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Briefing Paper

Improving Allocation of En Bloc Kidneys

OPTN/UNOS Kidney Transplantation Committee

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Contents

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Affected Policies:	*Policy 2.11.A: Required Information for Deceased Kidney Donors, 5.3: Additional Acceptance and Screening Criteria, and 8.6: Double Kidney Allocation*
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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 Kidney Donor Profile Index (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 proposed policy includes donor criteria regarding the type of kidneys that can be allocated en bloc and mandates that programs must indicate in Waitlist℠ 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 four OPTN strategic goals. First, it should increase the number of transplants by utilizing kidneys previously left unrecovered or discarded. Second, most en bloc kidneys are transplanted into adult recipients; however, this proposal could expand the donor pool for pediatric candidates. Third, 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.

The proposal was amended after its first round of public comment. Following the spring 2017 cycle, the Committee voted to remove the provision granting OPOs the option to allocate kidneys from donors weighing between 15 and 25 kg en bloc or as singles and added a provision mandating en bloc allocation for kidneys from donors weighing 20kg or less. Following the June 2017 Board of Directors meeting, the Committee lowered the mandatory en bloc allocation donor weight threshold to 18kg in response to feedback.

What problem will this proposal solve?

Kidney transplantation is the preferred treatment for 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 dual kidneys, in that en bloc describes utilization of two kidneys from the same donor, clinically, en bloc kidneys are from very small donors that 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

[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 Transplantatio*n 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. Magliocca, 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 Kaczmorski, 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.

HLA match, cold ischemic time, en bloc, and dual kidney coefficients, along with the main 10 variables were ultimately included in the 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 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]

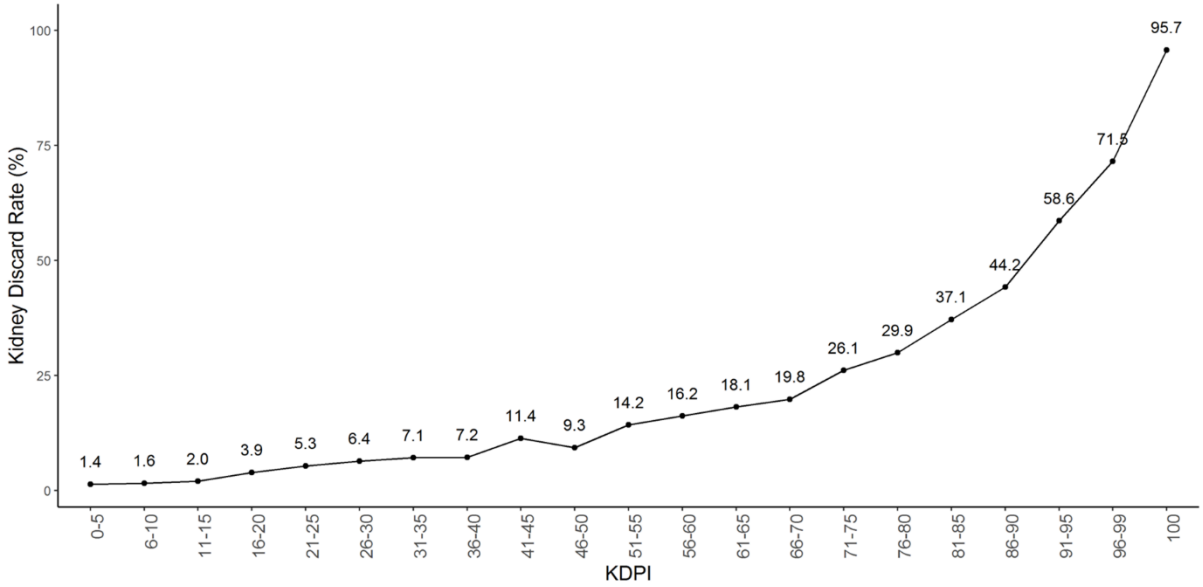
[12] Rao, Panduranga S., Douglas E. Schaubel, Mary K. Guidinger, Kenneth A. Andreoni, Robert A. Wolfe, Robert M. Merion, Friedrich K. Port, and Randall S. Sung. "A Comprehensive Risk Quantification Score for Deceased Donor Kidneys: The Kidney Donor Risk Index." *Transplantation* 88, no. 2 (July 27, 2009):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

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 track 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 two percent of all transplants.[36] En bloc kidney transplantation is a complex procedure and many programs may lack technical expertise. Of the 89 programs in the U.S. that performed at least one en bloc transplant post-KAS, 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.[37] 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.[38] 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.[39]

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 dual 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] 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.
[38] 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.
[39] Ibid.

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

- Age
- Height
- 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 in 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 used by programs when evaluating whether to use kidneys from small pediatric donors singly or en bloc.[40,41,42,43] Furthermore, several studies report that donor weight is a much more sensitive indicator of pediatric kidney graft survival than donor age.[44,45,46]

Although there was consensus among the workgroup members 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.[47,48,49]

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 of the higher-volume en bloc transplant programs.[50] Others felt this was too liberal and suggested the threshold 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

[40] Pelletier, 1647.
[41] Maluf, 2704, 2708-2709.
[42] 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.
[43] Al-Shraideh, 245.
[44] Kayler. 2750.
[45] 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.
[46] Maluf, 2708.
[47] Pelletier, 1647-1648, 1651.
[48] Al-Shraideh, 245.
[49] Stewart, *Double and En Bloc Kidney Data.*
[50] Al-Shraideh, 245.

community supports this weight threshold. Public comment predominantly favored this proposed weight threshold, although some advocated for a higher or lower threshold. The workgroup and Committee debated raising it to accommodate current practice in regions that 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 proposed 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.[51] 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.[52] 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 2**). 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.[53]

Some workgroup members, however, raised concerns about unnecessarily complicating the policy with the inclusion of an optional single or en bloc allocation pathway.[54,55] 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 feedback from the first round of public comment (fall 2016), 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. Finally, the Committee opted to lower the mandatory allocation weight threshold to 18kg following the June 2017 OPTN/UNOS Board of Directors. The proposal was not approved in part due to concerns over the change in weight threshold (see "Was this proposal changed in response to public comment?" below).

