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Public Comment Proposal

Improving Allocation of En Bloc Kidneys

OPTN/UNOS Kidney Transplantation Committee

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Contents

Improving Allocation of En Bloc Kidneys

Affected Policies:	*Policy 2.11.A: Required Information for Deceased Kidney Donors, Policy 8.6 Double Kidney Allocation*
Sponsoring Committee:	*Kidney Transplantation Committee*
Public Comment Period:	*January 23, 2017 – March 24, 2017*

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 utilize kidneys from small pediatric donors. However, centers may be reluctant to transplant single kidneys from small donors due to technical challenges, inferior function, and poor 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 how to allocate en bloc kidneys
- DonorNet® overestimates the KDPI score for en bloc kidneys, which has the potential to screen medically suitable candidates off the match run and other programming limitations make allocating kidneys en bloc a challenge

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

This proposal aligns with three OPTN strategic goals. First, it should increase the number of transplants by utilizing kidneys previously left unrecovered or discarded. Second, it will 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 pediatric candidate's time on the waitlist, conferring not only a survival advantage, but 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.

Is the sponsoring Committee requesting specific feedback or input about the proposal?

1. Should the weight threshold for mandatory en bloc kidney allocation be increased (i.e. 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 altogether? The provision allowing surgeons to split them if they determine upon receipt that they can be transplanted singly would remain.

What problem will this proposal solve?

Kidney transplantation is the preferred treatment for end stage renal disease (ESRD), yet demand for kidneys far exceeds supply. At the conclusion of 2016, there were 98,962 candidates waiting for a kidney transplant, but only 12,245 deceased donor kidney transplants occurred.[1,2] One strategy to increase the donor pool is to utilize kidneys small pediatric donors (≤ 25 kg). However, centers may be reluctant to transplant kidneys from very small donors singly due to technical challenges, inferior function and poor 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 how to allocate en bloc kidneys
- DonorNet® overestimates the KDPI score for en bloc kidneys, which has the potential to screen medically suitable candidates off the match run and other programming limitations make allocating kidneys en bloc 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 will not meet the criteria in that policy. Approximately two percent of all kidney transplants are en bloc kidney transplants.[11] However, increasingly frequent questions from members indicating confusion about how to allocate en bloc kidneys prompted the Kidney Transplantation Committee (Committee) to develop a policy.

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

When the concept of the Kidney Donor Risk Index model (KDRI) for deceased donor kidneys was introduced, the authors identified HLA match, cold ischemic time, en bloc, and dual kidney coefficients in addition to the 10 variables that were ultimately included in the Kidney Donor Profile Index (KDPI) score.[12] When KDPI was implemented into DonorNet® in 2012, it omitted these 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 versus as singles, and the match run needs KDPI to determine which allocation sequence to use and

[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.
[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.

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 of 2012, several members asked about whether and how KDPI accounts for en bloc use of kidneys.

Table 1 illustrates the vast majority (82%) of en bloc transplants between January 2000 and December 2007 had KDPI scores (retrospectively calculated) between 50% and 85%.[13] Although this data is dated, more recent analyses show the KDPI scores for en bloc kidneys remain essentially unchanged: 84% of en bloc kidney transplants from 2010-2015 had KDPI scores between 51-90%, which is consistent with the 82% between 50-85% indicated in Table 1.[14] Among kidneys recovered for transplantation, kidneys with KDPI above 50% are at increased risk of discard, and kidneys with KDPI above 85% have particularly high discard rates, approaching and even exceeding 50%.[15] Further, these scores are not reflective of graft failure risk for kidneys transplanted en bloc, since the implemented KDPI score assumes each kidney will be transplanted singly and does not account for the survival advantage associated with en bloc usage.[16] 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.[17,18,19,20,21,22,23,24,25] Therefore, candidate populations who might benefit from en bloc kidney transplant may be screened off the match run because DonorNet® may inflate the KDPI to a value over 85%, by assuming single-kidney transplantation.[26],[27] Many candidates on the waiting list, in particular pediatric candidates, have a maximum acceptable KDPI value of 85%, and policy requires transplant programs to obtain additional consent from candidates to receive kidneys with a KDPI value over 85%.[28]

