

**OPTN/UNOS Operations and Safety Committee (OSC)
Report to the Board of Directors
November 12-13, 2014
St. Louis, Missouri**

**Theresa Daly, Chair
David Marshman, Vice Chair**

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This report reflects the work of the OPTN/UNOS Operations and Safety Committee from June through September, 2014.

Action Items

1. Modifying Requirements for ABO Determination, Reporting and Verification

Public Comment: [March 14 – June 12, 2014](#)

Assuring blood type compatibility (or intended incompatibility) between donors and candidates is one of the most critical safety steps in transplantation. Failure leads to patient death or hyperacute organ rejection. The OPTN has taken steps over the years to improve blood type determination, reporting, and verification requirements. In 2012, a work group was formed to examine policy compliance issues observed by both the OPTN/UNOS and Centers for Medicaid and Medicare Services (CMS). The transplant community had raised issues with confusing and inconsistent requirements.

The work group conducted a Failure, Modes, and Effects Analysis (FMEA) to examine all steps required in blood type determination, reporting, and verification. This FMEA included data analysis of errors, including near-misses, to guide recommendations to address safety gaps and inconsistencies. FMEA recommendations address proposed policy changes, programming enhancement, and education solutions for the top 11 potential failure points identified in the process. Proposed policy was aligned with CMS rules where possible.

Many of the proposed changes address language style, consistency, and clarity. The major changes discussed during public comment are as follows:

Table 1: Summary of Changes in ABO Proposal

Requirement		Current	Proposed	Align with CMS
Timing Changes	Two ABO results must be obtained for deceased donors	Prior to incision	Prior to match run	✓
	Living donor recovery verification must be conducted	Prior to leaving OR	Prior to general anesthesia for donor	✓ incision
Current Practice Expanded to All Cases	Deceased donor pre recovery verification (time out) must be conducted	If organs remain in same OR suite	All cases	✓ OPO

Requirement		Current	Proposed	Align with CMS
New Conditional Actions	Living donor recovery verification (time out) must be conducted	If organs remain in same OR facility	All cases Eliminates verification when leaving donor OR	✓
	Organ check-in	None	If organ arrives from different OR suite	no rule
	Pre-procedure ABO verification	None	If recipient surgery starts prior to organ receipt	no rule

During its September 23, 2014 in person meeting, the Committee reviewed final proposed policy language **Exhibit A**. This final language included:

- Two substantive changes: Eliminating the option for OPOs to conduct one blood collection and send samples to two different laboratories and limiting the verification done at deceased donor organ recovery to cases when “the intended recipient is known.” These substantive changes will mirror CMS requirements. These substantive changes were developed with input from the OPO Committee.
- Separate sections for deceased donor, living donor, and pre-transplant verifications. These requirements had been in one table, but were separated based on public comment feedback.
- Addition of instructions for handling discrepant blood types and living donor vascularized composite allograft (VCA) blood type reporting.
- Other minor modifications based upon public comment feedback received.
- Stylistic edits suggested by Committee members and UNOS staff for clarity.

After a line-by-line review of each of the proposed modifications, the Committee voted unanimously to recommend the proposal for consideration by the Board of Directors (17 support, 0 oppose, 0 abstentions).

RESOLVED, that additions and modifications to Policies 1.2 (Definitions), 2.6 (Deceased Donor Blood Type Determination and Reporting), 2.15.B (Organ Procurement Procedures) 3.3 (Candidate Blood Type Determination and Reporting before Waiting List Registration), 5.4.B (Order of Allocation), 5.5.A (Receiving and Reviewing Organ Offers), 5.6 (Blood Type Verification Upon Receipt), 5.7 (Released Organs), 13.6.A (Requirements for Match Run Eligibility for Candidates), 13.6.B (Requirements for Match Run Eligibility for Potential KPD Donors), 14.4.A (Medical Evaluations for Living Donors), 14.6 (Registration and Blood Type Verification of Living Donors before Donation), 16.1 (Organs Not Requiring Transport), and 16.4.C (Internal Labeling of Blood and Tissue Typing Materials) as set forth in Exhibit A, are hereby approved, effective May 1, 2015.

FURTHER RESOLVED, that programming modifications to ABO incompatible liver registrations and match run displays for candidate blood type and compatibility status as set forth in Exhibit B are hereby approved, effective pending programming and notice to the OPTN membership.

2. Modifying Subtyping Terminology for Consistency

Public Comment: [March 14 – June 12, 2014](#)

Current OPTN/UNOS policy subtyping terminology uses different terms, such as A₂ (A2) and non-A₁, which are intended to mean the same thing but can cause confusion and are not clinically identical. [OPTN/UNOS guidance](#) published in June 2011 states, “It is important to know that the technically accurate term for A2 and A2B donors is “A1-negative” or “A, non-A₁”. Routine subtyping does not detect results other than the presence or absence of A₁ or A₁B antigens, therefore all references are proposed to be modified to reflect technically accurate terminology.

Certain OPTN allocation policies use subtyping to broaden the cohort of potential recipients. Blood type A or AB organs, in general, are not allocated to blood type O or B recipients. Certain subtypes of these primary groups, blood type A, non-A₁ and blood type AB, non-A₁B, however, can be allocated and successfully transplanted into certain blood type O or B recipients. This helps increase the probability of these recipients receiving organs in a timely manner. This proposal will clarify but not change the substance of any allocation policy.

Table 2: Examples of Subtyping Terminology Changes:

Policy	Current Terminology	Proposed Terminology
2.6.B	“found to be non-A1 or non-A1B”	“found to be blood type A, non-A₁ or blood type AB, non-A₁B ”
13.7.B	“to a blood type A2 or A2B”	“to a blood type A, non-A₁ or blood type AB, non-A₁B ”
14.4.A.i:	“donor to be non-A1 (negative for A1) or non-A1B (negative for A1B)”	“donor to be blood type A, non-A₁ or blood type AB, non-A₁B ”

During its September 23, 2014 in person meeting, the Committee reviewed final proposed policy language. No changes were made post public comment. After a line-by-line review of each of the proposed modifications, the Committee voted unanimously to recommend the proposal for consideration by the Board of Directors (17 support, 0 oppose, 0 abstentions).

RESOLVED, that additions and modifications to Policies 2.6. B (Deceased Donor Blood Subtype Determination), 5.3. C (Liver Acceptance Criteria), 9.5.B (Points Assigned by Blood Type), 13.7.A (Blood Type), 13.7.B (A2 and A2B Matching), 14.4.A.i (Living Donor Blood Subtype Determination), and 8.5. E (Allocation of Kidneys by Blood Type) as set forth in Exhibit C, are hereby approved, effective May 1, 2015.

Committee Projects

3. Allowing Collective Patient and Wait Time Transfers

Public Comment: [September 30 - December 5, 2014](#)

Board Consideration: June 2015 (Estimated)

Current OPTN Policy provides a specific mechanism using an individual Wait Time Transfer Form when a transplant candidate wishes to transfer primary waiting time from one transplant hospital to another. When transplant programs go into long-term inactive status, close, or have their membership terminated, a significant cohort of patients’ needs to be transferred. With the individual transfer process, UNOS manually processes individual forms, each taking up to 30 minutes to complete. This method may not be the most efficient

or safe method. Individually transferring large numbers of patients creates a data entry backlog with potential for delayed entry, missing patient forms, and delayed transplant opportunities.

In one instance, a hospital and all its transplant programs closed in December 2011 leaving over 400 candidates without access to services. Subsequently, another hospital started transplant services in early 2012 to serve the area which otherwise had no nearby providers. To restore and expedite their opportunity for transplant, a request was made to process these candidates as a group rather than individually. Consents were obtained and documented by the active transplant hospital and a list of these patients provided to the OPTN. An information technology solution to transfer these patients collectively was employed substituting the new program's 8-character OPTN center code from the closed program. This effectively and efficiently transferred the entire candidate record, including waiting time. This situation required special considerations and highlighted the need to address these types of circumstances in policy.

A work group formed in 2013 with representatives from the Transplant Administrators, Transplant Coordinators, and Patient Affairs Committees and staff from the Membership Department and Organ Center, which provide assistance during program closures, to address this concern. This work group also developed a resource tool kit to help answer common questions, share effective practices, and highlight current requirements when transplant programs inactivate long-term or close. The work group developed a policy proposal to allow collective patient and wait time transfers. Input from the Membership and Professional Standards Committee (MPSC) was obtained during this process.

The Committee first considered draft language at their April 8, 2014 in-person meeting. The Committee debated options on ways to provide some level of assurance by the closing transplant program that patients were being timely transferred, such as a monthly call or report to UNOS. Committee members agreed that requiring a status report be made to the OPTN Contractor would make transplant hospitals more cognizant of operations. The Committee proposed adding language requiring the receiving hospital to develop and submit a plan for evaluating the transferred patients and providing periodic status reports to the OPTN Contractor.

During its June 10, 2014 teleconference, the Committee reviewed final proposed policy language. The Committee voted in favor of the proposed language (9 yes, 0 no, 1 abstain) to send out for Fall 2014 public comment.

4. Develop Infectious Disease Verification Requirements

Public Comment: January 2015 (Estimated)

Board Consideration: June 2015 (Estimated)

While there is a clear process for ABO verification to prevent accidental transplant of incompatible blood types, there is no similar process of verification related to infectious disease. Current policy requires verification of all infectious disease results prior to use of deceased donor extra vessels in secondary recipients or living donor recipients as well as for deceased donor organ transplants not on a match run. Policy for these organs specifies that the transplant hospital verify the medical suitability between the deceased donor organ and recipient prior to transplant. Current policy does not require this type of verification in all organ transplants.

There have been cases where positive serology results have been available but inadvertently missed resulting in preventable disease transmission or near-misses of

preventable disease transmission. In March 2014, the MPSC referred this issue to the Committee and requested development of a policy proposal requiring infectious disease verification at two points during living donor procedures. This safety check will become increasingly important as the HIV Organ Policy Equity (HOPE) Act will allow use of organs from HIV positive donors in HIV positive candidates starting in November 2015 under approved research protocols. The HOPE Act safety sub group discussed this issue and recommended a process be developed. In June 2014, the full HOPE Act work group also recommended this issue be referred to Operations and Safety to develop a proposed process and policy.

A work group with members of the HOPE Act safety sub group and additional representatives from the OPO, Transplant Administrators, and Transplant Coordinators Committees has been formed and is currently meeting monthly. Available data have been reviewed. There were five proven/probable viral disease transmission advisory cases between 2009 to the present related to this issue. Among these cases, 60% were from deceased donor organs and 40% were from living donor organs. In addition, three cases were related to donor HCV infection and two cases were related to donor CMV infection. Twelve recipients received infected organs and five recipients became infected following the transplantation. In addition, there have been two living donor and one deceased donor cases with similar process issues reported that were not classified as proven/probable transmission.

A document comparing current and proposed verification requirements has been prepared for living and deceased donors. The work group is in the process of overlaying possible infectious disease verification requirements at points where ABO checks are required to see where these could be done together. Infectious disease verification poses several unique challenges such as the number of infectious disease tests, the timing of when results are received, differences between deceased and living donor testing requirements, and possibilities of discordant results between serology and nucleic acid testing (NAT). The DTAC is preparing recommendations for which infectious disease tests should be included in a verification process.

Candidates must be tested for HIV, HBV, and HCV, however these results are not required to be reported. HOPE Act candidates will have results reported- a change being initiated by the HOPE Act work group. All transplant programs must report acceptance criteria for certain positive results from donors (e.g. HCV). The work group has had preliminary discussions that this might be a point to require second user verification of acceptance of infected organs. These discussions have just started and source documentation is one related question under consideration. Work will continue to develop infectious disease verification requirements to enhance patient safety and protect candidates from accidental transmission of infectious disease.

5. Modify or Eliminate the Internal Vessels Label

Public Comment: January 2015 (Estimated)

Board Consideration: June 2015 (Estimated)

Current policy requires that vessels packaged separately from an organ be protected by a triple sterile barrier one of which must be a rigid container. In January 2011, use of the standardized OPTN vessels label went into effect. In February 2012, policy was amended to require use of standardized labels on both the sterile rigid container and the outermost layer of the triple sterile barrier. The sterile internal vessel label is frequently cited as a problem with the current labeling system. The very small label must be filled out in the sterile field

where the sterile pen may run and make marking the label illegible. Up to 20 data fields must be handwritten. The sterile internal label, having to be filled out in the sterile field using source documentation for infectious disease results, is often not as accurate as the other internal vessel label (orange and white polyplastic) which can be filled out in an easier setting. The sterile internal label is problematic to produce. This issue ranked as the 6th highest failure mode identified during the Failure Modes Effects and Criticality Analysis (FMECA) conducted by Northwestern University on the deceased donor organ procurement process as part of the Electronic Tracking and Transport (ETT) Project.

A sub group of the ETT work group has been meeting since December 2013. The group has reviewed the following data elements: vessels labeling and packaging safety situations, disposition of extra vessels, and site survey compliance. Less than 2% of extra vessels are transplanted into secondary recipients (i.e., recipients who received a solid organ from a different donor), which averages about 120 vessels annually. These vessels are of most concern since they would have been stored and certain, such as infectious disease testing results, must be verified prior to use. In addition, usage in secondary recipients is limited to less than 30% of all transplant hospitals. The majority of hospitals (83%) have used only 1-10 extra vessels in secondary recipients over a four-year period. The sub group discussed that the sporadic and often infrequent use indicates repackaging of extra vessels is not a skill set readily developed and presents a challenge facing transplant hospitals.

Repackaging vessels may be required prior to storage. Transplant hospitals have raised concerns about what to do if the orange and white polyplastic label gets lost during the original unpackaging and transplant. Several representatives shared that most OR staff do not have access to DonorNet[®] due to the large numbers of OR staff. When infectious disease results do need to be confirmed, it is often the surgeon or the fellows that access DonorNet[®] to verify results on stored vessels. Transplant hospital members expressed concerns in emergencies where accessing DonorNet[®] for infectious disease verification becomes challenging due to time sensitivity and lack of OR staff access. Although transplant hospitals have concerns, the entire group acknowledged the many challenges with the internal sterile label such as possible outdated results and the inability to read results without disrupting the sterile field.

The potential impact of ETT on labeling was discussed. The ETT application will print out information for the poly plastic label. It cannot be used for the internal sterile label due to sterility issues. ETT staff shared that while they do not have hard data, the impression is that the sterile internal label is more error prone.

The group has come to consensus on eliminating the infectious disease results on the internal sterile label. They are debating whether to retain the question on whether the vessels are from a PHS increased risk donor. Most current data on extra vessel usage, vessel risk status, and transmission of disease through extra vessels have been requested. These data will be used to develop final recommendations for full Committee consideration regarding possible proposed policy changes.

The group will continue to troubleshoot ways to address transplant hospital concerns such as education on repackaging. In addition, OPOs may be encouraged to provide repackaging kits to assist transplant hospitals. The group will continue work on education materials for vessels addressing packaging and repackaging of vessels.

6. Electronic Tracking and Transport Project (TransNet-A Service of the OPTN)

Public Comment: August 2015 (Estimated)

Board Consideration: November 2015 (Estimated)

Electronic Tracking and Transport Project (TransNet-A Service of the OPTN)

Public Comment: August, 2015 (Estimated)

Board Consideration: November, 2015 (Estimated)

In December 2012, the Ad Hoc Organ Tracking Committee was formed to examine issues related to the transport and tracking of organs. The group agreed on the problem definition and scope which would be limited to deceased donors. The solution would focus first on eliminating manual, handwritten labels and secondly on, creating a strategy to enable the ability to track organs. Four goals were set: reduce incorrect transplantation by eliminating transcription errors and legibility errors; minimize complexity and transport errors; accelerate organ information transfer; and capture organ procurement and transport data.

Safety situation reports to the OPTN do reflect issues with labeling, packaging, and shipping. Since 2012, there were 61 unique labeling safety situations and 63 unique packaging and shipping safety situations reported to the OPTN. Labeling issues related to incorrect donor ID and blood, nodes, and spleen were among the top 5% most frequently reported events (2012-June 2014). Labeling issues related to switched kidney laterality and missing labels showed a statistically significant increase between 2012-2013 and the first half of 2014. Since 2012, safety situation narratives have revealed that 19 organs were not transplanted (either not recovered or recovered and discarded) due to labeling issues and/or packaging/shipping issues. For more information, see **Exhibit D**.

The first phase of the ETT project included an immersion and discovery phase with observation site visits to OPOs, a Failure, Modes, and Effects Criticality Analysis (FMECA), and development of a prototype proof of concept stand-alone application using a portable printer and tablet. Five OPOs participated in the original phase one pilot and conducted field-testing between August 2013 and March 2014. Participants included LifeNet Health (VA), Life Source (MN), California Transplant Donor Network (CA), LifeLink of Georgia (GA), and the Living Legacy Foundation (MD). More information is available in [previous reports](#).

A full time project manager was assigned in November 2013 to facilitate next steps. TransNet project support includes the HRSA Innovations Fellow and UNOS staff. During summer 2014, a beta test version (5.0) was developed using feedback to date. On September 10-11, 2014, eight OPOs each sent two representatives for training at UNOS to learn how to use the system as well as go through competency training to be certified to use the system. The train-the-trainer session also included sessions on how to go back and train OPO staff at home to use the system. Participants included the five field test OPOs and three new OPOs (New England Organ Bank, LifeCenter Northwest, and Mid-America Transplant Services).

UNOS is providing up to eight Android tablets and portable printers to use during the beta testing from September 18, 2014 through January 15, 2015. If additional devices are desired, participating OPOs will purchase these on their own. Each set (tablet and printer) costs approximately \$800. At completion of each case, participants will be required to submit a survey answering how beta testing went, ease of use, and suggested enhancements or improvements. TransNet project support staff travelled to the three new OPO sites to assist with deployment. Results from beta testing will be used to determine future enhancements.

Enhancements between the field and beta versions include the ability to pull case data directly into the system from DonorNet. The following fields can be imported: donor hospital, donor identification data, ABO (if double verified), date of birth, donor initials, and infectious disease results. The beta version can print labels for blood tubes with and without ABO. Case transfers can be completed via Wi-Fi or Bluetooth. Authentication is done with the user name and password that associate the user with their DonorNet permissions. Anyone using the application must be certified in proficiency by their OPO. The beta version requires validation of infectious disease results for the vessels label. Second user verification can be done locally or remotely.

The beta version allows the coordinator to choose organs planned for recovery and print associated documentation and specimen labels. The application produces all shipping labels that are both bar coded and human readable. Each organ package contents are scanned as they are placed in external shipping container and ice time is entered.

TransNet project staff are working with seven transplant hospitals to recruit for testing. These transplant hospitals are located in the same areas where these five original OPOs are located. Transplant hospitals planning to participate in the HOPE Act may also be recruited for pilot participation. UNOS will supply pilot sites with a portable printer to be able to print a recipient ID band. Staff are investigating the possible use of existing hospital handheld scanners. If these are not compatible, UNOS will provide them with a scanner.

Transplant hospital training will be completed via webinar for each of the sites starting in October with testing beginning after training through January 2015. Monthly progress calls will be made to provide support and receive feedback. The goals for transplant hospitals will be to print the recipient ID band from match run; scan external organ label upon arrival, and scan recipient ID band and internal organ labels in the recipient OR. As of October 22, 2014, one hospital has started to pilot the system.

User data will be gathered through January 2015. The current application works only on an Android device. Feedback from multiple sources has been the desire to have the application available for on other platforms (e.g. iPads and Surface tablets). Multi-platform application development will start in November 2014. Beta testing for transplant hospitals and on multi-platforms is planned for late summer 2015.

An ETT progress update will be presented to the OPTN/UNOS Board of Directors (BOD) at the upcoming November 2014 meeting. Based on preliminary findings up to this point, plans are to start a voluntary national OPO deployment starting March 2015.

The OSC ETT subcommittee has been meeting since August 2013. This subcommittee has provided feedback and been informed of progress to date at multiple steps. At the September 23, 2014 in-person meeting, the Committee discussed potential mandatory usage. The Committee agreed that use should be mandated when the product is completely ready. The sentiment was expressed that if use were voluntary then not everyone would adopt its usage and the full benefits of the system would not be realized.

The Committee did not recommend a limited mandatory deployment for HOPE Act participants. The Committee's opinion is that deployment should not be mandated partially or before the system is ready for full deployment. The Committee also wanted to give sufficient time for OPOs to budget for purchasing and spoke of the need for multi-platform ability before full acceptance and mandatory deployment.

7. Developing a System to Review and Share Safety Event Data

Public Comment: N/A

Board Consideration: N/A

There is currently no process developed to share de-identified, real time information related to patient safety events with members. Data is collected regarding safety events that happen in the transplant community, yet much of this information is not shared due to concerns of harming the confidential peer review system in place. Learning that could benefit other centers and enhance patient safety is lost. The Committee believes that members could benefit from being aware of this information by:

- Enabling centers to resolve hazards proactively before tragic or costly incidents
- Engaging transplant staff at all levels in solving problems
- Increasing safety ownership and reinforces responsibility for patient safety
- Exposing valuable information that otherwise might not be discussed
- Developing a positive attitude surrounding safety in practice and reporting

The Committee has worked to develop mechanisms to encourage collaboration where possible, and develop channels for communicating safety issues to members. A process to issue safety alerts has been developed and refined. Four alerts have been sent to over 6,000 interested parties since November 2013. Alerts must meet certain criteria such as situations that have caused or have potential to cause significant harm and contain a call to action for members.

Starting in March 2014, MPSC attendees are queried at the end of every meeting for topics to be referred to Operations and Safety for further action such as education or policy development. The Committee is working on two MPSC originated topics: infectious disease verification and hemodilution calculation/documentation errors where donors end up being classified as increased risk post-transplant.

