OPTN | UNOS Public Comment Proposal

Transplant Program Performance Measures (Outcome Measures)

OPTN/UNOS Membership and Professional Standards Committee

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Transplant Program Performance Measures (Outcome Measures)

Affected Policies:	*OPTN Bylaws, Appendix D, D.11.A. Transplant Program Performance*
Sponsoring Committee:	*Membership and Professional Standards*
Public Comment Period:	*August 14, 2016 – October 14, 2016*

Executive Summary

When the OPTN/UNOS Board of Directors approved the OPTN Strategic Plan in June 2015, they chose increasing the number of transplants as a high priority. The Membership and Professional Standards Committee (MPSC) has heard from the transplant community that the current post-transplant outcome review process creates disincentives for programs to transplant higher risk kidneys into patients for concern that the program will come under review if the transplants are not successful. While current risk-adjustment models appear to adequately adjust for the increased risk associated with use of higher risk kidneys, the perception remains. Data suggests that potentially hundreds of transplantable kidneys from higher risk donors are being discarded each year. Further research suggests that donor kidneys with similar characteristics to many of those discarded kidneys have been successfully used for transplant and may provide a better survival rate and quality of life than remaining on the waiting list for some patients.

In order to address this perceived disincentive, the MPSC is proposing an operational rule that would modify the current method for identifying kidney programs for outcomes review. The MPSC expects that this change would help eliminate concern that a kidney program would be identified for post-transplant outcomes review by the MPSC based on its performance in transplants using higher risk donor kidneys for higher risk recipients. Specifically, the MPSC would *only* make an inquiry to a kidney transplant program if the program falls outside the threshold for review of kidney graft or patient survival using all kidney transplants currently included in the analysis, *and* if they fall outside the threshold in an analysis of kidney transplants excluding higher risk transplants. Higher risk transplants would include any kidney transplant in a recipient with an estimated post-transplant survival (EPTS) score > 80 using a kidney from a donor with a KDPI ≥ 85. This two-step review process will avoid penalizing those kidney programs that are currently having successful outcomes with higher risk kidney transplants.

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

Should the MPSC implement an operational rule to forgo reviews of flagged programs that do not meet the review criteria when higher-risk kidney transplants are excluded?

Please note that the MPSC is also sponsoring a proposal this public comment cycle that specifically impacts how kidney transplant programs are reviewed, and that the MPSC developed independently from this proposal. Reviewing both of these proposals, do you recognize advantages or concerns with moving both forward in parallel?

What problem will this proposal solve?

When the OPTN/UNOS Board of Directors approved the OPTN Strategic Plan in June 2015, they also prioritized the goals in order to emphasize the primary areas of interest for the network for the next three years, and increasing the number of transplants was chosen as the highest priority.[1] During discussions of the Strategic Plan and this goal at regional meetings, committee meetings and at the Board of Directors meeting in Fall 2014, numerous comments and anecdotes were shared noting that the current post-transplant outcome review process is creating disincentives for programs to transplant higher risk organs into patients for concern that the program will come under review if the transplants are not successful.[2] An OPTN study conducted by the UNOS Research department, as well as a recently published article on discarded kidneys[3] suggest that potentially hundreds of transplantable kidneys from higher risk donors are being discarded each year. Further research suggests that donor kidneys with similar characteristics to many of those discarded kidneys have been successfully utilized for transplant and may provide a better patient survival rate and quality of life than remaining on the waiting list for some patients.[4]

Why should you support this proposal?

Under the proposed operational rule, no kidney program would be reviewed by MPSC based solely on the outcomes in the higher risk kidney transplants. By excluding these higher risk kidney transplants from the metrics used to identify programs for review, the concern that a program will come under review if a higher risk transplant is not successful will be removed. Adoption of this proposed operational rule may encourage increased usage of higher KDPI transplantable kidneys that are currently being discarded and will provide substantial survival benefit for some patients who might have otherwise remained on the waiting list.

How was this proposal developed?

The MPSC conducts reviews of transplant program post-transplant outcomes to identify underperforming programs and work with those programs to implement performance improvement measures. The principal tool used by the MPSC to identify programs that may merit closer review is outcomes metrics, specifically risk adjusted one year graft and patient survival, produced by the Scientific Registry of Transplant Recipients (SRTR). Using data analysis provided by the SRTR and UNOS staff, the MPSC develops thresholds for identification of programs that may warrant closer review by the Committee. The current thresholds utilized by the MPSC can be found in Bylaws Appendix D.11.A. Transplant Program Performance, and are:

> For programs performing 10 or more transplants in a 2.5 year period, the MPSC will review a transplant program if it has a higher hazard ratio of mortality or graft failure than would be expected for that transplant program. The criteria used to identify programs with a hazard ratio that is higher than expected will include either of the following:
>
> 1. The probability is greater than 75% that the hazard ratio is greater than 1.2.
> 2. The probability is greater than 10% that the hazard ratio is greater than 2.5.
>
> For programs performing 9 or fewer transplants in a 2.5 year period, the MPSC will review a transplant program if the program has one or more events in a 2.5 year cohort.

The MPSC has also established operational rules to further evaluate which of the programs that have fallen outside the thresholds should receive an inquiry. Currently, the MPSC does not send inquiries for

[1] OPTN Strategic Plan, available at: https://optn.transplant.hrsa.gov/governance/strategic-plan/.
[2] Schold J, Buccini L, Goldfarb D, Flechner S, Poggio E, Sehgal A. Association between kidney transplant center performance and the survival benefit of transplantation versus dialysis. CJASN. 2014 Oct 7; 9(10): 1773-1780.
[3] Reese P, Harha, M, Abt P, Levine M, Halpern S. New solutions to reduce discard of kidneys donated for transplantation. JASN 2016 April; 27(4): 973-980.
[4] Schold J, Buccini L, Goldfarb D, Flechner S, Poggio E, Sehgal A. Association between kidney transplant center performance and the survival benefit of transplantation versus dialysis. CJASN. 2014 Oct 7; 9(10): 1773-1780.

graft or patient outcomes if the program is not active at the time of receipt of the SRTR reports or has been released from review for outcomes within the last two MPSC meeting cycles. In addition, for small volume programs that have been identified based on the occurrence of at least one event during the cohort period, an initial inquiry is sent only if the program has had an additional event since the end of the report cohort. Generally, operational rules become effective upon approval by the MPSC and are not released for public comment or subject to approval by the Board of Directors. However, the MPSC's goal with this operational rule is to change acceptance behavior that is currently based on a perception of risk to the program. Therefore, the MPSC is soliciting public comment on this proposed operational rule for two reasons:

- To continue to gather feedback on whether this operational rule will indeed result in behavior change.
- To widely broadcast this proposal in the community since behaviors based on a perception of risk would not be changed if the community was not broadly aware of the change.

The MPSC is sponsoring another proposal this public comment cycle that also impacts how the OPTN reviews transplant program outcomes - Proposed Changes to the OPTN Transplant Program Outcomes Review System. The MPSC developed these proposals independently of one another, and each of these proposals separately focus on different aspects of the OPTN transplant program outcomes review system. The Proposed Changes to the OPTN Transplant Program Outcomes Review System proposal is recommending systematic changes to how programs (for every organ type) are identified for MPSC review. This proposal, the Transplant Program Performance Measures (Outcome Measures), recommends excluding certain types of kidney transplants from hazard ratio analyses to determine whether the program should be reviewed by the MPSC. These proposals can be implemented together to supplement the impact each may have, but as these proposals are not interconnected, there is nothing in either proposal that would prohibit them from being implemented separately or in isolation. Additionally, both of these proposals are also separate from the COIIN pilot project currently being undertaken by UNOS.