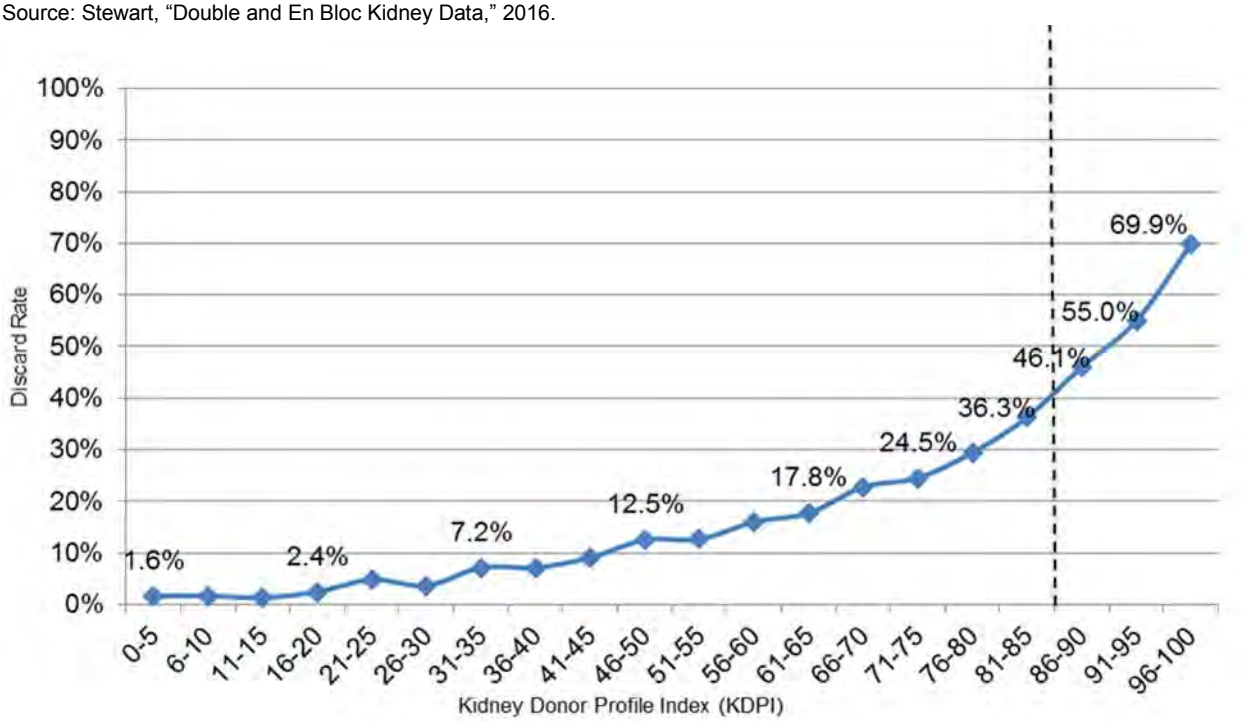
[13] Stewart, *Double and En Bloc Kidney Data*.
[14] Stewart, Darren. *Analysis of Dual (double) and En Bloc Kidney Transplants, 2010-2015.* OPTN/UNOS Descriptive Data Analyses. Prepared for Double and En Bloc Kidney Workgroup Conference Call, April 15, 2016.
[15] Stewart, *Double and En Bloc Kidney Data.*
[16] Rao et al, 232.
[17] Pelletier et al, 1649-1651.
[18] Sureshkumar et al, 351-352.
[19] Mohanka et al, 266-267.
[20] Kayler et al, 2745-2749.
[21] Beltrán et al, 2842-2843.
[22] Sharma et al, 565-568.
[23] Maluf et al, 2705-2708, 2710-2711.
[24] Al-Shraideh et al, 243-245.
[25] 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).
[26] Al-Shraideh, 245.
[27] Preczewski et al.
[28] 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: Kidney Transplants by Procedure Type and KDPI

Jan 2000 – Dec 2007	TRR KIDNEY PROCEDURE TYPE						
	Single kidney		En bloc kidneys		Sequential (dual)		All
	N	%	N	%	N	%	N
KDPI (ref. population = 2011)							
Could not be calculated	743	1.3	11	1.2	25	2.6	779
0-20%	13,711	23.8	3	0.3	8	0.8	13,722
21-49%	18,470	32.0	50	5.3	39	4.0	18,559
50-75%	14,983	26.0	595	62.7	181	18.8	15,759
76-85%	4,754	8.2	181	19.2	130	13.5	5,065
86-90%	2,309	4.0	57	6.0	124	12.8	2,490
91-95%	1,720	3.0	35	3.7	186	19.3	1,941
96-100%	981	1.7	17	1.8	272	28.2	1,270
All	57,671	100.0	949	100.0	965	100.0	59,585