OSC has worked to formalize and make sharing mechanisms routine. Efforts include publishing a patient safety news article after every in-person meeting highlighting data and linking to the full report and including safety data or messages as part of every regional meeting presentation. Presenting findings to professional groups is another goal and regular annual presentations have been made to AOPO including one in June 2014. A manuscript outlining a history of the development of safety situation reporting with key data highlights is under development. Presentations are being made to other interested Committees such as the Transplant Administrators Committee. Two instructional events will be conducted every year based on top safety situation reports/compliance concerns and a topic identified through the MPSC referral process. An internal UNOS group is meeting as well to guide these efforts, ensure collaboration, and produce educational materials.

At the September 23, 2014 in-person meeting, the Committee reviewed the latest safety situation data. The formal report is contained in **Exhibit D**. Reporting has continued to increase since 2006 with an exception in 2009. During the first half of 2014, 81 events were reported through the electronic Improving Patient Safety Portal (IPS) and 50 events were reported through “other pathways” (e.g. emails, calls or letters to UNOS). There were 213 events reported through both the IPS and other pathways in 2012 and again in 2013. Based on the current reporting rate, reporting in 2014 is projected to exceed the previous levels. These data are “front end” reports and do not contain investigative follow up or findings.

OPTN/UNOS Operations and Safety Committee

The most frequently reported events were related to communication issues (23%), transplant process/procedure issues (23%), packaging/shipping issues (18%), labeling issues (15%), testing issues (14%), recovery process/procedure issues (12%), and organ allocation/placement issues (11%). Nearly 80% of issues reported by labs between 2012 and the first half of 2014 were either testing issues (50%) or data entry issues (29%). Transplant hospitals most often reported communication issues (32%), while OPOs most frequently reported testing issues (25%).

The data review included additional information on high occurrence subcategories with unusually high frequencies relative to other subcategories. There were 14 subcategories between 2012-June 2014 that fell in the top 5% in terms of high frequency. The review included four subcategories that showed a statistically significant increase between 2012-2013 and the first half of 2014. Situations where organs were not transplanted (either not recovered or recovered and discarded) were reviewed. A total of 51 subcategories had an associated organ not transplanted and the Committee reviewed any subcategory that had at least two events resulting in organs not transplanted. The Committee chose to focus on the most frequently occurring events where an organ was not transplanted. They chose the top priority situations. These findings will go to the OSC Patient Safety Advisory Group. This group will conduct additional work such as failure, modes, and effects analysis to identify areas for possible action. The Committee will seek additional root cause information and subject matter experts to assist these efforts. Recommendations will be brought back to the full Committee. The internal UNOS group will help develop educational efforts associated with the recommendations.

Table 3: Priority Safety Situation Report Subcategories

Events related to Organ Not Tx'd (2012-Jun 2014)	Event Frequency and Organ Not Tx'd*	High Frequency	Increased Frequency	Selected as Priority
communication issue – delayed communication	9	Yes	Yes	Yes
communication issue - inaccurate/insufficient donor or organ/extra vessels information	8	Yes		Yes
recovery procedure/process issue - injury to organ or extra vessels	7	Yes		
living donor issue – organ recovered but not transplanted	5			Yes
switched laterality - kidneys (packaging/shipping issue and/or labeling issue)	5	Yes	Yes	Yes
recovery procedure/process issue – poor donor management	5			

**Since patient safety events may involve more than one subcategory, some events may appear multiple times in this table.*

8. Patient Safety Newsletter

Public Comment: N/A

Board Consideration: N/A

Methods to share real time data and issues related to patient safety within the OPTN are needed. Sharing data and articles related to patient safety heightens awareness. With the realization of errors or failures that exist within the transplantation system, members can proactively review their policies and procedures to reduce harm to patients and improve outcomes.

Since November 2011, the Committee has published the *Patient Safety News* newsletter. In 2013, the Committee decided to publish stories on a real time basis on the OPTN and other websites as opposed to a quarterly publication. The following stories have been published since the last Board of Directors report.

May 14, 2014: [A new way for transplant professionals to report patient safety events.](#)

Committee Projects Pending Implementation

9. Improvements to Vessels Disposition Reporting

Public Comment: [March 16 - June 25, 2012](#)

Board Approval: [November, 2012](#)

Projected Implementation: First half 2015

When programming for the extra vessels disposition electronic reporting form is completed and released, then policy approved to require reporting within seven days will go into effect.

10. Clarify Data Entry Screens for A2 and A2B in UNet

Public Comment: N/A

Board Approval: [November, 2011](#)

Projected Implementation: Second half 2015

Implemented Committee Projects

11. Modify Patient Safety Situation Reporting Portal

Public Comment: N/A

Board Approval: [November, 2012](#)

Implementation Date: May 29, 2014

Enhancements to the patient safety situation portion of the Improving Patient Safety portal were implemented in production on May 29, 2014. Enhancements include:

- More options to describe and provide specifics on reports
- Improved and increased high-level description categories (7 to 10)
- New subcategory description choices under each high level category
- Additional information will be collected relevant to the event including:
 - Who/what is involved (candidate/recipient, donor organs/extra vessels, or other)
 - Candidate/recipient or donor ID will be collected as appropriate
 - Specific organs impacted (all or choice of individual organs)
 - Impact of situation on organs (not recovered, delay in transplant, discard)

- Whether root cause analysis has been done
 - Contact information
 - Easier access for searches
- These enhancements will help make reporting more consistent and assist with enhanced analysis including impact of safety situation on transplantation.

Review of Public Comment Proposals

The Committee reviewed eight of the proposals released for public comment March 14, 2014 – June 13, 2014. The Committee's comments on one other proposal from this public comment cycle were included in the Committee's [Report to the Board of Directors in June, 2014](#).

12. Proposal to Clarify Data Submission and Documentation Requirements (Membership and Professional Standards Committee)

The committee considered this proposal during its meeting and voted in support as written (9 support, 0 oppose, 1 abstain).

13. Proposal for Adolescent Classification Exception for Pediatric Lung Candidates (Thoracic Committee)

The committee considered this proposal during its meeting and voted in support as written (11 support, 0 oppose, 2 abstain).

14. Proposal to Require the Reporting of Aborted Living Donor Organ Recovery Procedures (Living Donor Committee)

The committee considered this proposal during its meeting. After clarification of one point, the committee voted in support as written (11 support, 0 oppose, 3 abstain).

15. Proposal to Modify Existing or Establish New Requirements for the Informed Consent of all Living Donors (Living Donor Committee)

The committee considered this proposal during its meeting. One member asked several questions about selection of risks that must be conveyed and development of the proposal for general living donation versus specific organ types. The committee voted in support as written (10 support, 0 oppose, 4 abstain).

16. Proposal to Modify Existing or Establish New Requirements for the Psychosocial and Medical Evaluation of all Living Donors (Living Donor Committee)

The committee considered this proposal during its meeting and voted in support as written (10 support, 0 oppose, 4 abstain).

17. Proposed Membership and Personnel Requirements for Intestine Transplant Programs (Liver and Intestine Committee)

The committee considered this proposal during its meeting and voted in support as written (11 support, 0 oppose, 2 abstain).

18. Expanding Candidate and Deceased Donor HLA Typing Requirements to Provide Greater Consistency Across Organ Types (Histocompatibility Committee)

The committee considered this proposal during its meeting. The committee discussed the safety aspects and support for looking into this issue. Questions surrounding whether thresholds could be established versus need for individual evaluation were debated in relation to individual transplant surgeon screening versus automated screening. Another question related to using consensus on which new epitopes should be considered as new ones arise and if this could be done in conjunction with professional societies such as ASHI. The committee voted in support of the proposal as written (11 support, 0 oppose, 2 abstain).

OPTN/UNOS Operations and Safety Committee

Other Committee Work

None

Meeting Summaries

The committee held meetings on the following dates:

- June 10, 2014
- August 19, 2014
- September 23, 2014

Meetings summaries for this Committee are available on the OPTN website at:
<http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=60>.

Proposal to Modify ABO Determination, Reporting, and Verification Requirements

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Proposal to Modify ABO Determination, Reporting, and Verification Requirements

Affected/Proposed Policies: 1.2 (Definitions), 2.6 (Deceased Donor Blood Type Determination and Reporting), 2.15.B (Organ Procurement Procedures) 3.3 (Candidate Blood Type Determination and Reporting before Waiting List Registration), 5.4.B (Order of Allocation), 5.5.A (Receiving and Reviewing Organ Offers), 5.6 (Blood Type Verification Upon Receipt), 5.7 (Released Organs), 13.6.A (Requirements for Match Run Eligibility for Candidates), 13.6.B (Requirements for Match Run Eligibility for Potential KPD Donors), 14.4.A (Medical Evaluations for Living Donors), 14.6 (Registration and Blood Type Verification of Living Donors before Donation), 16.1 (Organs Not Requiring Transport), and 16.4.C (Internal Labeling of Blood and Tissue Typing Materials)

Operations and Safety Committee (OSC)

Summary and Goals of the Proposal:

Member feedback has long noted the complex phrasing and requirements related to ABO blood type determination and verification. These requirements are a fundamental step in safe and successful organ transplantation. The Committee is proposing clarifications and improvements to these requirements.

These recommendations are based, in part, from a Failure Modes and Effects Analysis (FMEA) conducted to proactively identify areas of risk related to ABO processes in deceased donation.

This policy proposal is only one facet in the Committee's approach to improving ABO blood type determination and verification. Other strategies to minimize identified risks and maximize human factors engineering include member education and competency training, programming changes to UNetSM, and collaboration with the Electronic Tracking and Transport (ETT) project to improve technological capabilities.

This policy proposal contains the following features:

- Clarified existing requirements related to commonly asked questions
- Strengthened safety components to ensure the correct organ is transplanted into the correct recipient and that the match is ABO compatible or intended incompatible
- Modified the timing of deceased donor blood type determinations and reports prior to executing the match run with an exception for accelerated donor cases
- Modified the timing and scope of verifications for deceased and living donor organ recoveries
- Clarified specific verification elements and sources
- Better aligned OPTN and Centers for Medicare and Medicaid Services (CMS) requirements
- Added conditional requirements to check in organs upon arrival and to perform a pre-transplant verification
- Added a requirement for qualified health care professionals to perform ABO reporting and verification functions
- Made deceased and living donor standards more consistent.

ABO blood type is a primary principle used to match organ donors and recipients. Correct determination, reporting, and verification of ABO blood type constitutes a major safety system

built within OPTN policy and procedures to assure that the correct organ will be transplanted into the correct recipient and that the match is ABO compatible (or intended incompatible). Having this system be clear, robust, and built to overcome human error, where possible, is critical to safe transplantation and maintaining public trust.

The current system has multiple steps, which include: (1) determining blood type for candidates and donors; (2) reporting these blood types to the OPTN Contractor; (3) using UNetSM computer programming to generate appropriate donor/candidate matches based on blood type; and (4) verifying donor/candidate information prior to transplant. Failure in any of these areas can have significant consequences including graft failure or even patient death. In 2003, an accidental ABO incompatible transplant resulted in patient death, which made national headlines and consequently prompted development of additional safeguards to prevent future occurrences.

Current system safeguards include a series of double checks that require two separate lab tests to determine blood type and two-person independent reporting of blood type to the OPTN contractor. UNetSM applications assure that the two reported blood types are identical prior to donors and candidates being eligible for match runs. UNetSM programming also assures that donors and candidates are matched according to ABO blood type in accordance with existing policy. Other safeguards include verification(s) of donor and recipient identification and blood type prior to transplantation.

In addition to OPTN policy, the CMS maintains regulations for both Organ Procurement Organizations (OPOs) (42 CFR 486, Subpart G)¹ and transplant hospitals (42 CFR 482, Subpart E)² which mandate certain practices to assure ABO compatibility in transplants. Some requirements differ between the two organizations. Compliance with policies affecting ABO reporting and verification has been noted as problematic from both the OPTN and CMS.

An ABO verification work group with representatives from several committees, including Transplant Coordinators and Transplant Administrators, have met to identify the issues and solutions since early 2012. Due to the complexity and importance of the topic, the group has pursued a multi-faceted set of solutions. To date, project products include an educational webinar, a verification documentation template, and a crosswalk between OPTN and CMS policies. The group also worked with consultants in patient safety and human factors engineering to examine ABO processes using a proactive Failure Modes and Effects Analysis (FMEA) approach to map out process and identify points of risk. Strategies to lessen these risks were developed by the work group and endorsed by the Operations and Safety Committee.

Following safety experts' recommendations, providing education and competency training for the existing system will be a significant overall strategy in addition to clarifying areas of question through proposed policy changes. The Operations and Safety Committee plans to develop an e-learning module to educate transplant professionals about the principles behind ABO blood type requirements. This education effort will include competency training covering both policy knowledge and result reporting skills. In addition to an e-learning module, a guidance document

¹ Conditions For Coverage of Specialized Services Furnished by Suppliers, Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations. [42 CFR 486, Subpart G](#) (2006).

² Conditions of Participation for Hospitals, Requirements for Specialty Hospitals. [42 CFR 482, Subpart E](#) (2007).

with frequently asked questions and best practices will be developed. Simple and easy to understand tools including a one-page summary of requirements and checklists will supplement existing tools such as the verification template. These resources will be packaged and promoted as part of building a robust and clear to understand system.

The Operations and Safety Committee has formally reached out to the Transplant Administrators, Living Donor, and Organ Procurement Organization (OPO) Committees to request pre-public comment feedback on the recommended strategies. The OPO and Living Donor Committees assisted with proposed language development for issues pertinent to their Committees.

These strategies include:

- Proposed policy language to:
 - Define source document
 - Further align language for blood type determination and reporting across donor types for clarity and consistency
 - Require that the match run be rerun prior to organ allocation when the organ was not allocated on the initial run and candidate acceptance criteria or other data are updated and reported to host OPO
 - Require that both donor ABO blood type determinations be completed prior to the match run with an exception for cases where recovery must be accelerated to avoid organ wastage.
 - Clarify what information must be verified during a verification
 - Clarify what sources can be used to verify required information elements
 - Condense and clarify verification requirements related to ABO compatibility and correct organ/correct recipient into one policy section
 - Change verification at living donor organ recovery to include all cases (not just those within same operating facility) and move up timing from “prior to leaving the operating room” to “prior to induction of anesthesia” to provide safer timing and more closely align with CMS
 - Change verification at deceased donor organ recovery to include all cases (not just those within same operating suite) with the timing to be “prior to organ release from the operating room” and place responsibility with OPOs to provide safer timing and more closely align with CMS
 - Add a requirement for organ check in for organs arriving from a different operating room suite
 - Add a requirement for recipient pre-procedure verification prior to induction of anesthesia if surgery will begin prior to organ arrival
 - Add a requirement that OPOs and transplant hospitals use a “qualified health care professional” to perform reporting and verification functions as defined within individual programs’ protocols
 - Remove requirement that ABO type must not be on label of blood tube sent with the organ
- Education efforts to:
 - Develop simple, easy to use tools such as a one page guide to ABO processes
 - Develop a guidance document with frequently asked questions and effective practices related to ABO processes
 - Develop an e-learning competency module for knowledge and skills required to comply with ABO requirements
- Programming efforts to:

- Add warnings for registering liver ABO incompatible candidates
- Add candidate blood type and highlight ABO compatibility status on the match run
- Future plans also include:
 - Developing requirements and future proposal for a separate ABO tab in UNetSM to record results, upload source documentation, compare source documentation, record results verification, operationalize second person verification for subtyping results, and track verification results
 - Collaborating with the ETT project to improve labeling and verification procedures. This project is developing stand-alone technology to produce specimen and organ labels printed on demand; bar code scanning for identification of correct organ/correct recipient and ABO compatibility; expanded organ tracking capabilities; and documentation of verifications.

This proposal is part of a comprehensive effort to improve the clarity and efficiency for ABO determination, reporting, and verification requirements. While not included specifically in this proposal, the Committee will continue work in areas to improve electronic capabilities. Future plans include developing requirements for a separate ABO tab in UNetSM and collaborating with the Electronic Tracking and Traceability (ETT) project to assist with developing requirements for electronic labeling and verification functions. This work will be conducted in 2014.

Alternatives considered included a wide array of recommendations related to FMEA risk points. One alternative would be to focus solely on educational or programming efforts. The Operations and Safety Committee decided to include policy clarification and modifications aimed at improving process steps to bolster overall system safety as part of a multi-pronged approach. Strategies are based on the comprehensive examination to mitigate risk at numerous points that might lead to an accidental ABO incompatible transplant or organ wastage from errors or ABO related issues.

Strengths of the proposal include validation of the basic fundamental safety principles in place to maintain organ transplantation safety. One strength the proposal provides is safer timing and scope for verification during the organ recovery phase. Another strength is the addition of organ check in and pre-procedure verification requirements. Some changes better align with CMS requirements, simplify language, and address compliance questions. Other strengths include movement towards standardized principles and processes across donation type with similar requirements for donors and candidates. The basic strength of the proposed changes will be increased safety and diligence in assuring ABO compatibility and correct organ/correct recipient. In addition, the proposal is part of a set of multiple strategies including policy, education, and programming geared to reduce risk from multiple potential fail points.

Weaknesses of the proposal include that some transplant programs and OPOs may need to change existing ABO determination, reporting, and verification processes. OPOs may need to change practice in obtaining the second ABO determination prior to the match run that may necessitate changing labs or other existing processes. While some transplant hospitals report currently performing an organ check in and a pre-procedure verification, other transplant hospitals will need to develop protocols and practices to put these additional steps in place. This will require additional work and documentation.

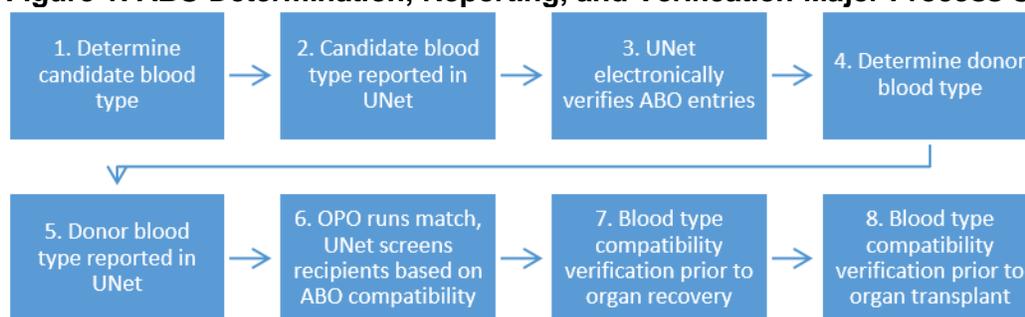
Supporting Evidence/Modeling

Overall, the principles of using double checks, verifications, and computer assisted checking make for a robust system. Patient safety consultants working with the OPTN commented on the overall

resiliency of the existing system. ABO incompatible transplants are considered “never events”. The occurrence is very low, yet devastating if it happens. Once study estimated the probability of a thoracic ABO incompatible transplant to be 1.38×10^{-5} per donated organ prior to 2003. Following the changes made after patient death from an ABO incompatible transplant which added the redundancies in blood typing and reporting, the probability was estimated to be lowered to 3.08×10^{-6} per donated organ.³

After examining potential fail points and “near miss” data, measures are proposed to reduce risk further. Conducting a FMEA provided the framework for reviewing all ABO requirements and processes. FMEA is a technique used in many industries such as aerospace and aviation as well as health care to identify areas of risk. The FMEA mapped out eight major steps (Figure 1) and corresponding sub-processes within each step that make up current OPTN requirements.

Figure 1: ABO Determination, Reporting, and Verification Major Process Steps



Through the FMEA, 62 potential fail points were identified. Each of these fail points was ranked using available occurrence data, severity of risk, and detectability. Of these fail points, 11 were prioritized as highest risk (Table 1). [Exhibit A](#) contains more details on FMEA results.

Supporting data were reviewed from OPTN safety situation reports and other relevant studies. Between January 2012 and June 2013, a total of 349 situations were reported between the on-line Improving Patient Safety Portal and reports to the OPTN through other channels such as e-mail. Of these 349 safety situations, 43 (12.3%) involved errors in processes related to ensuring ABO compatibility. For example, many of these situations involved blood type testing errors, problems with packaging or labeling, and data entry errors pertaining to blood types. Errors in these areas could increase the likelihood of an unintended ABO incompatible transplant. While on-line reporting has increased from 22 reports in 2006 to 99 reports in 2013, safety situations are believed to be underreported as reporting of most event types is voluntary. Data used may not include the full scope of actual occurrences. [Exhibit B](#) shows how these 43 safety situations were categorized in a report produced for the Committee.

³ Cook, R. et al. Probabilistic Risk Assessment of Accidental ABO-Incompatible Thoracic Organ Transplantation Before and After 2003. *Transplantation* 2007; 84: 1602–1609.

