5.H Kidney Allocation Classifications and Rankings*, before offering both kidneys to a single candidate, as is current practice.⁵² An early draft of proposed policy language presented to the workgroup applied some of the language from current *Policy 8.6 Double Kidney Allocation* to these donors:

Kidneys from deceased donors greater than or equal to 15 kg must be offered individually through one of the allocation sequences in *Policy 8.5: Kidney Allocation Classifications and Rankings* before offering both kidneys to a single candidate...

Some workgroup members did not support this integration, and felt that the en bloc policy should include another weight stratification for donors between 15 and 20 kg. The workgroup wanted to balance utilization of single kidneys from small pediatric donors with the positive outcomes en bloc kidney transplants confer, and thus opted not to mandate these kidneys be allocated en bloc, but allowed the option for OPOs to allocate kidneys from donors in this weight range en bloc or as single kidneys. The workgroup debated whether to cap the donor weight in policy at 20 kg, but a member from a high-volume en bloc kidney transplant center suggested raising the weight to 25 kg to accommodate unique circumstances.⁵³ Less than half of kidney transplants from donors in this weight range are done en bloc, as programs may be more comfortable transplanting these kidneys singly; the number of en bloc transplants decreased as donor weight increased (**Figure 3**). Although less than 5 percent of transplants from donors 21 to 25 kg are performed en bloc, the workgroup voted to include the higher weight threshold for optional en bloc allocation.⁵⁴

Some workgroup members, however, raised concerns about unnecessarily complicating the policy with the inclusion of an optional single or en bloc allocation pathway.^{55,56} As is the challenge currently, the proposed policy language does not explicitly provide direction to OPOs on when, if after attempting to allocate kidneys from donors in this weight range as singles, it could switch to allocating those kidneys en bloc (or vice versa). These members thought excluding the 15 to 25 kg weight range would make for a simplified policy and would not negatively impact allocation of single pediatric kidneys given that surgeons will still have the option to split them upon clinical inspection. Based on public comment feedback, the Committee removed the option to allocate kidneys singly versus en bloc for 15 kg to 25 kg donors in the proposed policy but replaced it with options to allocate kidneys from donors greater than or equal to 20 kg (see **Was this proposal changed in response to public comment?** below).

⁵¹ Al-Shraideh, 245.

⁵² *Meeting Minutes*. En Bloc Kidney Workgroup. OPTN/UNOS Kidney Transplantation Committee. September 16, 2016.

⁵³ *Ibid*.

⁵⁴ Stewart, *Double and En Bloc Kidney Data*.

⁵⁵ En Bloc Kidney Workgroup Meeting Minutes, September 16, 2016.

⁵⁶ Turgeon, Nicole. "En Bloc Update." E-mail to UNOS staff. December 22, 2016. Primary thread.

Balancing utilization and outcomes

The workgroup acknowledged that transplanting kidneys en bloc into a single recipient may be deemed inefficient utilization of a scarce resource, and that transplanting two kidneys into a single recipient with the goal of improved outcomes comes at the expense of transplanting those kidneys into two separate recipients. There was strong consensus among the workgroup that it would reject a policy that would prevent a surgeon from splitting en bloc kidneys if the surgeon felt they were eligible to be transplanted into two recipients. Further, the workgroup agreed it was not a function of the OPTN to dictate clinical decision-making, but that a check needed to be included to prevent transplant programs from accepting and splitting en bloc kidney offers and transplanting both kidneys into two of their own patients. Therefore, the workgroup included a stipulation that if the transplanting surgeon determines, based on medical judgment, that the en bloc kidneys should be split and transplanted into two recipients, the receiving program must do one of the following:

- Transplant one of the kidneys into the originally designated recipient and document the reason for not transplanting the kidneys en bloc. The receiving transplant program will decide which of the two kidneys to transplant into the originally designated recipient, and release the other kidney according to Policy 5.9: Released Organs
- Release both kidneys according to Policy 5.9: Released Organs

Policy 5.9: Released Organs states that if deceased donor organs cannot be transplanted into the originally intended recipient, the transplant program must release the organs back to the host OPO and notify the host OPO or UNOS for further allocation. The host OPO must allocate the organ to other candidates according to the organ-specific policies (i.e., according to a match run), or can opt to let the Organ Center or the OPO serving the candidate transplant program's designated service area (i.e. the "importing OPO") allocate the organ instead.⁵⁷ This policy applies to all organ allocation. Reallocation of the kidney to other candidates would still be according to the kidney allocation policies whether it was allocated by the host OPO, the importing OPO, or the Organ Center.

Facilitated placement

During the development of the proposed policy, workgroup members acknowledged that certain regions have more experience transplanting kidneys from small pediatric donors (single or en bloc) than others. Several studies report that a number of DSAs have limited to no experience with transplantation of small pediatric kidneys (single or en bloc), yet only half of the kidneys from this particular group of DSAs were shared with regions with that experience.^{58,59} Allocating kidneys can be a time-intensive process, and the OPO members felt that getting these kidneys to the programs most likely to utilize them as quickly as possible would increase the likelihood they would be accepted and transplanted. Workgroup members, including those whose programs do not perform en bloc transplants, agreed; facilitated sharing to DSAs with more experience may help increase utilization. Therefore, transplant programs will have to indicate that they accept en bloc kidneys under the proposed policy. If an OPO allocates kidneys en bloc, only candidates willing to accept en bloc kidneys will appear on the match run. As there are currently fewer programs that perform a high volume of en bloc kidney transplants, this should expedite the allocation process.⁶⁰

⁵⁷ OPTN *Policy 5.9 Released Organs*. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_05. Accessed January 3, 2017.

⁵⁸ Pelletier, 1651.

⁵⁹ Maluf, 2704, 2707.

⁶⁰ Stewart, *Analysis of Dual (double) and En Bloc Kidney Transplants, 2010-2015*, April 15, 2016.

KDPI

Once the workgroup had settled on en bloc kidney criteria for policy, it moved on to the KDPI issue. The workgroup wanted to ensure that en bloc kidneys would be allocated to those candidates expected to survive an extended period of time post-transplant. These candidates are currently missing en bloc offers due to the potentially inflated KDPI score calculated for en bloc kidneys. The workgroup considered several options proposed by the Scientific Registry of Transplant Recipients (SRTR) on how to address this issue:^{61,62}

- Include the original coefficient for en bloc kidneys of -0.364 in the displayed KDPI
- Re-estimate KDRI/KDPI to include en bloc kidney coefficient only
- Create a pediatric-specific KDRI
- Mask the KDPI value for en bloc kidneys in DonorNet

Include original coefficient for en bloc kidneys of -0.364 in the displayed KDPI

In the original KDRI developed by Rao et al, there were several coefficients that were not ultimately included in the KDPI formula that is used in allocation.⁶³ One of those is a yes/no indicator for whether a kidney is en bloc. If so, -0.364 is added to the raw KDRI score, which lowers the estimated risk of graft failure for those kidneys. If the kidney is transplanted singly, the KDRI is unchanged; in effect, the current KDRI/KDPI score assumes all kidneys are from single donors.