[51] *Meeting Minutes.* En Bloc Kidney Workgroup. OPTN/UNOS Kidney Transplantation Committee. September 16, 2016.
[52] Ibid.
[53] Stewart, *Double and En Bloc Kidney Data.*
[54] En Bloc Kidney Workgroup Meeting Minutes, September 16, 2016.
[55] 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.[56]

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.[57,58] 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 whether 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.[59]

[56] OPTN *Policy 5.9 Released Organs*. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_05. Accessed January 3, 2017.
[57] Pelletier, 1651.
[58] Maluf, 2704, 2707.
[59] 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:[60,61]

- 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.[62] 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
(Based on the 2015 KDRI to KDPI conversion)

	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%

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.

[60] *Meeting Minutes*. En Bloc Kidney Workgroup. OPTN/UNOS Kidney Transplantation Committee. August 30, 2016.
[61] SRTR. "Question re: en bloc modeling options." Email to UNOS staff. December 19, 2016.
[62] 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 to program these changes in UNet 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 in the short-term. The workgroup also had to consider the competing interests of the dual 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 twenty 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%*.[63] 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.[64,65,66,67]

Previous Public Comment and Board of Director's Feedback

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

[63] En Bloc Kidney Workgroup Meeting Minutes, September 16, 2016.
[64] 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.
[65] 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.
[66] 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.
[67] 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.

favorable, with various recommendations suggested. 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. 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.

Following public comment, 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). The Board of Directors voted against approval of this proposal at its June 2017 meeting (16-yes, 21-no, 0 abstentions), citing concerns with two provisions: releasing the second kidney after splitting an en bloc kidney according to *Policy 5.9* and the mandatory en bloc allocation donor weight threshold of 20kg.

Consequently, this feedback, among Board of Director's suggestions, is reflected in the overarching themes, detailed below. The Committee's response and any subsequent changes made post-public comment and post-Board of Director's meeting are elaborated upon within each theme or sub-theme:

1. Releasing second kidney from a split en bloc unit according to *Policy 5.9 Released Organs*
2. Weight threshold for mandatory en bloc kidney allocation
3. Recommendation to remove the option to allocate en bloc/single from donors 15 kg to 25 kg
4. Other criteria to drive allocation of en bloc kidneys
5. KDPI and risk adjustment
6. Financial implications

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 kidneys knowing that it is permissible to split the kidneys. 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 Committee discussed these concerns at length, consulting with OPO and UNOS Organ Center staff to gain a clear understanding of what occurs following separation of a pair of kidneys. The Kidney Committee also considered several alternative policy solutions to reallocating the second kidney, including:

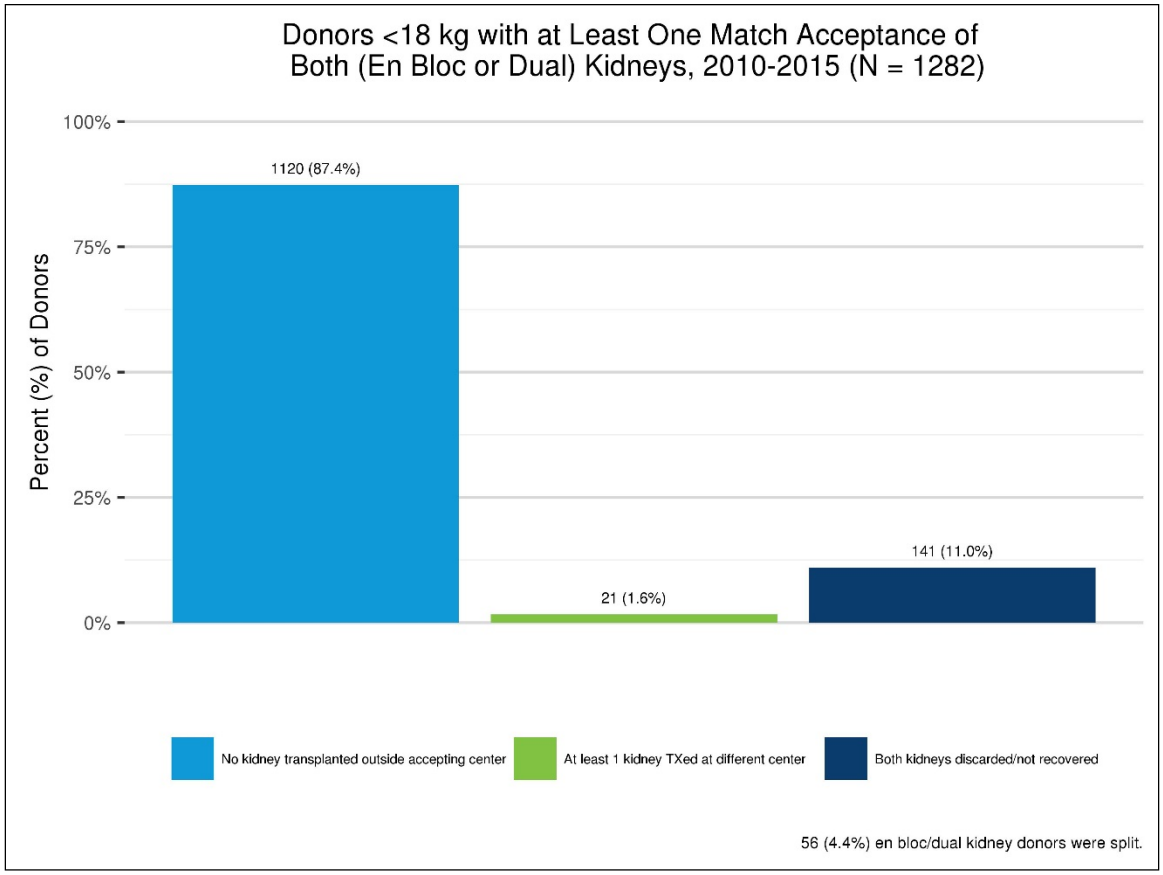
- Replacing the split kidneys provision with an exception to current *OPTN Policy 5.9* in the Dual and En Bloc Kidney proposals using the following models.
  - Modeled after *Policy 9.6.A Segmental Transplant and Allocation of Liver Segments*
  - Modeled after *Policy 9.8.A Open Variance for Segmental Liver Transplantation*
  - Modeled after *Policy 14.6.B Placement of Non-directed Living Donor Organs*
  - New model