Table 1: Top Identified ABO Failure Modes

Rank	Failure Mode	Process Step
1	OPO releases organ to recipient not on match run	6
1	Blood type verification does not occur prior to implantation	8
2	Candidate erroneously listed as accepting an ABO incompatible (pediatric heart, liver)	2
2	Wrong organ arrived-not checked at arrival to verify correct organ arrived for the correct potential recipient	8
2	If intended recipient surgery begins prior to arrival, no requirement for blood source documentation availability to confirm compatibility prior to anesthesia	8
3	Blood samples are mislabeled (candidate)	1
3	Verification occurs without both source documents for recipient and donor	8
4	One blood sample sent and tested twice	1
4	Only one sample drawn and tested prior to match (no ABO confirmation by second sample)	4
5	No pre-transfusion specimen is available for testing	4
5	Blood samples are mislabeled (donor)	4

The process for ensuring that transplants are ABO blood type compatible involves multiple steps starting with specific requirements and safety checks for blood type determination for both donors and candidates. The Committee is proposing modifications to policy requirements that affect many of these steps, including:

- ABO Blood Type Determination (Steps 1 and 4 in Figure 1)
- ABO Blood Type Reporting (Steps 2 and 5 in Figure 1)
- ABO Match Run (Step 6 in Figure 1)
- ABO Compatibility Verifications (Steps 7 and 8 in Figure 1)

ABO Blood Type Determination

ABO blood type determination is the first step which is conducted on both donors and candidates. For deceased donors and candidates, two separate ABO tests are required. The underlying principle is to reduce the possibility of error in accurately determining ABO blood type. The American Association of Blood Banks (AABB) uses this principle in its standards which requires two tests or one test and historical comparison to prior blood type results on potential blood product recipients prior to release of blood for transfusion purposes. In one study of over 100,000 blood type and screens performed between 1987 and 2003, 94 wrong blood in tube errors were discovered and 65% of those errors were discovered through comparison to historical type and/or the required double check test.⁴

A current weakness in organ transplantation is that patients awaiting a living donor transplant but not registered on the waitlist do not fall under the requirement for two blood type tests and two-person reporting of test results prior to transplant. Lack of consistency among donation types can create disproportionate risk and cause confusion. The Living Donor Committee, however, has a current public comment to require registration of all living donor candidates in UNetSM prior to

⁴ Figueroa, P. et al. Nearly Two Decades Using the Check-Type to Prevent ABO-Incompatible Transfusions. *American Journal of Clinical Pathology* 2006; 126:422-426.

transplantation⁵. Should the proposal become policy, it will align with the process already in place for deceased donor candidates.

Four of the top 11 FMEA fail points relate to the blood type determination phase (See Table 1): candidate blood samples are mislabeled (3rd); one blood sample is sent and tested twice (4th); no pre-transfusion specimen is available for testing (5th); and donor blood samples are mislabeled (5th) (See [Exhibit A](#)). Supporting evidence includes over 100 patient safety situation reports related to mislabeling errors received by the OPTN since 2006.

Other comparable health care areas have similar concerns and related safety goals. Patient misidentification accounted for 182 out of 253 safety events related to blood transfusion errors according to a 2011 College of American Pathologists (CAP) Q-Probe study. Specimen mislabeling during collection was associated with “batching” of specimens and printed labels (n=35), and misinformation from manual entry on laboratory forms (n=14) were nearly 20% of errors.⁶ The Joint Commission on Health Care has adopted National Patient Safety Goal 01.03.01⁷ to eliminate transfusion errors related to blood transfusion using matching steps including a two-person verification process or a one-person verification process accompanied by automated identification technology, such as bar coding.

These data support continuing basic existing principles in ABO determination. Proposed policy changes in this area seek to clarify and to use consistent language across donors and candidates of all donation types.

Under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 (42 CFR 493.959)⁸ laboratories must demonstrate 100% proficiency for ABO blood group testing (excluding subgroups). Proficiency testing results indicate that ABO mistypes occur infrequently at approximately 0.8 to 2.5 per 1,000 typings⁹. ABO subtyping proficiency is not required in proficiency testing, and error rates are even higher than for primary ABO typing. The largest area of concern remains the accuracy of subtyping performed on blood type A donors. OPTN requirements to perform two primary blood typings and two subtypings on all blood group A, non-A₁ and blood group AB, non-A₁B results remain. The Histocompatibility Committee has proposed requirements to follow testing kit manufacturer’s instructions for ABO blood group typing in their recent policy rewrite proposal¹⁰.

⁵ OPTN Living Donor Committee. Proposal to Require UNetsm Registration of all Living Donor Organ Candidates Prior to Transplant. Fall 2013 public comment.

http://optn.transplant.hrsa.gov/PublicComment/pubcommentPropSub_326.pdf (accessed 22 Jan. 2014).

⁶ Grimm, E. et al. Blood Bank Safety Practices: Mislabeled Samples and Wrong Blood in Tube—A Q-Probes Analysis of 122 Clinical Laboratories. *Archives of Pathology and Laboratory Medicine*. 2010; 134: 1108-1115.

⁷ Joint Commission on Health Care. Hospital: 2014 National Patient Safety Goals.

http://www.jointcommission.org/assets/1/6/HAP_NPSG_Chapter_2014.pdf (accessed 22 Jan. 2014).

⁸ Clinical Laboratory Improvement Amendments of 1988. Immunohematology. [42 CFR 493.959](#) (1992).

⁹ Bryan, C. et al. Implications of ABO Error Rates in Proficiency Testing for Solid Organ Transplantation. *Transplantation* 2006; 82: 733–736.

¹⁰ OPTN Histocompatibility Committee. Proposed Histocompatibility Policy Rewrite. Fall 2013 public comment. http://optn.transplant.hrsa.gov/PublicComment/pubcommentPropSub_324.pdf (accessed 22 Jan. 2014).

Collaboration with the ETT project is another future strategy to reduce patient mislabeling errors. Currently, 40-70 labels are often handwritten for a single deceased donor recovery in the donor management phase. Although still in development, ETT technology will produce bar code and printed human readable labels for blood specimens. These labels will be produced on demand to help avoid “batching” errors on specimens being sent for ABO blood typing. This proposal removes the requirement that ABO type must not be included on specimen labels for blood being sent with an organ. This provision is being removed, as no other rules or regulations exist to support this practice. Its removal will streamline development requirements with the ETT.

ABO Blood Type Reporting:

The ABO reporting process employs an independent two-person reporting strategy for both donors and candidates. Each ABO determination is the result of two separate lab typing procedures. For each determination, at least two source documents exist containing typing results. Source documents are required to be consulted when reporting results to the OPTN Contractor. A definition for source documents has been proposed due to policy interpretation questions from the community. Specific questions and answers regarding source documentation will be incorporated into competency training and guidance documents.

For deceased donor blood type determination and reporting, both ABO typing procedures must be completed currently “prior to incision”. The match run, however, can be executed based on one blood type result only. During the FMEA process, the potential fail point for only one sample drawn and tested prior to match (with no ABO results confirmation by a second sample) tied for the 4th most problematic fail point. (See Table 1.) A FMEA participant shared a situation where a transplant team had been dispatched based on one ABO result which turned out to be erroneous. This reflects a possible “near miss” of an accidental ABO incompatible transplant as well as increased time in identifying an appropriate recipient.

Proposed policy will require both deceased donor ABO typings to be completed and reported “prior to the match run” versus the current “prior to incision”. Exception language is proposed where circumstances require an accelerated recovery process to avoid organ wastage at the request of the OPO Committee. In these cases, the ABO determination and reporting must be completed prior to organ release and documentation will need to be maintained by the OPO. The proposed change will reduce the possibility of matches being performed on one potentially erroneous ABO blood typing result.

Having two separate ABO tests with two-person verification and reporting for deceased donors prior to the match run will align, in principle, with the current requirement for waitlisted candidates. All living donor candidates will fall under this safety check should the previously described public comment proposal pass requiring Waitlist registration prior to transplantation. Together these actions add more consistency on typing and reporting requirements prior to matching and transplantation regardless of donation type or donor/candidate status and help to reduce confusion and safety risk.

Proposed policy will require that OPOs and transplant hospitals have ABO determination and reporting protocols that define a “qualified health care professional”. Both initial and secondary reporting of blood type will need to be completed by a “qualified health care professional” as defined in the programs’ protocol. The Committee considered requiring use of licensed health care professionals, but decided to allow OPOs and transplant hospitals to construct their own definitions for flexibility to include staff who may be trained but not licensed.

These proposed actions are supported by the volume of ABO blood type changes between first and second reports, and resulting potential for patient harm. From 2009-2012, deceased donor ABO type was changed in 76 deceased donors (0.24% of all deceased donors 2009-12) between the first and second data entry in DonorNet[®]. An additional 100 donors had duplicate records created due to differences in subtype results. Candidate ABO type was changed in 153 cases (0.07% of all candidates added to the waitlist in 2009-2012). The changes could indicate the correction of either a clerical data entry error or a lab report interpretation error by the initial user. Of these 329 candidate and donor ABO and subtype changes, 297 (e.g. non-A₁ changed to A₁) represent a possible “near miss” which could have led to an incompatible transplant, had the change not been made. This evidence support the need for double typing and reporting prior to eligibility for a match run by a qualified health care professional with sufficient competency training. Details on blood type report changes are available in [Exhibit C](#).

Another area of concern related to ABO reporting involves unintended ABO incompatible transplants. Having a candidate erroneously listed as willing to accept an ABO incompatible transplant tied for the 3rd highest potential FMEA fail point. In some clinical circumstances, such as a gravely ill liver patient for whom death is imminent without a transplant, intended ABO incompatible transplants are performed. Between 2005 and June 2013, 276 ABO incompatible deceased donor transplants (heart=109, liver=162, kidney=5), and 667 ABO incompatible living donor transplants (kidney = 657, liver = 10) took place according to OPTN data.

The OPTN Contractor has received reports of patients being erroneously listed for an ABO incompatible transplant. In one such case, a transplant surgeon traveled to recover organs and aborted recovery once ABO incompatibility was discovered although the listing did indicate willingness to accept an ABO incompatible transplant. In another reported case, the transplant surgeon had given instructions for listing compatible types including a non-identical but compatible type (blood type B candidate with intention to receive blood type B or O organ). The person performing the data entry misinterpreted the term “incompatible” to mean any non-identical type and listed the candidate erroneously.

Currently in UNetSM, only one person is required to list a candidate as willing to accept an ABO incompatible organ. Pediatric heart candidates must have candidate titer reports to be listed in this category and therefore the likelihood of incorrect data entry is significantly lowered. Among liver patients, however, no additional related data is required. Since 2005, over 2,400 liver registrations were listed as willing to accept an ABO incompatible organ at some point in time. Over 300 of these were then switched from “Yes” to “No,” indicating a possible data entry error, although changes may have been intentional due to circumstance changes. This proposal recommends a programming change in UNetSM that will warn users to verify that an ABO incompatible transplant is clinically appropriate for each liver registration before the candidate is permitted to receive such offers.

In addition, match run display enhancements are proposed to improve communicating candidate blood type and biological compatibility status. Candidate ABO will be added as a new display field on the match results view page. Candidates who are blood type incompatible (including “subtype-compatible” candidates, e.g., O or B candidates receiving blood group A, non-A₁ organs) will be highlighted in the match run results. The highlight will be some type of symbol such as a red exclamation mark immediately to right of the blood type. An explanation will be displayed at the top of the page such as: “! = Candidate is either ABO incompatible, or compatibility depends on donor subtype and candidate titers. Please verify”. This is proposed to display candidate ABO and compatibility status as additional visual cues to avoid potential miscommunication when organs are being placed. This may also assist with ABO verification requirements.

Although not part of this current proposal, future plans include developing business requirements for a separate ABO tab in UNetSM. A functionality requested by users, a separate ABO tab could have various functions which align with resiliency and human factors engineering. These include having a central location for “all things ABO” including a place to enter ABO results, second person reporting for subtype results, source documents upload in a central location for ease of retrieval, date and time documentation of blood draws, ability to view source documents side by side, verification documentation to carry throughout the process, and a possible place to receive and store future verification data from the ETT project. This will need to be done in conjunction with ETT transplant program requirements over the upcoming year.

ABO Match Run:

The match run, also referred to as identification of potential transplant recipients, is a fundamental cornerstone in the OPTN system to assure ABO compatible or intended incompatible transplants. The match run generates a list of potential transplant candidates according to numerous criteria including ABO type as reported to the OPTN Contractor. Keeping the match run robust and strengthening identified gaps is a priority to maintain ABO checks and balances although the ultimate responsibility for assuring medical suitability remains with the transplant surgeon.

Having an OPO release an organ to a patient not-on-match-run (NOMR) tied for the number one prioritized FMEA risk point (See Table 1). An analysis of OPTN data between 2009 and 2012 found that approximately 60 deceased donor organ transplants each year occur in NOMR candidates. NOMR cases are primarily due to two causes: directed donation (70%) and avoiding organ wastage (30%). The majority of cases (88%) involve kidney transplants. This proposal seeks to reduce the number of NOMR recipients by changing policy language to require host OPOs to rerun the match prior to allocation if candidate acceptance criteria or other data impacting matches is updated and reported to the host OPO following an organ not being placed on an initial match run. In 2012, a sample of 20 NOMR cases showed that updating candidate data (e.g., increasing maximum acceptable donor age) would have added 6 candidates (30%) to the match run. The other cases are organs from blood type O or B donors who are ABO compatible but do not appear on match runs due to allocation policy. For example, kidney allocation policy restricts blood type O kidneys from going to candidates other than those with blood type O, except for zero-antigen mismatches. Having all ABO-compatible candidates appear on a match run remains the goal and the Committee plans to approach organ-specific Committees to help with this goal. If the ETT project incorporates bar code use into verification processes using match run results to help assure correct organ/correct recipient then this goal will become more critical. [Exhibit D](#) contains details on the NOMR analysis.

ABO Compatibility Verifications:

Performing compatibility checks to assure that the correct organ will be transplanted into the correct recipient and that blood types are compatible or intended incompatible represents an area where members have struggled with clarity, varying requirements, and documentation. In 2012, UNOS and CMS collaborated to produce a webinar on blood type compatibility requirements, a verification documentation template, and a crosswalk between the two organizations' requirements. Recent reviews for compliance with (former) Policy 3.1.2 (ABO verification upon receipt of the organ and prior to implantation) found that 32 of 139 (23%) reviewed programs demonstrated compliance with this OPTN policy. Demonstrating the organ was present at the time of verification was identified to be the most significant compliance challenge for transplant

centers. These data, however, represent a three-year cohort and may not reflect any more recent improvements following 2012 ABO education efforts.

The concept of verifying critical data using a time out process is an accepted safety practice and promoted by various health care organizations such as the Joint Commission on Health Care. For 2014, two Joint Commission hospital patient safety goals will be measured on conducting verifications. Safety goal UP .01.01.01 is to conduct a pre-procedure verification process and safety goal UP .01.03.01 is to conduct a time-out before the procedure. Elements for UP .01.03.01 include conducting the time out immediately before the starting the procedure or making the incision¹¹.

Four of the top 11 identified failure modes relate to verification issues (See Table 1). Blood type verification not being performed prior to implantation is tied for the number one most concerning risk. Having the wrong organ arrive and not be checked at arrival is ranked in the 2nd highest group. Two other high ranked risk points are concerns where verification is performed without source documents for both donor and candidate as well as no requirement for source documents for recipients whose surgery must begin prior to organ arrival. Work group discussions on these topics led to several recommendations for policy clarity, guidance, improved use of source documents, and further collaboration on future efforts to improve verification documentation (e.g. separate ABO tab and ETT bar code scanning).

This proposal clarifies verification requirements. Two current policy sections containing verification/time out requirements have been condensed into one section with a table organized by organ transplantation phase. The proposed policy spells out specific information to be verified, sources that can be used, and timings of verifications. This is done in response to transplant community feedback on lack of clarity around verification requirements and low policy compliance rates.

Organ recovery verification changes are proposed for both deceased and living donors. For deceased donors, host OPOs will be responsible for conducting a verification prior to organ release to the transplant hospitals. This represents a change from only requiring a time-out and blood type verification when deceased donor organs will remain within the same operating room suite. The timing of the recovery verification has been moved up from “prior to leaving the operating room” to “prior to induction of anesthesia” for living donors. This verification will apply to all living donor organ recoveries not just to those that remain within the same facility as is currently in policy. The supporting evidence is that a verification done after living donor organ removal but prior to leaving the operating room is not the safest time. These changes will better align OPTN and CMS requirements. Transplant community feedback regarding questions on this timing and policy compliance are two additional reasons for this change.

Two other conditional items are being proposed: a check-in at organ arrival if the organ will be arriving from a different operating room suite and a pre-procedure verification done prior to induction of anesthesia if transplant surgery will begin prior to organ arrival. The check in can be combined with the final verification if the organ is delivered immediately into the operating room with no break in chain of custody. These items are not required by CMS; however, the pre-procedure verification is consistent with Joint Commission National Patient Safety Goals. Several

¹¹ Joint Commission on Health Care. Hospital: 2014 National Patient Safety Goals. http://www.jointcommission.org/assets/1/6/HAP_NPSG_Chapter_2014.pdf (accessed 22 Jan. 2014)

transplant hospitals report performing these steps currently. Cases have been reported where the wrong organ was transplanted and incorrect recipient have been transplanted. These cases may have been prevented through an organ check-in or pre-anesthesia verification process.

Adding a check in at organ arrival for transported organs coming from other operating room suites arose out of concerns that organs may be shipped and sit prior to surgery. By the time a verification is performed on a stored organ, too much cold ischemic time may have accrued to redirect if a wrong delivery or accidental ABO incompatibility is discovered resulting in organ wastage. During 2012 and the first half of 2013, 13 kidneys of wrong laterality were shipped and three were discarded. In addition, one report was received through the OPTN Improving Patient Safety portal of the wrong organ being shipped in 2013. In its audits of transportation failures, the UNOS Organ Center identified a case in 2010 in which the shipment of a heart (intended for research) was switched with a kidney, a scenario in which an organ check-in procedure could help rectify the situation more quickly. In addition, 56 deceased donor kidneys were discarded in 2012 due to the reason "too old on ice." Though it is unknown whether the lack of an immediate organ check-in upon arrival contributed to the increased cold ischemic time (CIT) in these cases, requiring the check-in immediately upon arrival is not only designed to increase patient safety, but may also help prevent cases of organ wastage by allowing organ redirection before the accumulation of additional CIT. The existing data do not indicate at what point in time these issues were discovered after organ arrival. It is possible that some were impacted due to an organ not receiving an immediate check in.

If surgery is planned to begin prior to organ arrival, the proposed pre-anesthesia verification will add to patient safety. If an accidental incompatibility is discovered after surgery has started when the organ arrives, then patient harm could be done which could have been avoided. This would be more consistent with the CMS requirement to perform a verification prior to recipient organ removal in living donation if applicable.

The final verification prior to transplant remains for all deceased and living donor procedures. Timing language specifies that this verification must occur between the time the organ is delivered into the operating room and the first anastomosis to address transplant community questions. Language has been added to include the transplanting surgeon as part of the process consistent with current CMS requirements.

Exhibit E contains a comparison of requirements.

Moving toward these additions is consistent with other national patient safety goals. As the OPTN moves toward use of bar code and scanning automated information technology, the ability to document and capture these actions may be improved.

Expected Impact on Living Donors or Living Donation

The impact on Living Donors or Living Donation would be increased safety throughout the evaluation and transplant processes as further safeguards, educational efforts, and policy improvements will assist with reducing the likelihood of an ABO incompatible transplant.

Expected Impact on Specific Patient Populations

This proposal will not have a disproportionate impact on any specific patient population.

Expected Impact on OPTN Key Goals and Adherence to OPTN Final Rule:

This proposal is consistent with provisions in the Final Rule (42 CFR Part 121) Sections 121.6 (a) related to testing to determine contraindications for donor acceptance in accordance with OPTN policies and 121.7 (d) related to determining medical suitability upon organ receipt.

This proposal supports the following OPTN Strategic Plan Goals:

- Promote transplant patient safety
- Promote living donor safety
- Promote efficient management of the OPTN

Transplant patient safety will be enhanced by strengthening the system in place to prevent ABO incompatible transplants. These proposed changes will promote safer practices for both deceased and living donation. In addition, this proposal promotes efficient management of the OPTN through clarifying points in policy and a plan to provide broad based education surrounding ABO policy including competency training and guidance to address frequently asked questions and promote effective practices.

Plan for Evaluating the Proposal:

The primary goal of this proposal is to enhance patient safety, in particular with respect to ensuring the suitability of the donor’s blood type for every transplant patient.

This evaluation plan is designed to track effectiveness of this proposal, which includes policy changes, corresponding UNetSM system enhancements, member education, and collaboration with the ETT project.

The proposal will be evaluated by tracking the following:

Indicator	Evaluation Starting Time Point
Number of patient safety situation reports regarding labeling, typing, reporting, and verification errors related to ABO*	6 months, 1 year, and 2 years post-implementation
Number of patient safety situation reports reflecting an unplanned ABO incompatible transplant*	6 months, 1 year, and 2 years post-implementation
Number of patient safety situation reports reflecting a transplant of the wrong organ into the wrong recipient (or near misses)*	6 months, 1 year, and 2 years post-implementation
Number of candidates transplanted not appearing on match run (NOMR cases)*	1 and 2 years post-implementation
Number of corrections made after initial entry of candidate and donor blood types*	1 and 2 years post-implementation
Number of persons completing ABO competency training	6 months and 1 year post-implementation

The committee hypothesizes that implementation of this proposal will lead to a decrease in the actual number of patient safety situations related to errors in blood type. However, comparisons of patient safety situation reports before vs. after implementation must be interpreted cautiously, in light of the overall increasing trend observed from 2006 to 2013 in patient safety situation reporting.

The committee hypothesizes that the additional safeguards included in this proposal will further reduce the already-low risk of an unplanned ABO incompatible transplant or a wrong organ into wrong patient transplant. However, given the rarity of such “never events,” detecting a statistically significant change is highly unlikely.

Due to the new requirement for OPOs to rerun the match after not finding an acceptor on the initial match run and being notified by transplant program(s) that candidate data has been updated, it is hypothesized that the number of not-on-match-run transplants (NOMR) cases may decrease.