Practically, by introducing an additional predictor, the meaning of the KDRI would change. All else equal, a kidney pair that is offered en bloc versus as two singles will have a raw KDRI 31% less risky than a single kidney:

Table 2: Effect of including original coefficient for en bloc kidneys of -0.364 in displayed KDPI

| | KDRI (single) | KDPI (single) | KDRI (en bloc) | KDPI (en bloc) | Difference |
|-----------|---------------|---------------|----------------|----------------|------------|
| Example 1 | 1.0 | 50% | 0.69 | 13% | -37% |
| Example 2 | 1.5 | 87% | 1.04 | 55% | -32% |
| Example 3 | 2.0 | 98% | 1.39 | 82% | -16% |

Based on the 2015 KDRI to KDPI conversion

As the conversion from KDRI to KDPI is not linear but percentile-based, it is not possible to estimate the change in the KDPI score. If the raw KDRI score is more extreme (low or high), the magnitude of any change is reduced in the KDPI conversion.

Statistically, the issue with adding (or dropping) covariates from a model is the degree to which the variables are correlated. It is not any worse to add back in a variable than it is to have dropped it in the first place without re-estimating the equation, which is what was done with the KDRI/KDPI. Theoretically, a model would only be improved upon by adding a predictor that was originally selected for inclusion.

The workgroup debated whether to treat en bloc kidneys the same as single kidneys by assigning them their own KDPI and displaying that KDPI when allocating, or allocate them differently because they are a different class of kidney and direct them towards programs that will use them. Currently, DonorNet treats en bloc kidneys the same as singles, but with their estimated risk incorrectly elevated. Including a term for en bloc kidneys in the KDPI would do the same thing (i.e. treat them as single kidneys), but with a lower KDPI. However, use of en bloc kidneys is not equally distributed across programs; it seems to be a program-specific decision. Attempting to allocate these kidneys in the same way as single kidneys (i.e. by the KDPI metric) may not be the best way to get them to the programs that want to use them.

⁶¹ Meeting Minutes. En Bloc Kidney Workgroup. OPTN/UNOS Kidney Transplantation Committee. August 30, 2016.

⁶² SRTR. "Question re: en bloc modeling options." Email to UNOS staff. December 19, 2016.

⁶³ Rao et al.

Re-estimate KDRI/KDPI to include en bloc kidney coefficient only

Practically, this would also change the meaning of the KDRI. It is almost certain that the betas associated with each donor covariate would change, at least slightly. Additional predictors could be selected, or some current predictors might be dropped or re-parameterized. These potential changes would be a significant alteration to the allocation system. Further, the cost, level of effort and time may not justify the addition of a single variable, especially since this single variable represents a small number of transplants. Although the Committee may decide to re-estimate the KDRI/KDPI in the future, at which time they may include the en bloc coefficient, there is no intent to do so short-term. The workgroup also had to consider the competing interests of the double kidney workgroup to avoid duplicating or contradicting their work; re-estimation of the KDRI might present challenges to their plans. Statistically, re-estimating KDRI/KDPI to include the en bloc kidney coefficient may be the most thorough and defensible option. However, for the reasons cited above, forcing en bloc kidneys into the current KDPI framework may not serve programs and patients well.

Create pediatric-specific KDRI

The workgroup agreed that the small sample size of en bloc kidney transplants makes it difficult to model outcomes well. It is also not practical to create a different KDPI score for every special circumstance. The workgroup debated this option and felt a pediatric-specific KDRI may be a long-term goal the Committee could consider at a future time.

Mask the KDPI value for en bloc kidneys – i.e. allocate them separately

As previously mentioned, use of en bloc kidneys is a program-specific decision. They also may not work equally well for all recipients. Leaving these decisions to the program (i.e. by blanking out or “masking” the KDPI value when an offer is made) may be the best choice. Several workgroup members were receptive to this option. Although this solution would remove the KDPI from factoring into allocation, and thus prevent candidates from being screened off the match run for high KDPI kidneys, it would not correct the calculation in DonorNet or provide clinicians with estimated risk for graft failure information. Despite these short-comings, the group acknowledged that this was an adequate short-term fix and there was consensus that this option was most feasible, as the KDPI calculation as applied to en bloc kidneys does a disservice to candidates who may get screened off the list.

Given this decision, the workgroup discussed how en bloc kidneys should be allocated, in the absence of using the KDPI. Based on the optimal en bloc kidney transplant outcomes, the workgroup members wanted to ensure that all eligible candidates would receive en bloc offers, not just those who were willing or had consented to accepting high KDPI kidneys. As these kidneys’ outcomes are more similar to kidneys with KDPI less than or equal to 20 percent, they should be allocated accordingly. Therefore, the workgroup agreed that en bloc kidneys (all kidneys from donors less than 20 kg or kidneys from donors greater than or equal to 20 kg an OPO has opted to allocated en bloc) should be allocated according to Policy 8.5.H Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%.⁶⁴ No changes were made to the classifications. Kidneys allocated singly will be allocated according to the deceased donor’s KDPI in allocation policy Tables 8-5 through 8-8.^{65,66,67,68}

How well does this proposal address the problem statement?

This proposal is informed by OPTN descriptive analyses, current peer-reviewed literature and, in matters of behavior, clinical consensus. In collaboration with other stakeholders, this is the Committee’s first

⁶⁴ En Bloc Kidney Workgroup Meeting Minutes, September 16, 2016.

⁶⁵ OPTN Policy 8.5.G Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_08. Accessed January 3, 2017.

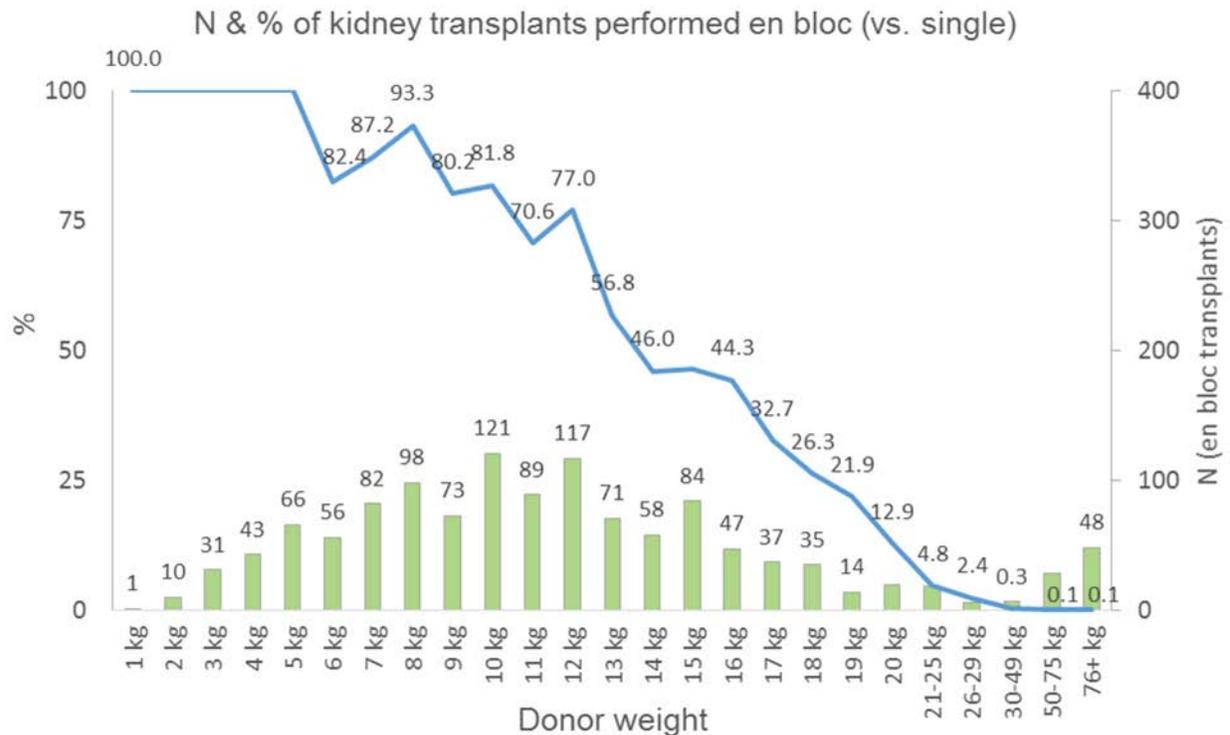
⁶⁶ OPTN Policy 8.5.H Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less Than 35%. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_08. Accessed January 3, 2017.