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

Figure 1: Discard Rates among Recovered Kidneys, by KDPI
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 can be allocated en bloc and mandates that centers must indicate in DonorNet® that they are willing to accept en bloc kidneys. The proposed policy will facilitate placement of en bloc kidneys to centers that will utilize them, thereby increasing use of kidneys that might have previously been discarded or unrecovered due to reluctance to

transplant small donor kidneys singly. In addition, the Committee proposes omitting 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 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 and transplant 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.[29,30,31,32,33,34,35,36]

How was this proposal developed?

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

The workgroup considered several solutions. They quickly dismissed education or guidance because although those options would provide some direction to OPOs on how to allocate kidneys en bloc, they would not address the lack of a policy, nor would they address the issues with KDPI and the challenges with DonorNet®. It is difficult to assess the impact of guidance or education on behavior, and guidance is not enforceable. Similarly, a DonorNet® programming fix 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 2 percent of all transplants.[37] En bloc kidney transplantation is a complex procedure and many centers may lack technical expertise; of the 264 kidney transplant centers in the United States, 89 centers performed any en bloc kidney transplants during the year pre-and year post-KAS.[38] Of those 89 centers, just 10 percent performed 10 or more en bloc kidney transplants, 26 percent performed between 5 and 8 en bloc kidney transplants, and 64 percent performed between 1 and 4 en bloc kidney transplants.[39] However, the workgroup felt that creation of an en bloc policy was long overdue and with the OPTN strategic plan emphasis on increasing the number of transplants, this strategy could address, in part, the problem of a dearth of donor organs.[40]

[29] Pelletier et al, 1649-1651.
[30] Sureshkumar et al, 351-352.
[31] Mohanka et al, 266-267.
[32] Kayler et al, 2745-2749.
[33] Beltrán et al, 2842-2843.
[34] Sharma et al, 565-568.
[35] Maluf et al, 2705-2708, 2710-2711.
[36] Preczewski et al.
[37] Stewart, *Double and En Bloc Kidney Data.*
[38] "US Hospitals with Kidney Transplant Centers." Scientific Registry of Transplant Recipients. http://www.srtr.org/csr/current/Centers/TransplantCenters.aspx?organcode=KI. Accessed December 14, 2016.
[39] 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.
[40] Klassen, D. K., L. B. Edwards, D. E. Stewart, A. K. Glazier, J. P. Orlowski, and C. L. Berg. "The OPTN Deceased Donor Potential

The OPTN's Deceased Donor Potential Study recently estimated a gap of that may be as high as about 800 unrealized potential donors per year within the 5 and under age range.[41]

Once the workgroup settled on proposing a policy, it considered whether a single policy could effectively inform how to allocate both en bloc and double kidneys, as both entail transplanting two kidneys from a single donor into a single recipient. The workgroup felt that because the donor populations were distinctly different, there should be two separate policies. Therefore, a separate workgroup is developing a double kidney allocation policy.

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

1. Develop criteria targeting kidneys at risk of being unrecovered or discarded
2. Avoid decreasing the number of transplants
3. Facilitate placement of en bloc kidneys to centers who will use them

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 is currently no universally agreed upon donor characteristics to help centers determine which kidneys to transplant singly versus en bloc. Based on an initial literature review, the workgroup debated including the following donor characteristics:

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

It also considered KDPI, anatomy (kidney size) and donor type (donation after circulatory death (DCD) donor vs. brain dead (BD) donor). The workgroup eliminated donor height as a criterion, as clinicians do not tend to consider donor height in evaluation of kidney offers. Likewise, it dismissed age as a criterion, as donor weight and anatomy (kidney size) were deemed to be more critical decision points in the evaluation process. There was consensus that donor type would not necessarily influence a center's decision whether or not to use kidneys en bloc versus singly. The OPO members of the workgroup favored criteria that was 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 that programs consider when evaluating whether to use kidneys from small pediatric donors singly or en bloc.[42,43,44,45]

