OPTN | UNOS

Mini-Brief

Post-Implementation Modifications to ABO Verification Policies

OPTN/UNOS Operations and Safety Committee

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Contents

Post-Implementation Modifications to ABO Verification Policies

Affected Policies: 2.15 B (Pre-Recovery Verification), 5.8.A (Pre-Transplant Verification Prior to Organ Receipt), 5.8.B (Pre-Transplant Verification Upon Organ Receipt), and 14.7 (Living Donor Pre-Recovery Verification)

Sponsoring Committee: *Operations and Safety*

Public Comment Period: 8/15/2016 - 10/15/2016 *(Infectious disease verification to enhance patient safety)*

Executive Summary

This proposal contains policy modifications to the recently approved and implemented ABO verification policies. These modifications are a combination of:

- Modifications that were released for public comment as part of the infectious disease verification proposal. This proposal has been delayed for further development. These specific modifications received no negative feedback as they were not adding requirements but only reformatting existing requirements.
- Clarifications and modifications requested as part of the committee's post implementation evaluation of the ABO verification proposal. One proposed change provides clarification, other changes modify what can be used to verify items, and one change eliminates a verification requirement.

The Committee would like to move forward with the following modifications:

- Rework of policy language allowing use of "organ tracking system" now defined in OPTN policy for OPOs, transplant hospitals, and recovery hospitals
- Rework of policy language that moves language containing who performs the verification into the existing table format versus list format (no change in actual requirement). This was done so that programs can cut out and use the tables as needed.
- Modify language to alleviate confusion between acceptable source and source document. Source document is defined in OPTN/UNOS policy.
- Modify language regarding use of donor identification band (and OPTN computer system) to identify OPTN/UNOS issued donor ID
- Modify language to use the OPTN computer system for verification purposes in additional places
- Add attestation as a method to verify correct donor organ/correct intended recipient for living donor recovery verifications
- Remove requirement to verify organ laterality at pre-transplant verification prior to organ receipt in the OR.

What problem will this proposal solve?

Since the ABO verification policies became effective in June 2016, the community has requested clarifications or modifications to some of those policies. This proposal will address the least controversial of those requests. Some of the issues that have arisen since the implementation of the ABO verification policies include:

- Policy now includes a definition for an "organ tracking system" that originated with the electronic organ tracking system (TransNet) proposal. Members have asked whether that is the same as the phrase "OPTN-approved electronic method" that is used in the ABO verification policies.
- Members have asked for policies to be formatted into tables so that they will be easier to copy and paste into member specific documents.
- Members have asked for clarification between the phrases "acceptable sources" which is not defined and "source documents" which is a defined term.
- Members have asked for modifications regarding the use of donor identification band (and OPTN computer system) to identify OPTN/UNOS issued donor ID
- Members have asked to add attestation as a method to verify correct donor organ/correct intended recipient for living donor recovery verifications
- Members have asked to remove the requirement to verify organ laterality at pre-transplant verifications.

Why should you support this proposal?

This proposal will help clarify questions about policy and assist with implementation of ABO policies that became effective in June 2016.

The Operations and Safety Committee sent out a public comment proposal to add infectious disease verification processes where ABO verifications currently occur at pre-recovery and pre-transplant time points. The infectious disease verification proposal builds upon many of the same principles as the ABO verification policies therefore the policies are structured similarly. In developing the infectious disease verification proposal, the committee uncovered opportunities to improve the already approved ABO verification policies. Due to the adjustments still needed to operationalize ABO within the transplant community and public comment response to the infectious disease verification proposal, the Operations and Safety Committee decided not to move forward with infectious disease proposal at this time. Instead, the Committee plans a spring 2017 public comment proposal for the infectious disease verification issue.

The committee did not want to wait to make the corresponding improvements to the ABO verification policies that were included in the original public comment proposal. One of these is to identify the organ tracking system as a method that can be used for assistance. This was in the old language but since that implementation, a policy definition for the organ tracking system (TransNet) has been approved and needs to be used for clarity. The other modification in the original public comment was to move those persons that perform verifications into table format, as is the current style for OPO recovery verification policy. Putting this information in the table could allow the tables to be used more effectively. No public comments were made in opposition to these proposed changes.