⁶⁷ OPTN Policy 8.5.I Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than or Equal to 35% but Less than or Equal to 85%. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_08. Accessed January 3, 2017.

⁶⁸ OPTN Policy 8.5.J Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_08. Accessed January 3, 2017.

attempt at crafting en bloc allocation policy. The workgroup determined donor weight would be the driving allocation criteria based on OPTN data, previous studies and clinical practice of workgroup members: significant predictors of organ recovery from small pediatric donors included donor age and weight.^{69,70,71,72}

Figure 3: Describing Current En Bloc Kidney Practice Deceased Donor Kidney Transplants, 2010-2015, by Donor Weight



Source: Stewart, "Double and En Bloc Kidney Data," 2016.

In terms of kidneys that were transplanted from 2010-2015, all kidney transplants from donors less than or equal to 5 kg were performed en bloc, and a vast majority of transplants from donors less than or equal to 12 kg were performed en bloc. For donors weighing 13 to 16 kg, about half were performed en bloc, and half as single kidney transplants. En bloc transplants were very rare for donors greater than 25 kg.⁷³

This proposal aims to address in part the number of discards or kidneys left unrecovered from this donor population. According to Maluf et al, in an analysis of 1,203 pediatric kidney donors less than 20 kg, 75% were either unrecovered or discarded after recovery.⁷⁴ Reasons for discard of pediatric donor kidneys include vascular damage, donor medical history, organ trauma, organ not as described, biopsy findings, poor organ function and anatomic abnormalities. However, in some cases the reason was missing or specified as "other".^{75,76}

⁶⁹ Pelletier, 1647.

⁷⁰ Maluf, 2704, 2708-2709.

⁷¹ Sureshkumar, *When Is It Reasonable to Split Pediatric En Bloc Kidneys?* 3522.

⁷² Al-Shraideh, 245.

⁷³ Stewart, Darren and Tim Baker. *Analysis of Dual (double) and En Bloc Kidney Transplants, 2010-2015*. OPTN/UNOS Descriptive Data Analyses. Prepared for Double and En Bloc Kidney Workgroup Conference Call, April 15, 2016.

⁷⁴ Ibid.

⁷⁵ Pelletier, 1648.

⁷⁶ Maluf, 2711.

Table 3: Numbers of small (≤ 20 kg) pediatric organ donors, kidney donors and kidney transplants (single and en bloc)

| Weight (kg) | Donors ¹ | | Kidneys | | | | Transplants ² | |
|-------------|---------------------|-----------------------------------|--------------|-------------------------------|----------------------------------|----------------------------------|----------------------------|-----------------------------|
| | N | Kidney donors, ³ N (%) | Recovered, N | Discarded, ⁴ N (%) | Transplanted, ⁴ N (%) | Not transplanted, ⁵ N | Single, ⁶ N (%) | En bloc, ⁶ N (%) |
| <8 | 431 | 119 (28) | 382 | 145 (38) | 237 (62) | 625 | 21 (16) | 108 (84) |
| 8 | 110 | 66 (60) | 149 | 21 (14) | 128 (86) | 92 | 14 (20) | 57 (80) |
| 9 | 92 | 61 (66) | 150 | 30 (20) | 120 (80) | 64 | 16 (24) | 52 (76) |
| 10 | 176 | 131 (74) | 294 | 38 (13) | 256 (87) | 96 | 44 (29) | 106 (71) |
| 11 | 89 | 67 (75) | 158 | 25 (16) | 133 (84) | 45 | 21 (28) | 56 (72) |
| 12 | 139 | 114 (82) | 247 | 25 (10) | 222 (90) | 56 | 54 (39) | 84 (61) |
| 13 | 123 | 103 (84) | 229 | 26 (11) | 203 (89) | 43 | 71 (52) | 66 (48) |
| 14 | 114 | 98 (86) | 216 | 23 (16) | 193 (84) | 35 | 69 (52) | 62 (48) |
| 15 | 160 | 145 (91) | 307 | 24 (8) | 283 (92) | 37 | 89 (48) | 97 (52) |
| 16 | 74 | 68 (92) | 140 | 9 (6) | 131 (94) | 17 | 59 (62) | 36 (38) |
| 17 | 61 | 54 (89) | 118 | 12 (10) | 106 (90) | 16 | 48 (63) | 29 (37) |
| 18 | 65 | 64 (99) | 127 | 4 (3) | 123 (97) | 7 | 63 (68) | 30 (32) |
| 19 | 37 | 34 (92) | 72 | 4 (5) | 68 (94) | 6 | 40 (74) | 14 (26) |
| 20 | 86 | 79 (92) | 164 | 15 (9) | 149 (91) | 23 | 101 (81) | 24 (19) |
| Total | 1757 | 1203 (68) | 2753 | 401 (15) | 2352 (85) | 1162 | 710 (46) | 821 (54) |

¹Donors: defined as someone who donates at least one solid organ for transplantation.

²Includes solitary and multi-organ kidney transplants (either single or en bloc).

³The number signifies the number of donors who had at least one kidney transplanted. The percentage is calculated using the total number of donors as the denominator. For donors <8 kg, there were 312 donors (431–119) for whom no kidneys were transplanted; 119 of 431 donors = 28% were kidney donors.

⁴The percentage is calculated using the number of recovered kidneys as the denominator. For donors <8 kg, the discarded percentage is $145/382 = 38\%$; the transplanted percentage is $237/382 = 62\%$.