Community Engagement

In the summer of 2014, a group of leaders from American Society of Transplant Surgeons (ASTS), American Society of Transplant (AST), Association of Organ Procurement Organizations (AOPO), and United Network for Organ Sharing (UNOS) (AAAU group) began discussions of ways to increase transplants through the removal of perceived disincentives to transplant. Based on these discussions, an MPSC work group was formed in January 2015 at the request of the President of the OPTN/UNOS Board of Directors. The AAAU group gave a presentation to the work group summarizing the discussions and ideas that the group had generated over the previous six months. The core concepts presented included the creation of a secondary allocation pathway and modification of the outcome measuring system to incentivize programs to perform transplants using organs that programs currently do not accept based on a concern for the effect on their post-transplant outcomes but that could result in a better survival rate and quality of life for some patients than remaining on the waiting list.

Although many members of the MPSC expressed an interest in pursuing options for all organs, the MPSC work group ultimately determined that in order to move more quickly toward implementation of a change, the work group should focus initially on one organ and use lessons learned during the process to form operational changes for other organs. The work group chose to initially focus on kidneys based on the availability of a significant amount of data and the decreased magnitude of harm that could result if this change resulted in a significant increase in poor outcomes. In addition, the work group focused on adjustments to the methodology for identifying programs for post-transplant outcomes reviews rather than a possible change in allocation since any change to allocation would require lengthy deliberations regarding potential policy changes and a significant IT effort that would delay implementation.

On the other hand, changes to how the MPSC reviews outcomes can be implemented more quickly, particularly if the change is incorporated into an MPSC operational rule. The work group considered the alternatives of a bylaw change or a variance. Both of these require formal public comment and OPTN Board of Director's approval and do not have the flexibility the work group wanted. The flexibility provided by an MPSC operational rule would allow application of the change to begin more quickly and to be

suspended quickly if it resulted in an unacceptable decrease in graft or patient survival in the excluded group of transplants or if it did not fulfill its goal of increasing transplants. The work group endorsed the use of an operational rule.

Evidence Gathering

Over the next several months, the MPSC work group reviewed data on the SRTR risk adjustment models for kidneys, characteristics of unused kidneys, outcomes for kidneys with similar characteristics to currently discarded kidneys, and the effect of decreased kidney discard rates on program evaluations. Detail on the data reviewed can be found in **Exhibit A**.

Based on the data presented by the SRTR, the work group concluded that the current SRTR risk-adjusted models appear to adequately adjust for the increased risk associated with use of higher kidney donor profile index (KDPI) donor kidneys. In fact, the data suggested that programs that currently use higher risk donor kidneys for transplant do not have worse outcome evaluations, and that no programs were identified for review by the MPSC based only on the program's performance on transplants utilizing kidneys from high risk donors. See Figures 9, 10, 11 and 12 in Exhibit A. The work group supports further education on the performance of the SRTR risk adjustment models but concluded that education alone would not be sufficient to change a program's organ acceptance behavior. Work group members' experiences with other unsuccessful OPTN/UNOS efforts to change behavior through the use of education led them to the conclusion that the perceived threat of outcomes review would need to be removed.

Criteria

The work group, along with representatives from the AAAU group, reviewed characteristics of discarded kidneys as well as the outcomes associated with similar kidneys that were transplanted to determine the appropriate criteria for those transplants that would be excluded from post-transplant outcomes reports. Based on the experience of those on the work group and the data, the work group considered and rejected the following criteria:

- *Characteristics related to age*: including kidneys from donors greater than 65 years of age did not significantly increase the number of donor organs that would be included in the higher risk donor kidney category and would make the criteria more complicated. See Figure 2 and Tables 1 and 2 in Exhibit A.
- *Cold ischemia time, allocation post-recovery, and placement efforts*: although the work group felt these factors are indicative of whether a kidney is hard to place, cold ischemia time, allocation post-recovery and placement efforts were rejected because these factors are more easily manipulated and more difficult to capture.
- *Performance of biopsy and percentage of glomerulosclerosis*: these factors appear to also be closely associated with higher rates of discard but the work group concluded that the biopsy readings are too variable to be included. See Figures 3 and 4 in Exhibit A.
- *Pumping*: although kidneys are less likely to be discarded when pumped (see Figure 1 in Exhibit A), the work group expressed concern that use of failure to pump as an exclusion criteria may have the unintended consequence of encouraging members to not pump kidneys that otherwise would have been pumped.

Following extensive discussion of the various characteristics, the work group settled on the most objective and reliable donor characteristic, specifically KDPI of 85 or greater. Data clearly demonstrates that as KDPI increases, the number of discarded or not recovered kidneys also increases. See Figure 1 in Exhibit A. Further, the ranges of KDPI of not recovered and discarded kidney donors are largely contained within the range of other kidney donors that resulted in a transplant. In other words, some donor kidneys with similar characteristics to the currently discarded or not recovered kidneys are transplanted. See Figures 6 and 7 in Exhibit A. Finally, donor KDPI is readily available to the transplant hospital at the time of an organ offer so kidneys eligible for the exclusion would be easily identifiable.

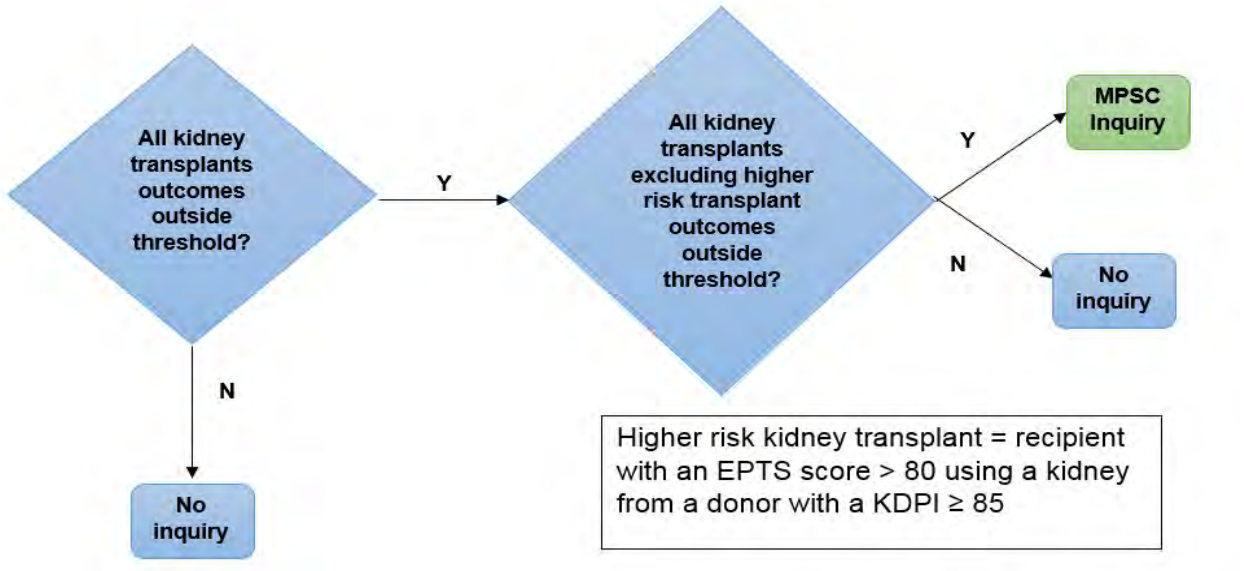
The MPSC expressed concern that an exclusion based solely on donor characteristics might encourage programs to transplant higher risk kidneys into inappropriate candidates. In response to these concerns, the work group considered whether the criteria should include recipient characteristics and determined that an EPTS score of greater than 80 would serve as a sufficient objective criteria to identify appropriate candidates to receive the higher risk donor kidneys. Data analysis published on this topic indicates that the candidates that benefit from the use of a higher KDPI kidney versus remaining on the waiting list are older patients and patients with diabetes, both characteristics that are included in the EPTS calculation.[5] The EPTS score provides a simple estimation of recipient risk post-transplant. Following implementation of the new kidney allocation system, all adult patients on the kidney waiting list have an EPTS score. The current stratification for EPTS is in 20 percent increments and the candidates above 80 percent include the patients with the highest risk in terms of post-transplant survival. See Figure 8 in Exhibit A. As with KDPI, the EPTS score of a candidate is readily available to the transplant hospital at the time of an organ offer.