Ultimately, the Committee reconfirmed its commitment to current policy and practice per *Policy 5.9* for two primary reasons. First, the Committee felt that creating an exception to *Policy 5.9* for en bloc transplants could increase instances of gaming; an en bloc offer could easily be split to turn one transplant into two at a given center. Second, the Committee believes strongly that consistency with the kidney allocation system is the most fair and ethical approach to increasing utilization of this resource.

However, functionality in DonorNet may be adjusted to improve efficiencies in the process and reduce the time needed to determine whether a split en bloc kidney can be reallocated to a nearby candidate. En bloc allocations may be configured with IT programming to create two match runs at once: the first for en bloc allocation with KDPI masked, and the second for single allocation in case of the need to split, with KDPI shown. Instructions to use the single match run only in the event of a split will be included. This will allow the OPO to immediately identify the next candidate on the list without having to run a new match as soon as the surgeon indicates they are planning to split the pair.

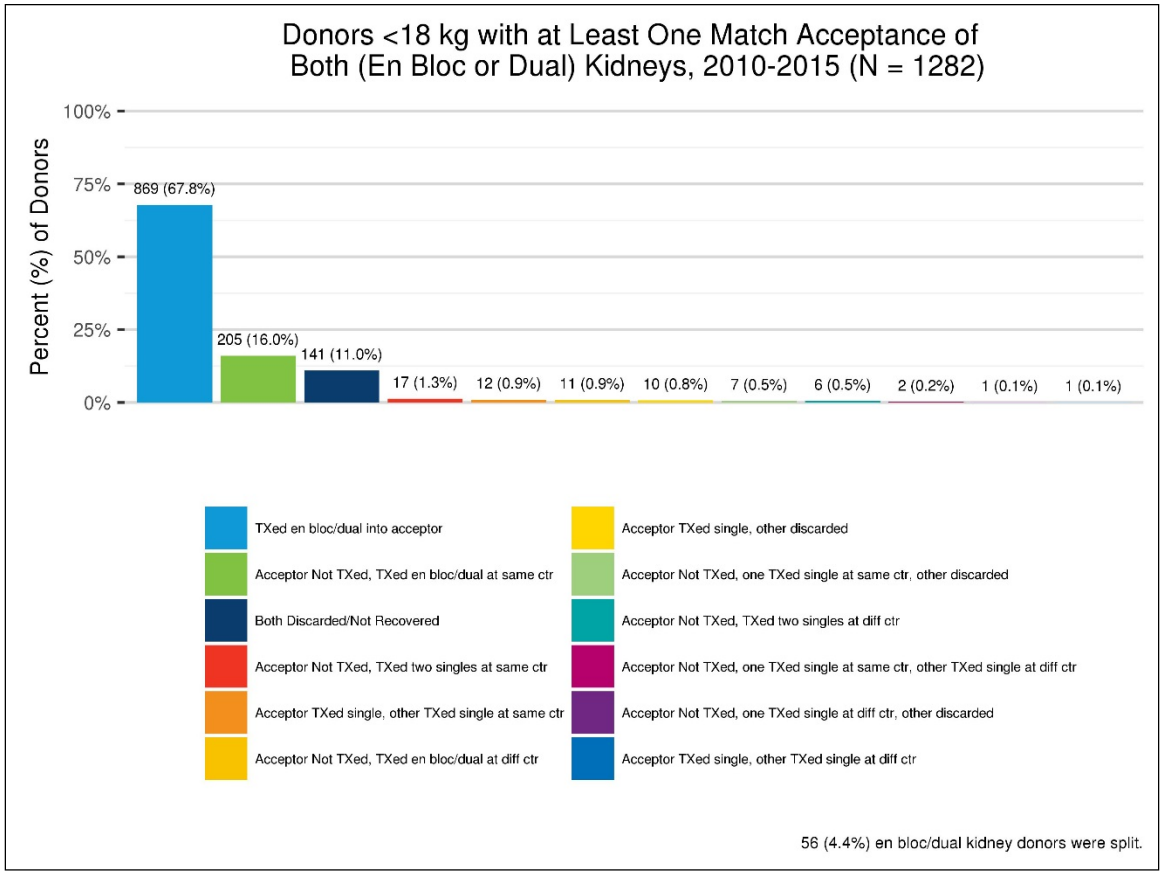
While the Committee acknowledged the concern over added cold ischemia on the second kidney, the members agreed that confusion or lack of exposure to the application of *Policy 5.9* in practice might be driving some to oppose its inclusion in this project. *Policy 5.9* is current practice for OPOs and transplant programs. As shown in Figure 7, for donors less than 18kg, just 1.6% of offers, in which both kidneys were accepted between 2010 and 2015, had at least one kidney transported outside of the accepting center.