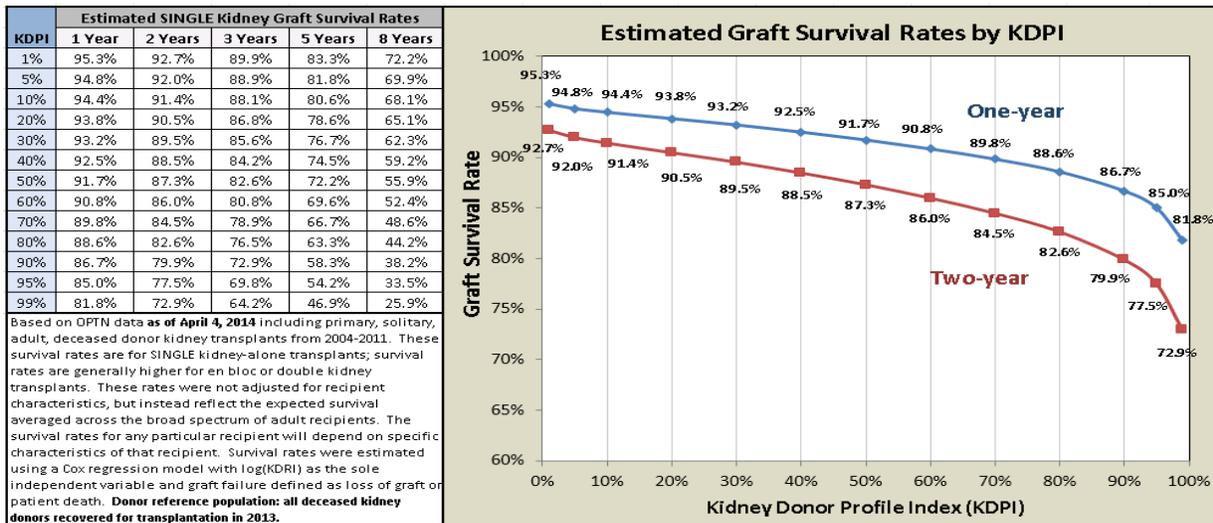
⁵Sum of kidneys not recovered and kidneys discarded after recovery. For donors <8 kg, there are 862 available kidneys (431×2); 480 were not recovered ($862 - 382$ recovered kidneys = 480) and 145 discarded kidneys to total 625 kidneys that were not transplanted.

⁶The percentage is calculated using the total number of kidney transplants as the denominator. For donors <8 kg, the total number of transplants performed was 129; $21/129 = 16\%$ single kidney transplants and $108/129 = 84\%$ en bloc transplants.

Source: Maluf et al, "Optimizing Recovery, Utilization and Transplantation Outcomes for Kidneys from Small, ≤ 20 kg, Pediatric Donors," *AJT*, 2705

As previously noted, KDPI, as currently calculated, is not optimal in en bloc kidney allocation as potentially eligible candidates are screened off the match run for en bloc kidney offers based on their acceptance criteria. The workgroup's decision to mask en bloc kidney offers' KDPI is due to the fact it does not accurately convey graft survival for en bloc kidneys. Although Figure 4 (included in DonorNet) shows survival rates for single kidney transplants, it is helpful to illustrate the inaccuracy of KDPI in the setting of en bloc kidney transplants:

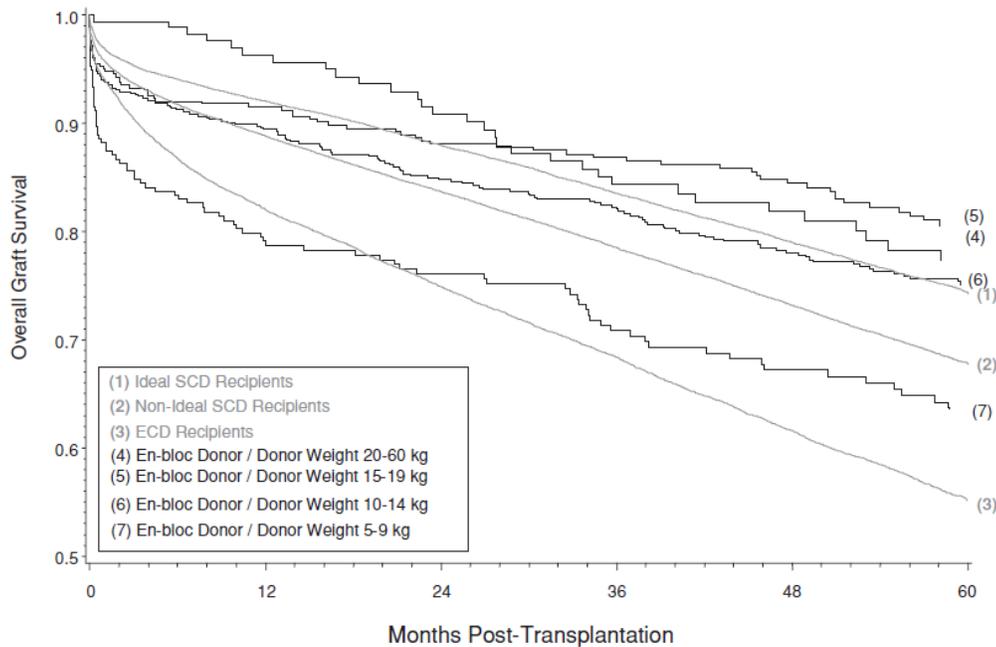
Figure 4: Current Survival Rate Guide Provided for Members in DonorNet



Source: UNOS Research Department, Current Survival Rate Guide Provided for Members in DonorNet, 2014.

The original intent of the policy was not necessarily to increase the number of programs performing en bloc kidney transplants, as Maluf et al found some correlation between en bloc transplant volume and outcomes.⁷⁷ However, in tandem with expertise and training, a favorable unintended consequence may be that more programs choose to perform en bloc kidney transplants. While experienced programs are familiar with the advantageous outcomes en bloc kidney transplants confer, other programs may not be aware that en bloc kidney transplants have been shown to offer favorable short-, medium-, and even long-term outcomes.

Figure 5: Kaplan-Meier plots of overall graft survival for pediatric en bloc transplants by donor weight and ideal standard criteria donor (SCD), non-ideal SCD and ECD donor transplants



Source: Kayler et al, "Single Kidney Transplantation from Young Pediatric donors in the United States," *AJT*, 2748.

⁷⁷ Maluf, 2707-2708, 2710.

Was this proposal changed in response to public comment?

This proposal represents the work of a diverse group of kidney transplant professionals, including representatives from both high-volume and low-volume en bloc kidney programs, OPO staff, pediatric specialists and transplant program administrative personnel. The response to the proposal was generally favorable, with various recommendations suggested. Table 4 summarizes the diversity of respondents and the overall level of support. Eight regions, two Committees, two individuals and all societies supported a majority of the proposal. Three regions opposed the proposal and six Committees were neutral:

Table 4: Public Comment Overview

| Regions | Committees | Societies | Individuals |
|------------|---------------------------|-----------|-------------|
| 8 Approved | Minority Affairs | AST | 2 |
| | Pediatric | | |
| | OPO | ASTS | |
| | Transplant administrators | | |
| 3 Opposed | Transplant coordinators | AOPO | |
| | Operations & Safety | | |
| | MPSC | NATCO | |
| | Patient Affairs | ANNA | |

*American Nephrology Nurses Association

The proposal garnered 26 comments. The Committee requested specific feedback from the community regarding whether the weight threshold for mandatory en bloc kidney allocation should be increased (from less than 15 kg to 20 kg, 25 kg or other) and the option for OPOs to allocate kidneys from donors 15 to 25 kg as singles or en bloc be removed. Consequently, this feedback, among other suggestions, is reflected in the overarching themes, detailed below. The Committee’s response and any subsequent changes made post-public comment are elaborated upon within each theme or sub-theme.