Additional information on KDPI and EPTS scores can be found on the OPTN website under allocation calculators in the resources section of the website.

Method for Exclusion

Several methods for excluding transplants were considered. Initially, the work group considered removing transplants that met the criteria totally from the MPSC post-transplant outcomes reports. However, this would have penalized programs that achieve good outcomes with higher risk transplants, since those programs would no longer get credit for performing higher risk transplants well.

Under the method being considered, the MPSC will *only* make an inquiry to a kidney transplant program if they fall outside the threshold for review of kidney graft or patient survival using all kidneys currently included in the analysis, *and* if they fall outside the threshold for review in an analysis of kidney transplants with higher risk transplants excluded. As noted above, higher risk transplants would include any kidney transplant in a recipient with an EPTS score > 80 using a kidney from a donor with a KDPI ≥ 85. Both EPTS score and KDPI are readily available to the program at the time of organ offer so those transplants that would be excluded could be easily identified.



Another issue the work group considered was whether criteria should be established for programs to be initially eligible for the alternate evaluation criteria. The work group considered the possibility of an opt-in process where programs would need to express an interest in being included in this alternate evaluation

[5] Massie A, Luo X, Chow E, Alejo J, Desai N, Segev D. Survival benefit of primary deceased donor transplantation with high-KDPI kidneys. Am J Transplant 2014; 14: 2310-2316.

criteria. There was discussion of the possibility of initially excluding programs that are currently under review for post-transplant outcomes. Some work group and MPSC members raised concerns about encouraging programs that are currently under review for underperformance to transplant higher risk donor kidneys. However, after review of the data and further discussion, work group members concluded that underperforming programs would still likely be captured under the proposed new flagging system. Therefore, the work group concluded that all kidney programs would be evaluated initially using the exclusionary criteria.

If this operational rule is implemented, the MPSC would monitor the national one year graft and patient survival rate in those higher risk transplants to make sure that survival rates were not dropping below an acceptable level and to determine appropriate thresholds for minimum survival to be used in the future. Through this monitoring, the MPSC would make sure that the exclusion of these transplants from its outcomes review does not result in an unacceptable risk to patient safety.

In summary, the operational rule being considered would not make any changes to allocation policy. Implementation of this operational rule would not require a change to the OPTN/UNOS Bylaws and would not change the criteria used by the Centers for Medicare and Medicaid Services (CMS) for evaluation or change public reporting of outcomes which is dictated by the Health Resources and Services Administration (HRSA) through its contract with the SRTR. The operational rule being considered would remove flagged programs from MPSC outcomes review if the program does not meet the flagging criteria when high risk kidney transplants (high donor KDPI and high recipient EPTS scores) are excluded thereby removing the concern that use of higher risk donor kidneys in a higher risk candidate could result in being reviewed for outcomes by the MPSC.

Concept Feedback from Spring 2016

The MPSC requested feedback from the community and the public during the spring 2016 public comment period posing the following questions:

1. Would you support a specific exclusion of higher risk transplants from the data analysis used to identify programs for MPSC review of one year patient and graft survival?
    a. If so, should higher risk transplants be defined using only donor characteristics, only recipient characteristics or both?
    b. If so, explain whether you agree with the specific criteria identified in this concept paper.
2. Would a system like this encourage you to use kidneys that are acceptable for transplant but that you may be unlikely to accept today?
3. Are there other issues that the MPSC work group should consider?

The MPSC received general support for the concept from all regions, the Kidney Transplantation Committee and the American Society for Transplant Surgeons. Many felt that this concept was a step in the right direction. There was not consensus on the characteristics that should be included: donor only, recipient only or both. And there was concern that the impact would be limited if CMS and the SRTR public reports did not adopt this same criteria. The American Society of Transplantation (AST) did not support the concept. The AST relied on two major points as the basis for its opposition to the concept. First, the characteristics defining higher risk transplants are in the SRTR model and are accounted for by risk adjustment. Second, the AST noted that the question of whether this proposal would increase utilization of the higher risk organs is untested and in fact, the increased utilization of higher risk organ/recipient combinations if taken to the extreme could result in significantly reduced graft survival. The work group and the MPSC reviewed the feedback received and provide the following responses:

- Why include donor and recipient characteristics in the criteria for exclusion of higher risk transplants?

  Feedback from the community did not result in consensus regarding the criteria for exclusion. Comments were divided between using both donor and recipient criteria as included in the

proposal or donor criteria only or any transplant that met either the donor or recipient criteria. In providing the context for the work group charge, the OPTN/UNOS President and the AAAU group described the survival benefit to candidates receiving an organ that may be considered "marginal" versus remaining on the waiting list. Data analysis has indicated that candidates with specific criteria benefit from the use of these higher KDPI kidneys rather than remaining on the waiting list until a lower KDPI kidney is available (See footnote 2). The two major factors are increased age and diabetes which are two of the main characteristics in the EPTS score. Based on the review of data, the work group and the MPSC supported an exclusion based on both donor and recipient criteria. Donor criteria were developed to make sure that the transplantable kidneys that are currently being discarded or not recovered would be utilized. Recipient characteristics are included to encourage use of these higher risk kidneys in those candidates that would benefit from the transplant rather than staying on the waiting list. In addition, including recipient characteristics will avoid creating an incentive to use high KDPI donor kidneys in inappropriate candidates who will not have the same benefit from transplant.

- The biggest concern expressed in the feedback received was a feeling that the impact will be limited if CMS and the SRTR public reports do not adopt similar criteria.

  The MPSC acknowledges that this proposal would not affect CMS review or the SRTR reports. However, it is unlikely that programs will cross the CMS threshold for condition level deficiency based solely on an increased frequency of these higher risk transplants being performed since the factors defining these transplants are adjusted for in the SRTR risk-adjusted model used by CMS. However, if a program does come under review by CMS, it would have the results of both data analyses with and without higher risk transplants to evaluate the effect of increased use of these higher risk transplants on the overall analysis.

- Why exclude these transplants if the characteristics included in KDPI and EPTS scores are taken into account in the risk adjusted model?

  The MPSC acknowledges that the model adjusts for the factors included in the KDPI and EPTS score. In spite of this, many in the community believe that the use of higher KDPI kidneys or transplanting patients with higher EPTS scores will result in a program being flagged for outcomes. This belief has resulted in the discard of kidneys that if transplanted, could provide a survival benefit to some patients as opposed to remaining on the waiting list. The intent of this proposal is to remove the perception that higher risk transplants will result in a program being flagged.

- What if this system encourages utilization of kidneys that should not be transplanted resulting in a significantly reduced graft survival?

  The implementation plan for this proposal includes the MPSC closely evaluating the results of transplants performed post implementation to determine if graft survival is decreased to an unacceptable level. One of the advantages of the proposal being reflected in an MPSC operational rule is the rule can be suspended quickly without public comment if a patient safety concern is raised by a significant increase in graft failure or death in the higher risk transplants.