Although there was consensus among the workgroup to include weight as a criterion, there was much 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 significantly change current practice. Likewise, it felt comfortable expanding that mandate to donors between 5-10 kg, as a majority of those kidneys are currently allocated en bloc. It acknowledged that the

Study: Implications for Policy and Practice." *American Journal of Transplantation* 16, no. 6 (2016): 1707-714. doi:10.1111/ajt.13731.
[41] Ibid.
[42] Pelletier, 1647.
[43] Maluf, 2704, 2708-2709.
[44] 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.
[45] Al-Shraideh, 245.

weight range less than 10 kg would make the biggest impact in increasing utilization of kidneys at highest risk of discard or being left unrecovered. Studies confirm this recommendation.[46,47,48]

Next, the workgroup debated whether the policy should extend to kidneys from donors between 10-20kg. Some workgroup members felt because en bloc transplants confer favorable outcomes, and approximately half of transplants from donors 10-15 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 high-volume en bloc transplant centers.[49] Others felt this was too liberal and the threshold should be scaled back to 10 kg. Ultimately, the workgroup was able to come to consensus that for donors less than 15 kg, OPOs *must* allocate kidneys en bloc, but requests feedback from the community on whether the community supports this weight threshold. As the workgroup proposes mandating en bloc allocation from this donor group, they felt strongly that they needed to include language permitting surgeons, based on their medical judgment, to split en bloc kidneys if they felt they could transplant into two recipients (see *Balancing utilization and outcomes* below*).*

The workgroup initially discussed keeping allocation of kidneys from donors greater than or equal to 15 kg unchanged, allocating as singles by KDPI first through one of the allocation sequences in *Policy 8.5 Kidney Allocation Classifications and Rankings*, before offering both kidneys to a single candidate, as is current practice.[50] 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.[51] Less than half of kidney transplants from donors in this weight range are done en bloc, as centers may be more comfortable transplanting these kidneys singly: the number of en bloc transplants decreased as donor weight increased (**Figure 3**). Although less than 5% of transplants from donors 21-25 kg are performed en bloc, the workgroup voted to include the higher weight threshold for optional en bloc allocation.[52]

Some workgroup members, however, raised concerns about unnecessarily complicating the policy with the inclusion of an optional single or en bloc allocation pathway.[53,54] 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 en bloc, it could switch to allocating those kidneys as singles (or vice versa) and how, although UNOS determined how that would work operationally (see **How will the OPTN implement this proposal?** below). These members thought excluding the 15-25 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. The

[46] Pelletier, 1647-1648, 1651.
[47] Al-Shraideh, 245.
[48] Stewart, *Double and En Bloc Kidney Data.*
[49] Al-Shraideh, 245.
[50] *Meeting Minutes.* En Bloc Kidney Workgroup. OPTN/UNOS Kidney Transplantation Committee. September 16, 2016.
[51] Ibid.
[52] Stewart, *Double and En Bloc Kidney Data.*
[53] En Bloc Kidney Workgroup Meeting Minutes, September 16, 2016.
[54] Turgeon, Nicole. "En Bloc Update." E-mail to UNOS staff. December 22, 2016. Primary thread.

Committee seeks input regarding whether to remove the option to allocate kidneys singly versus en bloc for 15 kg-25 kg donors in the proposed policy.

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. The workgroup acknowledged 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 he/she 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 OPTN Contractor or the OPO serving the candidate transplant program's designated service area (i.e. the "importing OPO") allocate the organ instead.[55] 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, the OPO representatives on the workgroup felt strongly that the policy should indicate *when* the OPO could allocate kidneys en bloc. Allocating kidneys can be a time-intensive process, and the OPO members felt that getting these kidneys to the centers most likely to utilize them as quickly as possible would increase the likelihood they would be accepted and transplanted. Workgroup members, including those whose centers do not perform en bloc transplants, agreed. Therefore, for donors at least 15 kg but less than 25 kg, OPOs will be able to indicate to centers via DonorNet® whether offers will be en bloc or single kidneys. This choice will need to be entered into DonorNet® prior to running the match. DonorNet® will automatically assume en bloc allocation of kidneys from donors less than 15 kg. There is also a provision in the proposed policy that requires transplant centers to indicate that they accept en bloc kidneys. If an OPO allocates kidneys en bloc, only candidates registered at centers who accept en bloc kidneys will appear on the match run. As there are relatively few[16] centers that perform a high volume of en bloc kidney transplants, this should expedite the allocation process.

