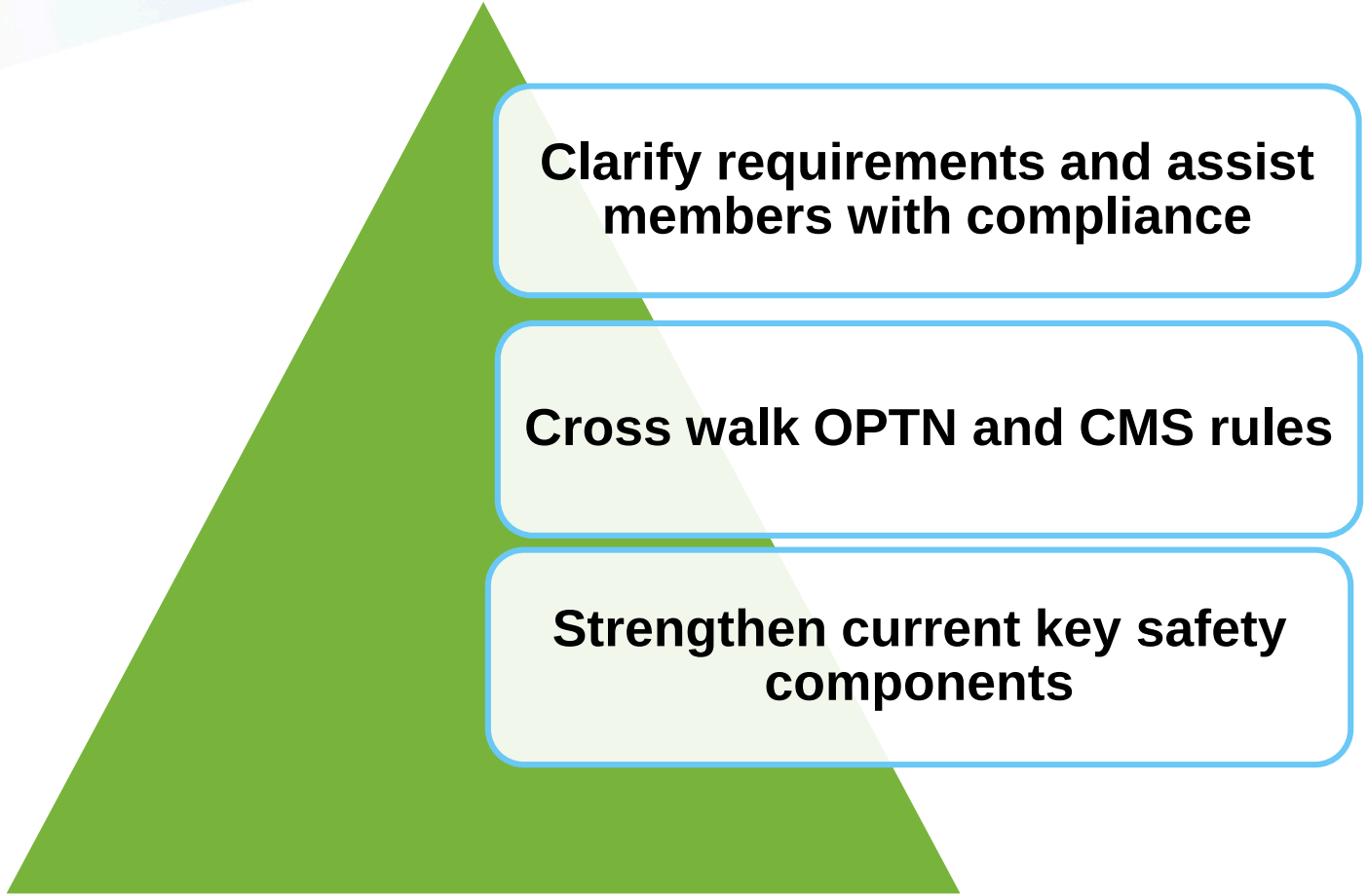
Proposal to Modify ABO Determination, Reporting, and Verifications Requirements

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



Strategic Plan Alignment

Promote transplant patient safety

- Reduce risk of accidental ABOi transplant
- Reduce risk of wrong organ/wrong recipient

Promote living donor safety

- Reduce risk of accidental ABOi transplant
- Reduce risk of wrong organ/wrong recipient

Promote efficient management of the OPTN

- Clarify policy
- Align with CMS
- Provide support tools

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^{sm}/Phase in with TransNet^{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