Releasing second kidney from a split en bloc unit according to Policy 5.9 Released Organs

Concern regarding releasing the second kidney split from an en bloc unit (hereafter, referred to as the “second kidney”) back to the OPO for reallocation was one of the most prolific themes, and several sub-themes were identified. The community strongly suggested the Committee consider allowing the receiving center to keep the second kidney, or at least keep it within the DSA or region. The community was very concerned the second kidney would be vulnerable to increased cold ischemic time and at high risk of being discarded. The Committee also heard that programs will be disincentivized to split the en bloc unit if they have to release the second kidney back to the pool. There were a few comments that the Committee should consider adding a timeframe for OPO’s attempting to allocate the second kidney; if it couldn’t be re-allocated within that designated timeframe, it could be released back to the original receiving center. Two regions questioned whether it was appropriate to include special consent for these kidneys or require programs to comply with *Policy 5.3.C Informed Consent for Kidneys Based on KDPI Greater than 85%*,

as some, not all, reflect a KDPI score of 85 or greater. There were also a few concerns that this provision could lead to gaming, meaning a receiving center could start accepting a lot of en bloc units knowing that it is permissible to split the unit. Members noted that a center was unlikely to accept a kidney split by another center, making that kidney difficult to place. Finally, there were several comments supporting the proposal as written (to release the second kidney according to *Policy 5.9 Released Organs*).

The workgroup discussed this feedback at length. They reviewed options to keep the requirement, eliminate the provision, or consider modeling language after Policy 9.8.A Open Variance for Segmental Liver Transplantation. Modeling language after Policy 9.8.A is not ideal because it lacks transparency; making such a change would be a significant modification post-public comment. Therefore, workgroup members felt this was not a fair option. They also quickly dismissed eliminating the requirement. In 2016, the OPTN/UNOS Board of Directors approved changes that aligned several conflicting kidney allocation policies that addressed what to do with a kidney that could not be transplanted into the originally intended recipient.⁷⁸ These changes made Policy 5.9: Released Organs the prevailing policy. This policy not only applies to kidneys, but all organs. Eliminating the requirement from the proposed en bloc language would introduce inconsistency those policy changes aimed to correct. Although the community did not favor this provision, both the workgroup and Committee were comfortable with it. Ultimately, they opted to leave this requirement unchanged. The workgroup agreed with UNOS' belief that this is the most fair, transparent option to allocation. Writing more prescriptive policy language would likely look very similar to the effect of Policy 5.9. Finally, keeping this provision maintains consistency throughout policy with regard to how to handle situations in which a deceased donor organ cannot be transplanted into the original recipient.

One of the challenges the workgroup acknowledged was the lack of data to help mitigate concerns for keeping this requirement. The OPTN cannot track the instances an en bloc unit is split, nor discards given the current limitations of the system that programming would address if this policy is approved. The Committee will ensure that appropriate metrics are included in the monitoring plan to capture how many en bloc units are split, as well as the number of discards (of en blocs or the second kidney) so that if over time it looks like something should be changed, the Committee will have data to support those changes.

Finally, although there were just two comments regarding requiring informed consent, the workgroup discussed whether *Policy 5.3.C* should apply to en bloc kidneys. This issue did not come up during the development of the proposal. Although a majority of en bloc kidneys have a KDPI score of 50-85%, there are some that have a score of 85 percent or greater (**Table 1**). However, as previously mentioned, these scores are inflated, and will be masked to the program upon receiving offers. If a program decides to split an en bloc unit and releases the second kidney to the OPO to re-allocate, the KDPI score will be revealed when a new match is run, allocating the second kidney according to the deceased donor's KDPI score. If that score is greater than 85 percent, only candidates who have previously consented according to *Policy 5.3.C* to receive offers for kidneys with a KDPI greater than 85 percent will appear on the new match run. One workgroup member suggested making reference to this within the proposed en bloc policy language, but a majority of the group did not feel strongly about adding this language.

Weight threshold for mandatory en bloc kidney allocation

The community largely concurred with the Committee's proposed weight threshold of less than 15 kg for mandatory en bloc kidney allocation. However, there was some variation across regions. Some regions suggested raising the weight threshold from 15 kg to 20 kg. One region even suggested raising the threshold to 25 kg. These regions cited OPTN data showing that there are kidneys being transplanted en bloc from donors as high as 25 kg, and even higher. Other regions felt the threshold should be decreased to less than 10 kg, or within the range of 10 to 15 kg. These commentators felt decreasing the weight threshold was appropriate for two reasons: first, their recommendations reflected their current center practice. Some programs are comfortable splitting en bloc units from donors as small as 10 kg (or even less) and with acceptable outcomes. Second, these members were concerned that mandating allocation of en bloc kidneys from donors of higher weights could reduce an opportunity to implant as singles. In addition, one Committee felt that increasing the weight range would slow down allocation: by increasing the threshold, more programs may opt in to receive offers, but only ever intend to accept kidneys from the

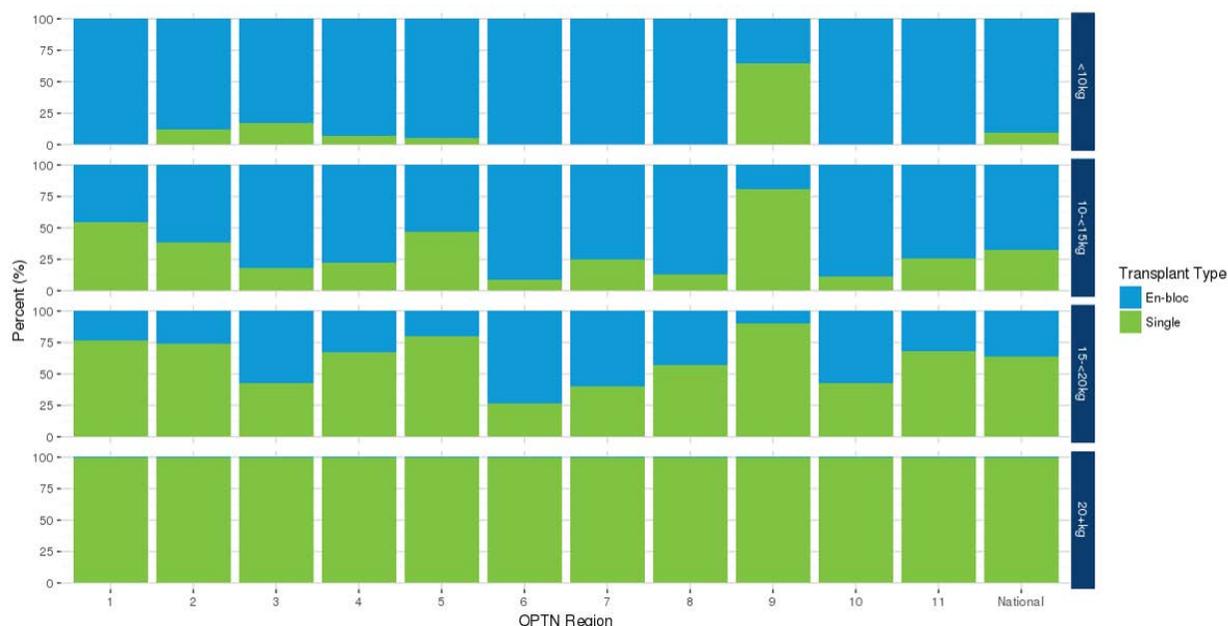
⁷⁸ KAS Clarifications. https://optn.transplant.hrsa.gov/media/1876/kidney_policynotice_kas_201606.pdf. OPTN Policy Notice. Approved by the OPTN Board of Directors June 2016.

larger donors. More people opting in equals less effective facilitated placement because the OPO has to go through a longer list. Finally, increasing the weight threshold may increase the instances of splitting kidneys. The provision to reallocate the second kidney from a split en bloc unit was not popular during public comment.