How well does this proposal address the problem statement?

The impact of the proposal on the number of program components identified for MPSC review was evaluated by the SRTR with the cohort from the June 2015 program specific reports (PSR) including deceased and living donors. The cohort is split into three different groups to facilitate understanding the implications of the proposal:

1. The overall transplant population - no exclusions are applied to the cohort and the flagged program components correspond the components flagged in the June 2015 PSR.
2. The low-risk transplants (LRTX): donors with KDPI < 85% or EPTS < 80%.

3. The high-risk transplants (HRTX): donors with KDPI ≥ 85% and EPTS ≥ 80%.

Table 1 presents the number of transplants in each category of KDPI and EPTS. The proposal would remove 901, or 4%, of the kidneys from program evaluation.

Table 1: The number of transplants in each category of EPTS and KDPI in June 2015 PSR.

	KDPI < 85%	**KDPI ≥ 85**
EPTS < 80%	**18148**	**1347**
EPTS ≥ 80%	**4730**	**901**

Table 2 presents the number of programs identified for graft survival under the current rule and under the proposed rule. Under the proposal ['Current Rule + LRTX'], three of the components flagged under the current system would not be identified for review by MPSC.

Table 2: Descriptive statistics for centers identified for graft survival in June 2015 PSR. The '# of Transplants', 'Observed', and 'Expected' are the mean values across the flagged centers for a given row.

Rule	**# of Centers**	**# of Transplants**	**Observed**	**Expected**
Current Rule	19	205.5	16.5	9.7
Current Rule + LRTX	16	166.2	13.7	7.4

The proposal has a similar impact on the programs identified for patient survival. Table 3 presents the number of programs flagged on patient survival under the current rule and under the proposed rule. Under the proposal ['Current Rule + LRTX'], three of the components flagged under the current system would not be identified for review by MPSC.

Table 3: Descriptive statistics for centers identified for patient survival in June 2015 PSR. The '# of Transplants', 'Observed', and 'Expected' are the mean values across the flagged centers for a given row.

Rule	**# of Centers**	**# of Transplants**	**Observed**	**Expected**
Current Rule	21	178.7	8.2	4
Current Rule + LRTX	18	167.1	7.6	3.7

In the June 2015 PSR, there are 901 transplants that would meet the criteria and six programs that were flagged under the current rule that would no longer be identified for review with application of the proposed operational rule. The MPSC would expect that the number of transplants that meet the criteria would increase once the operational rule is implemented and programs concern of being identified for MPSC review based on the higher risk transplants is alleviated.

You can find additional data that was used by the work group and the MPSC to evaluate appropriate criteria in Appendix A.

Which populations are impacted by this proposal?

If the proposed operational rule has the desired effect on behavior, an increase in overall number of transplants should result. The purpose of the proposal is to increase the number of transplants performed using transplantable higher KDPI kidneys that are now being discarded or not recovered. In addition, use of high EPTS scores in the criteria should encourage more transplants in older candidates and candidates with diabetes.

How does this proposal impact the OPTN Strategic Plan?

Increase the number of transplants: The expectation is that the MPSC operational rule proposed will result in an increase in transplants by removing the perceived disincentive associated with concern that use of higher risk donor kidneys for transplant will increase a program's probability of being identified for review for lower than expected post-transplant outcomes. If this disincentive is removed, it is thought that more transplants using transplantable higher risk donor kidneys will be performed contributing to an overall increase in transplants.

Improve equity in access to transplants: Use of the EPTS score as one of the criteria should result in an increase in transplants for older patients/candidates. Programs may list some older patients who may not have previously been placed on the waiting list due to concern over the higher risk for graft failure. In addition, this operational rule should increase the number of transplants for older candidates who may have otherwise died while on the waiting list.

Improve waitlisted patient, living donor, and transplant recipient outcomes: If the project succeeds in increasing transplants, waitlisted patients' outcomes could be improved due to decreased waiting time. However, this result would be tempered if the project resulted in programs' willingness to list patients that are currently not being listed for transplant. In addition, by excluding certain transplants from outcomes review, national aggregate transplant recipient outcomes could be negatively affected.

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

Promote the efficient management of the OPTN: There is no impact to this goal.

How will the OPTN implement this proposal?

To implement this proposal, the SRTR would need to produce two separate data analyses – one for all kidney transplants and one with the higher risk transplants excluded as described below.

> For kidney programs only, the MPSC will review programs for lower than expected graft or patient survival if one year kidney graft or patient survival meets the established criteria for both
>
> 1. All kidney transplants
> 2. Kidney transplants excluding higher risk transplants
>
> A higher risk transplant is defined as a transplant involving a recipient with an EPTS score greater than 80 using a kidney from a donor with a KDPI that is 85 or greater.

The process of MPSC review of programs for possible underperformance will not be affected by this change in the analyses for identification of programs that may enter MPSC performance review.

This proposal will not require programming in UNet^{SM}.

How will members implement this proposal?

Transplant Hospitals

The proposal is intended to encourage members to consider using the higher KDPI kidneys for their candidates with higher EPTS scores. It is believed that many of these kidneys are currently discarded but may, in fact, be transplantable. The intent is that programs will review and make changes to their candidate KDPI informed consent and offer acceptance protocols to consider high KDPI kidneys for candidates with high EPTS scores.

Will this proposal require members to submit additional data?

No, this proposal does not require additional data collection.

How will members be evaluated for compliance with this proposal?

This proposal does not have any member compliance implications.

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

The MPSC strongly believes that a perception of risk of coming under outcomes review is influencing programs in their decisions regarding transplantation of higher risk kidneys. Therefore, the Committee has proposed this operational change to see if a change in monitoring criteria will result in an increase in the number of kidney transplants performed. However, the Committee recognizes that this change has not been designed as a scientific study, and any changes observed may not be directly linked to the MPSC's operational change.

The Committee will use this operational definition for a period of three years, at which time they will review all data available to them, and decide whether to continue with this revised monitoring plan, or whether to revert to the previous criteria. The MPSC will also review a number of factors, in as near to real time as possible, to evaluate the criteria's effect on behavior and outcomes. If unacceptable changes are observed, the MPSC may eliminate the operational change before the three year trial ends. The following are among the factors to be reviewed:

- Post-transplant graft and patient survival of higher risk transplants to monitor for significant drops to unacceptable levels. The MPSC will review these data closely.
- Changes in acceptance and transplant behavior, particularly for higher risk kidneys
- Utilization, recovery, and discard rates from all deceased donors, particularly donors with KDPI ≥ 85%.
- Changes in minimum acceptance criteria and willingness to accept high KDPI kidneys, particularly for candidates with EPTS ≥ 80%
- Changes in transplant rate for candidates with EPTS ≥ 80% to determine if there is an increase in transplants for these candidates
- Changes to the composition of waiting list to include more high EPTS candidates

In addition, the MPSC will evaluate the effect on post-transplant graft and patient survival by producing reports three times a year detailing program specific and overall survival rates for kidneys meeting the exclusion criteria. If the overall survival rate for kidneys meeting the exclusion criteria falls below an acceptable level, the MPSC may eliminate the operational rule. The MPSC will also monitor the number of programs identified for review after implementation with the numbers identified prior to implementation of the new methodology.

The MPSC will monitor the characteristics of programs that are not being identified for review with the proposed approach that would have been identified using the entire cohort (current approach). The Bayesian criterion contained in the OPTN/UNOS Bylaws that were developed by the SRTR for the MPSC post-transplant outcomes evaluation process are specifically optimized for the entire set of transplants. This proposal will use the same Bayesian criterion for specified subsets of kidney transplants, specifically those transplants using kidneys from donors with KDPI ≥ 85% for recipients with an EPTS score > 80. The MPSC recognizes that this new proposed analysis will not have the same characteristics in identifying "true positive" centers with worse than expected post-transplant outcomes.

