Concept Paper

OPTN/UNOS Membership and Professional Standards Committee

Transplant Program Performance Measures Review (Outcomes Measures)

Committee Liaison
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Executive Summary

When the OPTN/UNOS Board of Directors approved the strategic plan in June 2015, they chose increasing the number of transplants as the highest 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 fear that the program will come under review if the transplants are not successful. While current risk-adjusted 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 have been successfully utilized 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 considering instituting a modified flagging method that 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 kidneys currently included in the analysis, *and* if they fall outside the threshold in an analysis of kidney transplants excluding high risk transplants. High 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. This two-step review process will avoid penalizing those kidney programs that are currently having successful outcomes with higher risk kidney transplants.

After reviewing the concept developed by the MPSC Outcome Measures Work Group, the MPSC agreed to seek public input. It is important to note that this document is not a policy proposal. It is a concept paper, intended to inform all interested parties about the status of the MPSC's discussion and seek valuable input for further consideration. **The MPSC plans to circulate the final proposal during the public comment cycle in the fall of 2016.**

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

We encourage all interested organizations and individuals to review the concept and supporting information in this paper, then provide responses to the questions below. These responses will be used to guide additional discussion by the work group and the MPSC. The work group and MPSC will use this input to assist in further development of the proposal. In addition to general input on the concept, the MPSC would appreciate feedback on 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?

Transplant Program Performance Measures Review (Outcomes Measures)

Sponsoring Committee: Membership and Professional Standards Committee

Public Comment Period: January 25, 2016 – March 25, 2016

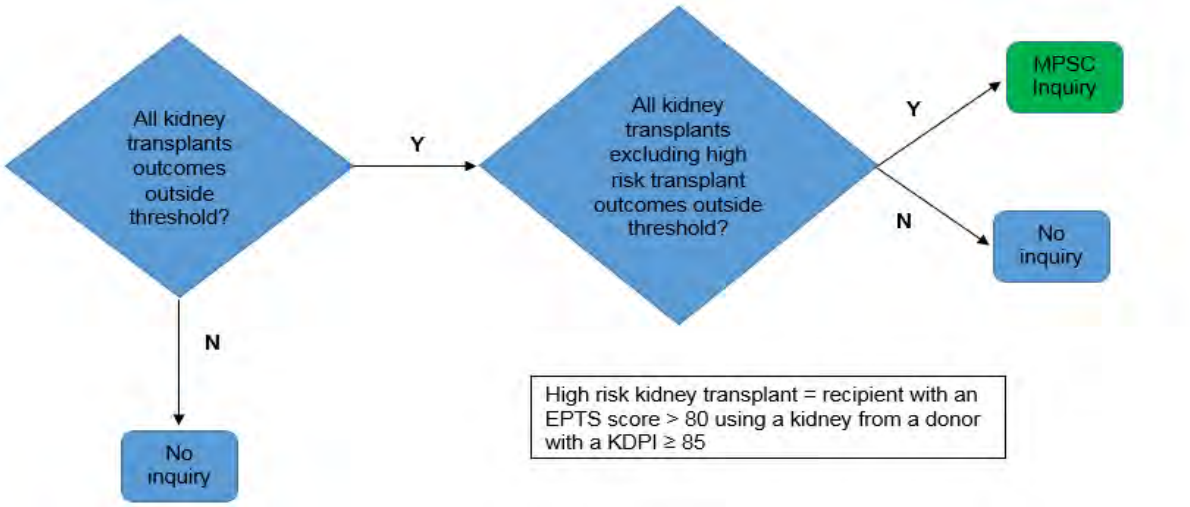
What problem will this concept solve?

When the OPTN/UNOS Board of Directors approved the strategic plan in June 2015, they chose increasing the number of transplants as the highest priority. The MPSC has heard from the transplant community through discussions at regional meetings, committee meetings and Board of Directors meetings that the current post-transplant outcome review process creates disincentives for programs to transplant higher risk kidneys into patients for fear that the program will come under review if the transplants are not successful. 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 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.[1]

What is the concept that is being considered?