The transplant community has made several requests through various channels including general public comment, member email communication, Transplant Administrators and Transplant Coordinators Committee discussions with Operations and Safety Committee leadership, regional administration, and site survey staff. Although many requests were not made in formal public comments, the Committee had planned to address these requests in post-public comment changes. These include clarifying the difference between acceptable sources and source documents and clarifying the requirements around verifying the donor ID. In some situations, donor ID was confused with a local identification number although donor ID has a specific OPTN policy definition. In addition, donor ID is not printed on a hospital patient identification band in various cases. Use of the OPTN computer system was added to assist in this verification part especially for those who do not have the option of using a TransNet printed identification band.

Other changes requested by the community and proposed here include to delete organ laterality verification and add attestation for living donor recovery correct organ/correct intended recipient.. The requirement to verify organ laterality on the pre-transplant side has been proposed for deletion due to issues in obtaining timely documentation and changes late in the transplant process. Members in some cases have had to document unknown laterality. The other proposed modification is to allow attestation (a verbal or written statement by the persons conducting the verification) to be used when verifying the correct donor organ for the correct intended recipient. The attestation is allowed currently for compatible or incompatible blood types. This provides more flexibility and helps address limitations in that linked donor and recipient information is difficult to obtain within UNet.

Note: this proposal was amended on November 22, 2016 to keep the requirement to verify lung laterality if applicable at the pre-transplant verification at prior to organ receipt in the OR due to clinical implications and safety concerns if surgery starts prior to organ receipt.

Table 1: Summary and Type of Proposed Changes

Proposed changes in original Infectious Disease Verification Public Comment Proposal	
Proposed changes	Comments
Rework policy language allowing use of "organ tracking system" now defined in OPTN policy for OPOs, transplant hospitals, and recovery hospitals	No opposing public comments made to this language. Members support use of the organ tracking system (TransNet) for verification purposes
Rework policy language that moves language containing who performs the verification into the existing table format versus list format (no change in actual requirement). This was done so that programs can cut out and use the tables as needed.	No opposing public comments made to this language although some have commented that the committee may want to revisit who performs the verification.
Proposed changes made in response to clarify member questions and requests	
Proposed changes	Comments
Modify language to alleviate confusion between acceptable source and source document. Source document is defined in OPTN/UNOS policy.	Request made by several transplant administrators via letter and other members via regional administration staff
Modify language regarding use of donor identification band (and OPTN computer system) to identify OPTN/UNOS issued donor ID	Request made by members via email , regional administration staff, and living donor site survey staff
Add attestation as a method to verify correct donor organ /correct intended recipient for living donor recovery verifications	Request made by members via email and regional administration staff. Adds another member option, but no new requirements, to existing policies.
Remove requirement to verify organ laterality at pre-transplant verifications	Request made by members via email and regional administration staff.

How does this proposal impact the OPTN Strategic Plan?

1. Increase the number of transplants: There is no impact to this goal.

2. Improve equity in access to transplants: There is no impact to this goal.

3. Improve waitlisted patient, living donor, and transplant recipient outcomes: There is no impact to this goal.

4. Promote living donor and transplant recipient safety: There is no impact to this goal

5. Promote the efficient management of the OPTN: This proposal will provide clarity and lessen the burden on members seeking answers or alternatives to comply with policy.

How will the OPTN implement this proposal?

The OPTN will implement this proposal through normal communication channels including a policy notice and Transplant Pro article highlighting changes made in response to member requests. Operations and Safety Committee members can give an update at regional meetings as well.

How will members implement this proposal?

Members will need to familiarize themselves with the policy clarifications and adapt their policies and practices as needed. This will not increase any member compliance costs but instead should make it easier for members to understand and comply with existing policy requirements.

Will this proposal require members to submit additional data?

No additional data will be required because of this proposal.

How will members be evaluated for compliance with this proposal?

At transplant hospitals, site surveyors would no longer:
1. Review the hospital's internal policies, procedures and/or protocols and interview staff to verify that the hospital has and follows a process that includes verification of the expected donor organ laterality as part of the pre-transplant verification.
2. Review a sample of medical records, and any material incorporated into the medical record for reference, for documentation that the organ laterality was verified between organ arrival and anastomosis as part of the pre-transplant verification.

Policy or Bylaws Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (example).