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

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

survive an extended period of time post-transplant. These candidates are currently missing out on 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:[56,57]

- 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.[58] One of those is a yes/no indicator for whether a kidney is en bloc. If so, -0.364 is added to the raw KDRI score, which lowers the estimated risk of graft failure for those kidneys. If the kidney is transplanted singly, the KDRI is unchanged; in effect, the current KDRI/KDPI score assumes all kidneys are from single donors.

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

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

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

Based on the 2015 KDRI to KDPI conversion

As the conversion from KDRI to KDPI is not linear but percentile-based, it isn't 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.

Re-estimate KDRI/KDPI to include en bloc kidney coefficient only
Practically, this would also change the meaning of the KDRI. It is certain that the betas associated with each donor covariate would change, at least slightly. Additional predictors could be selected, or some

[56] *Meeting Minutes*. En Bloc Kidney Workgroup. OPTN/UNOS Kidney Transplantation Committee. August 30, 2016.
[57] SRTR. "Question re: en bloc modeling options." Email to UNOS staff. December 19, 2016.
[58] Rao et al.

current predictors might be dropped or re-parameterized. These potential changes would be a significant alteration to the allocation system. Further, the cost, level of effort and time may not be justified for the addition of a single variable. Although the Committee may decide to re-estimate the KDRI/KDPI in the future, at which time they may include the en bloc coefficient, there is no intent to do so short-term. The workgroup also had to consider the competing interests of the double kidney workgroup to avoid duplicating or contradicting their work; re-estimation of the KDRI might present challenges to their plans. Statistically, re-estimating KDRI/KDPI to include en bloc kidney coefficient only may be the most thorough and defensible option. However, for the reasons cited above, forcing en bloc kidneys into the 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 Kidney 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 the 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.

Finally, the workgroup discussed how en bloc kidneys should be allocated, in the absence of using the KDPI. Based on the optimal en bloc kidney transplant outcomes, the workgroup members wanted to ensure that all eligible candidates would receive en bloc offers, not just those who were willing or had consented to accepting high KDPI kidneys. As these kidneys' outcomes are more similar to kidneys with KDPI less than or equal to 20 percent, they should be allocated accordingly. Therefore, the workgroup agreed that en bloc kidneys (all kidneys from donors less than 15 kg or kidneys from donors at least 15 kg but less than 25 kg an OPO has opted to allocated en bloc) should be allocated according to *Policy 8.5.G Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%*.[59] 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.[60,61,62,63]

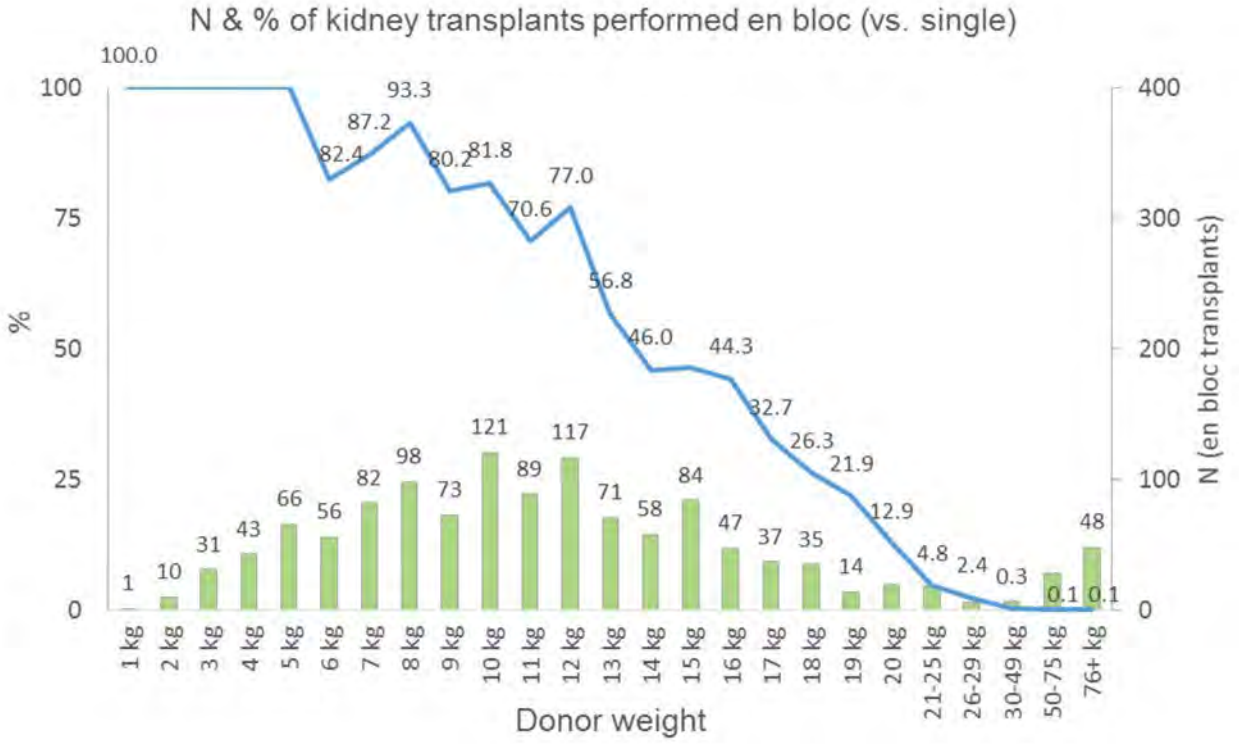
How well does this proposal address the problem statement?