* Note: Though formal evaluation of this proposal includes a review of aggregate data at 6 months and 1-year post implementation, these cases are also reviewed and followed-up by the OPTN Contractor on a real-time basis.

Additional Data Collection:

No additional data will be required to be reported in UNet.

Expected Implementation Plan:

If public comment on this proposal is favorable, this proposal will be submitted to the OPTN Board of Directors in November 2014. If approved, the proposal would go into effect February 1, 2015.

Members will need to familiarize themselves with policy changes related to ABO determination, reporting, and verification.

OPOs will need to complete the second ABO blood type determination and report results to the OPTN prior to running the match run.

OPOs will need to rerun the match run prior to allocation in cases where organs were not allocated on an initial match run and transplant candidate acceptance criteria or other data affecting the match run has been updated and reported to the host OPO.

Host OPOs will need to complete a verification at organ recovery prior to organ release to the transplant hospital.

Transplant hospitals will need to complete the following:

- Verification prior to induction of anesthesia for living donor organ recovery
- Organ check in for organs arriving from a different operating room suite
- Verification prior to induction of anesthesia for living or deceased donor organ recipients if surgery will start prior to organ arrival
- Verification once the organ is delivered into the operating room yet prior to first anastomosis for living or deceased donor organ recipients

ABO reporting and verifications will need to be performed by a qualified health care professional as defined by OPO and transplant hospital protocols.

Programming changes in UNetSM will be made but are independent of the proposed policy changes. The programming changes are enhancements to provide warnings for ABO blood type

incompatible listings and display all candidate blood types on match runs with highlights on intended ABO blood type incompatible matches. This will not require changes for member data entry but will require awareness of new warning and information displayed on match run.

Communication and Education Plan:

This proposal will involve a major educational effort, which is needed to provide competency training regarding ABO determination, reporting, and verification requirements. In addition to offering competency training, accompanying materials such as a guidance document with frequently asked questions and effective practices along with user-friendly handouts and checklists will be developed to comprehensively and clearly communicate policy requirements and assist members with completing these processes.

Communication & Education Activities:

- Policy notice
- System notice
- E-newsletter/member archive article
- Presentation at Regional Meetings
- Formal training (e-modules; GoToTraining; Webinars, etc.)
- Articles/Guidance Documents on the Web and Member Archive

Additional member education will be developed by the Instructional Innovations department. This may include and podcast or webinar to provide targeted education related to changes in requirements associated with this policy proposal.

Compliance Monitoring (Revised October 2014)

The following changes to existing routine monitoring of OPTN members will occur:

Policy 2.6.A Deceased Donor Blood Type Determination

At OPOs, site surveyors will review a sample of deceased donor records for the following documentation:

- The results of two blood typing tests
 - Based on two separate blood samples, drawn at different times

Policy 2.6.B Deceased Donor Blood Subtype Determination

At OPOs, site surveyors will review a sample of deceased donor records for the following documentation:

- When the donor's blood subtype was reported in UNetSM as non-A₁, that there are two results from two pre-transfusion typings that show the donor as non-A₁
- When the donor's blood subtype was reported in UNetSM as non-A₁B, that there are two results from two pre-transfusion typings that show the donor as non-A₁B
- When the donor's blood type is A, but the donor's blood subtype is not reported in UNetSM, the reason is documented, and the reason is either:
 - Pretransfusion samples were not available
 - The results from 2 tests were different
 - The result of subtype testing was A₁

Policy 2.6.C *Reporting of Deceased Donor Blood Type and Subtype* (previously monitored as Policy 2.6.D)

At OPOs, site surveyors will review the OPO's internal policies, procedures and/or protocols to verify that they include a description of the process for:

- Verification that the individuals performing the reporting consulted source documents from two blood type tests
- If subtype of non-A₁ or non-A₁B is reported:
 - Verification that two individuals separately reported the donor's blood subtype to the OPTN Contractor
 - Verification that both individuals consulted source documents from two blood subtype tests

Policy 3.3.A *Candidate Blood Type Determination*

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through UNetSM is consistent with source documentation, including:

- The results of two blood type tests
 - Indicating the same blood type
 - With results timed prior to the candidate's registration on the waiting list

Policy 14.5.A *Living Donor Blood Type Determination*

At living donor recovery hospitals, site surveyors will review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that there are results for:

- Two separately completed blood type tests
 - Based on two separate blood samples, drawn at different times
 - Before generation of the living donor ID

Policy 14.5.B *Living Donor Blood Subtype Determination*

At living donor recovery hospitals, site surveyors will review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that:

- When the living donor's blood subtype was reported in UNetSM as non-A₁, there are two results from two separately completed pre-transfusion subtyping tests that show the living donor as non-A₁
- When the living donor's blood subtype was reported in UNetSM as non-A₁B, there are two results from two separately completed pre-transfusion subtyping tests that show the living donor as non-A₁B
- The two subtyping tests were completed on two samples with different collection times
- If there are discordant subtyping results, subtype is not reported

Policy 14.5.C *Reporting of Living Donor Blood Type and Subtype*

At living donor recovery hospitals, site surveyors will:

Review the living donor recovery hospital's internal policies, procedures and/or protocols to verify that the hospital has developed and implemented written protocols that address:

- Verification by someone other than the person who entered the living donor's blood type (and subtype, if applicable) on the living donor feedback form that:
 - Blood type (and subtype, if applicable) was entered correctly
 - Blood type (and subtype, if applicable) was entered using the blood typing source documents from an initial and second determination

The following new routine monitoring of OPTN members will occur:

Policy 2.15.B Pre-Recovery Verification

At OPOs, site surveyors will review a sample of deceased donor records for the following documentation:

- That the verification took place before the recovery time
- That the onsite surgeons participated in the verification
- That the following information was verified:
 - Donor ID
 - Organ type
 - Organ laterality (if applicable)
 - Donor blood type (and subtype, if used for allocation)
 - Intended recipient unique identifier
 - Intended recipient blood type

Policy 5.7.B Pre-Transplant Verification upon Organ Receipt

At transplant hospitals, site surveyors will review a sample of medical records, and any material incorporated into the medical record by reference, for the following documentation:

- That the verification was completed after the organ arrived in the OR
- That the verification was completed before anastomosis
- That the transplant surgeon participated in the verification
- That a licensed health care professional participated in the verification
- That the following information was verified:
 - Expected Donor ID
 - Expected organ type
 - Expected organ laterality (if applicable)
 - Donor blood type (and subtype, if used for allocation)
 - Recipient unique identifier
 - Recipient blood type

Policy 14.8 Living Donor Pre-Recovery Verification

At living donor hospitals, site surveyors will review a sample of medical records, and any material incorporated into the medical record by reference, for the following documentation:

- That the verification was completed with the donor in the OR
- That the verification was completed before induction of general anesthesia
- That the recovery surgeon participated in the verification
- That the following information was verified:
 - Donor ID
 - Organ type
 - Organ laterality (if applicable)
 - Donor blood type (and subtype, if applicable)

- Intended recipient unique identifier
- Intended recipient blood type

Policy or Bylaw Proposal

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

1.2 Definitions

Source document

An original record of data or results recorded. A source document may be:

- Data transmitted directly into an electronic medical record.
- An original paper source document.
- An original handwritten medical note, or
- A copy or facsimile of an original paper source document.

A source document must not have been altered or transcribed following the first recording.

2.6 Deceased Donor Blood Type Determination and Reporting

The host OPO must:

1. ~~ensure~~ Ensure that each deceased donor's blood type is accurately determined, ~~and~~
2. ~~report~~ Report the blood type to the OPTN Contractor, ~~and~~
3. ~~then verify that the correct blood type was reported. Develop and comply with a written protocol for blood type determination and reporting that defines a qualified health care professional and includes a two-person verification and reporting process.~~

2.6.A Deceased Donor Blood Type Determination

The host OPO must ensure that each deceased donor's blood type is accurately determined by testing at least two donor blood samples prior to incision the match run.

Two samples may be drawn on two separate occasions defined as samples drawn at two different times or the two samples may be from the same blood draw.

If the two samples are from the same blood draw, then the samples must be tested by two different laboratories.

The host OPO must document that two separate tests to determine the deceased donor's blood type were performed.

2.6.B Deceased Donor Blood Subtype Determination

~~When a deceased donor is determined to be blood type A, then subtype testing must be completed. Subtype testing must be performed only on pre-transfusion blood samples. The host OPO may choose whether to perform subtype testing on deceased donors with blood type AB.~~

~~When deceased donor blood type A or AB is sub-typed and found to be non-A1 or non-A1B, the host OPO must complete a second subtype test. If the sample used for the second subtype test is from the same blood draw as the sample used for the first subtype test, the second sample must be tested by a different laboratory.~~

All of the following apply to subtype determination:

1. Pre-transfusion blood samples must be used for all subtype testing.

2. Subtyping on blood type A must be completed if pre-transfusion samples are available.
3. Subtyping on blood type AB is optional if pre-transfusion samples are available.
4. If the blood samples are from the same blood draw, then the samples must be tested by two different laboratories.
5. Two subtype tests must be completed if subtyping results will be reported to the OPTN for allocation use including all blood type A, non-A₁ and blood type AB, non-A₁B results.
6. If two tests do not indicate the same subtype, then the donor must be allocated on primary blood type.

The host OPO must document that blood subtype determination tests have been completed to determine the deceased donor's blood subtype.

2.6.C Primary Reporting of Deceased Donor Blood Type and Subtype

The host OPO must report the deceased donor's blood type to the OPTN Contractor. The OPO must only report the deceased donor's blood subtype to the OPTN Contractor if two pre-transfusion samples were tested and the test results agree. If there are conflicting subtype test results, the deceased donor must be allocated based on the primary blood type.

All blood types and subtypes reported to the OPTN Contractor must be entered by a person consulting the source documents from the blood samples used for testing.

2.6.D Secondary Reporting of Deceased Donor Blood Type and Subtype

In order to verify that the correct blood type and subtype is reported to the OPTN Contractor, each OPO must establish and then implement a protocol for secondary reporting of blood type that is completed by someone

1. Other than the individual who completed the primary reporting of the donor's blood type to the OPTN Contractor.
2. Consulting source documents from the blood samples used for blood type testing.

If sub-typing of A or AB blood types is reported and used for allocation, the subtype determination must also be verified. Each OPO must establish and then implement a protocol for secondary reporting of blood subtype that is completed by someone:

1. Other than the individual who completed the primary reporting of the blood subtype determination to the OPTN Contractor.
2. Consulting both source documents from the two samples used for the blood subtype testing.

All of the following apply to reporting of deceased donor blood type and subtype:

1. A. Blood Type: Two different qualified health care professionals must each make an independent report to the OPTN Contractor for blood type.
B. Subtype: One qualified health care professional must report blood subtype to the OPTN Contractor if used for allocation. Report accuracy must be verified by a different qualified health care professional in accordance with the OPO's protocol.
2. Both qualified health care professionals must consult all source documents used for blood type and subtype determination.
3. Each qualified health care professional must verify that the source documents:
 - A. contain blood type and subtype (if used for allocation) results for the donor
 - B. indicate two results with the same blood type and subtype (if used for allocation)

The OPO must maintain documentation that secondary reporting was completed using both sub-typing according to the OPO's protocol consulting source documents containing each blood type and subtype (if used for allocation) test result.

The deceased donor is not eligible for a match run until the host OPO completes two blood type and subtype (if used for allocation) determinations and two-person verification and reporting for two identical blood types and subtypes (if used for allocation).

If circumstances require accelerating the donation process to avoid organ wastage, the OPO may proceed and complete these requirements prior to organ release from the operating room.

In such an event, the host OPO must maintain documentation of *all* of the following:

1. The reason that both blood type tests (and subtype if used for allocation) could not be completed, verified, and reported prior to the match run.
2. That the host OPO completed all required blood type and subtype determinations and two-person verification and reporting prior to organ release from the operating room.

3.3 Candidate Blood Type Determination and Reporting before Waiting List Registration

Transplant programs The transplant program must determine and report each transplant candidate's actual blood type before registering them on the waiting list.

1. Ensure that each candidate's blood type is determined.
2. Report the blood type to the OPTN Contractor.
3. Develop and comply with a written protocol for blood type determination and reporting that defines a qualified health care professional and includes a two-person verification and reporting process.

3.3.A Candidate Blood Type Determination before Waiting List Registration on the Waiting List

Transplant programs The transplant program must determine ensure that each candidate's blood type is determined by testing at least two candidate blood samples prior to registration on the waiting list. Transplant programs must test at least two blood Blood samples must be taken on separate occasions defined as samples drawn from two separate blood draws taken at two different times.

The transplant hospital must document that two separate tests to determine the candidate's blood type were performed.

3.3.B Secondary Reporting of Candidate Blood Type

After the candidate's blood type data are reported to the OPTN Contractor, the candidate will be added to the waiting list but will not be registered as an active candidate until secondary reporting and verification of the candidate's blood type has been completed.

Each transplant program must develop and comply with a written protocol for secondary reporting of blood type that is completed by someone:

1. Other than the individual who reported the candidate's blood type determination at registration on the waiting list.
2. Using source documents from the two blood samples used for the blood type testing.

All of the following apply to reporting of candidate blood type:

1. Two different qualified health care professionals must each make an independent report to the OPTN Contractor for blood type.
2. Both qualified health care professionals must consult all source documents used for blood type determination.
3. Each qualified health care professional must verify that the source documents:
 - A. contain blood type results for the candidate
 - B. indicate two results with the same blood type

Once the second report is made and two identical blood types are verified, then the candidate will be registered on the waitlist and eligible for match runs.

The transplant program must maintain documentation of this verification that reporting was completed according to the program's protocol consulting source documents containing each blood type test result.

5.4.B Order of Allocation

The process to allocate deceased donor organs occurs with these steps:

1. The match system eliminates candidates who cannot accept the deceased donor based on size or blood type.
2. The match system ranks candidates according to the allocation sequences in the organ allocation policies.
3. OPOs must first offer organs to potential recipients in the order that the potential recipients appear on a match run.
4. If no transplant program on the initial match run accepts the organ, the host OPO may give transplant programs the opportunity to update their candidates' data with the OPTN Contractor. The If the transplant program notifies the host OPO of updated candidate data, and the organ has not been accepted on the initial match run, then the host OPO may must run an updated match run and to allocate the organ according to the updated candidate data.
5. If no transplant program within the DSA or through an approved regional sharing arrangement accepts the organ, the Organ Center will allocate an abdominal organ first regionally and then nationally, according to allocation Policies. The Organ Center will allocate thoracic organs according to *Policy 6: Allocation of Hearts and Heart-Lungs* and *Policy 10: Allocation of Lungs*.
6. Members may export deceased donor organs to hospitals in foreign countries only after offering these organs to all potential recipients on the match run. Members must submit the *Organ Export Verification Form* to the OPTN Contractor prior to exporting deceased donor organs.

5.5.A Receiving and Reviewing Organ Offers

Transplant hospitals must view organ offers and respond to these offers through the match system.

The transplanting surgeon at the receiving transplant hospital is responsible for ensuring the medical suitability of organs offered for transplant to potential recipients, including compatibility or intended incompatibility of deceased donor and candidate blood types (and donor subtype, when used for allocation).

5.6 ~~Blood Type Verification upon Receipt Organ Recovery, Check-In, and Pre-Transplant Verifications~~

~~When the organ arrives at the transplant hospital and prior to transplant, the transplant hospital must verify the accuracy of the donor ID and blood type against the potential recipient's blood type. Blood subtype accuracy for a deceased or living donor and potential recipient must also be verified if used for allocation. The transplant hospital must document that these verifications occurred.~~

Transplant hospitals and host OPOs must each develop and comply with their own written protocol to perform verifications as outlined in this policy.

A qualified health care professional as defined in the program's written protocol must perform and document all verifications.

Recovery and pre-transplant verifications must include a process to confirm that all of the following information is correct:

1. Donor ID, organ type, and laterality (if applicable)
2. Donor blood type and subtype (if used for allocation)
3. Recipient unique identifier
4. Recipient blood type
5. That the donor and recipient are the intended pair for transplant
6. That the donor and recipient are blood type compatible (or intended incompatible)

Verifications must be done using a two-person or a one-person assisted by an automated information technology bar code scanning process. Verifications must include confirmation of required information from at least two of the following:

1. Donor or recipient identification band
2. Donor or recipient medical record
3. OPTN computer system
4. Donor or recipient ABO blood type and subtype source documents
5. OPTN external labels (check-in verification only)

5.6.A: Host OPO Organ Recovery Verification

Host OPOs must complete and document deceased donor organ recovery verifications according to Table 5.1 below.

Table 5.1: Deceased Donor Organ Recovery Verification

<u>Requirement</u>	<u>Time</u>	<u>Place</u>
<u>The host OPO in conjunction with the on-site surgical recovery team must perform a deceased donor organ recovery verification.</u>	<u>Prior to organ release to the transplant hospital</u>	<u>Per OPO protocol</u>

5.6.B: Recovery and Transplant Hospital Organ Recovery, Check-In, and Pre-Transplant Verifications

Recovery and transplant hospitals must complete and document organ recovery, check-in, and pre-transplant verifications according to Table 5.2 below.

Table 5.2: Organ Recovery, Check-In and Pre-Transplant Verifications

	Requirement	Time	Place
<u>Recovery: Living Donation</u>	<u>The recovery hospital must perform a living donor organ recovery verification with the donor present in the operating room.</u>	<u>Prior to anesthesia of living donor</u>	<u>Living donor operating room</u>
<u>Check-In: Deceased and Living Donation</u>	<p><u>If the organ is received from a different recovery operating room suite, then the transplant hospital must check-in the organ.</u></p> <p><u>The external label or source documents accompanying the organ must be checked against expected donor ID, organ type, and laterality (if applicable) prior to opening the organ package.</u></p> <p><u>The check-in may be done in combination with the final verification if the organ is immediately brought into the recipient operating room upon arrival at the transplant hospital and chain of custody has been maintained.</u></p>	<u>When the organ becomes physically present at the recipient's operating room suite</u>	<u>Per transplant hospital protocol</u>
<u>Pre-Transplant: Deceased and Living Donation</u>	<u>If surgery will begin prior to organ arrival, the transplant hospital must perform an additional pre-procedure verification with the intended recipient present*.</u>	<u>Prior to anesthesia of intended recipient</u>	<u>Per transplant hospital protocol</u>
	<u>The transplant hospital including the transplanting surgeon must always perform a final verification with the organ and the intended recipient present in the operating room.</u>	<u>Between time of organ delivery into intended recipient's operating room and first anastomosis</u>	<u>Recipient operating room</u>

Once the organ has been released to the transplant hospital, if the intended recipient changes, then the verification is solely the responsibility of the final transplant hospital.

*If the intended recipient is under anesthesia prior to reaching the operating room and the organ is not present, then the additional pre-procedure verification must be conducted prior to incision.

13.6 Matching within the OPTN KPD Program

13.6.A Requirements for Match Run Eligibility for Candidates

The OPTN KPD program will only match candidates who comply with *all* of the following requirements:

1. The candidate's transplant hospital must comply with Policies *5.5.A: Receiving and Reviewing Organ Offers* and *5.5.D: Blood Type Verification upon Receipt* 5.6 Organ Recovery, Check-In, and Pre-Transplant Verifications

13.6.B Requirements for Match Run Eligibility for Potential KPD Donors

The OPTN KPD program will only match potential KPD donors that comply with *all* of the following requirements:

1. The transplant hospital registering the potential KPD donor must perform blood typing and subtyping as required by *Policy 14.4.A: Living Donor Blood Type Determination and Reporting* with the following modifications:
 - a. The transplant hospital registering the potential KPD donor must report the potential KPD donor's ~~actual~~ blood type to the OPTN Contractor
 - b. ~~Someone, other than the person~~ A qualified health care professional, other than the qualified health care professional who initially reported the potential KPD donor's blood type to the OPTN Contractor, must compare the blood type from the two source documents, and separately report the potential KPD donor's actual blood type to the OPTN Contractor
 - c. The potential KPD donor is not eligible for a KPD match run until the transplant hospital verifies and reports two identical blood types

14.4 Medical Evaluation Requirements for Living Donors

14.4.A Living Donor Blood Type Determination and Reporting

The recovery hospital must:

1. Ensure that each living donor's blood type is determined.
2. Report the blood type to the OPTN Contractor.
3. Develop and comply with a written protocol for blood type determination and reporting that defines a qualified health care professional and includes a two-person verification and reporting process.

14.4.A.i Living Donor Blood Type Determination

~~The recovery hospital must ensure that blood typing of each living donor's blood type is performed on two separate occasions before the recovery determined by testing at least two living donor blood samples prior to generation of the living donor ID. Blood samples must be taken on Two separate occasions are defined as two blood samples taken drawn at two different times, and sent to the same or different laboratories.~~

The recovery hospital must document that two separate tests to determine the living donor's blood type were performed.

14.4.A.ii Living Donor Blood Subtype Determination

~~The recovery hospital subtyping a living donor whose initial subtype test indicates the donor to be non-A₁ (negative for A₁) or non-A₁B (negative for A₁B), must ensure a second determination test is performed prior to living donation to assess the accuracy of the result. Blood samples for subtype testing must be taken on two separate occasions, defined as two samples taken at different times. Samples tested must not be taken after a blood transfusion. When the initial and second determination subtypings are the same result, the result can be used to determine transplant compatibility with the intended recipient or any other potential recipient. If the initial and second determination subtyping results are not the same, the donor must be allocated based on the primary blood type, A or AB.~~

All of the following apply to subtype determination:

1. Pre-transfusion blood samples must be used for all subtype testing.
2. Subtyping on blood type A and blood type AB is optional if pre-transfusion samples are available.
3. At least two blood samples must be taken on separate occasions defined as samples drawn at two different times.
4. Two subtype tests must be completed if subtyping results will be reported to the OPTN when used for transplant compatibility determination or allocation including all blood type A, non-A₁ and blood type AB, non-A₁B results.
5. If two tests do not indicate the same subtype, then transplant compatibility or allocation must be based on primary blood type only.