If there do not appear to be significant negative consequences to the change, and the number of transplants increases, particularly among higher risk recipients using higher risk donor kidneys, the MPSC may consider expanding this to other organs.

Exhibit A: Additional Supporting Data

The work group asked for data from UNOS Research as well as from the SRTR to help identify which subsets of kidney donors are more susceptible to discards and thus potentially underutilized as well as understand the effect that current utilization of these high risk kidneys has on program performance evaluations for the MPSC.

The first set of data that the committee requested was to study the variability in discard rates by KDPI and donor age, as well as differences in the tendency to use pulsatile perfusion (pumping) and perform biopsies for different types of recovered kidneys. Variability among OPOs was also evaluated. Deceased donor kidneys recovered in the United States from 1/1/2007 through 12/31/2014 were included in the study. This is a period of time where the national discard rate was relatively stable year to year at around 18-19%.

Figure 1. Discard rate of deceased donor kidneys recovered for transplant from 2007 through 2014 by KDPI and whether or not the kidney was pumped.

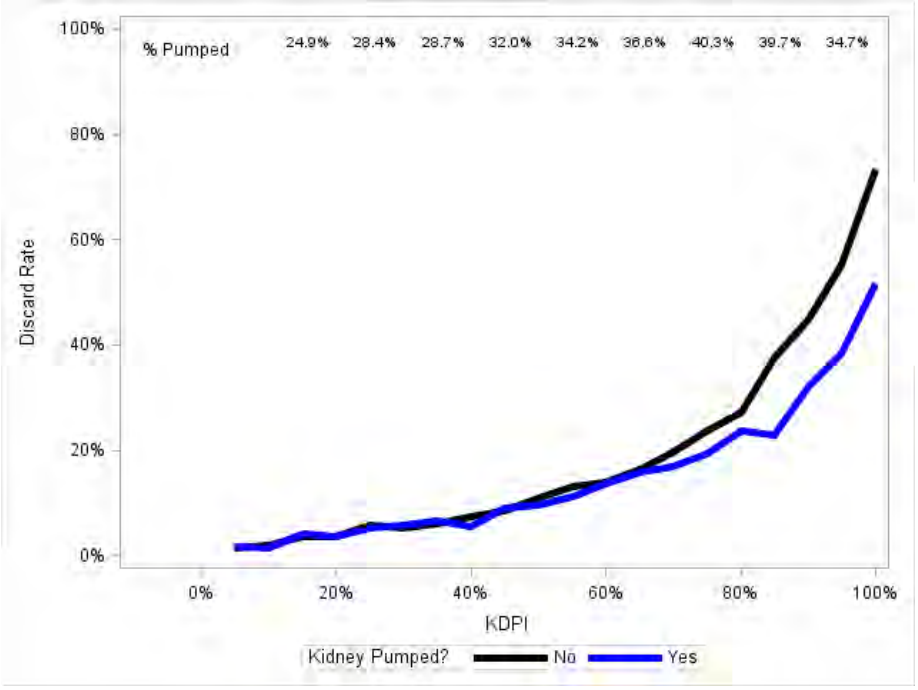
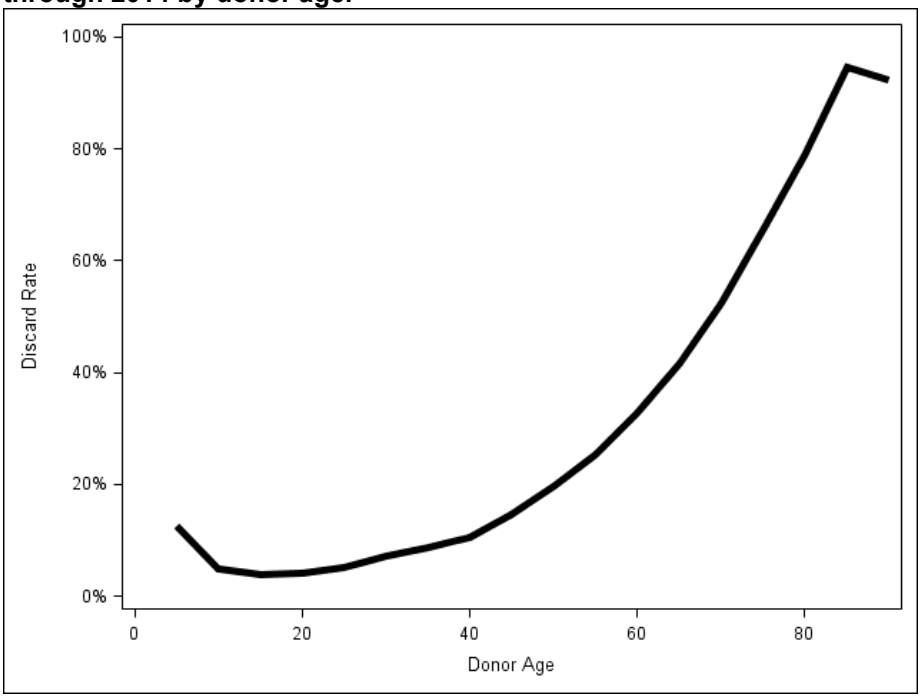


Figure 1 shows that discard rate rises with KDPI, and that when kidneys are pumped, they are generally less likely to be discarded.

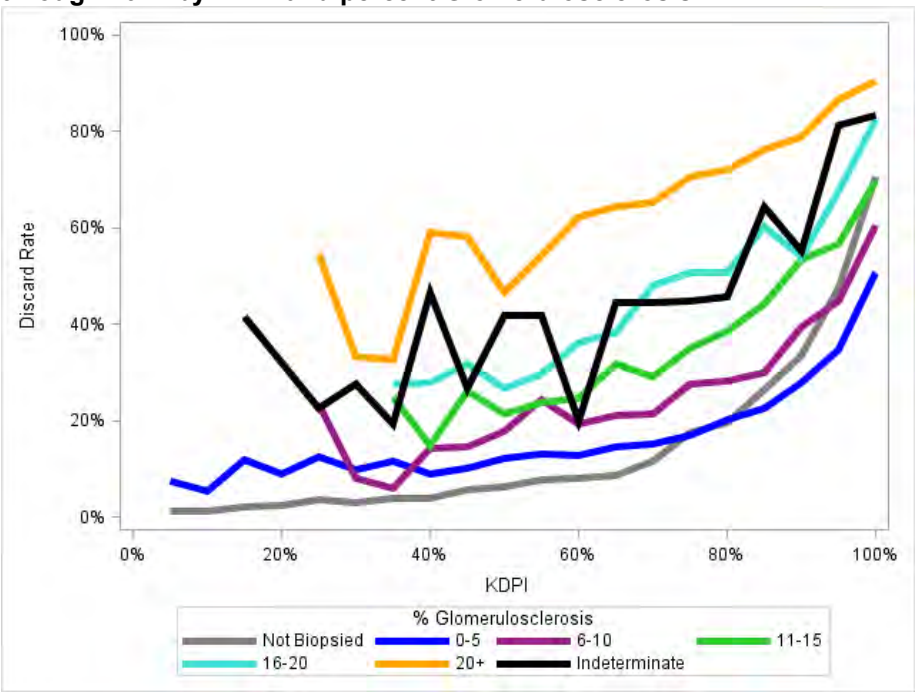
Figure 2. Discard rate of deceased donor kidneys recovered for transplant from 2007 through 2014 by donor age.



