Proposal to Modify ABO Determination, Reporting, and Verifications Requirements

Operations and Safety Committee
June 2015
The Problem

- Rules are misunderstood resulting in compliance issues
- Rules vary between OPTN and CMS creating more confusion
- Despite current policy, accidental ABO incompatible transplants have occurred
- Gaps exist in current policy creating risk
Project Goals

- Clarify requirements and assist members with compliance
- Cross walk OPTN and CMS rules
- Strengthen current key safety components
## Strategic Plan Alignment

<table>
<thead>
<tr>
<th>Promote transplant patient safety</th>
<th>Promote living donor safety</th>
<th>Promote efficient management of the OPTN</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Reduce risk of accidental ABOi transplant</td>
<td>• Reduce risk of accidental ABOi transplant</td>
<td>• Clarify policy</td>
</tr>
<tr>
<td>• Reduce risk of wrong organ/wrong recipient</td>
<td>• Reduce risk of wrong organ/wrong recipient</td>
<td>• Align with CMS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Provide support tools</td>
</tr>
</tbody>
</table>
Vision Statement Alignment

- To promote long, healthy and productive lives for persons with organ failure by promoting maximized organ supply, effective and safe care, and equitable organ allocation and access to transplantation.

- Values: stewardship, unity, trust, excellence, accountability
Spring 2015 Public Comment Themes

- Complexity
- Time out fatigue, too many verifications, effort to implement
- Documentation and misunderstanding over acceptable sources. Concerns about site survey requirements.
- Wait to adopt with TransNet\textsuperscript{sm}/Phase in with TransNet\textsuperscript{sm}
Spring 2015 Public Comment Themes

- Need to focus on right organ/right recipient (not ABO)
- Only make change if align with CMS
- Timing of living donor verification prior to anesthesia
- OPO requirements to perform verification at recovery
- Organ check-in
Spring 2015 Post-Public Comment Outreach

- OPTN/UNOS BOD including Regional Councillors
- AOPO
- AST
- ASTS
- Living Donor Committee
- OPO Committee
- Centers for Medicaid and Medicare Services (CMS)
Spring 2015 Post-public comment actions

- Simplify organ check-in and VCA living donor language
- Eliminate verification requirement LD to be done in OR
- Modify timing of living donor determination and verification due to UNet℠ functioning
- Working with TransNet℠ for programming options to meet requirements
- Addressed ABO verification at time of recovery
Why does this ‘policy’ feel so big and burdensome?

- 1.2
- 2.15b
- 2.6a
- 2.6b
- 2.6c
- 2.6d
- 3.3a
- 3.3b
- 5.4b
- 5.5a
- 5.6
- 5.7a
- 13.6a
- 13.6b
- 14.4a
- 14.5a
- 14.5b
- 14.5c
- 14.7
- 14.8
- 14.11
- 16.1
- 16.4c
Post- Spring 2015 Public Comment and Regional Meeting Proposal
ABO Determination, Reporting, and Verification Process

1. Determine candidate blood type
2. Candidate blood type entered into UNet\textsuperscript{sm} X 2
3. UNet\textsuperscript{sm} electronically verifies ABO entries
4. Determine donor blood type
5. Donor blood type entry into UNet\textsuperscript{sm} X 2
6. Match run: UNet\textsuperscript{sm} screens potential recipients based on ABO compatibility
7. Blood type compatibility verification prior to organ recovery
8. Blood type compatibility verification prior to organ transplant
ABO Process Step 4. Determine Deceased Donor Blood Type

<table>
<thead>
<tr>
<th>Current OPTN</th>
<th>Proposed OPTN</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1 ABO</strong></td>
<td><strong>2 ABO</strong></td>
</tr>
<tr>
<td>2 person verification on 1 or 2 separate samples</td>
<td>2 person verification on 2 separate samples</td>
</tr>
<tr>
<td><strong>PTR</strong></td>
<td><strong>PTR</strong></td>
</tr>
<tr>
<td>Generated on 1 result</td>
<td>Generated on 2 concurring results</td>
</tr>
<tr>
<td><strong>Pre-Op</strong></td>
<td><strong>Pre-Op</strong></td>
</tr>
<tr>
<td>2\textsuperscript{nd} ABO resulted and verified *</td>
<td>2\textsuperscript{nd} ABO already resulted and verified</td>
</tr>
<tr>
<td><strong>Donor OR</strong></td>
<td><strong>Donor OR</strong></td>
</tr>
<tr>
<td>Completed prior to incision</td>
<td>Incision</td>
</tr>
</tbody>
</table>
Current

OPTN: No policy

CMS CoP (§486.344(d)(2)(ii):
If the identity of the intended recipient is known, an individual from the OPO's staff compares the blood type of the donor with the blood type of the intended beneficiary, and the accuracy of the comparison is verified by a different individual.