The recovery hospital must document that blood subtype determination tests have been completed to determine the living donor's blood subtype when used for determining transplant compatibility or allocation.

14.4.A.iii Reporting of Living Donor Blood Type and Subtype

All of the following apply to reporting of living donor blood type and subtype:

1. A. Blood Type: Two different qualified health care professionals must each make an independent report to the OPTN Contractor for blood type.
B. Subtype: One qualified health care professional must report blood subtype to the OPTN Contractor if used for allocation. Report accuracy must be verified by a different qualified health care professional in accordance with the recovery hospital's protocol.
2. Both qualified health care professionals must consult all source documents used for blood type and subtype determination.
3. Each qualified health care professional must verify that the source documents:
 - A. contain blood type results for the living donor
 - B. indicate two results with the same blood type and subtype (if used for transplant compatibility or allocation)

The recovery hospital must maintain documentation that reporting was completed according to the program's protocol consulting source documents containing each blood type and subtype (if used for transplant compatibility or allocation) test result.

14.6 Registration and Blood Type Verification of Living Donors before Donation

Recovery hospitals must use source documents from both an initial and second determination blood typings and subtypings (when used to determine transplant compatibility), to enter the living donor's blood type data on the *Living Donor Feedback Form*. Additionally, each living donor program must develop and comply with a protocol to verify that the living donor's blood type and type was correctly entered on the *Living Donor Feedback Form* with both the initial and second determination blood typing and subtyping source documents by an individual other than the person initially entering the donor's blood type data.

Recovery hospitals must document that each blood typing and subtyping entry was performed according to the program's protocol and must maintain this documentation.

16.1 Organs Not Requiring

The transplant hospital and host OPO (if applicable) must develop and follow a protocol to ensure that the correct living or deceased donor organ is transplanted into the correct recipient when *either* of the following occurs:

- Organs are recovered from a deceased donor and remain in the same operating suite as the intended

recipient

- ~~Organs are recovered from a living donor and remain in the same facility as the intended recipient~~

Time-outs must occur:

1. ~~Before the organ leaves the deceased or living donor operating room~~
2. ~~Again when the organ arrives at the potential recipient's operating room~~

~~During these time-outs and before the transplant occurs, the transplant hospital must confirm and document that a member of the transplant team identified the correct organ for the correct potential recipient prior to transplant according to *Policy 5.6: Blood Type Verification upon Receipt*.~~

16.4.C Internal Labeling of Blood and Tissue Typing Materials

Each separate specimen container of blood or tissue typing material must have a label that will remain secured to the container under normal conditions of transport. The label must include the donor ID and at least *one* of the following identifiers:

- Locally assigned unique ID
- Donor date of birth
- Donor initials

Additionally each specimen should be labeled with *both* of the following:

1. The date and time the sample was procured
2. The type of tissue

The donor blood type and subtype, if used for allocation, should be included on tissue typing material ~~but must not be included on~~ and blood samples if known. If the donor ID or blood type is not available during the preliminary evaluation of a donor, a locally assigned unique ID and one other identifier for the transportation of initial screening specimens may be used. The OPO must document in the OPO donor record all unique identifiers used to label tissue typing specimens.

Public Comment Responses:

1. Public Comment Distribution

Date of distribution: March 14, 2014
 Public comment end date: June 13, 2014

Public Comment Response Tally					
Type of Response	Response Total	In Favor	In Favor as Amended	Opposed	No Vote/ No Comment/ Did Not Consider
Individual	24	16 (67%)	0	3 (13%)	5 (20%)
Regional	11	7 (64%)	0	4 (36%)	0
Committee	19	1 (5%)	1 (5%)	1 (5%)	16 (85%)

2. Primary Public Comment Concerns/Questions

Review of feedback on the proposal highlighted the following themes:

- Concerns related to OPO requirements
 - Ability to conduct verification at recovery when the intended recipient is not known
 - Requirement to have on-site surgical team participate in verification
- Concerns that additional requirements were not needed given the infrequency of accidental ABO incompatible transplants
- Concerns that the proposed policy was too prescriptive
- Concerns that the entire process has been redesigned
- Desire to have no differences from CMS requirements
- Request for updated templates and electronic solutions
- Desire to postpone policy requirements until after ETT implementation

The Committee appreciated the feedback related to these discussions and offered the following comments to address each of these categories of concern:

Concerns related to OPO requirements

Several individuals, committees, and regions made comments regarding requirements for OPOs and deceased donor recovery verification. The requirement as proposed would include the OPO “in conjunction with the on-site recovering surgical team” to conduct a verification. Concerns expressed were that the recovering surgeon may not “know” the recipient, would not have source documentation, or could not complete the requirements, as the recipient may not be decided at the time of surgery. In some cases, kidneys are recovered and put on a pump until allocation is complete yet the on-site surgical recovery team would have left prior to allocation completion.

The Committee considered these comments and did amend the proposed language so that this requirement is only for cases “when the intended recipient is known.” This will mirror the CMS

requirement. The requirement will cover the intended recipient for whom the organ is accepted. The OPO Committee was consulted and agreed with this change. CMS representatives providing guidance from their standpoint related that it is understood that the recipient may change and that the recovery team is not responsible for this situation. The verification is done at that point in time for the information available at recovery. If the recipient changes prior to transplant, there is another verification conducted by the transplant hospital. Both OPTN and CMS policies place the transplanting surgeon as the party ultimately responsible for ensuring medical suitability prior to transplant.

Performing a verification is not always synonymous with using source documentation. A verification is a check completed at a critical point in time to make sure that the process involves the correct donor, organ, and recipient. OPTN policies and computer systems are set up to ensure that source documents are used to enter ABO results with a double verification prior to registration in the system. This is done to ensure that match runs are based on source document data. At the time of recovery, the OPO and on-site surgical recovery team are not expected to perform a verification for the recipient using source documents. They are expected to perform a verification using the information from UNet that was entered using source documents. The underlying principle for verifications is that when source documents are readily available they will be used (e.g. for the donor at time of recovery) but, the system has multiple safeguards built in so it is acceptable to use the match run to verify intended recipient identifying information and ABO at deceased donor recovery.

The proposed policy that listed acceptable sources for all verifications has been separated into relevant policies. It is tailored to each point in the process to make expectations clearer. In Policy 2 (OPO Responsibilities), the post-public comment language contains specific instructions for conducting the verification and acceptable sources to use in confirming required data.

Having the on-site surgical recovery team participate in the verification is a requirement kept in the post-public comment language. This is consistent with OPTN and CMS requirements for OPOs to have a protocol that spells out roles and responsibilities for those participating in recoveries. This is reasonable and logical, as the recovery team is a critical part of the process. The language was amended to state that the on-site surgical recovery team is verifying that the intended recipient is on the match run as reported by the host OPO.

Recovery is the first surgical step in the complex process of transplantation. It also represents the first place of hand-off or transition. Studies have shown that patient transitions require transfer of all relevant information, authority, and responsibility from one entity to the next. Concerns for patient safety can arise when any elements are not effectively transferred during a transition. Transitions may be influenced by poor communication, which has been identified as a factor influencing quality and safety of care. Poor transitions can have a negative impact, including adverse events. Although transitions have been shown to be critical points at which failure may occur, they may also be considered as critical points for identifying potential errors and preventing failures.¹²

¹² Carayon, P and Wood, K. Patient Safety: The Role of Human Factors and Systems Engineering. National Institutes of Health-Public Access Author Manuscript accessed at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3057365/>. Published in final edited form as: *Student Health Technology Information*. 2010; 153: 23–46.

The second most common concern for patient safety in health care organizations identified by the ECRI institute, a patient safety organization, is poor care coordination with the patient's next level of care. The third most common concern is test results reporting errors¹³. Some of these principles can be applied to recovery, as it is the first step in transition of an organ that will be transplanted into a patient and correct test results are paramount to safety. Human factors and communication have been among the top three root causes for sentinel events reported to The Joint Commission since 2012¹⁴. Handover error is recognized as a potential hazard in patient care, and the information error rate has been estimated at 13%. Current literature examined in a meta-analysis does not confirm that any methodology reliably improves the outcomes of clinical handover, although information transfer may be increased¹⁵. These same principles and proactive steps are important throughout the transition from recovery to transplantation especially concerning communication at points of transfer in organ chain of custody.

Other relevant future changes involve the potential for HIV positive organs to be used in HIV positive recipients as allowed by the HOPE Act. This underscores the need to have verification processes at certain standing and multiple times during recovery and transplant procedures. Redundancy is major principle in human factors engineering to reduce error. Points may be repeated but they are done at different times by different parties. Each is a critical piece at a vulnerable point in time where mistakes are more likely to be made.

Concerns that additional requirements were not needed given the infrequency of accidental ABO incompatible transplants

It is true that accidental incompatible ABO transplants are very rare events. Unintentional ABO incompatible transplants have occurred since the 2003 event that led to a patient death, but may not be well known within the transplant community. Since 2006, there have been two accidental incompatible kidney transplants both leading to hyperacute graft rejection and three accidental incompatible liver transplants. These were due to several different root causes including lab error, documentation or communication errors, and verification errors.

The 2006-2013 accidental ABO incompatible (ABOi) rate is 2.2 per 100,000 recipients transplanted. The death rate, however, is 0 per 100,000 recipients. Although the years are not the same, a comparison to ABOi blood transfusions resulting in acute hemolysis would yield an approximate rate of 0.84 per 100,000 recipients transfused using 2011 National Blood Collection and Utilization Survey Report data¹⁶. Reporting of blood transfusion deaths to the Food and Drug Administration is mandatory. Between FY07 and FY13, 26 deaths were reported due to hemolytic transfusion reactions by ABO antibody¹⁷. Given the extensive work to assure

¹³ ECRI Institute. Top 10 Patient Safety Concerns for Healthcare Organizations 2014. Accessed at <https://www.ecri.org/Press/Pages/Health-IT-Care-Coordination-and-Drug-Shortages-Lead-ECRI-Institute-2014-List-of-Top-10-Patient-Safety-Concerns.aspx>.

¹⁴ The Joint Commission. Sentinel Event Data Summary 2014. Accessed at http://www.jointcommission.org/sentinel_event.aspx.

¹⁵ Robertson, E. et. al. Interventions employed to improve intrahospital handover: a systematic review. *British Medical Journal of Quality and Safety* 2014;23:7 600-607 Published Online First: 8 May 2014

¹⁶ Whitaker, B. and Henry, R. The 2011 National Blood Collection and Utilization Survey Report accessed at <http://www.hhs.gov/ash/bloodsafety/2011-nbcus.pdf>.

¹⁷ Fatalities Reported to FDA Following Blood Collection and Transfusion: Annual Summaries for Fiscal Years 2016-2013. Accessed at: <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/TransfusionDonationFatalities/default.htm>

blood safety with a significantly higher volume of transfusion recipients (n = ~5,000,000 in 2011) such as the promotion of hemovigilance, national incident reporting, and addition of hospital transfusion safety officers, the steps proposed in this ABO proposal relative to organ transplantation volume are reasonable. Although rates from both procedures are relatively low, safety must be a continuous effort. Never events can significantly disrupt trust in the system.

The opportunity and possible risk for unintentional ABOi will increase when the new Kidney Allocation System (KAS) goes into effect in December 2014. New policy will permit the nationwide transplantation of blood type A, non-A₁ and blood type AB, non-A₁B donors into blood type B candidates to increase transplant opportunities for this blood group. In addition, the kidney-paired donation program that already allows these type of subtype compatible transplants continues to grow. A mistake in transplanting a blood type A₁ or blood type A₁B can lead to an adverse event such as hyperacute graft rejection.

The system to protect recipients against accidental ABOi transplants has evolved through the years. Major changes, such as double verification of ABO entry to become active in UNet and computer generated match runs with ABO compatible logic, were instituted several years ago. These remain the cornerstone of safety checks in listing and matching donors and candidates. Many of these previous policy and programming changes were made as reactions to adverse events. The OSC, however, conducted a *proactive* risk assessment. The FMEA identified areas where further safety improvements could reduce risk.

Living donor recovery verification, for example, is not required in OPTN policy for all cases. It is only required for those cases where the organ remains in the same facility and the timing of this verification is prior to leaving the operating room. This leaves two major safety gaps. The first is that nearly 500 living donor recoveries occur where an organ is shipped. Currently these events would not be subject to a pre-recovery verification. In addition, the current required timing is prior to leaving the OR and would create a serious problem if an ABO discrepancy is not discovered until after organ removal. Living donors usually do not have the benefit of the computer generated match run to check compatibility. Current OPTN policy timing does not match current CMS requirements. This is an area where proactive risk identification and action can reduce the likelihood of a future ABOi transplant through the policy changes proposed.

While prevention of accidental ABOi was the focus of the FMEA. Some recommendations will also address prevention of wrong-organ/wrong-recipient. Wrong-patient, wrong-site, wrong-procedure has been the most common reported sentinel event (n= 1,072) to The Joint Commission between 2004-June, 2014. This error represents 13% of the 8,275 sentinel events that were voluntarily reported. The most common root causes for this error were leadership (n=865), communication (n=726), and human factors (n=722)¹⁸. Events may have more than one root cause.

In transplant, there have been at least nine cases involving wrong organ delivered, wrong-organ/wrong-candidate occurrences or near misses since 2006. In addition, there have been 21 switched kidney laterality cases since 2012 with five resulting in organ discard. Although this is not a risk for accidental ABOi transplant, it does represent unnecessary organ wastage. Other near miss data or risk situations in the original proposal include an average of 60 not on match run cases annually, 300 ABO data entry switches over a four-year period, and over 50 patient safety situations which could possibly lead to an unintentional ABOi transplant. Safety situation

¹⁸ The Joint Commission. Sentinel Event Data. 2014. Accessed at: http://www.jointcommission.org/assets/1/18/Root_Causes_by_Event_Type_2004-2Q_2014.pdf.

reporting is largely voluntary. In general, it is estimated that only about 5% to 15% of safety related events in a healthcare setting are typically reported through incident reporting systems^{19, 20}. In April 2014, OSC research staff conducted an analysis and estimated that only 13% of actual safety events are being reported to the OPTN.

The above-mentioned data and logic provide valid reasons for making changes to address safety gaps identified through the FMEA. Most of the safety components are already in place. The additions will not add an insurmountable burden given the problems potentially prevented by the checks.

Concerns that the proposed policy was too prescriptive

The transplant community in some areas related comments that the proposal was too prescriptive, yet others have asked for more clarity in requirements. The proposal sought to strike a balance between individual organization-specific practices (e.g. requirement of individual protocols) while addressing identified safety and transplant community concerns. During the FMEA, and in previous collaborative OPTN/CMS efforts, issues were identified where requirements were silent or vague leading to questions of what needs to be verified and what can be used as acceptable verification sources.

During the FMEA and policy development, it became clear that there was significant confusion in the current policy about the timing and number of pre-transplant verifications and other areas such as source documentation. The language developed was more specific to address these concerns. Overall, the proposal seeks to answer questions raised within the transplant community that had asked for more clarity.

Concerns that the entire process has been redesigned

While the proposed language changes may seem extensive, most of the language changes either clarify existing requirements or make language consistent across donation types as well as between donors and candidates. The existing process has not been redesigned. There have been changes to the scope and timing of two verifications and the addition of two conditional checks. Please see the table below for highlights.

Table 2: Highlights of Current and Proposed Changes

Requirement		Current	Proposed	Align with CMS
Timing Changes	Two ABO results must be obtained for deceased donors	Prior to incision	Prior to match run	✓
	Living donor recovery verification must be conducted	Prior to leaving OR	Prior to general anesthesia for donor	✓ incision
Current Practice	Deceased donor pre recovery verification (time out) must be conducted	If organs remain in same OR suite	All cases	✓ OPO

¹⁹ Levtzion-Korach, O. et al. Integrating incident data from five reporting systems to assess patient safety: making sense of the elephant. *Joint Commission Journal on Quality and Patient Safety / Joint Commission Resources*. 2010;36 (9):402-10.

²⁰ Vincent, C. et al. Safety measurement and monitoring in healthcare: a framework to guide clinical teams and healthcare organisations in maintaining safety. *British Medical Journal of Quality and Safety*. 2014;23(8):670-7.

	Requirement	Current	Proposed	Align with CMS
	Living donor recovery verification (time out) must be conducted	If organs remain in same OR facility	All cases Eliminates verification when leaving donor OR	✓
New Conditional Actions	Organ check-in	None	If organ arrives from different OR suite	no rule
	Pre-procedure ABO verification	None	If recipient surgery starts prior to organ receipt	no rule

Desire to have no differences from CMS requirements

OPTN policy and CMS policy are likely always to differ on some points. It is an unrealistic to expect no variation. First, OPTN policy includes allocation principles and that is out of scope for CMS. Part of OPTN ABO policy addresses subtyping because it is used to increase transplant opportunities.

In addition, CMS rules do not address reporting processes to the OPTN as that would be out of scope for CMS. An important component of OPTN policy is reporting process (e.g. using source documents with double user entry and verification) as the process contains safety checks approved several years ago. This proposal retools some of the reporting language for clarity and consistency but does not change the core principles.

CMS does not require two blood type determinations for candidates or living donors. OPTN policy does have this requirement for redundancy and consistency. To undo this existing requirement would remove critical safety checks and programming. It would not make sense for the OPTN to remove these requirements to match with CMS.

OPTN policy will further align with CMS on several critical points. These include:

- Verification requirements at deceased donor organ recovery
- Timing and scope for verification requirements at living donor recovery
- Requirement of transplanting surgeon and licensed health care professionals to conduct pre-transplant verification

The two new conditional requirements where OPTN will differ from CMS include the organ check-in and verification when surgery will begin prior to organ arrival. Previously cited data support the need for a check-in and the majority of transplant hospitals are already conducting a pre-procedure verification as part of The Joint Commission universal protocol requirements. The OPTN policy would add blood type and compatibility to this timeout already being conducted.

The organ check in was added to address the failure mode ranked second (three-way tie) in priority: “Wrong organ arrived-not checked at arrival to verify correct organ arrived for the correct potential recipient”. The conditional verification if surgery starts prior to organ arrival was proposed to address the failure mode ranked second (three-way tie) in priority: “If intended recipient surgery begins prior to arrival, no requirement for blood source documentation availability to confirm compatibility prior to anesthesia”.

Lastly, not all OPTN transplant programs are certified transplant providers under CMS. As of September 16, 2014, there were 104 organ specific transplant programs, including 12 kidney

programs, that were not CMS certified (as of June 30, 2014) for transplantation. The proposed policies will provide rules for these programs that are not bound to CMS transplant-specific requirements.

Request for updated templates and electronic solutions

The Committee agrees with requests for updated templates and plans to work with CMS to provide optional tools to assist with meeting requirements.

In addition, the Committee is continuing to work on possible programming modifications to have the system guide the requirements for example with second user subtype verifications that currently do not exist. The Committee also plans to work on an electronic solution to address issues that were uncovered during discussions of when the intended recipient changes or is unknown at recovery.

The Committee will apply human engineering factors and tools to make it “easy to comply and hard to fail” with meeting the requirements.

Desire to postpone policy requirements until after ETT implementation

The Committee appreciates the assistance and improvement that the ETT (TransNet-A Service of the OPTN) will bring to the process. This system will bring major advances for labeling, packaging, critical data verification including ABO, and assuring correct organ/correct recipient transplants. To wait for this system to be fully functional, however, would be a mistake. Currently, it is unknown when use might be made mandatory. The system is still under development and before mandatory use could be enacted, public comment and adoption by the OPTN/UNOS Board of Directors will be required. Some in the transplant community have stated they will have to develop a process now (e.g. for organ check in) and modify it with ETT and that this is not efficient or desired.

The Committee would respond that having an organ check in is being done already in many places. Postponing this requirement would not demonstrate good stewardship of a life-saving organ nor address risks proactively as identified through the FMEA. Transplant hospitals having to develop a check in can build their process with conversion to ETT in mind. In addition, while the ETT will address several areas where critical errors can occur (e.g. labeling), it does not address all facets covered in the proposal (e.g. both ABOs prior to match run).

3. Regional Public Comment Responses

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Meeting Format
1	5/5/2014	0 yes, 13 no, 2 abstentions		In person
2	3/28/2014	16 yes, 1 no, 5 abstentions		In person
3	5/30/2014	11 yes, 5 no, 0 abstentions		In person
4	5/9/2014	0 yes, 26 no, 0 abstentions		In person
5	6/12/2014	14 yes, 13 no, 0 abstentions		In person

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Meeting Format
6	5/16/2014	0 yes, 38 no, 0 abstentions		In person
7	5/9/2014	0 yes, 16 no, 0 abstentions		In person
8	4/4/2014	16 yes, 1 no, 0 abstentions		In person
9	5/21/2014	12 yes, 0 no, 0 abstentions		In person
10	5/15/2014	11 yes, 3 no, 3 abstentions		In person
11	5/30/2014	16 yes, 8 no, 0 abstentions		In person

Region 1:

The region did not approve the proposal and provided the following comments:

- The region recommends that the committee define anesthesia by adding the word “general.”
- Source documentation definition – the committee should consider defining when an original handwritten medical note is acceptable.
- If the policy is approved, the region requested that the Living Donor and Recipient OR Verification Templates be updated to include the new requirements.
- Policy 5.6.A, Table 5.1: The region identified a couple issues with this requirement as currently written:
 - The policy requires the host OPO in conjunction with the on-site surgical recovery team to perform a deceased donor organ recovery verification which requires the verification of a recipient unique identifier, recipient blood type and that the donor and recipient are blood type compatible, in addition to other elements.