RESOLVED, that changes to Policies 2.15 B (Pre-Recovery Verification), 5.8.A (Pre-Transplant Verification Prior to Organ Receipt), 5.8.B (Pre-Transplant Verification Upon Organ Receipt), and 14.7 (Living Donor Pre-Recovery Verification), are hereby approved, effective March 1, 2017.

1   **2.15.B   Pre-Recovery Verification**

2   Host OPOs must develop and comply with a written protocol to perform a pre-recovery
3   verification for each organ recovered as required below. Qualified health care professionals,
4   as defined in the host OPO's protocol, must perform all verifications. At least one of the
5   individuals performing a verification must be an OPO staff member.
6
7   The host OPO must conduct ~~a~~ the verification prior to organ recovery according to *Table 2-2*
8   below. ~~Assistance using an OPTN-approved electronic method is permitted.~~ OPOs may use the
9   OPTN organ tracking system to assist with completion of this verification.
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Table 2-2: Pre-Recovery Verification Requirements

The host OPO must verify *all* of the following information:	Using at least *one* of ~~these sources~~ the following:	By *both* of the following individuals:
Donor ID	• Donor~~'s~~ identification band containing the donor ID • Donor identification band and OPTN computer system	1. On-site recovering surgeon 2. Qualified health care professional
Organ (and laterality, if applicable)	• Donor medical record • OPTN computer system	1. On-site recovering surgeon 2. Qualified health care professional
Donor blood type and subtype (if used for allocation)	• Donor blood type and subtype source documents	1. On-site recovering surgeon 2. Qualified health care professional

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13   When the intended recipient is known prior to organ recovery, the host OPO must verify *all* of the
14   additional information according to *Table 2-3* below.
15
16   **Table 2-3: Additional Pre-Recovery Verification Requirements When the Intended Recipient
17   is Known Prior to Organ Recovery**

The host OPO must verify *all* of the following information:	Using ~~at least *one* of these sources~~ the:	By the following individuals:
Intended recipient unique identifier	• OPTN computer system	Two qualified health care professionals
Intended recipient blood type	• OPTN computer system	Two qualified health care professionals
Donor and intended recipient are blood type compatible (or intended incompatible)	• OPTN computer system	Two qualified health care professionals

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19   The host OPO must document that the verifications were completed according to the OPO's protocol and
20   the above requirements.

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5.8.A Pre-Transplant Verification Prior to Organ Receipt

If the recipient surgery will begin prior to organ receipt in the operating room, the transplant hospital must conduct a pre-transplant verification that meets *all* of the following requirements:

1. ~~Two licensed health care professionals must participate in the verification~~
2. ~~2.~~ 1. The intended recipient must be present in the operating room
3. ~~3.~~ 2. The verification must occur *either*:
    a. Prior to induction of general anesthesia
    b. Prior to incision if the patient has been receiving continuous sedation prior to arrival in the operating room
4. ~~4.~~ 3. Transplant hospitals must use at least one of the acceptable sources during the pre-transplant verification prior to organ receipt to verify all of the following information according to ~~in~~ Table 5-2 below. ~~Assistance using an OPTN-approved electronic method is permitted.~~ Transplant hospitals may use the OPTN organ tracking system to assist with completion of this verification.

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Table 5-2: Pre-Transplant Verification Prior to Organ Receipt Requirements

The transplant hospital must verify *all* of the following information:	Using at least *one* of ~~these sources~~ the following:	By the following individuals:
Expected donor ID	• OPTN computer system • Recipient medical record	Two licensed health care professionals
Expected organ (and lung laterality if applicable)	• OPTN computer system • Recipient medical record	Two licensed health care professionals
Expected donor blood type and subtype (if used for allocation)	• Donor blood type and subtype source documents • OPTN computer system	Two licensed health care professionals
Recipient unique identifier	• Recipient identification band	Two licensed health care professionals
Recipient blood type	• OPTN computer system • Recipient blood type and subtype source documents • Recipient medical record	Two licensed health care professionals
Expected donor and recipient are blood type compatible (or intended incompatible).	• OPTN computer system • Recipient medical record • Attestation following verification of donor and recipient blood types	Two licensed health care professionals

If a pre-transplant verification was conducted prior to organ receipt, the transplant hospital must document that the verification was completed according to the hospital's protocol and the above requirements.