The MPSC is considering excluding higher risk kidney transplants from the cohort of transplants analyzed to flag programs for outcomes review by the MPSC. This concept would be implemented as illustrated in the below algorithm.

[1] 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.



Kidney transplant programs would be identified for review by the MPSC for lower than expected graft or patient survival if one year kidney graft or patient survival falls outside the threshold for both:

1. All kidney transplants AND
2. Kidney transplants excluding high risk transplants.

High 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 kidney donor profile index (KDPI) ≥ 85.

How was this concept 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 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.

Community Engagement

The newly approved 2015-2018 OPTN strategic plan assigns increasing the number of transplants as the highest priority for the OPTN. During discussions of the strategic plan and this goal at regional meetings, committee meetings and at the Board of Directors meeting, 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 fear that the program will come under review if the transplants are not successful.

A group of leaders from ASTS, AST, AOPO, and UNOS (AAAU group) began discussions in the summer of 2014 of ways to increase transplants through the removal of perceived disincentives to transplant created by the current system for reviewing post-transplant outcomes. 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 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 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 which would delay implementation. On the other hand, changes to how the MPSC reviews outcomes can be implemented more quickly.

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 the Attachment to this concept paper.

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 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 Attachment, below. 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 programs' organ acceptance behavior. Work group members experience with other unsuccessful OPTN 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 high risk donor kidney category and would make the criteria more complicated. See Figure 2 and Tables 1 and 2 in Attachment, below.
- *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.
- *Performance of biopsy and percentage of glomerulosclerosis*: appears 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 Attachment, below.
- *Pumping*: although kidneys are less likely to be discarded when pumped (see Figure 1 in Attachment, below), 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 Attachment, below. Further, the ranges of KDPI of not recovered and discarded kidney donors are largely contained within the distributions 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 currently transplanted. See Figures 6 and 7 in Attachment, below. 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 estimated post-transplant survival (EPTS) score of greater than 80 would serve as a sufficient objective criteria to identify appropriate candidates to receive the higher risk donor kidneys. 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 the attachment, below. 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 at https://optn.transplant.hrsa.gov/resources/allocation-calculators/.

Method for Exclusion

Several methods for exclusion of these transplants were considered. Initially, the work group considered removing transplants that met the criteria totally from the MPSC post-transplant outcomes reports. However, this could have penalized those programs that are currently transplanting kidneys that meet the criteria since these transplants contribute to a higher expected rate within the SRTR risk adjusted model for those programs. Total removal of these transplants could result in identification of programs not currently identified for review for post-transplant outcomes due to a commensurate upward movement of the expected rate of survival in the SRTR model. 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, high 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 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 currently are 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 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 concept 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 concept being considered would not make any changes to allocation policy. Implementation of a proposal based on this concept would not change any criteria used by CMS for evaluation or change public reporting of outcomes which is dictated by HRSA through its contract with the SRTR. The concept being considered would exclude high risk kidney transplants (high donor KDPI and high recipient EPTS scores) from flagging criteria for MPSC outcomes reviews thereby removing the fear that use of higher risk donor kidneys in a higher risk candidate could result in being flagged for outcomes review by the MPSC.

How does this concept support the OPTN Strategic Plan?

1. *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 fear 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.
2. *Improve equity in access to transplants*: No expected impact for this goal.
3. *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 on the waiting list. 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, if certain transplants are excluded from outcomes review or subjected to a minimal survival threshold, nationally aggregate transplant recipient outcomes could be negatively affected.

4. *Promote living donor and transplant recipient safety*: No expected impact for this goal.
5. *Promote the efficient management of the OPTN*: No expected impact for this goal

Path Forward

Following receipt of input this spring, the work group and MPSC will review and make appropriate revisions to the concept. The concept will be presented and input requested from the OPTN/UNOS Board of Directors in June 2016. The resulting proposal will be circulated during the public comment cycle in the fall of 2016 with a final proposal to be considered by the Board of Directors in December 2016. If the Board approves the proposal, the MPSC would implement the new rule for its review of the spring 2017 SRTR MPSC outcomes reports.

Attachment to Transplant Program Performance Measures Review (Outcomes Measures) concept paper

The work group asked for data from UNOS Research as well as from the SRTR to help the work group 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.