What process does the host OPO follow when the intended recipient is unknown while the on-site surgical recovery team and OPO are conducting the verification? This does occur, particularly with kidney allocation.

Secondly, when the on-site surgical recovery team is recovering an organ for another transplant center, how can the OPO and surgical recovery team perform the verification without having the required documentation? Is the on-site recovery team expected to take responsibility for a potential recipient that is listed at another transplant center?

Committee Response:

The Committee agrees with the terminology comment regarding anesthesia and has added the word "general" prior to the word "anesthesia" for clarification.

The Committee has removed the examples from the proposed policy definition. The Committee plans to work on a guidance document regarding source documents. DEQ will put some additional information in the evaluation plan.

The Committee agrees with the suggestion to provide updated verification templates and will work with CMS to update these tools.

The Committee has received multiple comments concerning the ability to perform a verification at deceased donor organ recovery when the intended recipient is not known. The Committee has proposed post-public comment changes in response to these comments. Please see the Primary Public Comment Concerns/Questions section above for a full response.

Region 2:

There was concern that there was too much redundancy in this policy and that the additional requirements may go too far given the frequency of any problems.

Committee Response:

The Committee received several comments to this effect. Redundancy is a key part of the safety checks in current and proposed ABO policy. The redundancy however occurs at critical checkpoints when there is a hand-off or transition. These are times susceptible to error. Each determination, reporting, and verification step involves different persons participating in the transplantation process. The Committee conducted a proactive, not reactive exercise with the FMEA. The areas identified for change are supported by both general health care data and concepts as well as transplant-specific data. Please see the Primary Public Comment Concerns/Questions section above for a full response.

Region 3

No comments

Committee Response:

The Committee appreciates the vote of support on the proposal.

Region 4:

The region did not approve the proposal and provided the following comments:

- The region believes that the proposal is overly prescriptive and complex. The complexity of the modifications are not easy to follow in the proposed policy language. The policy needs to clearly outline the requirements.
- Adding a check-in and additional verification will not improve compliance with the ABO policies.
- Fortunately, an ABO incompatible transplant has not occurred for several years and there is only one reported case. The region doesn't find it necessary to redesign the entire process.
- Policy 5.6.A, Table 5.1: The region identified a couple issues with this requirement as currently written:
 - The policy requires the host OPO in conjunction with the on-site surgical recovery team to perform a deceased donor organ recovery verification which requires the verification of a recipient unique identifier, recipient blood type and that the donor and recipient are blood type compatible, in addition to other elements.

What process does the host OPO follow when the intended recipient is unknown while the on-site surgical recovery team and OPO are conducting the verification? This does occur, particularly with kidney allocation.

Secondly, when the on-site surgical recovery team is recovering an organ for another transplant center, how can the OPO and surgical recovery team perform the verification without having the required documentation? Is the on-site recovery team expected to take responsibility for a potential recipient that is listed at another transplant center?

Committee Response:

The Committee received several comments covering the themes raised in Region 4. Please see Primary Public Comment Concerns/Questions section above for a full response.

Region 5:

- UNOS needs to ensure that we modify the current ABO verification form to mirror any changes.
- The region strongly urges UNOS to work with CMS to determine their role in the ABO verification process. From a member's perspective, this is one of the most highly regulated process and the most complicated. Namely, because all the end result is the same (zero ABO mismatched transplants) it is hard for member to grasp why both UNOS and CMS require different elements to be recorded and reported. Members strongly urged that in the absence of no new cases, the addition of new policies and procedures seemed to be unwarranted.
- Members felt that UNOS does not comprehend the level of effort and work that transplant centers invest in not only changing policies but educating staff. Not just within the transplant program but with transplant and OR services. Again, in the absence of a true patient's safety threat, they are not clear why we would propose these modifications.
- It is also frustrating for members that this continues to an enormous work burden, is one of the leading causes of non-compliance and there is no data to define that because there is non-compliance, there is an increased patient safety risk. If the policies were being violated with such consistency, you would expect that you would see an increase in ABO mismatch transplant – but you don't. So, potentially many of these polices are not needed and are only administrative burden placed on transplant centers.

Committee Response:

The Committee will work with CMS to update the verification templates and provide educational tools to assist with compliance. UNOS staff and the Committee plan to provide educational materials and events to educate about the new policies and to help develop knowledge and skill competencies for those reporting ABO blood types.

ABO compatibility is a regulated area because in the absence of robust checks a patient death occurred. Strong and robust practices help prevent accidental ABO incompatible transplants. There have been subsequent ABO incompatible transplants and near-misses. Please see Primary Public Comment Concerns/Questions section above for a full response.

The Committee is not seeking to create an unnecessary burden. Policies have been rewritten to help make them clearer and make what is needed to comply more evident. Many changes made were for clarity and consistency among donation types and candidates and donors. Changes were proposed to either address safety gaps or further align OPTN policy with CMS.

The Committee strongly disagrees that these policies are not needed.

Region 6:

In many cases OPOs do not have and cannot verify recipient information. Some of the proposal is reasonable, but there is so much wrapped up into this one proposal there is no way to pull out the good sections from the sections that are inconsistent with practice.

Committee Response:

The Committee has received multiple comments concerning the ability to perform a verification at deceased donor organ recovery when the intended recipient is not known. The Committee has proposed post-public comment changes in response to these comments. Please see the Primary Public Comment Concerns/Questions section above for a full response.

The Committee acknowledges that the proposal contains proposed changes to multiple sections. The Committee is appreciative that the region acknowledges that the proposal contains good sections.

Region 7:

- Overall the region expressed frustration that UNOS continues to develop regulatory burden on a process that is already overly regulated. CMS has extensive ABO requirements that differ enough from this proposal that centers will still be required to maintain separate documentation for auditing purposes.
- Members in the region would like the committee to articulate what gaps in the CMS requirements they are trying to fill with this proposal. If there are none, then it would seem more efficient for UNOS to adopt the CMS standards as their own.
- At this point, the level of regulation on this process only assures that most transplant centers will end of being non-compliant since the level of resources that will need to be placed between this proposal and the current CMS requirement is excessive and extensive.
- The region strongly disagrees with requiring the on-sight surgical recovery team responsible for verifying information for recipients that are not their own. This is not only logistically complicated, it places an enormous disincentive to recover organs for other centers.
- Members in the audience who are participating or have been part of the ETT project voiced that many of the requirements are part of the automated system and they are impressed with the system. In light of that, members in the audience were unclear as to why UNOS would change policy now, create additional burden on centers by requiring them to create manual workflows/ documentation and then release an automated system/solution. The new requirements in this proposal should be placed on hold until the automated system is released to all centers and OPOs.

Committee Response:

The Committee has received multiple comments with the themes raised in Region 7. The Committee has proposed some post-public comment changes in response to these comments. Please see the Primary Public Comment Concerns/Questions section above for a full response.

Region 8:

Centers and OPOs will need the OPTN to provide educational resources prior to implementation to ensure that members understand all the changes and requirements. This includes revising the ABO form.

Committee Response:

The Committee will provide educational materials and tools to help the transplant community with changes should they pass including a revised ABO template and competency training.

Region 9:

The region approved the proposal with the following comments:

- Requiring two ABO typing results prior to executing the match run will lead to delays in allocation. In some areas obtaining a second blood type determination can take up to 8 hours. Sending both samples to the lab at the donor hospital doesn't help as the labs can't run a second blood type test without a supervisor signing off and this approval can be difficult to obtain in the middle of the night and on weekends and holidays.

Committee Response:

The Committee recognizes that OPOs may have to change or revisit their current process including working relationships with laboratories to enact this change. The Committee plans to keep this recommended provision in the proposed policy language since this timing is safer and more consistent with complete ABO policy. The Committee will work to provide educational materials and effective practices. The Committee recommends working with hospital and laboratory leadership and providing education on OPTN and CMS requirements. In many cases, OPOs will already have a "historical" blood type result done and will only need one additional sample. Several OPOs currently using this timing for their standard have successfully worked with laboratories to code the second test order differently or flag the second sample as required by regulation to make the practice routine without requiring special approval.

Region 10:

- Members were concerned that this proposal, with the exception of those elements that clarify current language, is not aimed at the right goal. Donor and candidates ABO does not change over time so they are unclear why they have to verify this information on multiple occasions. What is most important is to ensure that the donor organ is being given to the intended candidate – that is where the verification process need to focus.
- Members in the region felt strongly that it was wasteful for centers to spend their limited resources to manually implement these new proposed requirements while an automated solution is close to being released. Centers were concerned that even if there is a lag between this policy being implemented and ETT being universally utilized, they will be required to create new paperwork and educate staff on a manual process to only then turn around and have to create new process and new training for staff about ETT. Member strongly urged UNOS to hold implementation of the new requirements being proposed until ETT is released.

Committee Response:

The committee agrees that confirmation of right person/right organ is an important part of the process. Confirmation of ABO and confirmation of compatibility or intended incompatibility is part of the data checked as chain of custody may change and intended recipients may change. The

Committee has received several comments regarding themes raised in Region 10. Please see the Primary Public Comment Concerns/Questions section above for a full response.

Region 11:

The region approved this proposal and provided the following comments:

- There are many instances when recipients are not yet confirmed at the time of recovery, which is often the case with kidney allocation and local back up scenarios for all organs.
- Many surgical teams come to the recovery site directly from home and will not be equipped with a source that confirms recipient identification and ABO.
- The OPO should be responsible for verifying donor information and the transplant centers should be solely responsible for verifying their recipient and the recipient's compatibility with the donor.
- This proposal adds a level of complexity that will involve non transplant team staff in the ABO verification process which could present a problem for a small transplant program.

Committee Response:

The Committee has received several comments concerning the ability to perform a verification at deceased donor organ recovery when the intended recipient is not known. The Committee has proposed post-public comment changes in response to these comments. Please see the Primary Public Comment Concerns/Questions section above for a full response.

The Committee recognizes that smaller transplant programs may have some issues related to size and implementing certain parts (e.g. organ check in), but that the policy proposed is reasonable and achievable.

4. Committee Public Comment Responses

Kidney Committee:

Proposal to Modify ABO Determination, Reporting, and Verification Requirements

The Committee had some questions regarding the differences between what is being proposed and CMS requirements. UNOS policy staff explained that the two requirements are not exactly aligned (for instance, CMS does not require secondary verification for blood type), but UNOS recently constructed a crosswalk to help with identifying differences. Several committee members expressed the view that education on the changes and tools to help OPTN members comply will be key. In particular, it was suggested that a sample form be provided to transplant programs.

Several members commented in favor of the Committee's approach with respect to allowing transplant programs define 'qualified health care provider', instead of specifying that the individual be licensed.

Sponsoring Committee Response:

The Committee appreciates the opportunity to discuss the proposal. The Committee plans to provide educational tools and to update existing templates in collaboration with CMS.

Living Donor Committee:

A member of the living donor expressed concerns that the proposal should not differ from CMS requirements, as the additional burdens on transplant hospitals would be problematic. Concerns were also expressed about possible over regulation relative to the issues.

The Living Donor Committee invited Operations and Safety to speak to one of their subcommittees for further discussion of concerns. At this meeting, no additional concerns were raised after the presentation outlining the requirements.

Sponsoring Committee Response:

The Committee appreciates the opportunity to discuss concerns about the proposal. The Committee also met with the Living Donor Committee during the proposal's development. The Committee believes it was able to address the initial concerns through further discussion and information provided.

Membership and Professional Standards Committee:

The Committee reviewed this proposal and did not recommend any changes.

Sponsoring Committee Response:

The Committee appreciates the support for the proposal.

Organ Procurement Organization (OPO) Committee:

The proposed policy language states "OPOs and transplant centers must each develop and comply with their own written protocol to perform verifications as outlined in this policy." There was concern from several OPO Committee members about the OPO's ability to complete all of the verifications listed in the policy. The Committee recommended that the OSC consider clearly stating which member is responsible for the verifications listed.

The Committee discussed the issue of candidates not on the match run. The proposal states that most of these cases are due to directed donations or avoiding organ wastage. However, there was some concern that the new requirement to rerun the match run will not address the issue. The Committee asked if there was any discussion about requiring documentation when OPOs allocate to candidates not on the match run. OSC staff noted that the documentation requirements are listed in Policy 5.4.F (Allocation to Candidates Not on the Match Run).

Sponsoring Committee Response:

The Committee intends for the policy to be clear and specific. Original proposed language regarding pre-surgical verifications was written in one section to promote "one stop" shopping for required information. Based on several comments, the Committee has approved changing the proposed language that places specific requirements in appropriate policy sections (e.g. OPO recovery requirements in Policy 2 and recovery hospital living donor recovery requirements in Policy 14). The Committee has made an effort to standardize language used in all policies for donors and candidates and deceased and living donation on the same core safety principles (e.g., all persons have two blood typings prior to being "active" in the OPTN system and eligible for recovery or transplant).

Documentation requirements are listed in Policy 5.4.F (Allocation to Candidates Not on the Match Run). The committee will also pursue working with the kidney committee to add non-O candidates at the very end of allocation algorithms so that ABO blood type compatible candidates will be on match runs.

The Operations and Safety Committee consulted OPO leadership and presented relevant post public comment changes to the OPO Committee. The OPO Committee supported changing the verification at deceased donor recovery to cases “when the intended recipient is known” and eliminating the option for one blood draw sent to two different labs based on CMS feedback. Please see the Primary Public Comment Concerns/Questions section above for a full response.

Pancreas Transplantation Committee:

One of the Committee members asked if there have been recent incidents with ABO incompatibility, because if there had not been recent incidents then he did not see the purpose behind the proposal. The Operations and Safety Committee representative confirmed there had been a recent incident but could not share the details. In addition, UNOS staff explained that current studies show there have been recent near misses that also supports the need for this proposal.

The Operations and Safety Committee representative further explained that the goal of the proposal is to fill in any policy gaps and ensure that Operations and Safety related policies are in alignment with CMS, and to ensure consistent practice across OPOs and Transplant Centers. The representative explained that this proposal will create consistent and firm processes, and with consistent and firm processes in place, OPOs and transplant centers will be able to avoid adverse incidents.

A Committee member explained that it is not the OPO’s responsibility to perform the ABO verification, since the OPO does not know what the recipient’s ABO is except from what the OPO sees on the match-run. The Committee member further explained that transplant program representatives do not arrive at the operating room with printouts of their recipients ABOs. In other words, the proposed policy may be inconsistent with practice. The member explained that he supports the proposal, and supports any safety measure, but he does not believe that the proposal aligns with current practice.

The Operations and Safety Committee representative explained that this proposal is an effort to create consistent practice and that by the nature of the verification process it has to be done in partnership with the OPO and transplant center. Further, the burden of proof for documentation resides with the OPO.

The Committee member explained that he does not support the idea that the OPO has the burden of proof on the ABO verification because the OPO does not have source documentation to compare the donor’s ABO to the candidate’s ABO, and that burden cannot be on OPOs. The member wants to make sure that the CMS language and proposed policy language does not state that it is the OPO’s responsibility to ensure there is ABO compatibility between the donor and the recipient, beyond executing a match run and allocating the organ. The member explained that OPOs do not perform an ABO verification service, while in the donor’s operating room, for the intended recipient.

The Committee voted in support of the proposal pending clarification on what is sufficient practice for OPO’s to comply with the recipient ABO verification process. (13 yes; 0 no; 0 abstained)

Sponsoring Committee Response:

The Committee has received multiple comments concerning the ability to perform a verification at deceased donor organ recovery when the intended recipient is not known. The Committee has proposed post-public comment changes in response to these comments. Please see the Primary Public Comment Concerns/Questions section above for a full response.

Patient Affairs Committee:

The Committee reviewed this proposal and voted in favor of supporting the proposal as written.

Committee Vote: Support-11, abstain-0, against-0

Sponsoring Committee Response:

The Committee appreciates the support for the proposal.

Transplant Administrators Committee:

The TAC suggested that the Operations and Safety Committee (OSC) develop an optional standardized ABO form, template or checklist that transplant hospitals can use and/or reference. The Committee is not requesting the OPTN to be more prescriptive with policy but if the policy is requirement specific, then the OPTN needs to also provide the necessary tools and resources to maintain compliance with the policy.

Committee Vote: 0 in favor, 12 oppose, 0 abstention

Sponsoring Committee Response:

The Committee agrees with this suggestion and will work with CMS to update verification templates.

Transplant Coordinators Committee:

The Committee agreed that patient safety important; however, they did not vote on this proposal and would like the OSC clarify some terminology and consider the following comments:

- a. The proposal needs to better define the location for organ check-in. Currently, the proposal uses "OR suite" and this can have different meanings and can mean different locations for centers.
- b. If the proposal is intended to include both living and deceased donor recoveries from outside operating facilities, then that needs to be clear in the policy language. Current language in the proposal for organ check-ins seems to be for living donors not deceased donors from another hospital. The Committee suggested using "hospital facility" or "OR room" instead of "OR suite or building" as the latter tends to mean the same hospital. The organ check-in requirements for living donors and deceased donor recoveries need to be universal.
- c. The Committee requested clarification of the definition of organ check-in, definition of who is required to check-in the organ when it arrives at the transplant hospital, when is it required, and the required timeline. Also, documentation of the chain of custody is important.
- d. A member also suggested that it be a requirement that all organs are checked in at the OR.
- e. Members thought the electronic labeling system will be helpful in documenting the chain of custody and will decrease organ discards.
- f. The Committee had concerns that the way the proposal reads, it could be assumed that the with the blood specimen label that accompanies the organ can be used as an ABO source document. Members of the Committee agreed that there needs to also be some form of paper/electronic document besides the label on the blood specimen inside the box as a lot of times these labels are handwritten and lends itself to human error. It was also noted that

those labels sometimes fall apart or get damaged and therefore should not be used as the sole source documentation. The policy proposal requirements were reviewed with the Committee that source documents can include: data transmitted directly into an electronic medical record, an original paper source document, original handwritten medical note, a copy of facsimile or original paper source document. A member noted that source documentation should be directly from a lab. Another member stated that blood tube labels should never be allowed to be used as an option for source documentation as labeling is the single most common area of error for OPOs.

- g. Current policy states that you cannot label the red top tubes with ABO and proposed policy is to remove that you cannot label the red top tubes which has been occurring for quite a while now.

Sponsoring Committee Response:

The Committee agrees that the ETT system under development will be very helpful in documenting chain of custody and assist in making organ transplantation safer and more efficient, including reducing organ discards.

The proposed language states that the check in is for both deceased and living donation when an organ arrives from a different operating room suite. The committee intended that this would cover both organs arriving from other hospitals as well as organs arriving from other buildings that are part of the same hospital system. The word suite is used as the check in would not be required if the organ is traveling from one operating room to another operating room in the same operating suite of rooms. Transplant hospitals will need to develop their own protocols that meet the needs of their institutions.

The Committee has tried to achieve the correct balance in proposing this requirement that provides guidance but also allows for some flexibility on the transplant hospital side to carry out the requirement in a way that best meets their operations. The proposed language for the organ check in would require that the organ be checked in upon arrival at the operating suite. The Committee left the actual location to the discretion of the transplant hospital to accommodate varying practices (such as front OR versus blood bank check in).

Labels would not be considered source documents according to the proposal's definition. Labels will be used as part of the organ check-in procedure as that is the primary identification method for the organ at the check-in prior to opening the package.

The proposed policy removes the requirement that the ABO must not be on the red top tube sent with the organ. Current policy states "should" and is not proposed for change so this should accommodate either practice.

5. Individual Public Comment Responses

Comment 1:

Vote: Oppose

Date Posted: 06/13/2014

AOPO appreciates the work of the committee, however, we have concerns for those situations where the intended recipient is not known by the OPO. Section 5.6. When the recipient is not known, the OPO should not be responsible for confirming the 3) recipient unique identifier, 4) ABO, and 5) and 6). Clarification on the definition of a "qualified healthcare professional" would also be helpful.

Committee Response:

The Committee has received multiple comments concerning the ability to perform a verification at deceased donor organ recovery when the intended recipient is not known. The Committee has proposed post-public comment changes in response to these comments. Please see the Primary Public Comment Concerns/Questions section above for a full response.

The Committee has added a definition for “qualified health care professional” in the definitions section of Policy 1. This definition clarifies that the individual organization will define “qualified health care professional” within their own protocol. The OPTN policy does not provide a prescriptive definition.

Comment 2:

Vote: Oppose

Date Posted: 06/13/2014

Concerns with our OPO's ability to confirm ABO in the intended recipient when allocation is still ongoing. Consider adding “if the intended recipient is known” to the policy language. Concerns with our OPO's ability to complete all of the verifications listed in policy 5.6. Consider clearly stating which member is responsible for the verifications listed.

Committee Response:

The Committee has received multiple comments concerning the ability to perform a verification at deceased donor organ recovery when the intended recipient is not known. The Committee has proposed post-public comment changes in response to these comments. Please see the Primary Public Comment Concerns/Questions section above for a full response.

Comment 3:

Vote: Oppose

Date Posted: 06/16/2014

ABO Blood Type Reporting: Although the proposed changes in ABO verifications for donors and recipients are intended to lead to improved safety, they will initially represent a burden to both OPOs and transplant centers to implement and document. Although the requirements are quite clearly spelled out in Table 5-1 and Table 5.6.B, careful and ongoing education will be required to increase the likelihood of OPO and transplant center compliance with the proposed verification changes. Guidance as to best practices as to how to successfully perform the required verification with the least additional burden would be helpful.