5.8.B Pre-Transplant Verification Upon Organ Receipt

At the time of organ receipt in the operating room, the transplant hospital must conduct a pre-transplant verification with *all* the following requirements:

1. ~~The transplant surgeon and another licensed health care professional must participate in the~~

~~verification~~

2. 1. The intended recipient must be present in the operating room
3. 2. The verification must occur after the organ arrives in the operating room, but prior to anastomosis of the first organ
4. 3. Transplant hospitals must use at least one of the acceptable sources during the pre-transplant verification upon organ receipt to verify all of the following information ~~in~~ according to *Table 5-3* below. ~~Assistance using an OPTN-approved electronic method is permitted~~ Transplant hospitals may use the OPTN organ tracking system to assist with completion of this verification.

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Table 5-3: Pre-Transplant Verification Upon Organ Receipt Requirements

The transplant hospital must verify *all* of the following information:	Using at least *one* of ~~these sources~~ the following:	By *both* of the following individuals:
Donor ID	• External and internal organ package labels • Documentation with organ	1. Transplant surgeon 2. Licensed health care professional
Organ (and laterality if applicable)	• Organ received	1. Transplant surgeon 2. Licensed health care professional
Donor blood type and subtype (if used for allocation)	• Donor blood type and subtype source documents	1. Transplant surgeon 2. Licensed health care professional
Recipient unique identifier	• Recipient identification band	1. Transplant surgeon 2. Licensed health care professional
Recipient blood type	• Recipient blood type source documents • Recipient medical record	1. Transplant surgeon 2. Licensed health care professional
Donor and recipient are blood type compatible (or intended incompatible)	• OPTN computer system • Recipient medical record • Attestation following verification of donor and recipient blood types	1. Transplant surgeon 2. Licensed health care professional
Correct donor organ has been identified for the correct recipient	• Recipient medical record • OPTN computer system • Attestation following verification of donor ID, organ, and recipient unique identifier	1. Transplant surgeon 2. Licensed health care professional

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39 The transplant hospital must document that the pre-transplant verification upon organ receipt was
40 completed according to the hospital's protocol and the above requirements.
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42 **14.7 Living Donor Pre-Recovery Verification**

43 Recovery hospitals must develop and comply with a written protocol to perform pre-recovery
44 verifications as required below.
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46 The recovery hospital must conduct a pre-recovery verification that meets *all* of the following
47 requirements:

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1. ~~The recovery surgeon and another licensed health care professional must participate in the verification.~~
2. 1. The verification must occur prior to the induction of general anesthesia on the day of the living donor recovery.
3. 2. Recovery hospitals must use at least one of the acceptable sources during the pre-recovery verification to verify all of the following information ~~in~~ according to *Table 14-12* below. ~~Assistance using an OPTN approved electronic method is permitted.~~ Recovery hospitals may use the OPTN organ tracking system for assistance in completing these verifications.

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Table 14-12: Pre-Recovery Verification Requirements

The recovery hospital must verify *all* of the following information:	Using at least *one* of ~~these sources~~ the following:	By *both* of the following individuals:
Donor ID	• Donor identification band containing the donor ID • Donor identification band and OPTN computer system	1. Recovery surgeon 2. Licensed health care professional
Organ type and laterality (if applicable)	• OPTN computer system	1. Recovery surgeon 2. Licensed health care professional
Donor blood type and subtype (if used for ensuring transplant compatibility or allocation)	• Donor blood type and subtype source documents	1. Recovery surgeon 2. Licensed health care professional
Intended recipient unique identifier	• Recipient medical record • OPTN computer system	1. Recovery surgeon 2. Licensed health care professional
Intended recipient blood type	• Recipient medical record • OPTN computer system	1. Recovery surgeon 2. Licensed health care professional
Donor and intended recipient are blood type compatible (or intended incompatible).	• OPTN computer system • Recipient medical record • Attestation following verification of donor and recipient blood types	1. Recovery surgeon 2. Licensed health care professional
Correct donor organ has been identified for the correct intended recipient	• Donor medical record • OPTN computer system • Attestation following verification of donor ID, organ, and recipient unique identifier	1. Recovery surgeon 2. Licensed health care professional

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52 The recovery hospital must document that the verification was completed according to the hospital's
53 protocol and the above requirements.

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