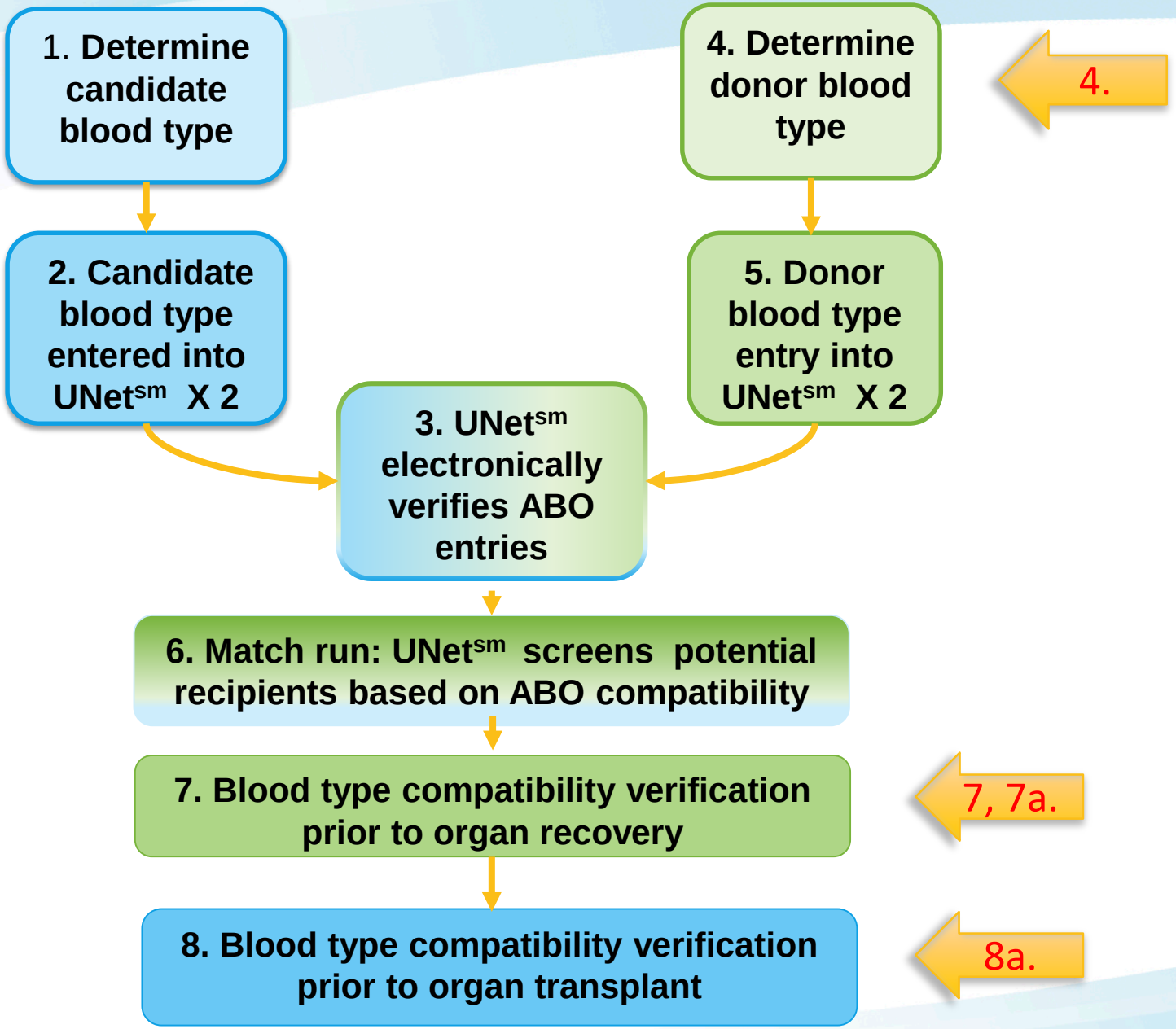
- Simplify organ check-in and VCA living donor language
- Eliminate verification requirement LD to be done in OR
- Modify timing of living donor determination and verification due to UNet^{sm} functioning
- Working with TransNet^{sm} for programming options to meet requirements
- Addressed ABO verification 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



OPTN | UNOS

ABO Process Step 4. Determine Deceased Donor Blood Type

Current OPTN

1 ABO	• 2 person verification on 1 or 2 separate samples
PTR	• Generated on 1 result
Pre-Op	• 2nd ABO resulted and verified *
Donor OR	• Completed prior to incision

Proposed OPTN

2 ABO	• 2 person verification on 2 separate samples
PTR	• Generated on 2 concurring results
Pre-Op	• 2nd ABO already resulted and verified
Donor OR	• Incision

ABO Process Step 7 / Proposed Policy 2.15B Pre-Recovery Verification

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

Current:

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.

Current:

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.

Determination

Proposed:

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

Proposed:

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

Requirement	OPTN Current Align with CMS?	OPTN Proposed Align with CMS?
Two ABO draws must be obtained for deceased donors	**No**	**Yes**
Deceased donor recovery verification must be conducted	**No**	**Yes**
Living donor recovery verification must be conducted on all living donors	**No**	**Yes**
Living donor recovery verification must be conducted prior to surgery	**No**	**Yes**
Transplant surgeon must participate in pre-transplant verification	**No**	**Yes**

Goal 3: Strengthen key safety measures

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

How we will help members comply

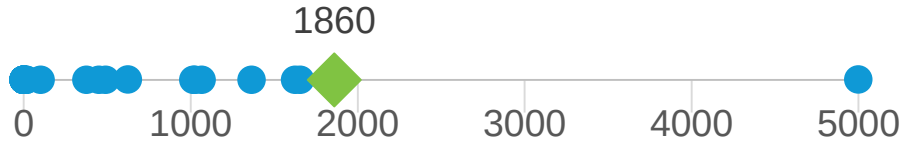
Education	Programming
FAQs	Liver ABOi warning
One page instructions	Candidate blood type on match run
Proficiency module	Symbol for compatibility status
Update OR templates	Second user subtype verification
Update Guidance	TransNet

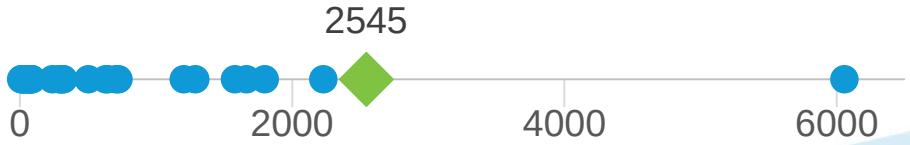
What Members will Need to Do

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

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

Resolution 8 (page 15)

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.

Resolution 8 (page 15) cont'd

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.