The AST agrees with the proposed policy that will require both deceased donor ABO typings to be completed and reported “prior to the match run” versus the current “prior to incision”. The proposed change will reduce the possibility of matches being performed on one potentially erroneous ABO blood typing result. Having two separate ABO tests with two-person verification and reporting for deceased donors prior to the match run will align, in principle, with the current requirement for waitlisted candidates. All living donor candidates will also fall under this safety check should the mandate be enforced for wait list registration of living donor cases prior to transplantation.

Currently in UNet, only one person is required to list a candidate as willing to accept an ABO incompatible organ. The AST disagrees with the proposal which recommends a programming change in UNet that will ONLY warn users to verify that an ABO incompatible transplant is clinically appropriate for each registration before the candidate is permitted to receive such offers. We recommend a proposal rewrite to mandate the two step/2 reviewer(s) process.

ABO Compatibility Verifications: The AST agrees with the proposed organ recovery verification changes for both deceased and living donors. For deceased donors, host OPOs will be responsible for conducting verification prior to organ release to the transplant hospitals. This represents a change from only requiring a time-out and blood type verification when deceased donor organs will remain within the same operating room suite. The timing of the recovery verification has been moved up from “prior to leaving the operating room” to “prior to induction of anesthesia for living donors”. This verification will apply to all living donor organ recoveries not just to those that remain within the same facility as is currently in policy.

The supporting evidence is that a verification done after living donor organ removal, but prior to leaving the operating room is not the safest time.

We also agree with the two other conditional items being proposed: a check-in at organ arrival if the organ will be arriving from a different operating room suite and a pre-procedure verification done prior to induction of anesthesia if transplant surgery will begin prior to organ arrival. The check in can be combined with the final verification if the organ is delivered immediately into the operating room with no break in chain of custody. If surgery is planned to begin prior to organ arrival, the proposed pre- anesthesia verification will add to patient safety. If an accidental incompatibility is discovered after surgery has started when the organ arrives, then patient harm could be done which could have been avoided. This would be more consistent with the CMS requirement to perform verification prior to recipient organ removal in living donation if applicable.

We also agree with the final verification prior to transplant remaining for all deceased and living donor procedures. Timing language specifies that this verification must occur between the time the organ is delivered into the operating room and the first anastomosis to address transplant community questions. Language has been added to the proposal to include the transplanting surgeon as part of the process consistent with current CMS requirements.

We believe the policy proposal to be overly prescriptive and complex and the AST is not supportive of the policy as currently drafted. The complexity of the modifications have not been easy to follow in the proposed policy language. The policy needs to clearly outline requirements. Adding check-in and additional verification will not necessarily improve compliance with ABO policies. In view of the very low reported incidence of catastrophic outcome with an ABO incompatible transplant, we do not find it necessary to redesign the entire process.

For policy 5.6.A, table 5.1, we identified a couple of serious issues with this requirement as currently presented:

1. The policy requires the host OPO in conjunction with the onsite surgical recovery team to perform a deceased donor organ recovery verification which requires a recipient to be identified with unique qualifiers, a recipient blood type, and compatibility in addition to other elements. What process does the host OPO follow when the intended recipient is unknown while the onsite surgical recovery team and OPO are conducting the verification? This being a common occurrence with kidney allocation.

2. When the onsite surgical team is recovering an organ for another transplant center, how can the OPO and surgical recovery team perform the verification without having the required documentation? Is the onsite recovery team expected to take responsibility of verifying a potential recipient who is listed at another transplant center?

Committee Response:

The Committee has received multiple comments concerning the ability to perform a verification at deceased donor organ recovery when the intended recipient is not known. The Committee has proposed post-public comment changes in response to these comments. Please see the Primary Public Comment Concerns/Questions section above for a full response.

ABO Blood Type Reporting:

The Committee appreciates support of this proposed change. The Committee debated what level of warning or process to propose for planned incompatible transplants. The decision to recommend a warning was chosen as this option would be less costly and timely to implement. The Committee, however, plans to research the additional cost and time involved to implement a two-person solution as recommended by the AST. This might be proposed in programming modifications planned for OPTN/UNOS BOD consideration in June 2015.

ABO Compatibility Verifications:

The Committee appreciates support of the following proposed changes:

- Proposed organ recovery verification changes for both deceased and living donors
- Two conditional items: a check-in at organ arrival if the organ will be arriving from a different operating room suite and a pre-procedure verification done prior to induction of anesthesia if transplant surgery will begin prior to organ arrival
- Final verification prior to transplant remaining for all deceased and living donor procedures

The Committee has received several comments regarding other themes raised by the AST. Please see the Primary Public Comment Concerns/Questions section above for a full response.

Comment 4:

Vote: Support

Date Posted: 03/21/2014

All good changes. The policy is still unclear about what type of documentation would be acceptable to prove two people reviewed / verified the candidates blood type prior to waitlist activation. Would be helpful, if some direction were given about the best way to document the two person verification against the blood type source documents. Also would like policy to make OPO generate a blood type source document only with the UNOS ID and not the real name of the patient. Often the UNOS ID is very hard to find when the patient's name is in the main name field. also frequently the UNOS ID is handwritten at the top of the blood type source document.

Committee Response:

The Committee appreciates overall support of the proposal. OSC plans to provide competency training to share effective practices in reviewing source documentation and examples of source documents.

The Committee has proposed a definition for source document. A source document could not be generated with altered data. Addressing how the UNOS ID is marked on a source document

when it was not part of the lab order or result will be further discussed by the Committee. Clinical Laboratory Improvement Amendments (CLIA) regulations require at least two patient identifiers on lab testing results. The test report must indicate the following for positive patient identification: either the patient's name and identification number, or a unique patient identifier and identification number.

Comment 5:

Vote: Support

Date Posted: 06/17/2014

ASTS supports this proposal designed to improve safety and consistency.

Committee Response:

The Committee appreciates support of their proposal.

Comment 6:

Vote: Support

Date Posted: 06/13/2014

ATCO supports this proposal, however, regarding Section 13.5.3 Documentation of updated unacceptable antigens should be programmed into UNET for entering efficiency for the transplant coordinator. If it is programmed into the screen it would be possible to automatically inactivate the recipient if they do not have updated unacceptable antigens in the UNET KPD system. The rationale is that data that is not kept up to date has a much higher risk of cxm failure. 13.10.2 It should be left to the discretion of the recipient transplant center if they want a final crossmatch.

Committee Response:

This comment was referred to the Histocompatibility Committee as it pertains to their proposal.

Comment 7:

Vote: Support

Date Posted: 04/16/2014

Inclusion of a blood type on specimen tube labels increases the risk of testing error due to expectation of a result, particularly in donors and recipients who have been recently transfused. Space limitations on computer-generated labels may allow appropriate reconsideration of this portion of the otherwise well crafted proposal. Additional personnel requirements are covered in 42CFR493.1449(q) and are not met by most OPO labs or HLA labs supporting solid organ transplantation.

Committee Response:

The Committee appreciates the support of the proposal.

Repeating ABO blood type on the red top tube of blood sent with the organ is not required. The red top blood sample is sent as option for transplant hospital use or retyping. In practice, it is unknown how many transplant hospitals are repeating the ABO type. While it could be argued that having the type on the label could introduce bias, there is not sufficient evidence. The current practice appears to be that many do currently label with the ABO blood type. The policy

change was proposed to assist with ETT production that allows either ABO blood type to be included or omitted on the red top tube label for blood specimen sent with the organ.

Comment 8:

Vote: Support

Date Posted: 05/28/2014

There may be a concern about what constitutes a "qualified health care professional" for ABO entry/verification as opposed to RN. Also concern regarding the language in 2.6 "If circumstances require accelerating the donation process to avoid organ wastage, the OPO may proceed and complete these requirements prior to organ release from the operation room", we would suggest "prior to organ release to a transplant center for transplantation", as there are circumstances where the OPO cannot remain in the OR awaiting an ABO result, but may choose to instead return to the office to put the kidneys on pump, for example.

Committee Response:

The Committee appreciates support of the proposal.

The Committee has added a definition for "qualified health care professional" in the definitions section of Policy 1. This definition clarifies that the individual organization will define "qualified health care professional" within their own protocol. The OPTN policy does not provide a prescriptive definition. The OPO and transplant hospital will be able to define what constitutes a qualified health care professional in their individual protocol. They may choose to limit their programs to only allowing "RNs" to report to the OPTN Contractor. The program will have to follow their own definition as they set it up in the protocol.

The Committee agrees with this comment and suggested change. The Committee will propose that the standard for completion of ABO determination and reporting for accelerated donation cases be completed "prior to organ release to a transplant hospital for transplantation".

Comment 9:

Vote: No Opinion

Date Posted: 06/13/2014

OPTN Policy 2.6A still reflects the ability to draw two samples at the same time if tested at different labs which is inconsistent with current CMS standards.

Committee Response:

The Committee acknowledges this inconsistency. CMS representatives participated in part of the public comment review process. Regarding this comment, the discussion involved whether one blood draw of two tubes of blood sent to two different labs (in current OPTN policy) would be acceptable under CMS rules. The OPO CMS representative stated that this would not be compliant under the CMS rules. Their interpretive guidance specifically addressed "split samples" indicating that they were not acceptable. Split samples would include a single needle stick or draw with blood samples drawn at different times.

This safety measure is about patient identification. The safe guard is to have two separate acts of patient identification. If a patient is approached one time and a mistake is made, then both tubes will carry the misidentification mistake.

The OSC after consultation with the OPO Committee is proposing post-public comment changes that will remove allowing one draw/two labs from OPTN/UNOS policy as CMS does not allow this. The OPO Committee provided feedback that they were able to get two blood samples. Policies between the two organizations will be further aligned. Clarification will be made in forthcoming educational materials that one blood draw (one needle stick or central line draw) and two tubes drawn a minute apart does not meet the standard.

Post Public Comment Consideration:

The OSC met via teleconference on August 19, 2014 and in Chicago, IL on September 23, 2014, to review public comment feedback on this proposal and consider post public comment proposal language. Exhibit F contains a comparison of public comment and post public comment language with notes explaining the changes.

The Committee voted unanimously (17 in favor, 0 opposed, 0 abstentions) to send the proposed policy language for consideration by the OPTN/UNOS Board of Directors.

At a meeting of the OPTN/UNOS Board of Directors convened on November 12, 2014 in St. Louis, MO, the following resolution is offered.

A resolution to modify ABO determination, reporting, and verification requirements.

Sponsoring Committee: Operations and Safety Committee

RESOLVED, that additions and modifications to Policies 1.2 (Definitions), 2.6 (Deceased Donor Blood Type Determination and Reporting), 2.15.B (Organ Procurement Procedures) 3.3 (Candidate Blood Type Determination and Reporting before Waiting List Registration), 5.4.B (Order of Allocation), 5.5.A (Receiving and Reviewing Organ Offers), 5.6 (Blood Type Verification Upon Receipt), 5.7 (Released Organs), 13.6.A (Requirements for Match Run Eligibility for Candidates), 13.6.B (Requirements for Match Run Eligibility for Potential KPD Donors), 14.4.A (Medical Evaluations for Living Donors), 14.6 (Registration and Blood Type Verification of Living Donors before Donation), 16.1 (Organs Not Requiring Transport), and 16.4.C (Internal Labeling of Blood and Tissue Typing Materials) as set forth below, effective May 1, 2015.

FURTHER RESOLVED, that programming modifications to ABO incompatible liver registrations and match run displays for candidate blood type and compatibility status as set forth in Exhibit B are hereby approved, effective pending programming and notice to the OPTN membership.

1.2 Definitions

The definitions that follow are used to define terms specific to the OPTN Policies.

Intended incompatible

Donor and candidate primary blood types that are biologically incompatible, but transplantation is permissible according to OPTN policy.

Qualified health care professional

A person who is qualified to perform blood type reporting or verification requirements as defined in the OPO, transplant hospital, or recovery hospital protocol.

Source document

An original record of results, or a photocopy or digital copy of the original record.

2.6 Deceased Donor Blood Type Determination and Reporting

The host OPOs must ensure that each deceased donor's blood type is accurately determined, report the blood type to the OPTN Contractor, and then verify that the correct blood type was reported develop and comply with a written protocol for blood type determination and reporting that includes a two-person verification and reporting process as required below.

2.6.A Deceased Donor Blood Type Determination

The host OPO must ensure that each deceased donor's blood type is accurately determined by testing at least two donor blood samples prior to incision the match run. If the two samples are from the same blood draw, then the samples must be tested by two different laboratories.

Donor blood samples must:

1. Be drawn on two separate occasions
2. Have different collection times
3. Be submitted as separate specimens
4. Have results indicating the same blood type

The host OPO must establish and implement a written protocol for resolving conflicting blood type results. If the final ABO result is different from the initial ABO on the original match run, the host OPO must re-execute the match run and allocate based on the new match run.

The host OPO must document that two separate tests to determine the deceased donor's blood type were performed.

2.6.B Deceased Donor Blood Subtype Determination

When a deceased donor is determined to be blood type A, then subtype testing must be completed. Subtype testing must be performed

~~only on pre-transfusion blood samples. The host OPO may choose whether to perform subtype testing on deceased donors with blood type AB.~~

~~When deceased donor blood type A or AB is sub-typed and found to be non-A₁ or non-A₁B, the host OPO must complete a second subtype test. If the sample used for the second subtype test is from the same blood draw as the sample used for the first subtype test, the second sample must be tested by a different laboratory.~~

~~Host OPOs must complete subtyping on blood type A donors if pre-transfusion samples are available. Subtyping blood type AB donors is optional. If subtyping is completed and used for allocation, then testing must meet *all* of the following requirements:~~

- ~~1. Pre-transfusion blood samples must be used.~~
- ~~2. A second subtype test must be completed if the first subtype result is *either*:
 - ~~• Blood type A, non-A₁~~
 - ~~• Blood type AB, non-A₁B~~~~
- ~~3. Blood samples must be drawn on two separate occasions, have different collection times, and be submitted as separate specimens.~~
- ~~4. Two subtype tests must be completed and indicate the same subtype if results will be reported to the OPTN.~~
- ~~5. If there are conflicting subtype test results, the deceased donor must be allocated based on the primary blood type.~~

~~For all blood type A donors, The the host OPO must document that blood subtype determination tests have been completed to determine the deceased donor's blood subtype subtyping was completed and if not completed, the reason it could not be completed.~~

2.6.C Primary Reporting of Deceased Donor Blood Type and Subtype

~~The host OPO must report the deceased donor's blood type to the OPTN Contractor. The OPO must only report the deceased donor's blood subtype to the OPTN Contractor if two pre-transfusion samples were tested and the test results agree. If there are conflicting subtype test results, the deceased donor must be allocated based on the primary blood type.~~

~~All blood types and subtypes reported to the OPTN Contractor must be entered by a person consulting the source documents from the blood samples used for testing.~~

2.6.D Secondary Reporting of Deceased Donor Blood Type and Subtype

~~In order to verify that the correct blood type and subtype is reported to the OPTN Contractor, each OPO must establish and then implement a protocol for secondary reporting of blood type that is completed by someone:~~

- ~~1. Other than the individual who completed the primary reporting of the donor's blood type to the OPTN Contractor.~~
- ~~2. Consulting source documents from the blood samples used for blood type testing.~~

~~If sub-typing of A or AB blood types is reported and used for allocation, the subtype determination must also be verified. Each OPO must establish and then implement a protocol for secondary reporting of blood subtype that is completed by someone:~~

3. ~~Other than the individual who completed the primary reporting of the blood subtype determination to the OPTN Contractor.~~
4. ~~Consulting both source documents from the two samples used for the blood subtype testing~~

The deceased donor is not eligible for a match run until the host OPO completes verification and reporting as follows:

1. Two different qualified health care professionals, as defined in the host OPO's protocol, must each make an independent report of the donor's blood type to the OPTN Contractor.
2. If the donor's blood subtype will be used for allocation, a qualified health care professional must report the subtype to the OPTN Contractor. This report must be verified by a different qualified health care professional according to the OPO's protocol.
3. Both qualified health care professionals must use all blood type and subtype determination source documents to verify they:
 - a. Contain blood type and subtype (if used for allocation) results for the donor
 - b. Indicate the same blood type and subtype (if used for allocation) on the two test results
 - c. Match the result reported to the OPTN Contractor

The OPO must maintain documentation document that secondary reporting was completed using both sub-typing according to the OPO's protocol and the above requirements.

If donation must be accelerated to avoid organ waste, the host OPO may instead complete these requirements after the match run, but prior to organ release to a transplant hospital for transplantation. The host OPO must document *both* of the following:

1. The reason that both blood type tests (and subtype tests, if used for allocation) could not be completed, verified, and reported prior to the match run.
2. If there are conflicting blood type test results, the host OPO must have protocol for resolving discrepancy and must rerun the match run if the final ABO result is different than the initial ABO on the original match run.
3. That all required blood type and subtype determinations and two-person verification and reporting were completed prior to organ release to a transplant hospital for transplantation.

2.15 Organ Procurement

2.15.A Conflicts of Interest

The organ recovery procedure and the transplantation of organs must *not* be performed by *either* of the following:

1. The potential deceased donor's attending physician at the time of death
2. The physician who declares the time of the potential deceased donor's death

~~2.15.B Organ Procurement Procedures~~ Pre-Recovery Verification

Host OPOs must develop and comply with a written protocol to perform a pre-recovery verification for each organ recovered as required below.

When the intended recipient is known prior to organ recovery, the host OPO must conduct a pre-recovery verification that meets all of the following requirements:

1. Two qualified health care professionals, as defined in the host OPO’s protocol, must perform all verifications.
2. The on-site recovering surgeon must participate to verify that the intended recipient reported by the OPO is on the match run.
3. Verifications must occur prior to organ recovery.
4. The host OPO must use at least one of the acceptable sources during the pre-recovery verification to verify all of the following information in Table 2.1 below. Assistance using an electronic scanner is permitted.

Table 2.1: Pre-Recovery Verification Requirements

<u>Information to verify:</u>	<u>Acceptable Verification Sources:</u>
<u>Donor ID</u>	<ul style="list-style-type: none"> • <u>Donor identification band</u> • <u>OPTN computer system</u>
<u>Organ (and laterality, if applicable)</u>	<ul style="list-style-type: none"> • <u>Donor medical record</u> • <u>OPTN computer system</u>
<u>Donor blood type and subtype (if used for allocation)</u>	<ul style="list-style-type: none"> • <u>Donor blood type and subtype source documents</u>
<u>Intended recipient unique identifier</u>	<ul style="list-style-type: none"> • <u>OPTN computer system</u>
<u>Intended recipient blood type</u>	<ul style="list-style-type: none"> • <u>OPTN computer system</u>
<u>Donor and intended recipient are blood type compatible (or intended incompatible).</u>	<ul style="list-style-type: none"> • <u>OPTN computer system</u>

The host OPO must document that the verifications were completed. The documentation must include date and time of verification, participants, and each information element verified according to the above requirements.

2.15.BC Organ Procurement Procedures

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

3.3 Candidate Blood Type Determination and Reporting before Waiting List Registration

~~Transplant programs must determine and report each transplant candidate's actual blood type before registering them on the waiting list~~ develop and comply with a written protocol for blood type determination and reporting that includes a two-person verification and reporting process as required below.

3.3.A Candidate Blood Type Determination before Registration on the Waiting List

~~The Transplant programs must determine~~ ensure that each candidate's blood type is determined 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 specimens
4. Have results indicating the same blood type

The transplant hospital must establish and implement a written protocol for resolving conflicting blood type results.

The transplant hospital must document that two separate tests to determine the candidate's blood type were performed.

3.3.B Secondary Reporting of Candidate Blood Type

~~After the candidate's blood type data are reported to the OPTN Contractor, the candidate will be added to the waiting list but will not be registered as an active candidate until secondary reporting and verification of the candidate's blood type has been completed.~~

~~Each transplant program must develop and comply with a written protocol for secondary reporting of blood type that is completed by someone:~~

1. ~~Other than the individual who reported the candidate's blood type determination at registration on the waiting list.~~
2. ~~Using source documents from the two blood samples used for the blood type testing.~~

The candidate is not eligible to appear on a match run until the transplant program completes verification and reporting as follows:

1. Two different qualified health care professionals, as defined in the transplant program's protocol, must each make an independent report of the candidate's blood type to the OPTN Contractor.
2. Both qualified health care professionals must use all blood type determination source documents to verify they:
 - a. Contain blood type results for the candidate
 - b. Indicate the same blood type on the two test results

c. Match the result reported to the OPTN Contractor

Once the second report is made and two identical blood types are verified, then the candidate has met blood type requirements to appear on a match run.

The transplant program must maintain documentation of this verification document that reporting was completed according to the program's protocol and the above requirements.

5.4.B Order of Allocation

The process to allocate deceased donor organs occurs with these steps:

1. The match system eliminates candidates who cannot accept the deceased donor based on size or blood type.
2. The match system ranks candidates according to the allocation sequences in the organ allocation policies.
3. OPOs must first offer organs to potential recipients in the order that the potential recipients appear on a match run.
4. If no transplant program on the initial match run accepts the organ, the host OPO may give transplant programs the opportunity to update their candidates' data with the OPTN Contractor. The host OPO may must run an updated match run and to allocate the organ according to the updated candidate data.
5. If no transplant program within the DSA or through an approved regional sharing arrangement accepts the organ, the Organ Center will allocate an abdominal organ first regionally and then nationally, according to allocation Policies. The Organ Center will allocate thoracic organs according to *Policy 6: Allocation of Hearts and Heart-Lungs* and *Policy 10: Allocation of Lungs*.
6. Members may export deceased donor organs to hospitals in foreign countries only after offering these organs to all potential recipients on the match run. Members must submit the *Organ Export Verification Form* to the OPTN Contractor prior to exporting deceased donor organs.