Figure 2: *Donors <18kg with at Least One Match Acceptance of Both (En Bloc or Dual) Kidneys, 2010-2015*[68]



[68] Wilk, Amber. *Donors <18kg with at Least One Match Acceptance of Both (En Bloc or Dual) Kidneys, 2010-2015*. Prepared for the OPTN/UNOS Kidney Transplantation Committee. 5 July 2017.

Figure 3: *Donors <18kg with at Least One Match Acceptance of Both (En Bloc or Dual) Kidneys, 2010-2015*[69]



Given that split kidneys often stay at their receiving hospital, the Committee was asked why the proposed policy does not default to allowing surgeons to keep both kidneys at their center. The Committee felt strongly that a patient-centered policy would ensure that candidates nearby (i.e. those for whom transporting the organ a second time would *not* put it at risk for discard) with higher priority on the Waitlist are first offered the organ before allowing the receiving surgeon to keep both kidneys. Between 2010 and 2015, there were 1,282 offers accepted for both (dual or en bloc) kidneys in the United States for donors less than 18kg. Of these offers, 56 (4.4%) were transplanted as single kidneys (i.e., the kidney unit was split), and of those offers that were split, just 10 offers had at least one of the single kidneys physically reallocated to a different hospital for transplant.[70] In other words, at least 10 candidates received transplants from transported split kidneys that otherwise may not have should the surgeon have been allowed to keep both kidneys. The Committee feels that every effort should be made to allocate the released organ to the next patient on the match run, and that deviating from the established match run without due diligence to the next candidate on the list would be in opposition to the core values of the OPTN.

The Committee found that alignment with current *OPTN Policy 5.9* is the most transparent and patient-centered method to managing released kidneys.

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 en bloc kidneys are split, nor discards

[69] Wilk, Amber. *Donors <18kg with at Least One Match Acceptance of Both (En Bloc or Dual) Kidneys, 2010-2015*. Prepared for the OPTN/UNOS Kidney Transplantation Committee. 5 July 2017.
[70] Wilk, Amber. "Data – OPTN," *United Network for Organ Sharing*, https://optn.transplant.hrsa.gov/data/. Accessed 8 July 2017.

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 that split kidney 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 single kidney 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

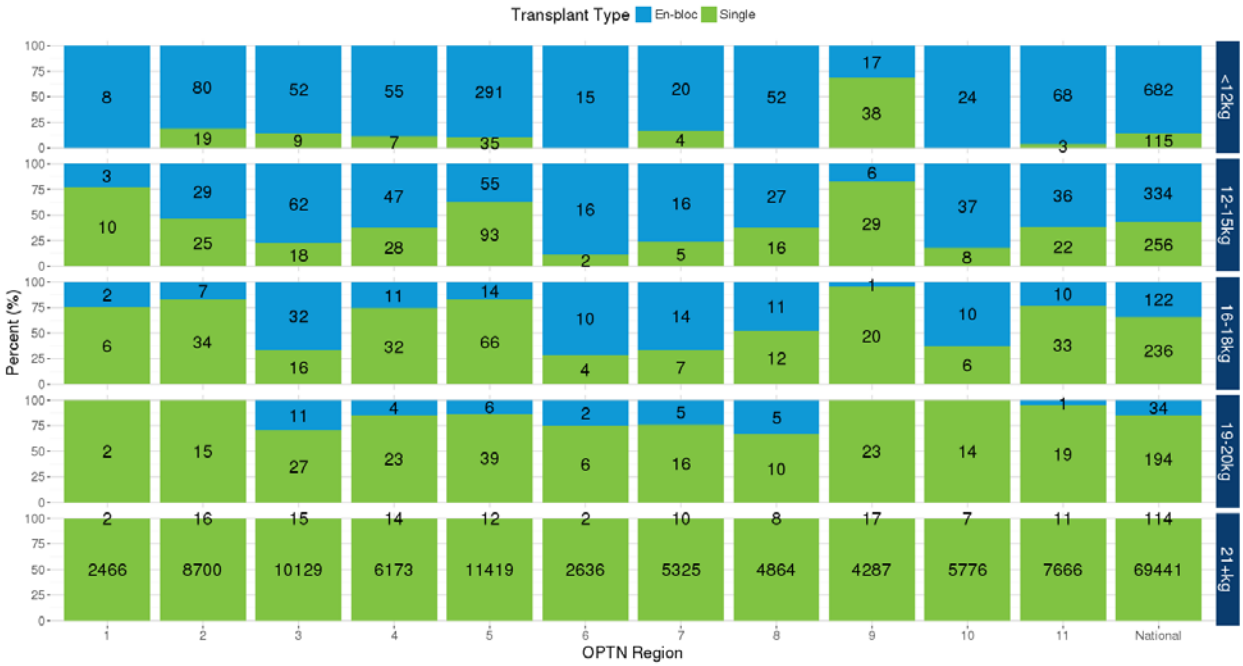
The community largely concurred with the Committee's proposed weight threshold of less than 15 kg for mandatory en bloc kidney allocation. However, there was some variation across regions. Some regions suggested raising the weight threshold from 15 kg to 20 kg. One region even suggested raising the threshold 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 commenters 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, the OPO 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 larger donors. More programs opting in could result in less effective placement if these additional programs only intend to transplant en bloc kidneys at the high end of the weight threshold. 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 (<12kg, 12-15kg, 16-18kg, 19-20kg, 21+kg) and OPTN Region (**Figure 4**).[71]

[71] 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, June 12, 2017.