The workgroup deliberated over this feedback. Although there was consensus for the less than 15 kg weight threshold during public comment, some members of the workgroup were concerned that programs transplanting kidneys en bloc from donors greater than or equal to 15 kg would be disadvantaged by the explicit cut-off, especially as the workgroup agreed to eliminate the optional provision for OPOs to allocate kidneys from donors greater than or equal to 15 kg. If the workgroup set the threshold at less than 15 kg, these programs would never see en bloc offers, unless they changed practice.

To assuage these concerns, the workgroup requested more granular data on en bloc transplant counts (versus single kidney transplants) by region and donor weight categories. UNOS provided a descriptive data analyses for deceased donor kidney transplants between 2010-2015 to analyze the number (percent) by kidney transplant type (single vs. en-bloc), donor weight (<10kg, 10-<15kg, 15-<20kg, 20+kg) and OPTN Region.⁷⁹

Figure 6: Percent En bloc by Region and Donor Weight



Source: Wilk, “En-bloc Deceased Donor Kidney Transplants by Region/Center and Donor Weight,” 2017.

Data shows that all OPTN regions (except 9), and nationally, had more en bloc versus single deceased donor kidney transplants with donor weights less than 10 kg and at least 10 but less than 15 kg. Across most OPTN regions (7 out of 11), and nationally, a higher percent of transplants were single vs. en bloc for donor weights at least 15 but less than 20 kg. A higher percent of transplants were single vs. en bloc for donor weights greater than or equal to 20 kg for all OPTN regions. Absolute data on number of potentially discarded or unrecovered kidneys in each of these classifications or potential donor organs in each subgroup is unknown.

This data confirmed the workgroup’s concerns. It demonstrates there are several regions that may be disadvantaged by mandating the weight threshold for en bloc kidney allocation be less than 15 kg because they are transplanting kidneys from donors 15 to 20 kg en bloc about 50 percent of the time (one

⁷⁹ Wilk, Amber. En-bloc Deceased Donor Kidney Transplants by Region/Center and Donor Weight. OPTN/UNOS Descriptive Data Analyses. Prepared for En Bloc Kidney Workgroup Conference Call, March 31, 2017.

region is doing more en bloc than single transplants with kidneys from donors in that weight range). Furthermore, the Maluf study demonstrates a similar pattern: 28 percent of all en bloc kidney transplants analyzed in that study were procured from donors weighing more than 14 kg.⁸⁰ The workgroup wanted to accommodate programs currently doing en bloc transplants with kidneys from donors in the at least 15 but less than 20 kg weight range. It is important to clarify the workgroup's original intent: it was not to increase the number of transplants by forcing programs that currently do no or few en bloc kidney transplants to now perform them. The intent was to facilitate procuring kidneys from an underutilized donor pool and get those kidneys to centers who are comfortable using them, primarily as en blocs, but also as singles.

Therefore, the workgroup opted to raise the weight threshold to less than 20 kg. There is currently no consensus regarding when en bloc kidneys should be split for transplantation into two recipients to maximize utility without compromising graft outcomes; rather it is typically based on the surgeon's discretion.⁸¹ Setting the threshold at 20 kg provides the most flexibility in that it allows the programs who want to transplant kidneys from heavier donors the ability to do so, while allowing programs who are comfortable splitting those kidneys to split. The workgroup acknowledged these are small numbers and conceded that once data is available, the Committee will be able to make changes if warranted.

Recommendation to remove the option to allocate en bloc/single from donors 15 to 25 kg

While not as strong as the two previous themes, there was consensus to eliminate this option. The original intent was to accommodate current practice across the various service areas and not to dictate medical practice. However, both OPOs and transplant programs felt that it did not provide explicit direction to OPOs on how and when to allocate organs from donors in that weight range and could lead to confusion.

It became apparent that once this option was removed, policy provided no explicit direction on how to allocate kidneys greater than or equal to 20 kg. UNOS staff was uncomfortable with this ambiguity and advised the Committee to add clarifying language. The Committee considered two options. The first option was the least flexible, in that it would mandate all kidneys from donors greater than or equal to 20 kg to be allocated individually, according to deceased donor's KDPI in allocation *Tables 8-5 through 8-8*. This option is explicit and tells OPOs exactly what to do with kidneys from donors greater than or equal to 20 kg, but it does not accommodate a large donor/small kidney situation.

The second option allows for more discretion. The proposed language indicates that if an OPO procures both kidneys from a single deceased donor greater than or equal to 20 kg, they may do any of the following:

- Offer each kidney individually according to the deceased donor's KDPI in revised allocation *Tables 8-5 through 8-8*
- Offer both kidneys according to Policy 8.6.B: Double Kidney Allocation
- Offer both kidneys en bloc according to Policy 8.5.H: Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%

These are the options OPOs currently have, and this language simply codifies current practice. In essence, this is the status quo. It provides direction, but is not explicit and still puts the OPO in the role of decision-maker. Although the community favored more explicit direction, ultimately the Committee opted for the more flexible option for more difficult to place kidneys.

With these options, it may seem that the weight threshold is somewhat arbitrary. However, this justifies the workgroup's desire to raise the mandatory weight threshold to 20 kg in an effort to accommodate programs transplanting kidneys en bloc from donors at least 15 but less than 20 kg. If the Committee kept the weight threshold at less than 15 kg for mandatory en bloc kidney allocation, OPOs would not be mandated to allocate kidneys from donors at least 15 but less than 20 kg as en bloc to programs who currently accept those organs as en bloc. They would have the option to, but it is not required. This

⁸⁰ Maluf, 2704.

⁸¹ Sureshkumar. *When Is It Reasonable to Split Pediatric En Bloc Kidneys?* 3521.

potentially could disadvantage specific patient populations that may benefit from en bloc kidneys from a slightly heavier donor.

Other criteria to drive allocation of en bloc kidneys

The community was predominantly silent regarding the actual criteria that will drive en bloc kidney allocation. However, there were a few suggestions of other criteria that could be used in place of or in addition to donor weight: donor height and kidney size. A single commenter suggested donor height; there was slightly more consensus around kidney size. Although the workgroup had considered kidney size, they chose weight as this donor characteristic is readily available prior to organ recovery and is a significant predictor of organ recovery from small pediatric donors. OPOs also favored this criterion. The Committee considered public comment feedback but ultimately decided to keep donor weight as the determining criterion in allocating kidneys en bloc.

KDPI and risk adjustment

The Committee did not receive many comments regarding their proposal to mask the KDPI score in DonorNet to mitigate the artificially high KDPI scores of en bloc kidneys. A single commenter felt omitting the KDPI takes away predictive information from coordinators and surgeons to consider when evaluating offers, but others from that region agreed that masking the KDPI is an appropriate compromise, as en bloc KDPI scores are too skewed to serve as a meaningful data point. There were two commenters that suggested a risk adjustment for en bloc kidney transplants in the same way that high KDPI kidney transplants will be excluded from outcomes monitoring.