In Figure 2, the image shows that as donor age increases, the discard rate rapidly increases.

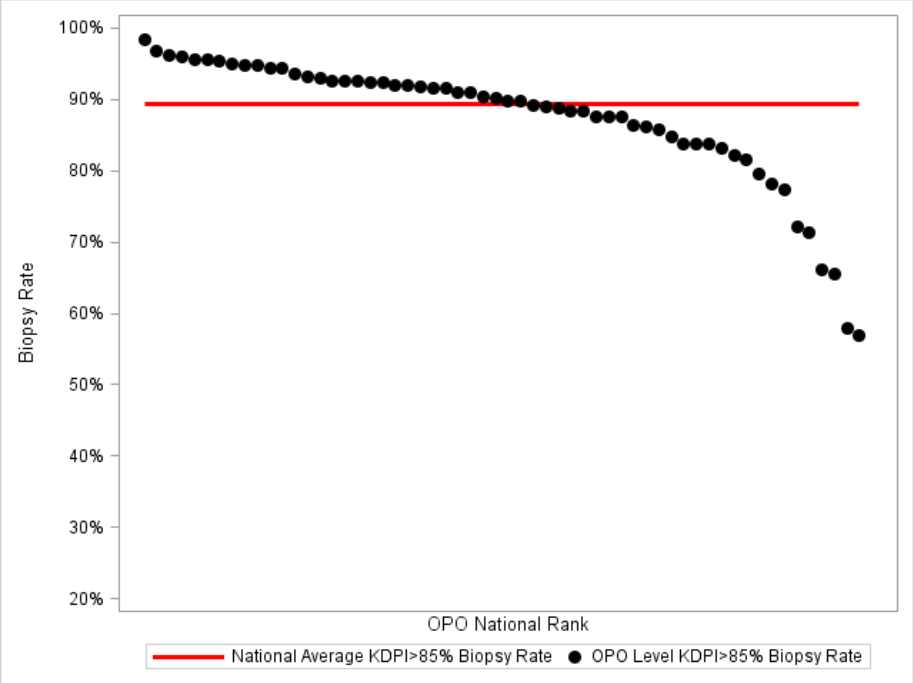
The vast majority of Figure 3 shows the discard rates by the results of biopsies.

Figure 3. Discard rate of deceased donor kidneys recovered for transplant from 2007 through 2014 by KDPI and percent Glomerulosclerosis.



The data in figure 3 shows the trend seen in figure 1, and that the discard rate increases with KDPI. It further shows that this effect is different based on biopsy results. As the percentage glomerulosclerosis increases, the likelihood of discard also increases. For example, KDPI 40% donors with 20+% glomerulosclerosis have about a 50% discard rate, whereas KDPI 40% donors with 0-5% glomerulosclerosis have only about a 10% discard rate. However, as seen in figure 4, the biopsy rates vary widely by DSA for high risk donors (KDPI>85%), and biopsy results are known to be subjective. Donor age and KDPI were initially chosen as stronger predictors of underutilization.

Figure 4. Percent of KDPI>85% kidneys recovered for deceased donor transplantation from 2007 through 2014 that were biopsied by OPO, ordered from the OPO with the highest rate to the OPO with the lowest rate.



Next, the work group studied data provided by the SRTR on deceased donors recovered between January 1, 2012 and June 30, 2014.

Figure 5. Distribution of donor age by disposition

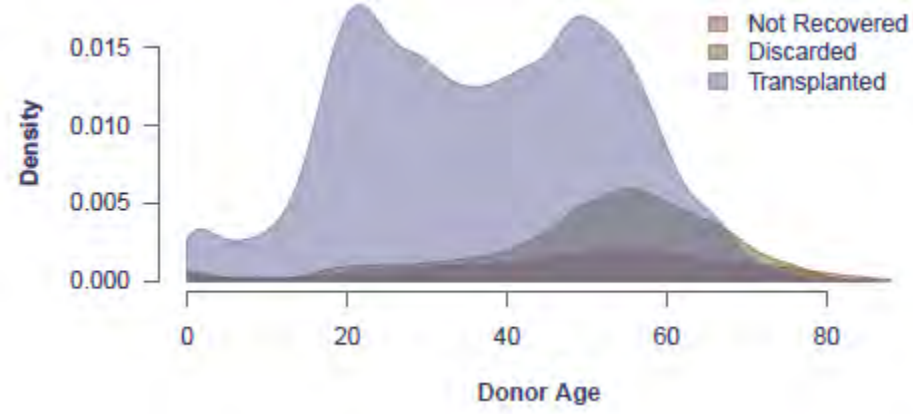
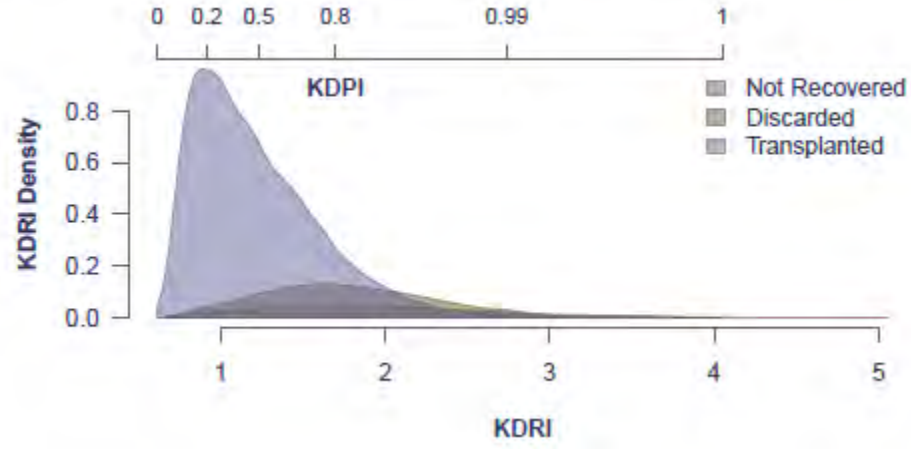


Figure 6. KDRI distribution by disposition



Figures 5 and 6 show that the ranges of age and KDRI of not recovered and discarded kidney donors are largely contained within the distributions of transplanted kidney donors. Only 17 organs in this time period that were not recovered had missing KDPI because the KDRI was higher than the KDRI range within the transplanted and discarded donors. Only 1.26% of organs that were not recovered had KDRI values greater than the highest KDRI for a transplanted kidney. Even fewer of the discarded kidneys (0.04%) had KDRI values greater than the highest KDRI for a transplanted kidney.

Figure 7. Disposition by KDPI. KDPI is missing when KDRI is greater than any KDRI for a transplanted or discarded organ.