Proposed

OPTN: The host OPO must verify all of the following information when the intended recipient is known:

* Intended recipient unique identifier
* Intended recipient blood type
* Donor and intended recipient are blood type compatible (or intended incompatible).

Use: OPTN computer system
ABO Process Step 7a / Proposed Policy 5.6: Organ Check-In

Current

OPTN: No policy

CMS: No policy

Proposed

OPTN: ... Use the OPTN external organ label to confirm that the correct Donor ID and organ type and laterality (if applicable) arrived
ABO Process Step 8a / Proposed Policy 5.7A: Blood type Compatibility Verification Prior to Organ Receipt

**Current**

OPTN: No policy

CMS: No policy

**Proposed**

OPTN: 2 licensed health care professionals must verify:

* Expected donor ID
* Expected organ
* Expected donor blood type
* Recipient unique identifier
* Recipient blood type
* Expected donor and recipient and blood type compatible or intended incompatible
Proposed Living Donor Policy 14.5A

- Current policy allows for:
  - “blood typing of each LD is performed on 2 separate occasions before the recovery”
  - LD ID to be generated on 1 ABO determination

- Proposed policy requires:
  - LD blood type is determined by testing at least 2 donor blood samples prior to generation of the living donor
Proposed Living Donor Policy 14.7: Living Donor Pre-Recovery Verification

- Current allows:
  - Verifications only when organs are recovered from a LD and remain in the same facility as the intended recipient
  - Time out must occur before organ leaves the LD operating room

- Proposed requires:
  - Verification must occur prior to the induction of general anesthesia on the day of LD recovery
  - All living donors
### Goal 1: Clarify requirements

<table>
<thead>
<tr>
<th>Current:</th>
<th>Proposed:</th>
</tr>
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</table>
| Transplant programs must determine each candidate’s blood type by testing at least two candidate blood samples prior to registration on the waiting list. Transplant programs must test at least two blood samples from two separate blood draws taken at two different times. | Candidate blood samples must:  
1. Be drawn on two separate occasions  
2. Have different collection times  
3. Be submitted as separate samples  
4. Have results indicating the same blood type |

<table>
<thead>
<tr>
<th>Current:</th>
<th>Proposed:</th>
</tr>
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</table>
| The recovery hospital must ensure that blood typing of each living donor is performed on two separate occasions before the recovery. Two separate occasions are defined as two blood samples taken at different times and sent to the same or different laboratories. | Living donor blood samples must:  
1. Be drawn on two separate occasions  
2. Have different collection times  
3. Be submitted as separate samples  
4. Have results indicating the same blood type |
## Goal 2: Crosswalk with CMS

<table>
<thead>
<tr>
<th>Requirement</th>
<th>OPTN Current Align with CMS?</th>
<th>OPTN Proposed Align with CMS?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two ABO draws must be obtained for deceased donors</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Deceased donor recovery verification must be conducted</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Living donor recovery verification must be conducted on all living donors</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Living donor recovery verification must be conducted prior to surgery</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Transplant surgeon must participate in pre-transplant verification</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>
## Goal 3: Strengthen key safety measures

<table>
<thead>
<tr>
<th>Proposed Requirement</th>
<th>Why?</th>
<th>OPTN Proposed Align with CMS?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two ABO tests and reporting must be done prior to running deceased donor match run</td>
<td>Reduce chance of match on one erroneous result</td>
<td>Yes and safer</td>
</tr>
<tr>
<td>Living donor recovery must be conducted prior to general anesthesia</td>
<td>Elective surgery. Anesthesia has risk</td>
<td>Yes and safer</td>
</tr>
<tr>
<td>Conduct organ check-in</td>
<td>ID wrong organ delivery before excessive CIT</td>
<td>CMS has no requirement</td>
</tr>
<tr>
<td>Conduct pre-transplant verification if surgery starts prior to organ arrival</td>
<td>Reduce risk of anesthesia and organ removal if ABOi discovered. Suggest adding ABO to JCAHO universal protocol</td>
<td>CMS has no requirement</td>
</tr>
</tbody>
</table>
How we will help members comply