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 Kidney Committee's first attempt at crafting en bloc allocation policy. The workgroup determined donor weight would be the

[59] En Bloc Kidney Workgroup Meeting Minutes, September 16, 2016.
[60] 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.
[61] 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.
[62] 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.
[63] 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.

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.[64,65,66,67]

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



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

In terms of kidneys that were transplanted, from 2010-2015, all kidney transplants from donors less than or equal to 5 kg were performed en bloc, and a vast majority of transplants from donors less than or equal to 12 kg were performed en bloc. For donors weighing 13-16kg, about half were performed en bloc, and half as single kidney transplants. En bloc transplants were very rare for donors greater than 25 kg.[68]

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.[69] 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".[70,71]

[64] Pelletier, 1647.
[65] Maluf, 2704, 2708-2709.
[66] Sureshkumar, 3522.
[67] Al-Shraideh, 245.
[68] 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.
[69] Ibid.
[70] Pelletier, 1648.
[71] Maluf, 2711.

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

	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.

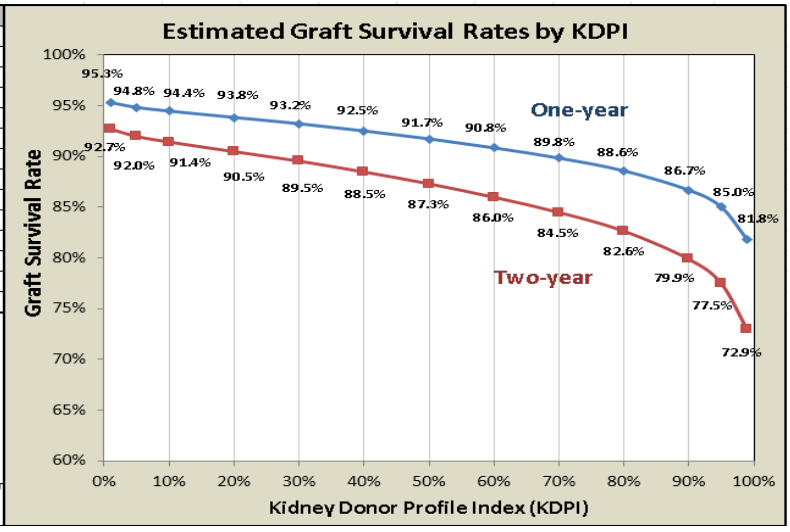
Source: Maluf et al, "Optimizing Recovery, Utilization and Transplantation Outcomes for Kidneys from Small, ≤20 kg, Pediatric Donors," *AJT*, 2705

As previously noted, KDPI, as currently calculated, is not optimal in en bloc kidney allocation as it causes potentially eligible candidates to be screened off the match run for en bloc kidney offers. 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 kidney usage. Although Figure 4 (included in DonorNet®) shows survival rates for single kidney transplants, it is helpful to illustrate the inaccuracy of KDPI in the setting of en bloc kidney transplants:

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

	Estimated SINGLE Kidney Graft Survival Rates				
KDPI	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%

