Review of Minimum Screening Requirements for Deceased Donor Evaluation

Ad Hoc Disease Transmission Advisory Committee (DTAC) Committee
June 23-24, 2014
The Problem

- “Commercially available” is a vague policy requirement
- Current testing requirements do not reflect updates to testing technology
- Current policy is no longer in line with current testing practices in the field
Strategic Plan

- **Goal:** Promote transplant patient safety
- **Objective:** Increase capacity to identify patient safety issues
Goal of the Proposal

- Clarify and update policy language related to deceased donor screening
- Enhance patient safety
- Help OPOs better understand how to remain compliant with OPTN requirement for testing deceased donors by
  - Eliminating confusing policy language
  - Re-organizing policy to be more clear and concise
  - Bringing testing language in line with current laboratory practices
How the Proposal will Achieve its Goal

- Replace general screening test requirements with pathogen-specific requirements
- Remove the term “commercially available”
- Provide new option for HIV testing-combination Ag/Ab test
- Simplify syphilis testing requirement
- Add flexible language for Toxoplasma screening testing for heart donors
## Public Comment Feedback

### Public Comment Response Tally

<table>
<thead>
<tr>
<th>Type of Response</th>
<th>Response Total</th>
<th>In Favor</th>
<th>In Favor as Amended</th>
<th>Opposed</th>
<th>No Vote/No Comment/Did Not Consider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual</td>
<td>46</td>
<td>35</td>
<td>0</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>(76%)</td>
<td>(91%)</td>
<td>(9%)</td>
<td>(11%)</td>
<td></td>
</tr>
<tr>
<td>Regional</td>
<td>11</td>
<td>10</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>(91%)</td>
<td>(9%)</td>
<td>(0%)</td>
<td>(0%)</td>
<td></td>
</tr>
<tr>
<td>Committee</td>
<td>19</td>
<td>9</td>
<td>0</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>(47%)</td>
<td>(0%)</td>
<td>(0%)</td>
<td>(0%)</td>
<td></td>
</tr>
</tbody>
</table>
Some concerns regarding offering diagnostic option for HIV
- Will this encourage OPOs to replace NAT with Ag/Ab test due to cost?
- Impact on contract labs?

ASTS feedback on language suggested to replace “commercially available”
- Accepted ASTS feedback
- Added requirement to report to Patient Safety System if HIV, HBV, or HCV testing not completed per policy
Estimates of window period length for different testing methods¹

<table>
<thead>
<tr>
<th></th>
<th>Standard Serology</th>
<th>Enhanced Serology</th>
<th>NAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV</td>
<td>17-22 days</td>
<td>~7-16 days</td>
<td>5-6 days</td>
</tr>
<tr>
<td>HCV</td>
<td>~70 days</td>
<td>~40-50 days</td>
<td>3-5 days</td>
</tr>
<tr>
<td>HBV</td>
<td>35-44 days</td>
<td>Not Applicable</td>
<td>20-22 days</td>
</tr>
</tbody>
</table>

Post-Public Comment Modifications

- Converted to plain language format
- Removed redundant language
- Replaces a “should” with a “must”
- Made PHS Guideline references consistent
The host OPO must provide *all* the following additional information for all deceased donor heart offers:

1. Height
2. Weight
3. Vital signs, including blood pressure, heart rate, and temperature
4. History of treatment in hospital including vasopressors and hydration
5. Cardiopulmonary, social, and drug activity histories
6. Details of any documented cardiac arrest or hypotensive episodes
7. 12-lead interpreted electrocardiogram
8. Arterial blood gas results and ventilator settings
9. Cardiology consult or echocardiogram, if the hospital has the facilities
10. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, and DQB antigens
11. Toxoplasma antibody (Ab) test result or an appropriate donor sample sent with the heart for testing at the transplant hospital
RESOLVED, that additions and modifications to Policies 2.3 (Evaluating and Screening Potential Deceased Donors), 2.4 (Deceased Donor Medical and Behavioral History), 2.5 (Hemodilution Assessment), 2.7 (HIV Screening of Potential Deceased Donors), 2.7.A ( Exceptions to HIV Screening Requirement), 2.8 (Required Deceased Donor Information), 2.9 (Requested Deceased Donor Information) and its subsections, 2.10 (Post Recovery Follow Up and Reporting) and its subsections 16.4.D ( Internal Labeling of Vessels, 2.11 ( Deceased Donor Management), 2.12 (Organ Procurement) and its subsections, 2.13 (Requirements for Controlled Donation after Circulatory Death (DCD) Protocols) and its subsections, Table 14-2: Requirements for Living Kidney Donor Medical Evaluations, 14.5.A (Living Kidney Donor Psychosocial Evaluation Requirements), and 16.4.D (Internal Labeling of Vessels) as set forth in Resolution 3, are hereby approved, effective September 1, 2014.
Thank you!

Michael Green, MD, MPH, Committee Chair
Michael.Green@chp.edu

Shandie Covington, Committee Liaison
shandie.covington@unos.org
HIV antigen/antibody combination testing recommended in 2013 PHS Guideline
- not meant to replace NAT
- Reduce the window period for recognizing infection
- Feedback sought from the FDA

Syphilis test options are equally effective and offer OPOs more flexibility

Toxoplasma screening already requested regularly by heart transplant programs