Figure 4: Percent of Transplants En Bloc vs. Single by OPTN Region and Donor Weight, 2010-2015



Source: Wilk, "Percent of Transplants En Bloc vs. Single by OPTN Region and Donor Weight, 2010-2015," 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 kg 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 kg 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 the 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 kg to 20 kg en bloc about 50 percent of the time (one 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.[72] 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.[73] 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.

[72] Maluf, 2704.
[73] Sureshkumar. *When Is It Reasonable to Split Pediatric En Bloc Kidneys*? 3521.

The Board of Directors expressed general concern about the increase in the weight threshold from 15kg to 20kg, citing the potential for disadvantaging centers who perform single transplants from smaller donors.

The Committee considered this feedback and voted to lower the weight threshold to an 18kg donor weight for mandatory allocation. This change is still supported by data on en bloc transplants (**Figure 6**) and mitigates disadvantaging centers that are transplanting single kidneys in the 15-20kg weight threshold at a rate of about 50%. The Committee is concerned that further lowering the threshold would disadvantage centers performing en bloc transplants in this weight range. This proposal allows for en bloc kidneys in this weight range to be transplanted as singles by being split if deemed appropriate by the transplanting surgeon.

Given that the intent of this policy is to increase transplants in part by facilitating procurement of lower weight donors, the Committee wanted to accommodate programs currently doing en bloc transplants with kidneys from donors in the at least 15 but less than 18kg weight range.

Recommendation to remove the option to allocate en bloc/single from donors 15 kg 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 this could lead to confusion.

It became apparent that once this option was removed from consideration, 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 kg 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 kg 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 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 UNet^{SM} 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, dual 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 was satisfied with this explanation and did not have any concerns.

Financial implications

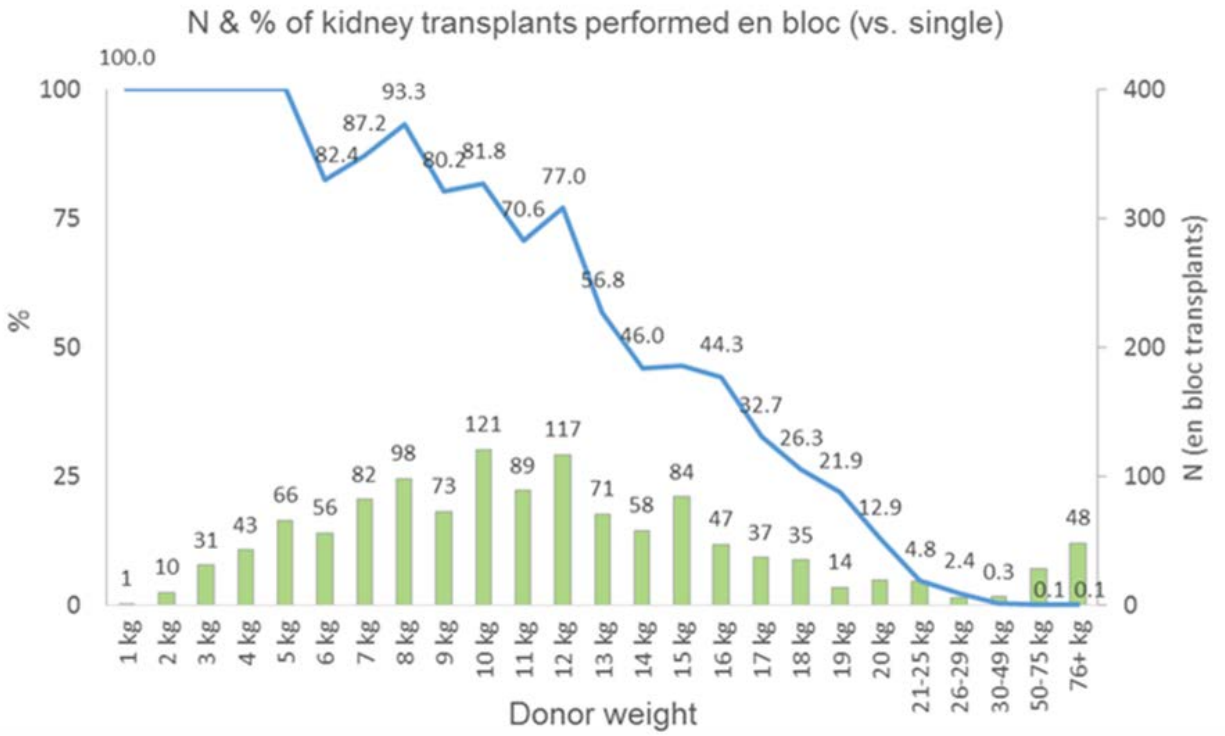
Finally, there were three comments regarding the financial implications of this proposal. The Transplant Administrators Committee asked if the Committee considered the financial impact to transplant programs. The Committee confirmed it had deliberated this, and acknowledged that facilitated placement 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.

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 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.[74,75,76,77]

[74] Pelletier, 1647.
[75] Maluf, 2704, 2708-2709.
[76] Sureshkumar, *When Is It Reasonable to Split Pediatric En Bloc Kidneys?* 3522.
[77] Al-Shraideh, 245.

Figure 5: 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.[78]

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 (**Figure 6**).[79] 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".[80, 81]

[78] 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.
[79] Ibid.
[80] Pelletier, 1648.
[81] Maluf, 2711.