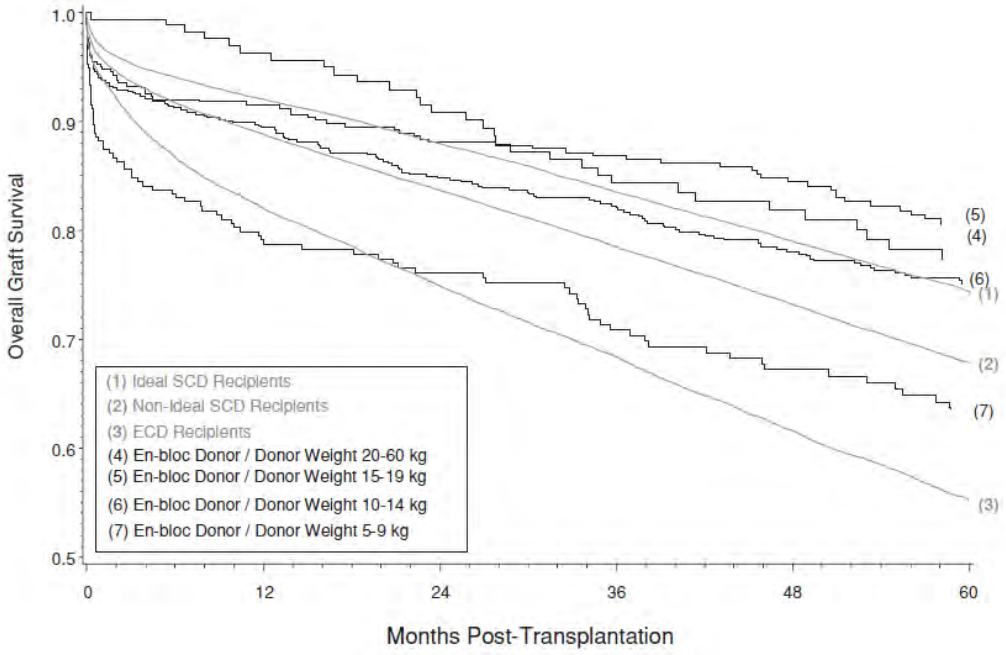
Based on OPTN data **as of April 4, 2014** including primary, solitary, adult, deceased donor kidney transplants from 2004-2011. These survival rates are for SINGLE kidney-alone transplants; survival rates are generally higher for en bloc or double kidney transplants. These rates were not adjusted for 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.[72] However, in tandem with eligible expertise and training, a favorable unintended consequence may be that more centers choose to perform en bloc kidney transplants. While experienced programs are familiar with the advantageous outcomes en bloc kidney transplants confer, other centers may not be aware that en bloc kidney transplants have been shown to offer favorable short-, medium-, and even long-term outcomes.

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



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

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.[73]

The proposed policy mainly impacts adult kidney transplant candidates, as a majority of en bloc kidneys are transplanted into adult recipients.[74]

[72] Maluf, 2707-2708, 2710.
[73] https://optn.transplant.hrsa.gov/data/
[74] Stewart, *Double and En Bloc Kidney Data.*

Table 4: Kidney Transplants by Procedure Type and Recipient Age

Jan 2000 – Dec 2007	TRR KIDNEY PROCEDURE TYPE						
	Single kidney		En bloc kidneys		Sequential (dual)		All
	N	%	N	%	N	%	N
RECIPIENT AGE							
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	100.0	949	100.0	965	100.0	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[75,76,77,78]. Waiting time was also found to be reduced for pediatric candidates.[79]

How does this proposal impact the OPTN Strategic Plan?

Increase the number of transplants: This policy informs OPOs how to allocate kidneys previously left unrecovered or discarded due to donor size; as previously stated, a majority of kidneys from donors less than 20 kg are either unrecovered or discarded after recovery. In addition, the OPTN estimates there were 800 unrealized potential donors per year within the 5 and under age range.[80] This policy also facilitates placement to centers with en bloc expertise. 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 issue.

Improve equity in access to transplants: There is no impact to this goal

Improve waitlisted patient, living donor, and transplant recipient outcomes: When kidneys from a small donor are transplanted into a recipient en bloc versus singly, they confer comparable to superior outcomes. In addition, accepting en bloc kidneys could shorten a pediatric candidate's time on the waitlist, conferring not only a survival advantage and minimizing time on dialysis, but additional benefits. Shorter duration of dialysis is associated with increased pre-transplantation height in pediatric patients, which correlates to greater final adult height. Earlier transplantation may also improve cognitive development and reduce overall stress to the child and family.[81]

[75] 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.
[76] 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.
[77] 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.
[78] 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.
[79] Winnicki, 170.
[80] Klassen, 1711.
[81] Winnicki, 171.