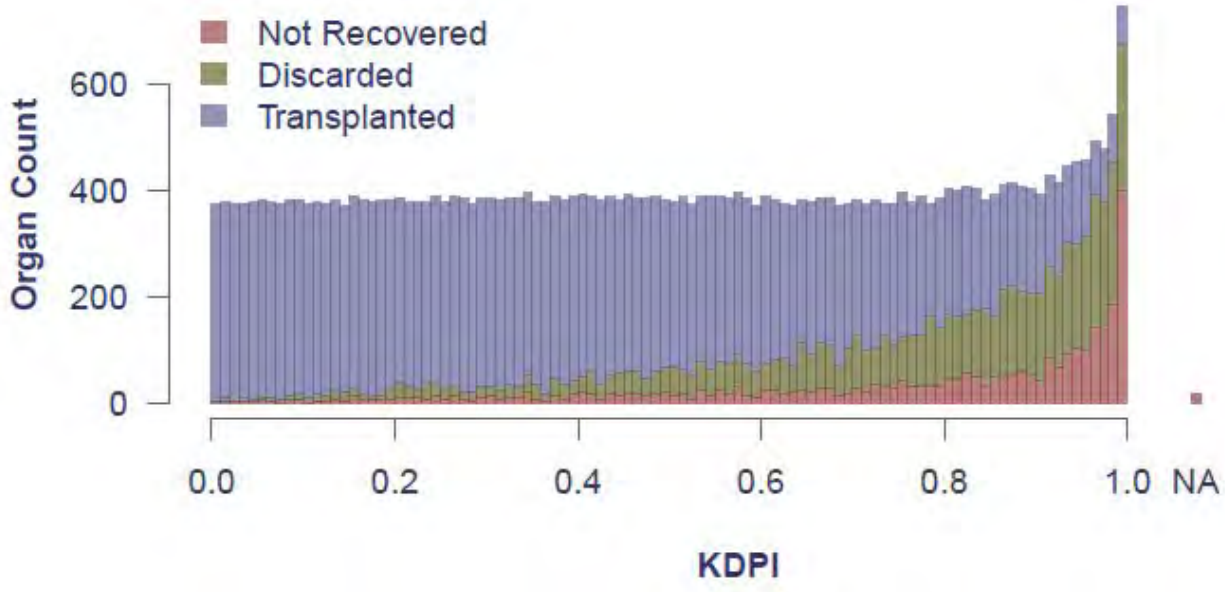


Figure 7 shows that the disposition of organs trends towards not recovered or discarded for higher values of KDPI – confirming similar results of previous analyses.

Tables 1 and 2 present the number of deceased donor kidneys that would qualify as high-risk for graft and patient survival, respectively, in the June 2015 PSR cohort. As expected, the vast majority of kidneys would not qualify as high-risk. In addition, the majority of kidneys from deceased donors over the age of 65 also possess KDPI ≥ 85, while less than two-thirds of the kidneys with KDPI ≥ 85 also have age ≥ 65. This implies that KDPI rather than donor age is the main component of determining high-risk kidneys.

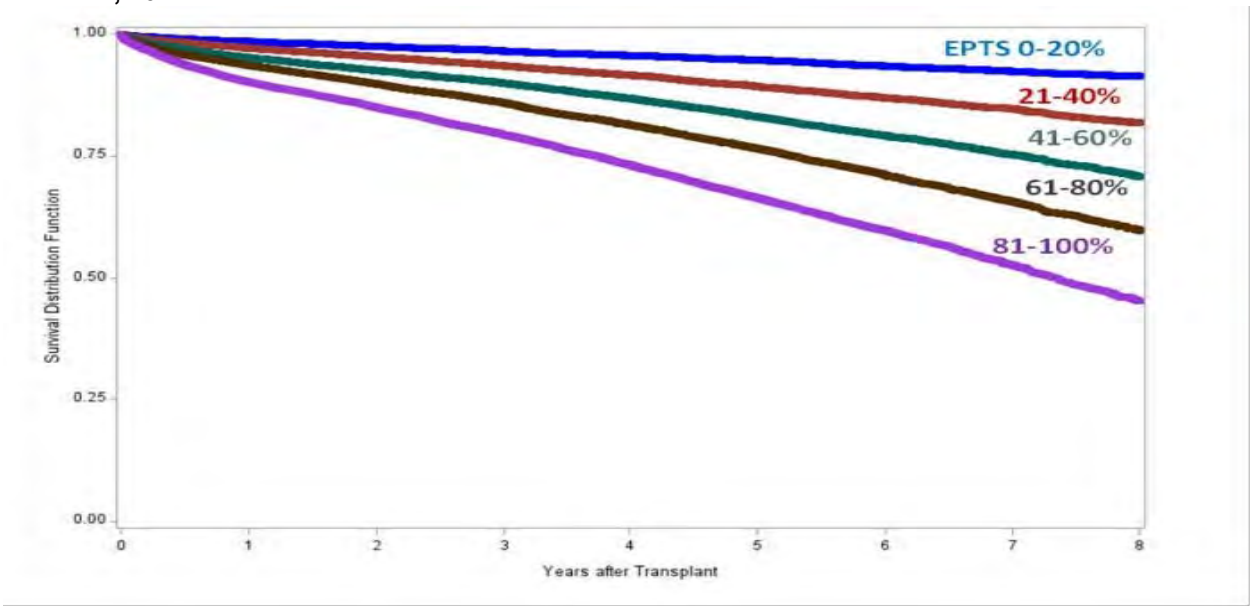
Table 1: The number of deceased donor kidneys evaluated for graft survival broken-down by KDPI and donor age.

	Age < 65	Age ≥ 65
KDPI < 85	**22,686**	**192**
KDPI ≥ 85	**1,543**	**705**

Table 2: The number of deceased donor kidneys evaluated for patient survival broken-down by KDPI and donor age.

	Age < 65	Age ≥ 65
KDPI < 85	**19,508**	**183**
KDPI ≥ 85	**1,456**	**684**

Figure 8. Kaplan-Meier Patient Survival Curves by EPTS Score, Deceased Donor, Adult, Solitary Kidney Transplants from 2003-2010. Based on OPTN data as of Feb 7, 2014



Next, the SRTR data shows the calibration of the outcomes models in the PSRs for varying levels of kidney donor risk using the June 2015 PSR cohort (1/1/2012 – 6/30/2014).

Figure 9. Model calibration for donor KDRI, June 2015 PSR deceased-donor adult 1-year graft survival model. Each of the 20 points aggregates approximately 5% of the transplants into bins based on KDRI.

Figure 10. Hazard ratio calibration for donor KDRI, June 2015 PSR deceased-donor adult 1-year graft survival model. Each of the 20 points aggregates approximately 5% of the transplants into bins based on KDRI.

In figures 9 and 10, the recipients included in the June 2015 PSR 1-year deceased donor adult graft survival cohort were divided into 20 groups by KDRI. Within each of the 20 KDRI groups, the total number of observed graft failures and the total number of expected graft failures were calculated. If the totals were exactly the same, then the points would fall along the 45-degree line on the plot.

Figure 10 contains the same information as Figure 9 but expressed differently. Figue 10 shows the hazard ratio (O/E) for each of the 20 KDRI groups. If the numbers of observed and expected graft failures were exactly the same, the points would fall precisely along the horizontal line (hazard ratio=1.0) in the plot.

Based on these two graphics, the model appears well calibrated for KDRI, in particular for high-KDRI transplants.

Figure 11. Scatterplot of hazard ratios for kidney adult graft survival.