Figure 6: Numbers of small (≤20 kg) pediatric organ donors, kidney donors and kidney transplants (single and en bloc) [82]

Donors[1]			Kidneys				Transplants[2]	
Weight (kg)	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)

[1]Donors: defined as someone who donates at least one solid organ for transplantation.
[2]Includes solitary and multi-organ kidney transplants (either single or en bloc).
[3]The 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.
[4]The 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%.
[5]Sum 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.
[6]The 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.

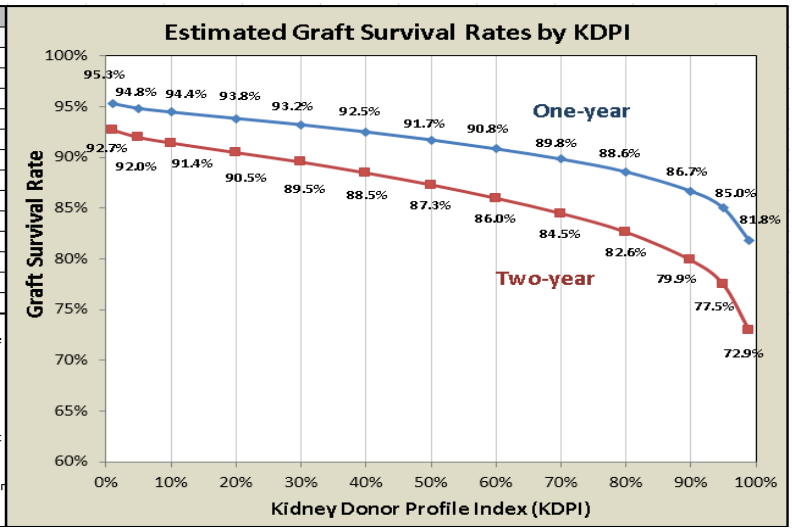
As previously noted, KDPI, as currently calculated, is not optimal in en bloc kidney allocation as potentially eligible candidates are screened off the match run for en bloc kidney offers based on their acceptance criteria. The workgroup's decision to mask en bloc kidney offers' KDPI is due to the fact 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:

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

Figure 7: Current Survival Rate Guide Provided for Members in DonorNet

KDPI	Estimated SINGLE Kidney Graft Survival Rates				
	1 Year	2 Years	3 Years	5 Years	8 Years
1%	95.3%	92.7%	89.9%	83.3%	72.2%
5%	94.8%	92.0%	88.9%	81.8%	69.9%
10%	94.4%	91.4%	88.1%	80.6%	68.1%
20%	93.8%	90.5%	86.8%	78.6%	65.1%
30%	93.2%	89.5%	85.6%	76.7%	62.3%
40%	92.5%	88.5%	84.2%	74.5%	59.2%
50%	91.7%	87.3%	82.6%	72.2%	55.9%
60%	90.8%	86.0%	80.8%	69.6%	52.4%
70%	89.8%	84.5%	78.9%	66.7%	48.6%
80%	88.6%	82.6%	76.5%	63.3%	44.2%
90%	86.7%	79.9%	72.9%	58.3%	38.2%
95%	85.0%	77.5%	69.8%	54.2%	33.5%
99%	81.8%	72.9%	64.2%	46.9%	25.9%

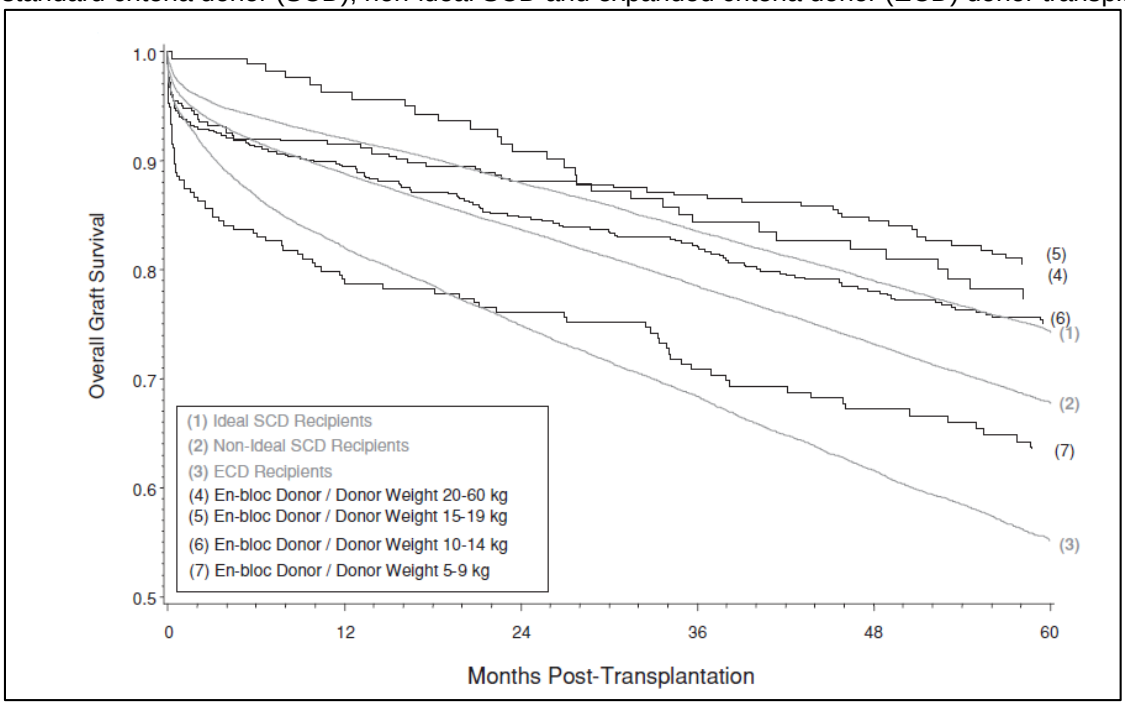
Based on OPTN data **as of April 4, 2014** including primary, solitary, adult, deceased donor kidney transplants from 2004-2011. These survival rates are for SINGLE kidney-alone transplants; survival rates are generally higher for en bloc or double kidney transplants. These rates were not adjusted for recipient characteristics, but instead reflect the expected survival averaged across the broad spectrum of adult recipients. The survival rates for any particular recipient will depend on specific characteristics of that recipient. Survival rates were estimated using a Cox regression model with log(KDRI) as the sole independent variable and graft failure defined as loss of graft or patient death. **Donor reference population: all deceased kidney donors recovered for transplantation in 2013.**