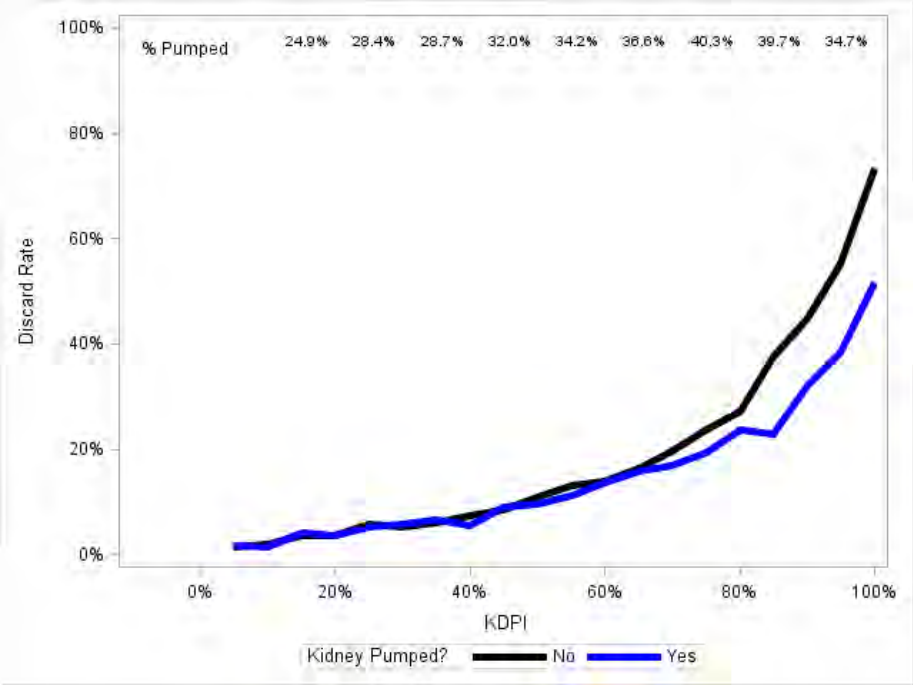
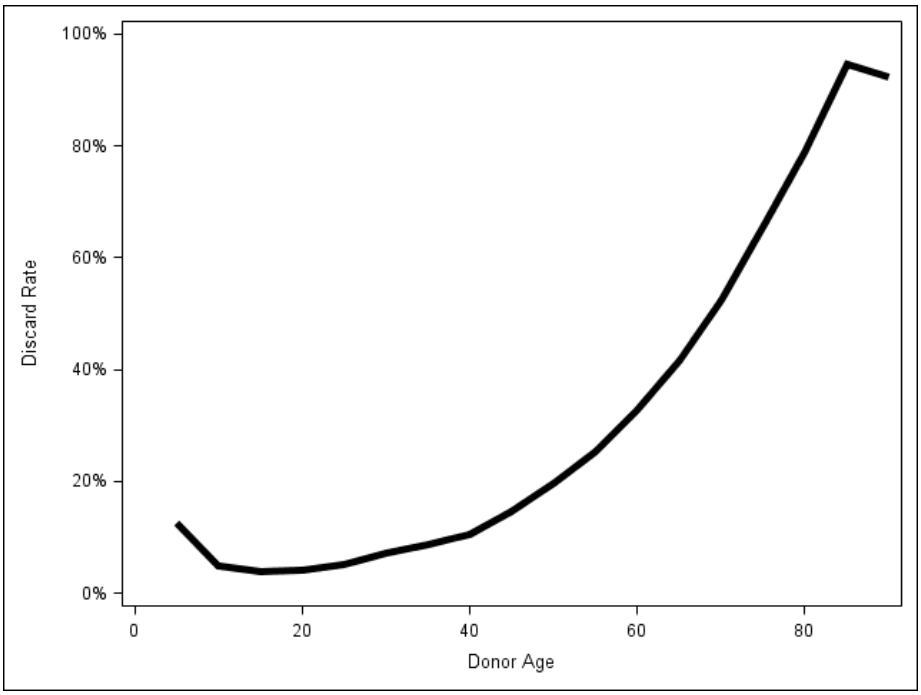


Figure 1 shows that discard rate rises with KDPI, and that when kidneys are pumped, they are generally less likely to be discarded.