Committee leadership discussed this feedback with SRTR. SRTR advised that in their program specific reports (PSRs), the KDPI equation is used exactly how it is programmed in UNetSM to estimate the risk of graft failure, i.e. without the en bloc coefficient. Currently, small donor en bloc kidneys reflect a relatively high KDPI score. The higher the KDPI of an organ, the higher its estimated risk of graft failure. However, this may not be an accurate reflection of the true risk for en bloc transplants. Furthermore, the PSRs include “procedure type” as a factor: for example, left kidney, right kidney, double kidney, or en bloc kidney. In the 1-year deceased donor graft survival models as of April 2017, there is no extra risk (or reduction of risk) associated with procedure type, aside from a very small protective effect for using the left kidney. The risk-adjustment model (i.e., outcomes calculations) will not harm or reward programs for completing en bloc transplants because both KDRI and en bloc are included in the model and can capture the potential effect of en bloc on one-year post-transplant outcomes. Committee leadership were satisfied with this explanation and did not have any concerns.

Financial implications

Finally, there were three comments regarding the financial implications of this proposal. The Transplant Administrators Committee asked if the Committee considered the financial impact to transplant programs. The Committee confirmed it had deliberated this, and acknowledged that facilitated placement might increase travel costs for high volume en bloc transplant programs who felt the need to send their own procurement team to retrieve organs from areas that may lack the surgical expertise for this specific recovery procedure. The OPO representative on the workgroup did not feel the current practice of charging one acquisition fee for en bloc kidneys will change in light of this proposal. This question was put forth to several other OPOs and they confirmed the same. One region pointed out that the allocation of UNOS resources to implement this project is large given the small number of en bloc kidney transplants nationally.

The Committee voted unanimously to approve the en bloc policy as amended and to send to the OPTN Board of Directors in June 2017 for consideration (19-yes, 0-no, 0-abstentions).

Which populations are impacted by this proposal?

All kidney transplant candidates could potentially be impacted by this proposal. At the conclusion of 2016, there were 98,962 candidates waiting for a kidney transplant.⁸²

⁸² <https://optn.transplant.hrsa.gov/data/>

The proposed policy mainly impacts adult kidney transplant candidates, as a majority of en bloc kidneys are transplanted into adult recipients.⁸³

Table 5: Kidney Transplants by Procedure Type and Recipient Age, January 2000 – December 2007

| RECIPIENT AGE | Single Kidney N (%) | En Bloc Kidney N (%) | Dual Kidney N (%) | All N |
|----------------------|--------------------------------|---------------------------------|------------------------------|------------------|
| 18-49 | 23,897 (41.4) | 523 (55.1) | 185 (19.2) | 24,605 |
| 50-64 | 24,489 (42.5) | 326 (34.4) | 485 (50.3) | 25,300 |
| 65+ | 9,285 (16.1) | 100 (10.5) | 295 (30.6) | 9,680 |
| All | 57,671 (100) | 949 (100) | 965 (100) | 59,585 |

Source: Stewart, "Double and En Bloc Kidney Data," 2013.

However, recent studies, though limited, suggest en bloc kidney transplantation might also be a viable option for pediatric candidates, as graft function, at least short-term, was found to be similarly favorable in adult candidates receiving en bloc kidneys^{84,85,86,87}. Waiting time was also found to be reduced for pediatric candidates.⁸⁸

How does this proposal impact the OPTN Strategic Plan?

Increase the number of transplants: This policy mandates OPOs allocate kidneys previously left unrecovered or discarded due to donor size. As previously stated, a majority of kidneys from donors less than 20 kg are either unrecovered or discarded. In addition, the OPTN estimates there are 800 unrealized potential donors per year within the 5 and under age range.⁸⁹ This policy also facilitates placement to programs with en bloc expertise so that OPOs can allocate kidneys to those centers with the interest and expertise to use them, even if there are no local centers that accept kidneys from small pediatric donors. Although this policy potentially could reduce the number of transplants as two kidneys are being transplanted into a single recipient versus two recipients, it includes provisions to mitigate this concern.

Improve equity in access to transplants: Generally, most en bloc kidneys are transplanted into adult recipients, however, as previously mentioned, this could expand the donor pool for pediatric candidates.

Improve waitlisted patient, living donor, and transplant recipient outcomes: When kidneys from a small donor are transplanted into a recipient en bloc versus singly, they confer comparable to superior outcomes. In addition, accepting en bloc kidneys could shorten a pediatric candidate's time on the waitlist, conferring not only a survival advantage and minimizing time on dialysis, but additional benefits. Shorter duration of dialysis is associated with increased pre-transplantation height in pediatric patients, which correlates to greater final adult height. Earlier transplantation may also improve cognitive development and reduce overall stress to the child and family.⁹⁰

Promote living donor and transplant recipient safety: There is no impact to this goal.

⁸³ Stewart, *Double and En Bloc Kidney Data*.

⁸⁴ Lau, Keith K., Gerre M. Berg, Yolanda G. Schjoneman, Richard V. Perez, and Lavjay Butani. "Pediatric en bloc kidney transplantation into pediatric recipients." *Pediatric Transplantation* 14, no. 1 (2010): 100-04. doi:10.1111/j.1399-3046.2009.01137.x.

⁸⁵ Butani, Lavjay, Christoph Troppmann, and Richard V. Perez. "Outcomes of children receiving en bloc renal transplants from small pediatric donors." *Pediatric Transplantation* 17, no. 1 (2012): 55-58. doi:10.1111/ptr.12021.

⁸⁶ Winnicki, Erica, Madan Dharmar, Daniel Tancredi, and Lavjay Butani. "Comparable Survival of En Bloc versus Standard Donor Kidney Transplants in Children." *The Journal of Pediatrics* 173 (2016): 169-74. doi:10.1016/j.jpeds.2016.01.054.

⁸⁷ Whittaker, Vaughn E., and Rainer W.g. Gruessner. "En Bloc Kidney Transplants from Pediatric Donors into Children—An Underutilized Transplant Option?" *The Journal of Pediatrics* 173 (2016): 9-10. doi:10.1016/j.jpeds.2016.03.037.

⁸⁸ Winnicki, 170.

⁸⁹ Klassen, 1711.

⁹⁰ Winnicki, 171.

Promote the efficient management of the OPTN: The creation of an en bloc kidney policy will improve efficiency of the OPTN as OPOs should no longer have to contact the Organ Center for guidance or assistance in allocating en bloc kidneys.

How will the OPTN implement this proposal?

This proposal will require programming in UNetSM. UNOS IT provides cost estimates for each proposal that will require programming to implement. The estimates can be small (108-419 hours), medium (420-749 hours), large (750-1,649 hours), very large (1,650-3,999 hours), or enterprise (4,000-8,000 hours). This proposal is estimated to be very large project due to changes required in both the WaitlistSM and DonorNet applications. In Waitlist, an additional data field will be added for transplant programs to opt-in to accept en bloc kidneys on an individual candidate level (both kidney alone and isolated kidney of a kidney-pancreas registration) and be able to manage via listing defaults and Waitlist update utility. Changes to the DonorNet application will include a new prompt for OPOs to designate that kidneys will be allocated en bloc. The kidney allocation system will be modified to enable OPOs to allocate for en bloc kidneys. Changes to both applications will involve thorough testing as well as additional quality monitoring.

UNOS will follow established protocols to inform members and educate them on any policy changes through Policy Notices. This proposal will require an instructional program and will be monitored for specific needs throughout the development and implementation to determine the eligible modality for educating members.

How will members implement this proposal?

This proposal will impact transplant hospitals and OPOs.

