Transplant Program Performance Measures Review

Outcome Measures Work Group Update

Membership and Professional Standards Committee
December 2015
Collaboration

MPSC Work Group
David Cronin, Chair
David Axelrod
Tim Taber
Rob Kochik
Dennis Martin
Nader Moazami
Jeff Orlowski
Chris McLaughlin, Ex Officio
Shannon Dunne, Ex Officio
Raelene Skerda, Ex Officio

AAAU Group
Tim Schmitt – ASTS
Mark Ghobrial – ASTS
Kim Gifford – ASTS
Tom Pearson – AST
John Friedewald – AST
Shandie Covington – AST
Kevin O’Connor – AOPO
Jay Campbell – AOPO
Elling Eidbo – AOPO
Carl Berg – UNOS
Betsy Walsh – UNOS
Stuart Sweet – UNOS

OPTN | UNOS
Evaluate ways to decrease the perceived disincentives to transplant created by the current system for reviewing post-transplant outcomes.

Goal: Increase the number of transplants.
Initial Focus

- Work group limited initial focus to kidney – significant data available on kidney
- Consider similar process for other organs following implementation for kidney
- Focus on adjustments to the methodology for post-transplant outcomes review rather than allocation change
Draft proposal considered October 2015

Committee had additional questions for the work group to consider

Work group met November 23rd to consider MPSC questions.
Outstanding questions –

- Inclusion of recipient characteristics?
  - Work Group continues to support including only donor characteristics

- Criteria to protect patient safety in the high risk transplants
  - Work Group supported the use of a separate review of high risk transplants alone if the program falls outside the threshold for all transplants

- Informed consent required?

- Evaluation post-implementation details
  - Length of initial evaluation period
  - More detail on evaluation plan
Suggested criteria

- Kidney transplant programs will be identified for review by MPSC for lower than expected graft or patient survival if kidney graft or patient survival falls outside the threshold for both
  1. All kidney transplants
  2. Either of the following:
     a. Kidney transplants other than those using kidneys from donors KDPI ≥ 85 or age ≥ 65
     b. Kidney transplants using a kidney from a donor with a KDPI ≥ 85 or age ≥ 65

- Apply to all kidney programs regardless of whether the program currently under review for outcomes
Proposed Identification Process

1. All Transplants outcomes outside threshold?
   - Y: Additional data review
     - Y: Low Risk Transplants outcomes outside threshold?
       - Y: MPSC Inquiry
       - N: No inquiry
     - N: High Risk Transplants outcomes outside threshold?
       - Y: MPSC Inquiry
       - N: No inquiry
   - N: No inquiry
Path Forward

- MPSC December conference call
- Spring 2016 – request for pre-public comment feedback
- Early Summer 2016 – Board feedback
- Summer 2016 – public comment
- December 2016 – Board of Directors review of proposal
Questions?
Additional Slides
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.
Data reviewed to determine criteria

- SRTR risk adjustment in kidney model – 2/26/2015
- UNOS Research data on characteristics of unused kidneys – 4/2/2015 and on kidneys discarded by DSA, region, and median waiting time to transplant – 5/28/2015
- UNOS Research data on relationship between discard rate, KDPI and % glomerulosclerosis for deceased donors based on DSA, region and waiting times – 5/28/2015
- SRTR data on effect of decreased discard rates on program evaluations – 8/4/2015
Data reviewed to determine criteria

- SRTR suggested reweighting the model to put less emphasis on higher risk transplants rather than excluding them from model – 9/18/2015

- Data for upcoming late Nov/early Dec meeting
  - UNOS Research data on graft and patient survival for high KDPI/older donor recipients
  - SRTR analysis of the programs that would be identified under the proposed process
  - UNOS Research data on high KDPI recipient profiles
Additional Data Slides
Gradual decline in graft survival, yet steep increases in kidney discard rates.

Stewart, et al, ATC 2013 Abstract #301
Figure 3. Discard rate of deceased donor kidneys recovered for transplant from 2007 through 2014 by KDPI and whether or not the kidney was pumped. (% pumped inset)

- 31% of all kidneys were pumped
- Pumping varies by OPO
Figure 5. Discard rate of deceased donor kidneys recovered for transplant from 2007 through 2014 by KDPI and percent Glomerulosclerosis.

<table>
<thead>
<tr>
<th>% Glomerulosclerosis</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Biopsied</td>
<td>60095</td>
<td>51.17</td>
</tr>
<tr>
<td>0-5</td>
<td>35533</td>
<td>30.25</td>
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<tr>
<td>6-10</td>
<td>8557</td>
<td>7.29</td>
</tr>
<tr>
<td>11-15</td>
<td>4197</td>
<td>3.57</td>
</tr>
<tr>
<td>16-20</td>
<td>2574</td>
<td>2.19</td>
</tr>
<tr>
<td>20+</td>
<td>5790</td>
<td>4.93</td>
</tr>
<tr>
<td>Indeterminate</td>
<td>707</td>
<td>0.6</td>
</tr>
<tr>
<td>Total</td>
<td>117453</td>
<td>100</td>
</tr>
</tbody>
</table>
Disposition by KDPI. KDPI is missing when KDRI is greater than any KDRI for a transplanted or discarded organ.
Model calibration for 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.
Scatterplot of hazard ratios for kidney adult graft survival.
Scatterplot of hazard ratios for kidney adult patient survival.
## High Risk Donor Transplants

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

<table>
<thead>
<tr>
<th>KDPI</th>
<th>Age &lt; 65</th>
<th>Age ≥ 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 85</td>
<td>22686</td>
<td>192</td>
</tr>
<tr>
<td>≥ 85</td>
<td>1543</td>
<td>705</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>KDPI</th>
<th>Age &lt; 65</th>
<th>Age ≥ 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 85</td>
<td>19508</td>
<td>183</td>
</tr>
<tr>
<td>≥ 85</td>
<td>1456</td>
<td>684</td>
</tr>
</tbody>
</table>
Proposed Flag – Graft Survival Results

Graft Survival

- Flagged (Current)
- Flagged (Proposed)
- Not-Flagged

Correlation = 0.95

Hazard Ratio (High-Risk Donors Removed)

Hazard Ratio (Every Transplant)
Proposed Flag – Patient Survival Results

Patient Survival

- Flagged (Current)
- Flagged (Proposed)
- Not-Flagged

Correlation = 0.94

Hazard Ratio (High-Risk Donors Removed)

0.0 0.5 1.0 1.5 2.0 2.5
Hazard Ratio (Every Transplant)

Wey, SRTR, November 2015
Graft survival.

Patient survival.