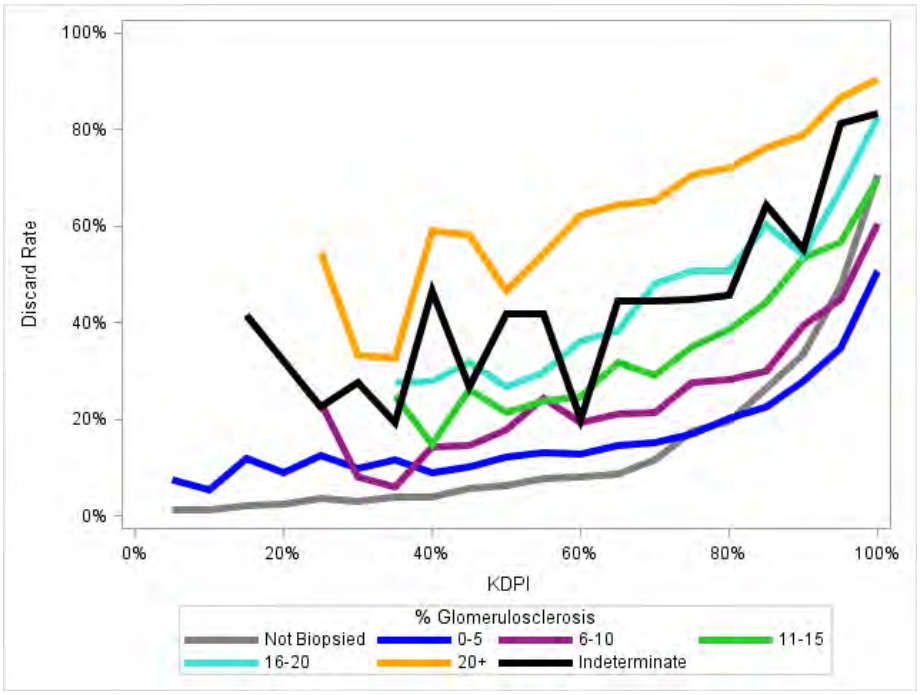
Figure 2. Discard rate of deceased donor kidneys recovered for transplant from 2007 through 2014 by donor age.



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

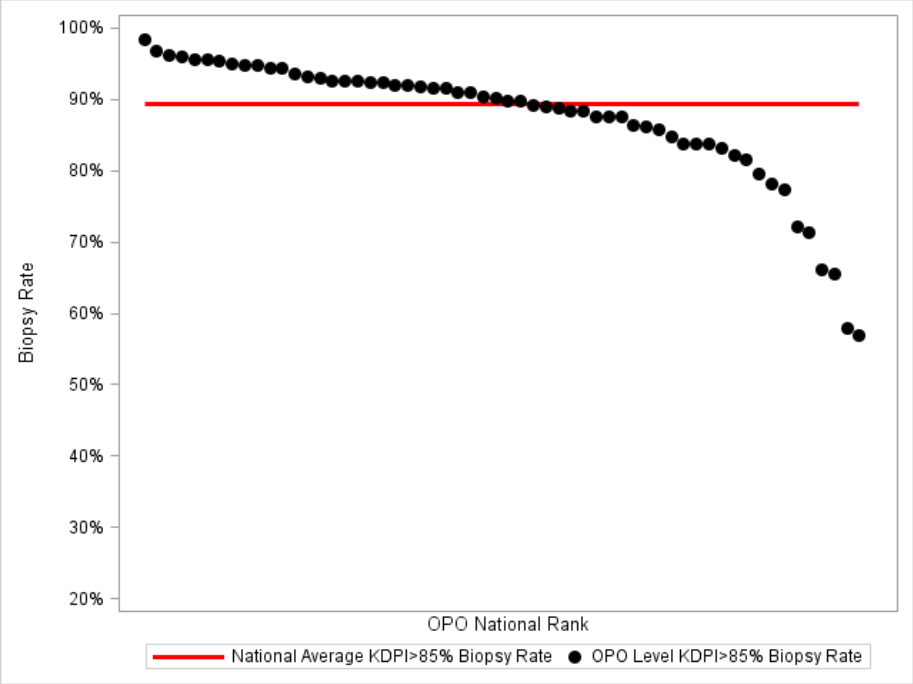
The vast majority of Figure 3 shows the discard rates by the results of biopsies.