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.[83] 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 8**).

Figure 8: 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 expanded criteria donor (ECD) donor transplants



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

[83] Maluf, 2707-2708, 2710.

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

This policy proposal was open to public comment for the second time from July – October 2017. The proposal received 25 comments on the OPTN website. Comments were from OPTN/UNOS Committees, regions, professional societies, and individuals in the transplant community. Seven committees requested presentations on this proposal and all seven of them were supportive of the proposal moving forward to the Board of Directors with no changes, but suggested specific monitoring plans (Ethics, MPSC, OPO, Operations and Safety, Patient Affairs, Pediatric Transplantation, and Transplant Coordinators Committees). Five professional societies responded to feedback requests for the proposal and four were supportive of the proposal moving forward to the Board of Directors (ANNA, AOPO, AST, and ASTS). NATCO opposed the proposal as written but provided recommendations (see theme sections below for explanations). All eleven regions heard presentations for the en bloc allocation proposal and nine regions supported proceeding to the Board of Directors. Two regions (Region 5 and 8) supported the proposal with amendments (see theme sections below for explanations).

The Committee met on October 23, 2017, to discuss the following three themes resulting from public comment, and how to proceed with the en bloc allocation policy changes.

1. Weight threshold for mandatory en bloc kidney allocation
2. Releasing second kidney from a split en bloc unit according to *Policy 5.9 Released Organs*
3. Other themes

Weight threshold for mandatory en bloc kidney allocation

A majority (21 of 25) of the commenters support the current 18kg weight threshold for en bloc kidneys. Four commenters opposed the 18kg weight threshold; three of which (NATCO, Regions 2, 5) suggested a weight threshold of 15kg and one simply suggested a lower weight threshold.

The reasoning in the lower threshold recommendation is to force an increase in splitting above 15kg, which will increase the number of transplants. Changing the weight threshold to 15kg would eliminate centers that perform en bloc transplants using higher weight donors from receiving match offers. The en bloc match run will only include those centers that opt in for their candidates for the established weight threshold. Lowering weight threshold would involve changing proposal policy language, but would not have further effect on IT or other costs.

The Committee considered this feedback and voted to keep the current proposed 18kg donor weight for mandatory allocation. The Committee anticipated this theme of questioning based on earlier public comment and had supporting data available for all presentations, which helped garner buy-in and support. The data on en bloc transplants still supports this change and mitigates disadvantaging centers that are transplanting single kidneys in the 15-18kg weight threshold at a rate of about 50% (see data in the "*Weight threshold for mandatory en bloc kidney allocation*" [page 14] above in the "*How was this proposal developed*" section). The Committee is concerned that further lowering the threshold would disadvantage centers performing en bloc transplants in this weight range. This proposal allows for en bloc kidneys in this weight range to be transplanted as singles by being split if deemed appropriate by the transplanting surgeon.

Given that the intent of this policy is to increase transplants in part by facilitating procurement of lower weight donors, the Committee wanted to accommodate programs currently doing en bloc transplants with kidneys from donors in the at least 15kg but less than 18kg weight range.

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

In response to Board of Director's feedback, and to provide more data during the most recent public comment period, The Committee teamed with UNOS IT staff to ensure en bloc allocations will be configured with IT programming to create two match runs at once: the first for en bloc allocation with KDPI masked, and the second for single allocation in case of the need to split, with KDPI shown. Instructions to use the single match run only in the event of a split will be included. This will allow the OPO to

immediately identify the next candidate on the list without having to run a new match as soon as the surgeon indicates they are planning to split the pair.

While the Committee acknowledged the concern over added cold ischemia on the second kidney, the members agreed that confusion or lack of exposure to the application of *Policy 5.9* in practice might be driving some to oppose its inclusion in this project. *Policy 5.9* is current practice for OPOs and transplant programs. As shown in **Figure 3** [page 12], for donors less than 18kg, just 1.6% of offers, in which both kidneys were accepted between 2010 and 2015, had at least one kidney transported outside of the accepting center.

Most commenters supported the Kidney Committee's decision to follow *Policy 5.9* when splitting en bloc kidneys at an accepting program. The OPO Committee, NATCO, and Regions 2, 8, and 9 submitted comments that advocate for the accepting program to keep both kidneys upon splitting kidneys originally allocated as en bloc kidney offers. The reason given was to lessen cold ischemia time on the second kidney, thereby preventing possible discard of the organ. OPTN data shows that over six years, 56 kidney pairs from donors under 18kg were split, and only 21 offers had at least one kidney travel to a new center for transplant. It's important to note that none of the transplanted kidneys from the previously mentioned 21 donors left the accepting candidate's DSA. The Committee reinforced during each presentation that alignment with *Policy 5.9* is the most transparent and patient-centered method to managing released kidneys, even if rare. The Committee feels that every effort should be made to follow the OPTN's established allocation sequences. Deviating from these sequences without conducting due diligence to the next candidate on a given match run would be in opposition to the core values of the OPTN. The Committee was consistent in its discussion of this topic, as it was intently discussed earlier in the process as well (see "Releasing second kidney from a split en bloc unit according to *Policy 5.9: Released Organs*" [page 11] above). Post-implementation monitoring will help the Committee review these scenarios (see "How will the sponsoring Committee evaluate whether this proposal was successful post implementation?" section below).