Transplant Hospitals

This proposal requires transplant programs to indicate to the OPTN Contractor whether they accept en bloc kidneys. Although this preference is already a part of the kidney minimum acceptance criteria programs are required to submit annually, many programs do not update their acceptance criteria on an annual basis or leave the en bloc kidney question unanswered. Furthermore, these criteria are only applied when non-local offers are facilitated by the Organ Center. This proposal will allow transplant programs to manage acceptance of en bloc kidneys at the candidate or center level via listing defaults and Waitlist utilities. This option should mitigate administrative burden and more effectively ensure that only those candidates and programs willing to consider accepting an en bloc kidney offer appear on the match run.

The receiving transplant program must document the reason for not transplanting the kidneys en bloc, if the surgeon determined the en bloc kidneys could be split and transplanted into two recipients.

There may be financial implications to transplant programs. Facilitated placement might increase travel costs for high volume en bloc transplant programs to procure en bloc kidneys from regions or geographies that lack a center that transplants en bloc kidneys. Current practice of charging one acquisition fee for en bloc kidneys is not expected to change in light of this proposal.

Minimal staff training to implement is required, unless programs are not already participating in en bloc transplants. Implementation can occur immediately up to two months, allowing for staff education. Staff training is estimated to be \$0-1,000 for training hours, and can likely be absorbed.

Additional time may be required of both administrative and clinical staff to review and prepare pre-transplant, remain on call, and complete transplant. This is dependent on volume and complication of en bloc cases. If additional time and supplies are required, it is undetermined if additional costs are reimbursable. While higher cost cases may result, the volume of en bloc transplants overall is minimal. There are no substantial ongoing cost identified. Potential efficiencies include reduced wait-list maintenance and a reduction in patient stay.

OPOs

As en bloc allocation already occurs, this proposal increases efficiency in the allocation process. If the kidneys are split, the OPO will need to run a new match to allocate the second kidney based on KDPI. Otherwise, minimal staff training on new policy allows implementation to be effective immediately to one month. Since volume of en bloc cases is low, there is minimal impact on operations.

Will this proposal require members to submit additional data?

Donor weight is a KDRI factor and is required to run a kidney match, so although *Policy 2.11A Required Information for Deceased Kidney Donors* does not currently list donor weight as a required data element for kidney offers, OPOs must enter this to run a match. The addition of donor weight to *Policy 2.11A* is just a clarification. No additional data collection is proposed.

How will members be evaluated for compliance with this proposal?

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

UNOS allocations staff will continue to review all deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to policy requirements and will continue to investigate potential policy violations.

Allocations staff will review en bloc kidney allocations resulting in a single kidney being transplanted into the intended recipient. Staff will request the transplant program's documentation about why the kidneys were not transplanted en bloc and will also verify that the second kidney was allocated according to *Policy 5.9*.

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 number of en-bloc kidney transplants increased?
- Has the number of patients transplanted from very small pediatric donors (single and en-bloc) increased?
- Has efficiency of en-bloc transplants improved given there is now policy in place regarding these transplants?
- Has there been a decrease in kidney discards?
- Has the number of programs performing en-bloc kidney transplants increased?

The following metrics, and any others subsequently requested by the Committee, will be evaluated as data become available to compare performance before and after the implementation of this policy:

- The number (and percent) of transplants (single vs. en-bloc), overall, and by both recipient and donor demographics, including but not limited to donor weight, KDPI (for singles), and recipient age.
- How many kidneys allocated as en bloc are subsequently split?
- The number (and percent) of deceased donor kidney transplant programs performing en-bloc transplants.
- Descriptive statistics on cold ischemic time of kidneys transplanted en-bloc.
- The number (and percent) of kidneys recovered en-bloc that are utilized vs. discarded, overall and by demographics, including but not limited to donor age, donor weight, and KDPI (for singles).

Policy or Bylaws Language

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

RESOLVED, that changes to Policies 2.11.A (Required Information for Deceased Kidney Donors) and 8.6 (Double Kidney Allocation), as set forth below, are hereby approved, effective pending implementation and notice to OPTN members.

2.11.A Required Information for Deceased Kidney Donors

The host OPO must provide *all* the following additional information for all deceased donor kidney offers:

1. Date of admission for the current hospitalization
2. Donor name
3. Donor ID
4. Ethnicity
5. Relevant past medical or social history
6. Current history of abdominal injuries and operations
7. Current history of average blood pressure, hypotensive episodes, average urine output, and oliguria
8. Current medication and transfusion history
9. Anatomical description, including number of blood vessels, ureters, and approximate length of each
10. Human leukocyte antigen (HLA) information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to organ offers
11. Indications of sepsis
12. Injuries to or abnormalities of blood vessels, ureters, or kidney
13. Assurance that final blood and urine cultures are pending
14. Final urinalysis
15. Final blood urea nitrogen (BUN) and creatinine
16. Recovery blood pressure and urine output information
17. Recovery medications
18. Type of recovery procedure, flush solution and method, and flush storage solution
19. Warm ischemia time and organ flush characteristics
20. Weight

8.6 ~~Double Kidney Allocation~~ of Both Kidneys from a Single Deceased Donor to a Single Candidate

8.6.A. Allocation of Kidneys En Bloc from a Single Deceased Donor

If a host OPO procures both kidneys from a single deceased donor less than 20 kg, the host OPO must offer both kidneys en bloc according to *Policy 8.5.H: Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%*. En bloc kidneys will only be offered to candidates at transplant programs that have specified to the OPTN Contractor that they are willing to accept en bloc kidneys.

If a host OPO procures both kidneys from a single deceased donor greater than or equal to 20 kg, the host OPO may do *any* of the following:

- 40 • Offer each kidney individually according to the deceased donor's KDPI in allocation Tables 8-5
- 41 through 8-8
- 42 • Offer both kidneys according to Policy 8.6.B: Double Kidney Allocation
- 43 • Offer both kidneys en bloc according to Policy 8.5.H: Allocation of Kidneys from Deceased Donors
- 44 with KDPI Scores less than or equal to 20%

45

46 If the transplanting surgeon determines, based on medical judgment, that en bloc kidneys should be split,

47 then the receiving transplant program must do one of the following:

48

- 49 • Transplant one of the kidneys into the originally designated recipient and document the reason for not
- 50 transplanting the kidneys en bloc. The receiving transplant program will decide which of the two
- 51 kidneys to transplant into the originally designated recipient, and release the other kidney according
- 52 to Policy 5.9: Released Organs.
- 53 • Release both kidneys according to Policy 5.9: Released Organs.

54 **8.6.B. Double Kidney Allocation**

56 If kidneys are not offered en bloc according to Policy 8.6.A, then an OPO must offer kidneys individually

57 through one of the allocation sequences in Policy 8.5: Kidney Allocation Classifications and Rankings

58 before offering both kidneys to a single candidate unless the OPO reports to the OPTN Contractor prior to

59 allocation that the deceased donor meets at least two of the following criteria:

60

- 61 • Age is greater than 60 years
- 62 • Estimated creatinine clearance is less than 65 mL/min based upon serum creatinine at admission
- 63 • Rising serum creatinine (greater than 2.5 mg/dL) at time of organ recovery
- 64 • History of longstanding hypertension or diabetes mellitus
- 65 • Glomerulosclerosis greater than 15% and less than 50%

66

67 The kidneys will be allocated according to sequence of the deceased donor's KDPI.

#