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

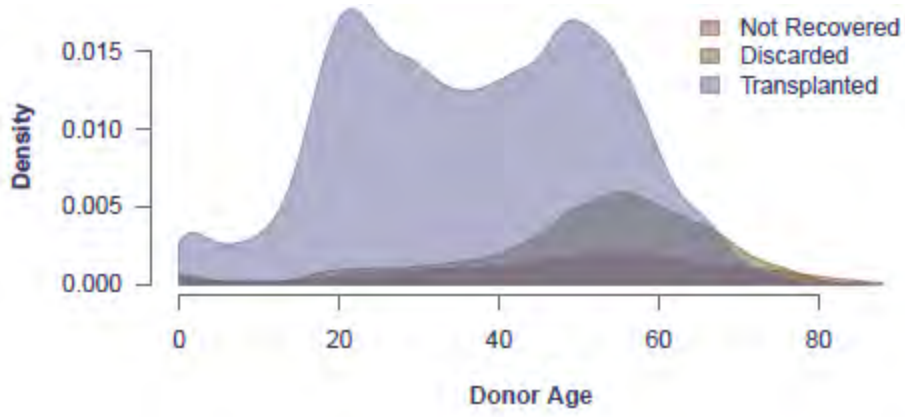
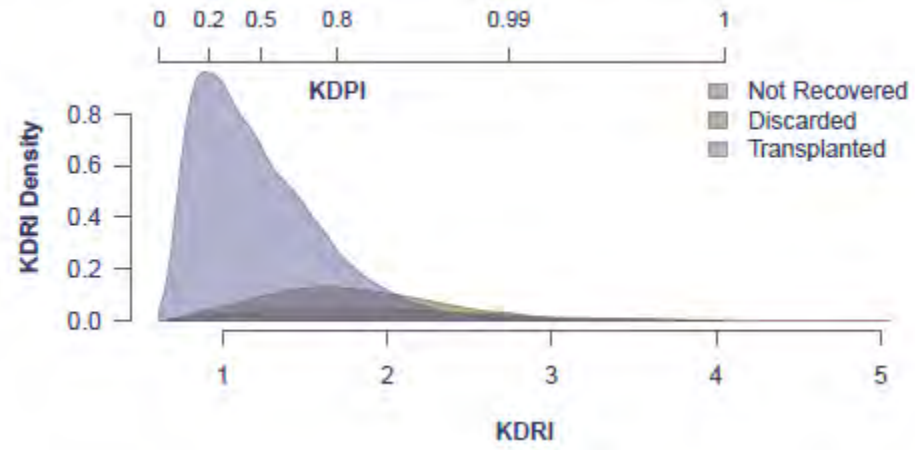


Figure 6. KDRI distribution by disposition



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.