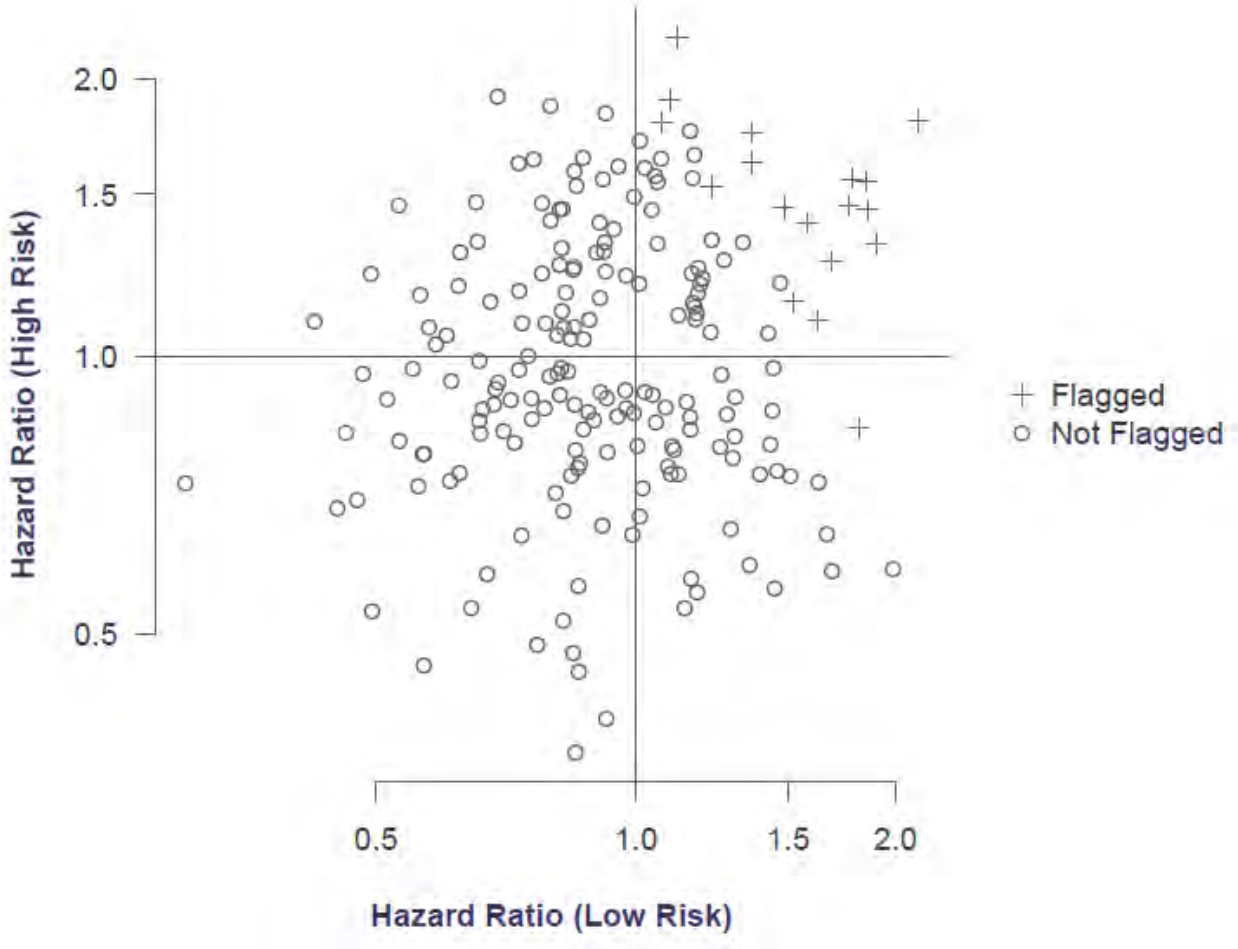
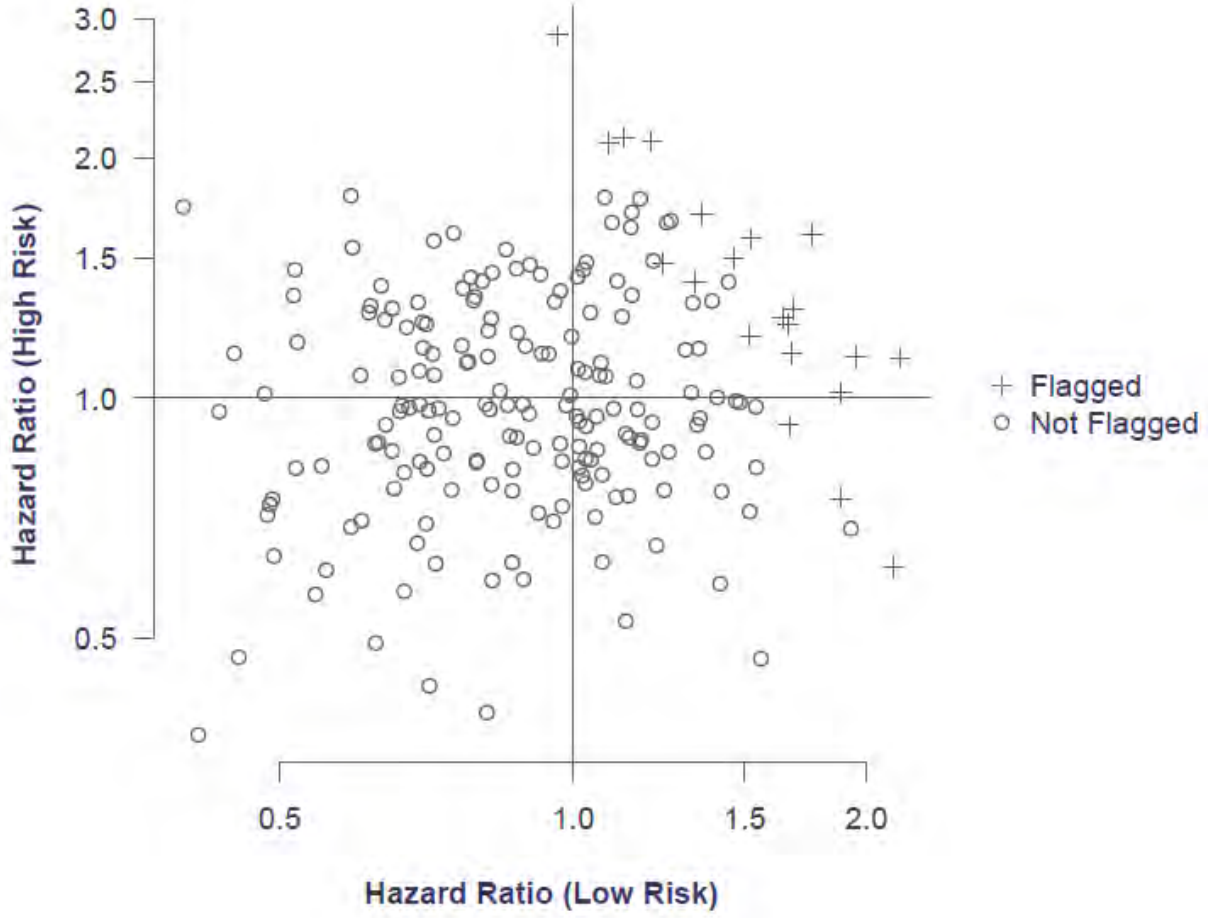


Figure 11 shows the scatterplot of hazard ratios for kidney adult graft survival for low-risk and high-risk transplants. For kidney programs, deceased donor transplants in the highest 20% of modeled risk, which includes both recipient and donor risk factors, were considered high risk transplants. Deceased donor transplants in the lowest 80% of modeled risk and all living donor transplants were considered low risk. Each point is a single program, and the symbol indicates whether the program met the Bayesian identification criteria currently in use by the MPSC to identify programs for review. Of the 18 programs that met the identification criteria, zero had a hazard ratio less than 1.0 for low-risk transplants, and one had a hazard ratio less than 1.0 for high-risk transplants. Thus, 17 of the 18 programs identified for review had hazard ratios greater than 1.0 for both high- and low-risk transplants.

Figure 12 shows the scatterplot of hazard ratios for kidney adult patient survival for low-risk and high-risk transplants. Of the 21 programs that met the identification criteria, one had a hazard ratio less than 1.0 for low-risk transplants, and three had a hazard ratio less than 1.0 for high-risk transplants. The other 17 programs had hazard ratios greater than 1.0 for both high- and low-risk transplants.

Figure 12. Scatterplot of hazard ratios for kidney adult patient survival.



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