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

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 DonorNet®. UNOS IT provides cost estimates for each public comment proposal that will require programming to implement. The estimates can be small (108-419 hrs.), medium (420-749 hrs.), large (750-1,649 hrs.), very large (1,650-3,999), or enterprise (4,000-8,000). This proposal is a very large scale project due to changes required in both the Waitlist[SM] and DonorNet® applications. In Waitlist[SM], an additional data field will be added for transplant centers to opt-in to accepting en bloc kidneys (both kidney alone and isolated kidney of a kidney-pancreas registration) and will be able to manage via listing defaults and Waitlist[SM] 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 for en bloc kidney allocation: the match results will be updated to enable OPOs to allocate for en bloc kidneys; if allocation subsequently changes to single kidney (or vice versa), OPOs would use the same match run to offer kidney as singles (lift en bloc 'screening'/refusals and apply KDPI 'screening'). These changes to the match results offering are unique. Changes to both applications will involve thorough testing as well as additional quality monitoring.

Any data entered in UNet[SM] may be subject to OPTN review. Members are required to provide documentation as requested and UNOS staff will continue to review deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to OPTN requirements.

The OPTN 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 centers 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 centers are required to submit annually, many centers 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 allocation is facilitated by the Organ Center. This proposal will allow transplant centers 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 centers 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 centers. Facilitated placement might increase travel costs for high volume en bloc transplant centers to procure en bloc kidneys from regions or geographies that lack a center that transplants en bloc kidneys. Current practice of charging one acquisition fee for en bloc kidneys is not expected to change in light of this proposal.

Will this proposal require members to submit additional data?

OPOs must now include donor weight in deceased donor kidney offers. It is likely that they already do this, since weight is already required to run kidney matches, although *Policy 2.11A Required Information for Deceased Kidney Donors* does not currently list donor weight as a required data element for kidney offers. No additional data collection is proposed.

How will members be evaluated for compliance with this proposal?

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

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

The following new reviews may also occur, but are subject to change based on the outcome of additional implementation discussions:

- Allocations staff may verify that the host OPO offered kidneys en bloc when both kidneys were recovered from a deceased donor weighing less than 15 kg.
- Allocations staff may review en bloc kidney allocations resulting in a single kidney being transplanted into the intended recipient. Staff may request the transplant program's documentation about why the kidneys were not transplanted en bloc and will also verify that the second kidney was released back to the host OPO according to policy requirements.

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, decreased, or remained the same?
- Has the number of centers performing en-bloc kidney transplants 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?

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 (<15 kg, 15-<25 kg), KDPI, and recipient age.

- The number (and percent) of deceased donor kidney transplant centers performing en-bloc transplants.
- Descriptive statistics on cold ischemic time of kidneys transplanted en-bloc.
- The number (and percent) of kidneys recovered en-bloc that are utilized vs. discarded, overall and by demographics, including but not limited to donor age, donor weight, and KDPI.

Policy or Bylaws Language

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

2.11.A Required Information for Deceased Kidney Donors

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

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

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

8.6.A. Allocation of Kidneys En Bloc from a Single Deceased Donor less than 25 kg to a Single Candidate

If a host OPO procures both kidneys from a single deceased donor less than 25 kg the host OPO must initially offer the kidneys according to *Table 8-9* below.

Table 8-9: Allocation of Kidneys from Deceased Donors less than 25 kg

If the deceased donor is:	Then the host OPO:
Less than 15 kg	*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%.*

If the deceased donor is:	Then the host OPO:
At least 15 kg and less than 25 kg	*May* do *either* of the following: • 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%.* • Offer each kidney individually according to the deceased donor's KDPI in allocation *Tables 8-5* through *8-8.*

En-bloc kidneys will only be offered to candidates at transplant programs that have specified to the OPTN Contractor that they are willing to accept en bloc kidneys.

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

8.6.B. Double Kidney Allocation

If kidneys are not offered en bloc according to *Policy 8.6.A*, then 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.

#