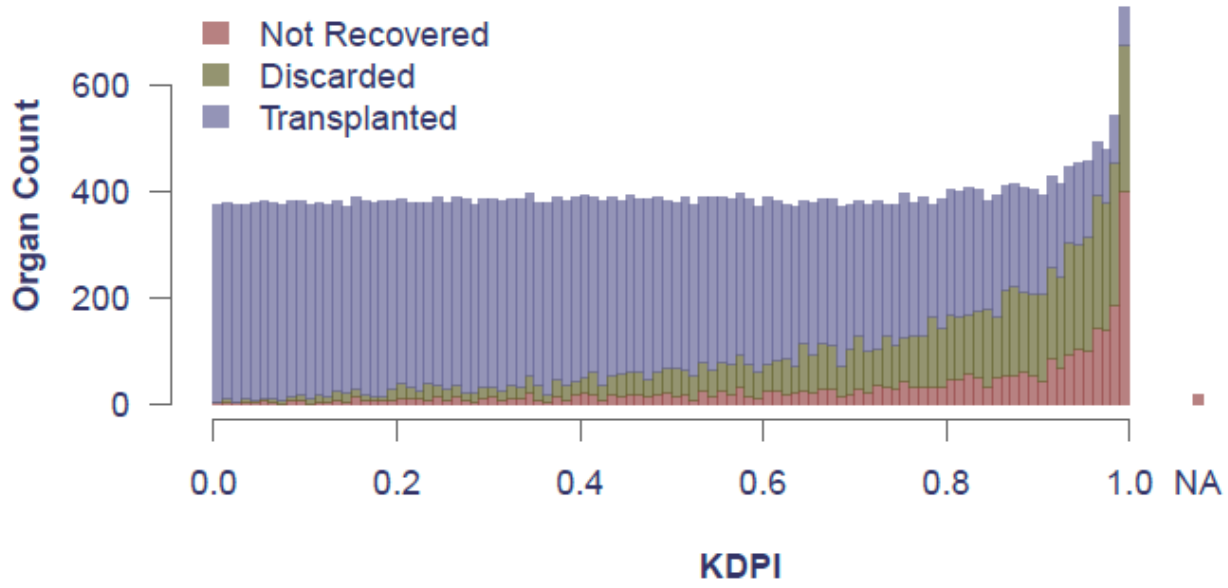


Figure 7 shows that the disposition of organs trends towards not recovered or discarded for higher values of KDPI – confirming similar results of previous analyses.

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.

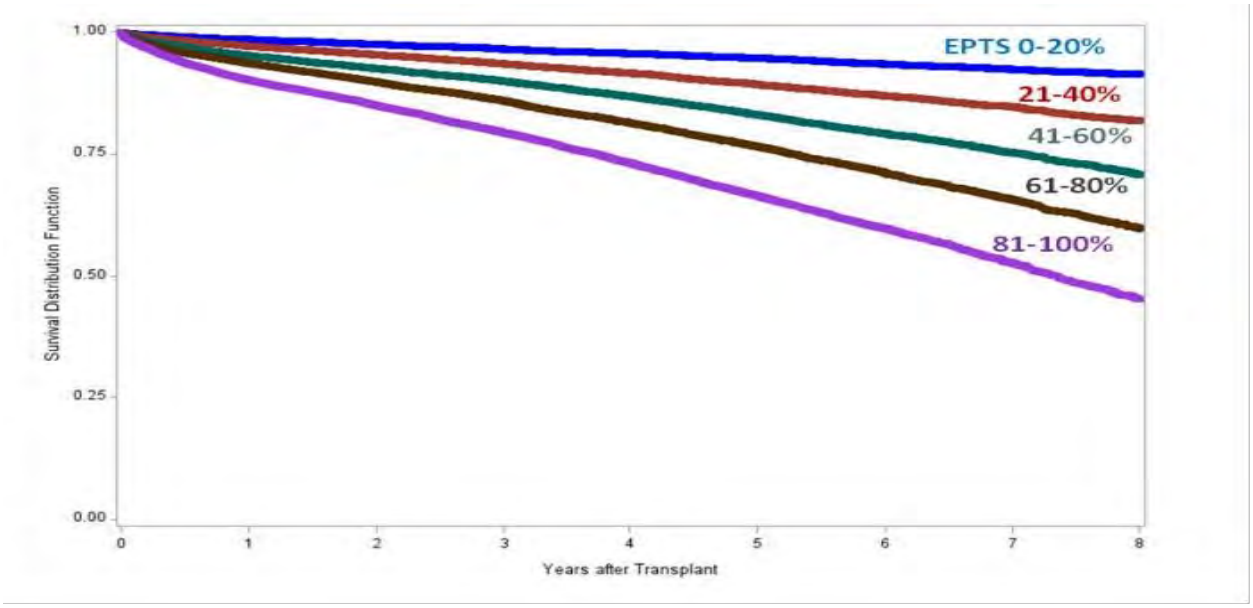
Table 1: The number of deceased donor kidneys evaluated for graft survival broken-down by KDPI and donor age.

	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.