<table>
<thead>
<tr>
<th>Education</th>
<th>Programming</th>
</tr>
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<tbody>
<tr>
<td>FAQs</td>
<td>Liver ABOi warning</td>
</tr>
<tr>
<td>One page instructions</td>
<td>Candidate blood type on match run</td>
</tr>
<tr>
<td>Proficiency module</td>
<td>Symbol for compatibility status</td>
</tr>
<tr>
<td>Update OR templates</td>
<td>Second user subtype verification</td>
</tr>
<tr>
<td>Update Guidance</td>
<td>TransNet</td>
</tr>
</tbody>
</table>
## What Members will Need to Do

<table>
<thead>
<tr>
<th>OPOs</th>
<th>Recovery Hospitals</th>
<th>Transplant Hospitals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have protocols that include process for resolving primary blood type conflicts and define qualified health care professional to conduct reporting and verification</td>
<td>Complete both ABO determination and reporting prior to the match run</td>
<td>Conduct organ check-in</td>
</tr>
<tr>
<td>Complete both ABO determination and reporting by activating donor through Living Donor Feedback Form</td>
<td>Conduct pre-recovery verification on all living donors prior to general anesthesia</td>
<td>Complete separate pre-recovery verification if surgery starts prior to organ arrival</td>
</tr>
</tbody>
</table>
# Overall Project Impact

**Product**

Policy, Education, Programming

| Target Population Impact: | Deceased and Living Donors  
|                          | Transplant Candidates |

| Total IT Implementation Hours | 1,860/16,680 |

| Total Overall Implementation Hours | 2,545/23,685 |
Board Policy Group Recommendation

- Discussion Agenda
  - 0-Approve without further discussion
  - 3-Approve but discuss
  - 1-Decline but discuss
  - 6-No recommendation but discuss
RESOLVED, that Policies 1.2 (Definitions), 2.6 (Deceased Donor Blood Type Determination and Reporting), 2.6.A (Deceased Donor Blood Type Determination), 2.6.B (Deceased Donor Blood Subtype Determination), 2.6.C (Primary Reporting of Deceased Donor Blood Type and Subtype), 2.6.D. (Secondary Reporting of Deceased Donor Blood Type and Subtype), 2.15.B (New: Pre-Recovery Verification), 3.3 (Candidate Blood Type Determination and Reporting before Waiting List Registration), 3.3.A (Blood Type Determination before Registration on the Waiting List), 3.3.B (Secondary Reporting of Candidate Blood Type), 5.4.B (Order of Allocation), 5.5.A Receiving and Reviewing Organ Offers), 5.6 (Blood Type Verification Upon Receipt), 5.7 (New: Pre-Transplant Verification), 5.7.A (New: Pre-Transplant Verification Prior to Organ Receipt), 5.7.B (New: Pre-Transplant Verification Upon Organ Receipt), 13.6.A (Requirements for Match Run Eligibility for Candidates), 13.6.B (Requirements for Match Run Eligibility for Potential KPD Donors), 14.4 (Medical Evaluation Requirements for Living Donors), 14.4.A (Living Donor Blood Type Determination), 14.4.Ai (Living Donor Blood Subtype Determination), 14.4.B (Living Donor Medical Evaluation Requirements) 14.5 (Registration and Blood Type Verification of Living Donors before Donation), 14.5.A (New: Living Donor Blood Type Determination), 14.5.B (New: Living Donor Blood Subtype Determination) 14.5.C (New: Reporting of Living Donor Blood Type and Subtype), 14.7 (New: Living Donor Pre-Recovery Verification), 14.9 (New: Living Donor Organ Check-In), 14.10 (New: Living Donor Pre-Transplant Verification), 16.1 (Organs Not Requiring Transport), and 16.4.C (Internal Labeling of Blood and Tissue Typing Materials) are modified as set forth in Exhibit C, and are hereby approved, effective February 1, 2016.
FURTHER RESOLVED, that programming modifications to ABO incompatible liver registrations, match run displays for candidate blood type including compatibility status, and second user subtype verification are hereby approved, effective pending programming and notice to the OPTN membership.