Theme 3: Other Concerns

The concept of split en bloc kidneys incentives or disincentives is tied to the right of first refusal for the second kidney when splitting. A few members from the Pediatric Transplantation Committee and an individual surgeon commenter stated that the decision to release the second kidney after splitting according to *Policy 5.9* at the proposed 18kg weight threshold does not incentivize surgeons to split the en bloc kidneys. The intent of the proposed policy is to direct OPOs to allocate en bloc kidneys and to continue to allow splitting en bloc kidneys under the clinical judgment of the transplant team. The purpose of this policy is not to incentivize any surgical decisions, but allow the transplant team to make those decisions using their medical judgment.

There were several comments (from members on Patient Affairs Committee, Regions 2 and 6) directed at the potential effect of the en bloc kidney proposal on the pediatric population receiving small single kidneys. If the en bloc kidneys are split and the KDPI of the remaining kidney is above 85 percent, then pediatric candidates do not receive that offer. A select number of pediatric programs (in select regions) are transplanting small single kidneys into pediatric patients routinely. Although en bloc kidneys are not typically transplanted into (small) pediatric candidates, they can be transplanted into adolescents. Pediatric programs will still have access to small kidneys, providing they opt-in to receiving en bloc kidney offers. Screening pediatric candidates off KDPIs of 85 percent or above is not a new practice, it is current allocation, and does not change with this proposal. The Committee decided that education for pediatric programs is essential to prepare them for the opt-in system changes, as well as monitoring the effect of the policy changes on the pediatric population.

The Committee met on October 23, 2017, and voted to send the en bloc kidney allocation policy language to the Board of Directors in December 2017 with no changes (19-yes, 0-no, 0-abstain).

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.[84]

The proposed policy mainly impacts adult kidney transplant candidates, as a majority of en bloc kidneys are transplanted into adult recipients (**Table 4**).[85]

Table 4: Kidney Transplants by Procedure Type and Recipient Age, January 2000 – December 2007

RECIPIENT AGE	*Single Kidney*	*En Bloc Kidney*	*Dual Kidney*	*All*
	N (%)	**N (%)**	**N (%)**	**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[86,87,88,89]. Waiting time was also found to be reduced for pediatric candidates.[90]

How does this proposal impact the OPTN Strategic Plan?

1. *Increase the number of transplants:* This policy aims to increase the number of transplants with added efficiencies targeted at kidneys that are currently left unrecovered of 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 years and under age range.[91] 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.
2. *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.
3. *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

[84] https://optn.transplant.hrsa.gov/data/
[85] Stewart, *Double and En Bloc Kidney Data.*
[86] 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.
[87] 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/petr.12021.
[88] 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.
[89] 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.
[90] Winnicki, 170.
[91] Klassen, 1711.

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.[92]

4. *Promote living donor and transplant recipient safety:* There is no impact to this goal
5. *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 UNet^{SM}. UNOS IT provides cost estimates for each proposal that will require programming to implement. IT Implementation effort to modify waitlist and allocation is substantial. If this proposal and the Dual Kidneys proposal are approved, IT would implement these together over approximately 6,510 hours. If this proposal was implemented as a single effort, IT hours would be less, at just under 3,600 hours (very large). Architecture work to separate kidney allocation logic from other organs is estimated at 2,200 hours, in addition to IT hours estimated. Architecture work assumes the en bloc and dual kidneys proposals are executing together.

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 the allocation will result in both an en bloc match run and single kidney (in case of split kidneys) match run available at the same time. 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

[92] Winnicki, 171.

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 for programs already participating in en bloc transplants. Implementation can occur immediately or 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 costs identified. Potential efficiencies include reduced waitlist maintenance and a reduction in patient stay.

OPOs

As en bloc allocation already occurs, this proposal increases efficiency in the allocation process. 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 2.11.A: 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 2.11.A* is just a clarification.

Upon implementation, members will need to opt-in to receive en bloc kidney offers at the candidate level in Waitlist.

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 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.

UNOS 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?

- If en bloc kidneys are split, did the remaining kidney stay local?
- 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 (and split).
- 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), 5.3 (Additional Acceptance and Screening Criteria), 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

5.3.G Dual and En Bloc Kidney Acceptance Criteria

In order for a kidney candidate to receive offers of both kidneys from a single deceased donor, a transplant hospital must specify to the OPTN Contractor that the candidate is willing to accept these kidneys.

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

~~An OPO must offer kidneys individually through one of the allocation sequences in *Policy 8.5: Kidney Allocation Classifications and Rankings* before offering both kidneys to a single candidate unless the OPO reports to the OPTN Contractor prior to allocation that the deceased donor meets *at least two* of the following criteria:~~

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

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

8.6.B Allocation of En Bloc Kidneys

If a host OPO procures both kidneys from a single deceased donor less than 18 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%.*

8.6.C Transplanting Kidneys Individually after Allocation of Both Kidneys from a Single Deceased Donor to a Single Candidate

If the transplanting surgeon determines, based on medical judgment, that kidneys procured together from a single donor should instead be transplanted individually, then the receiving transplant 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 together. 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*.

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