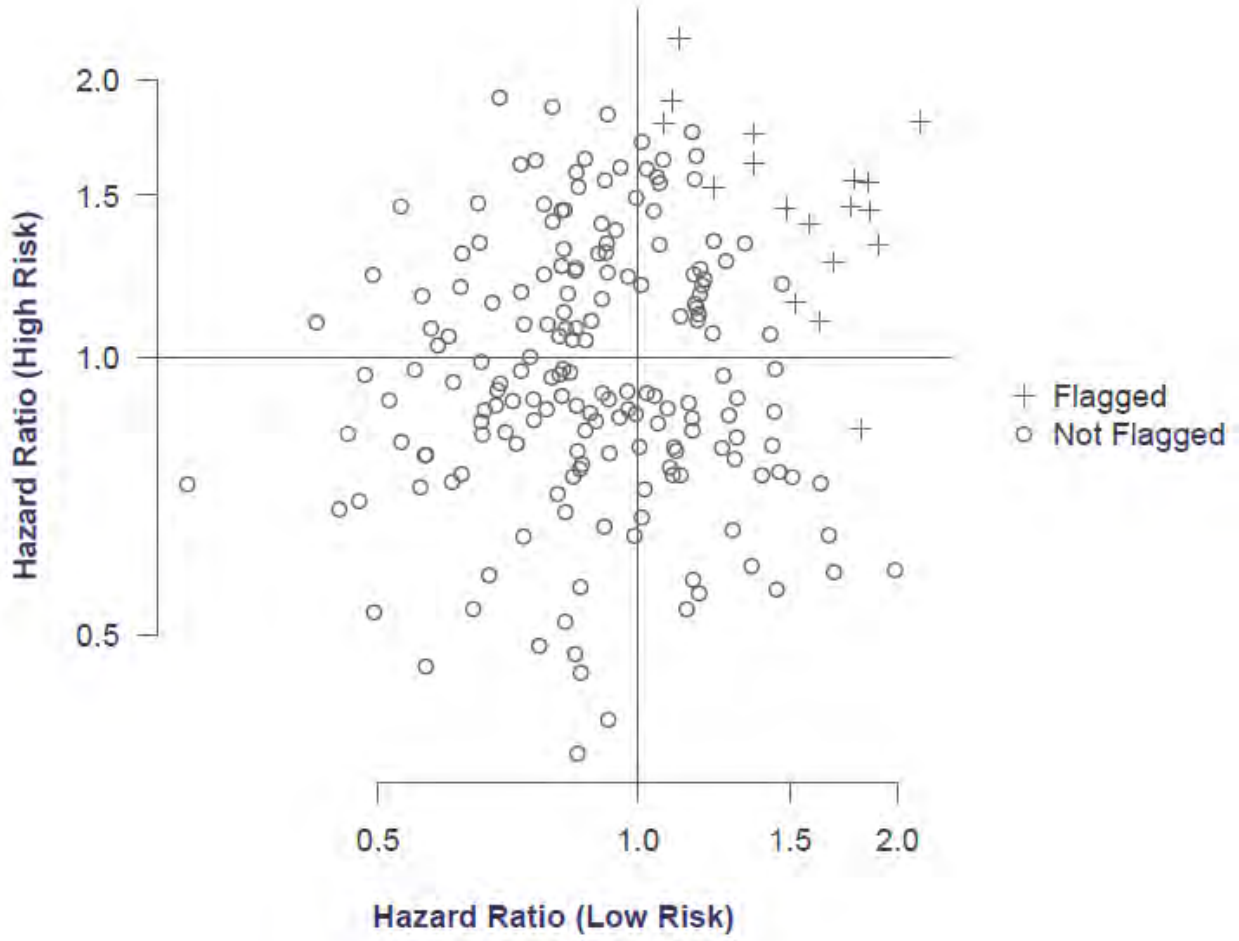


Figure 11 shows the scatterplot of hazard ratios for kidney adult graft survival for low-risk and high-risk transplants. For kidney programs, deceased donor transplants in the highest 20% of modeled risk, which includes both recipient and donor risk factors, were considered high risk transplants. Deceased 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.