This policy does not apply to VCA transplants; instead, members must allocate VCAs according to Policy 12.2: VCA Allocation.

5.5 Receiving and Accepting Organ Offers

5.5.A Receiving and Reviewing Organ Offers

Transplant hospitals must view organ offers and respond to these offers through the match system. The previous sentence does not apply to VCA transplants.

The transplanting surgeon at the receiving transplant hospital is responsible for ensuring the medical suitability of organs offered for transplant to potential recipients, including whether compatibility of deceased donor and candidate blood types (and donor subtype, when used for allocation) are compatible or intended incompatible.

5.6 Blood Type Verification upon Receipt Organ Check-In

~~When the organ arrives at the transplant hospital and prior to transplant, the transplant hospital must verify the accuracy of the donor ID and blood type against the potential recipient's blood type. Blood subtype accuracy for a deceased or living donor and potential recipient must also be~~

verified if used for allocation. The transplant hospital must document that these verifications occurred.

Transplant hospitals must develop and comply with a written protocol to perform organ check-ins as required below.

The transplant hospital must complete an organ check-in any time an organ is recovered outside the operating suite where the transplant will take place. The organ check-in must be completed when the organ arrives at the recipient's operating suite prior to opening the organ's external shipping container.

The transplant hospital must use the OPTN external organ label to confirm receipt of the expected organ by verifying:

1. The expected donor ID
2. Organ type and laterality (if applicable)

Assistance using an electronic scanner is permitted.

The organ check-in and pre-transplant verification according to *Policy 5.7 Pre-Transplant Verification* may be combined if *both* of the following occur:

1. A member of the organ recovery team is accompanying the organ
2. The organ is immediately brought into the recipient operating room upon arrival to the transplant hospital

The transplant hospital must document that the organ check-in was completed.

5.7 Released Organs Pre-Transplant Verification

Transplant hospitals must develop and comply with a written protocol to perform pre-transplant verifications as required below.

5.7.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. The intended recipient must be present in the operating room
3. The verification must occur:
 - a. Prior to induction of general anesthesia
 - b. If the patient has been receiving continuous sedation prior to arrival in the operating room, then prior to incision
4. 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 in Table 5.1 below. Assistance using an electronic scanner is permitted.

Table 5.1: Pre-Transplant Verification Prior to Organ Receipt Requirements

<u>Information to Verify:</u>	<u>Acceptable Verification Sources:</u>
<u>Expected donor ID</u>	<ul style="list-style-type: none"> • <u>OPTN computer system</u> • <u>Recipient medical record</u>
<u>Expected organ (and laterality if applicable)</u>	<ul style="list-style-type: none"> • <u>OPTN computer system</u> • <u>Recipient medical record</u>
<u>Expected donor blood type and subtype (if used for allocation)</u>	<ul style="list-style-type: none"> • <u>Donor blood type and subtype source documents</u> • <u>OPTN computer system</u>
<u>Recipient unique identifier</u>	<ul style="list-style-type: none"> • <u>Recipient identification band</u>
<u>Recipient blood type</u>	<ul style="list-style-type: none"> • <u>Recipient blood type and subtype source documents</u> • <u>Recipient medical record</u>
<u>Expected donor and recipient are blood type compatible (or intended incompatible).</u>	<ul style="list-style-type: none"> • <u>OPTN computer system</u> • <u>Recipient medical record</u> • <u>Attestation following verification of donor and recipient blood types</u>

If a pre-transplant verification was conducted prior to organ receipt, the transplant hospital must document that the verification was completed. The documentation must include date and time of verification, participants, and each information element verified according to the above requirements.

5.7.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 the following requirements:

1. The transplant surgeon and another licensed health care professional must participate in the verification
2. The intended recipient must be present in the operating room
3. The verification must occur after the organ arrives in the operating room, but prior to anastomosis of the first organ
4. 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 Table 5.2 below. Assistance using an electronic scanner is permitted.

Table 5.2: Pre-Transplant Verification Upon Organ Receipt Requirements

<u>Information to Verify:</u>	<u>Acceptable Verification Sources:</u>
<u>Donor ID</u>	<ul style="list-style-type: none"> • <u>External and internal organ package labels</u> • <u>Documentation with organ</u>
<u>Organ (and laterality if applicable)</u>	<ul style="list-style-type: none"> • <u>Organ received</u>
<u>Donor blood type and subtype (if used for allocation)</u>	<ul style="list-style-type: none"> • <u>Donor blood type and subtype source documents</u>
<u>Recipient unique identifier</u>	<ul style="list-style-type: none"> • <u>Recipient identification band</u>
<u>Recipient blood type</u>	<ul style="list-style-type: none"> • <u>Recipient blood type source documents</u> • <u>Recipient medical record</u>
<u>Donor and recipient are blood type compatible (or intended incompatible)</u>	<ul style="list-style-type: none"> • <u>OPTN computer system</u> • <u>Recipient medical record</u> • <u>Attestation following verification of donor and recipient blood types</u>
<u>Correct donor organ has been identified for the correct recipient</u>	<ul style="list-style-type: none"> • <u>Recipient medical record</u> • <u>OPTN computer system</u>

The transplant hospital must document that the pre-transplant verification after organ arrival was completed. The documentation must include date and time of verification, participants, and each information element verified according to the above requirements.

5.78 Released Organs

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

13.6 Matching within the OPTN KPD Program

13.6.A Requirements for Match Run Eligibility for Candidates

The OPTN KPD program will only match candidates who comply with *all* of the following requirements:

1. The candidate's transplant hospital must comply with *Policies 5.5.A: Receiving and Reviewing Organ Offers and 5.5.D: Blood-Type Verification upon Receipt, 5.6 Organ Check-In, and 5.7 Pre-Transplant Verification.*

13.6.B Requirements for Match Run Eligibility for Potential KPD Donors

The OPTN KPD program will only match potential KPD donors that comply with *all* of the following requirements:

1. The transplant hospital registering the potential KPD donor must perform blood typing and subtyping as required by *Policy 14.4.A 14.5: Living Donor Blood type Type Determination and Reporting* with the following modifications:
 - a. The transplant hospital registering the potential KPD donor must report the potential KPD donor's actual blood type to the OPTN Contractor
 - b. ~~Someone, other than the person~~ A qualified health care professional, other than the qualified health care professional who initially reported the potential KPD donor's blood type to the OPTN Contractor, must compare the blood type from the two source documents, and separately report the potential KPD donor's actual blood type to the OPTN Contractor
 - c. The potential KPD donor is not eligible for a KPD match run until the transplant hospital verifies and reports two identical blood types

14.4 Medical Evaluation Requirements for Living Donors

14.4.BA Living Kidney Donor Medical Evaluation Requirements

14.4.CB Required Medical Evaluation Protocols for Liver Recovery Hospitals

14.4.A 14.5 Living Donor Blood Type Determination and Reporting

Recovery hospitals must develop and comply with a written protocol for blood type determination and reporting that includes a two-person verification and reporting process as required below.

14.4.5.A Living Donor Blood type Type Determination

The recovery hospital must ensure that ~~blood typing of each living donor's blood type is performed~~ determined by testing at least on two separate occasions before the recovery donor blood samples prior to generation of the living donor ID. ~~are defined as two blood samples taken at different times, and sent to the same or different laboratories.~~

Donor blood samples must:

1. Be drawn on two separate occasions
2. Have different collection times
3. Be submitted as separate specimens
4. Have results indicating the same blood type

The recovery hospital must establish and implement a written protocol for resolving conflicting blood type results.

The recovery hospital must document that two separate tests to determine the living donor's blood type were performed.

14.5.B Living Donor Blood Subtype Determination

The recovery hospital subtyping a living donor whose initial subtype test indicates the donor to be non-A₁ (negative for A₁) or non-A₁B (negative for A₁B), must ensure a second determination test is performed prior to living donation to assess the accuracy of the result. Blood samples for subtype testing must be taken on two separate occasions, defined as two samples taken at different times. Samples tested must not be taken after a blood transfusion. When the initial and second determination subtypings are the same result, the result can be used to determine transplant compatibility with the intended recipient or any other potential recipient. If the initial and second determination subtyping results are not the same, the donor must be allocated based on the primary blood type, A or AB.

If subtyping is used to ensure transplant compatibility or allocation, then testing must meet *all* of the following requirements:

1. Pre-transfusion blood samples must be used.
2. A second subtype test must be completed if the first subtype result is *either*:
 - Blood type A, non-A₁
 - Blood type AB, non-A₁B
3. Blood samples must be drawn on two separate occasions, have different collection times, and be submitted as separate specimens.
4. Two subtype tests must be completed and indicate the same subtype if results will be reported to the OPTN.
5. If there are conflicting subtype test results, the living donor must be allocated based on the primary blood type.

When subtyping is used to ensure transplant compatibility or allocation, the recovery hospital must document that blood subtype determination tests have been completed according to the above requirements.

14.5.C Reporting of Living Donor Blood Type and Subtype

The living donor will not receive a donor ID until the recovery hospital completes verification and reporting as follows:

1. Two different qualified health care professionals, as defined in the recovery hospital's protocol, must each make an independent report to the OPTN Contractor for blood type. Recovery hospitals performing VCA recoveries must instead establish and implement a written protocol for two different qualified health care professionals, as defined in the recovery hospital's protocol, to make an independent report to the living donor's medical record.
2. If blood subtype is used for ensuring transplant compatibility or allocation, a qualified health care professional must report blood subtype to the OPTN Contractor. This report must be verified by a different qualified health care professional according to the recovery hospital's protocol. Recovery hospitals performing VCA recoveries must instead establish and implement a written protocol for a qualified health care professional to report the blood subtype to the living donor's medical record if the blood subtype is used for ensuring transplant compatibility or allocation.
3. Both qualified health care professionals must use all blood type and subtype determination source documents to verify they:
 - a. Contain blood type and subtype (if used for ensuring transplant compatibility or allocation) results for the donor
 - b. Indicate the same blood type and subtype (if used for ensuring transplant compatibility or allocation) on the two test results
 - c. Match the result reported to the OPTN Contractor

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

14.6 Registration and Blood Type Verification of Living Donors before

Recovery hospitals must use source documents from both an initial and second determination blood typings and subtypings (when used to determine transplant compatibility), to enter the living donor's blood type data on the *Living Donor Feedback Form*. Additionally, each living donor program must develop and comply with a protocol to verify that the living donor's blood type and type was correctly entered on *the Living Donor Feedback Form* with both the initial and second determination blood typing and subtyping source documents by an individual other than the person initially entering the donor's blood type data.

Recovery hospitals must document that each blood typing and subtyping entry was performed according to the program's protocol and must maintain this documentation.

This policy does not apply to VCA transplants.

14.56 Psychosocial Evaluation Requirements for Living Donors

14.7 Placement of Living Donor Organs

14.8 Living Donor Pre-Recovery Verification

Recovery hospitals must develop and comply with a written protocol to perform pre-recovery verifications as required below.

The recovery hospital must conduct a pre-recovery verification that meets *all* of the following requirements:

1. The recovery surgeon and another licensed health care professional must participate in the verification
2. The living donor must be present in the operating room
3. The verification must occur prior to the induction of general anesthesia
5. Recovery hospitals must use at least one of the acceptable sources during the pre-recovery verification to verify all of the following information in Table 14.3 below. Assistance using an electronic scanner is permitted.

Table 14.3: Pre-Recovery Verification Requirements

<u>Information to verify:</u>	<u>Acceptable Verification Sources:</u>
<u>Donor ID</u>	<ul style="list-style-type: none"> • <u>Donor identification band</u>
<u>Organ type and laterality (if applicable)</u>	<ul style="list-style-type: none"> • <u>OPTN computer system</u>
<u>Donor blood type and subtype (if used for ensuring transplant compatibility or allocation)</u>	<ul style="list-style-type: none"> • <u>Donor blood type and subtype source documents</u>

<u>Intended recipient unique identifier</u>	<ul style="list-style-type: none"> • <u>Recipient medical record</u> • <u>OPTN computer system</u>
<u>Intended recipient blood type</u>	<ul style="list-style-type: none"> • <u>Recipient medical record</u> • <u>OPTN computer system</u>
<u>Donor and intended recipient are blood type compatible (or intended incompatible).</u>	<ul style="list-style-type: none"> • <u>OPTN computer system</u> • <u>Recipient medical record</u> • <u>Attestation following verification of donor and recipient blood types</u>
<u>Correct donor organ has been identified for the correct intended recipient</u>	<ul style="list-style-type: none"> • <u>Donor medical record</u> • <u>OPTN computer system</u>

The recovery hospital must document that the verification was completed. The documentation must include date and time of verification, participants, and each information element verified according to the above requirements.

14.89 Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials

14.10 Living Donor Organ Check-In

Transplant hospitals must perform organ check-ins as required by *Policy 5.6: Organ Check-In.*

14.11 Living Donor Pre-Transplant Verification

Transplant hospitals must perform pre-transplant verifications as required by *Policy 5.7: Pre-Transplant Verification.*

14.9-12 Reporting Requirements

16.1 Organs Not Requiring Transport

~~The transplant hospital and host OPO (if applicable) must develop and follow a protocol to ensure that the correct living or deceased donor organ is transplanted into the correct recipient when *either* of the following occurs:~~

- ~~• Organs are recovered from a deceased donor and remain in the same operating suite as the intended recipient~~
- ~~• Organs are recovered from a living donor and remain in the same facility as the intended recipient~~

~~Time outs must occur:~~

- ~~1. Before the organ leaves the deceased or living donor operating room~~

~~2. Again when the organ arrives at the potential recipient's operating room~~

~~During these time outs and before the transplant occurs, the transplant hospital must confirm and document that a member of the transplant team identified the correct organ for the correct potential recipient prior to transplant according to *Policy 5.6: Blood Type Verification upon Receipt*.~~

16.4.C Internal Labeling of Blood and Tissue Typing Materials

Each separate specimen container of blood or tissue typing material must have a label that will remain secured to the container under normal conditions of transport. The label must include the donor ID and at least *one* of the following identifiers:

- Locally assigned unique ID
- Donor date of birth
- Donor initials

Additionally each specimen should be labeled with *both* of the following:

- The date and time the sample was procured
- The type of tissue

The donor blood type and subtype, if used for allocation, should be included on tissue typing material ~~but must not be included on and~~ blood samples if known. If the donor ID or blood type is not available during the preliminary evaluation of a donor, a locally assigned unique ID and one other identifier for the transportation of initial screening specimens may be used. The OPO must document in the OPO donor record all unique identifiers used to label tissue typing specimens.

#

Exhibit E: Comparison Between OPTN and CMS Requirements

(Revised October 2014)

Comparison of ABO Determination, Reporting, and Verification Requirements			OPTN	CMS	
ABO Determination	Candidate	Transplant hospital must have protocol	DD,LD ¹	DD,LD	
		Two separate blood type determination tests required	DD,LD		
		Blood samples must be drawn on separate occasions			
	Donor	Must have protocol	DD,LD	DD	
		Two separate blood type determination tests required	DD,LD	DD	
		Blood samples must be collected on separate occasions	LD		
		If samples are from same blood draw, then must go to different labs	DD		
		Blood type A must be subtyped	DD		
Pre-transfusion blood specimens must be used for subtyping		DD, LD			
If first subtype result is blood type A, non-A ₁ or blood type AB, non-A ₁ B, then two separate subtype tests must be done					
ABO Reporting	Candidate	Blood type tests must be completed and reported prior to Waitlist registration	DD, LD	DD,LD	
	Donor	Blood type tests must be completed and reported prior to:			DD
		• Organ recovery		DD	
		• Incision		DD	
		• Match run		DD	
	• Generation of Donor ID		LD		
	Both	Reports must be done by a qualified health care professional as defined in individual protocol		DD, LD ²	
Two different persons must each independently report identical blood types to OPTN Both persons must consult each source document with blood type and subtype test results when reporting			DD, LD ²		
ABO Verification	Organ Recovery	Must have protocol:			
		• Host OPO		DD	DD
		• Recovery (transplant) hospital		LD	LD
		Verification must be done:			
		• If organs will remain within same operating room suite		DD	
		• If organs will remain within same operating room facility		LD	
		• When intended recipient is known		DD	DD
		• All recoveries		LD	LD
Verification must be done:					

Comparison of ABO Determination, Reporting, and Verification Requirements			OPTN	CMS
		• Prior to general anesthesia	LD	
		• Prior to organ recovery	DD	DD,LD
		• Before the organ leaves the operating room	DD, LD	
Organ Check In		When organ recovered in different operating room suite from recipient, transplant hospital must check in the organ Requires confirmation of expected donor ID, organ type and laterality	DD,LD	
		May be combined with pre-transplant verification after organ arrival if member of recovery team accompanies organ and organ will go immediately into OR		
ABO Verification	Organ Pre-Transplant	Must have protocol	DD,LD	DD,LD
		Verification must be done:		
		• “Prior to removal of recipient organ (if applicable)”		LD
		• “After an organ arrives at a transplant center, prior to transplantation”		DD
		• After organ arrival and prior to first anastomosis	DD,LD	
• “Upon organ arrival and prior to transplantation”	DD,LD			
• Prior to general anesthesia, if surgery will start prior to organ arrival	DD,LD			
ABO Verification	Both	Verifications must be done by:		
		• Two persons	DD,LD	DD,LD
		Verifications must be done by:		
		• Licensed health care professional		DD,LD
		• Qualified health care professional	DD,LD	
		• Transplant surgeon must participate	DD,LD	DD,LD
		Verification must confirm the following information:		
		• Donor and recipient unique identifiers	DD,LD	DD,LD
• Donor and recipient blood types	DD,LD	DD,LD		
• Compatibility check of donor and recipient blood types	DD,LD	DD,LD		

Comparison of ABO Determination, Reporting, and Verification				
		• Donor and recipient are the intended pair for transplant	DD,LD	DD,LD
		Verification may be done using the following sources:		
		• Donor or recipient identification band	DD,LD	
		• Donor or recipient medical record	DD,LD	*
		• OPTN computer system	DD,LD	*
		• Donor or recipient ABO blood type and subtype source documents	DD,LD	*
		• OPTN external labels (check-in verification only)	DD,LD	

Key:

- OPTN = Organ Procurement and Transplantation Network
- CMS = Centers for Medicaid and Medicare Services
- BOLD** = OPTN Proposed
- ~~Strikethrough~~ = OPTN Deleted or Changed
- DD = Deceased Donation
- LD = Living Donation
- * Interpretive guidance

For more information on CMS regulations please see:

- Conditions For Coverage of Specialized Services Furnished by Suppliers, Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations. [42 CFR 486, Subpart G. \(§ 486.344\)](#)
- Conditions of Participation for Hospitals, Requirements for Specialty Hospitals. [42 CFR 482, Subpart E, Transplant Center Process Requirements: \(§ 482.90\)](#) and [\(§ 482.92\)](#)

Exhibit F: Comparison Between Public Comment and Post Public Comment Language

Public Comment (If adopted) Language does not contain strikethroughs and underlines	Post Public Comment (if adopted) Language does not contain strikethroughs and underlines	Summary of changes
<p>1.2 Definitions</p> <p>Source document An original record of data or results recorded. A source document may be:</p> <ul style="list-style-type: none"> • Data transmitted directly into an electronic medical record, • An original paper source document, • An original handwritten medical note, or • A copy or facsimile of an original paper source document. <p>A source document must not have been altered following the first recording.</p>	<p>1.2 Definitions The definitions that follow are used to define terms specific to the OPTN Policies.</p> <p>Intended incompatible Donor and candidate primary blood types that are biologically incompatible but transplantation is permissible according to OPTN policy.</p> <p>Qualified health care professional A person who is qualified to perform blood type reporting or verification requirements as defined in the OPO, transplant hospital, or recovery hospital protocol.</p> <p>Source document An original record of results or a or a photocopy or digital copy of the original record.</p>	<ul style="list-style-type: none"> • Intended incompatible-new definition as phrase used several times • Source document-removed examples. Examples not put into policy. Added photo or digital copy
<p>2.6 Deceased Donor Blood Type Determination and Reporting</p> <p>The host OPO must:</p> <ol style="list-style-type: none"> 4. Ensure that each deceased donor’s blood type is determined. 5. Report the blood type to the OPTN Contractor. 6. Develop and comply with a written protocol for blood type determination and reporting that defines a qualified health care professional and includes a two-person verification and reporting process. 	<p>2.6 Deceased Donor Blood Type Determination and Reporting</p> <p>Host OPOs must develop and comply with a written protocol for blood type determination and reporting that includes a two-person verification and reporting process as required below.</p>	<ul style="list-style-type: none"> • Substantive change: Removed option to have one blood draw for two samples sent to different labs after discussion with CMS OPO reps-this is not acceptable under CMS and they are not amenable to changing this. Must have two separate blood draw events. Two draws are safer to reduce patient identification/labeling errors. (OPTN had two options: 1 draw 2 labs or 2 draws but now only 2 draws to match with CMS)
<p>2.6.A Deceased Donor Blood Type Determination</p>	<p>2.6.A Deceased Donor Blood Type Determination</p>	

Public Comment (If adopted) Language does not contain strikethroughs and underlines	Post Public Comment (if adopted) Language does not contain strikethroughs and underlines	Summary of changes
<p>The host OPO must ensure that each deceased donor’s blood type is accurately determined by testing at least two donor blood samples prior to incision the match run.</p> <p>Two samples may be drawn on two separate occasions defined as samples drawn at two different times or the two samples may be from the same blood draw.</p> <p>If the two samples are from the same blood draw, then the samples must be tested by two different laboratories.</p> <p>The host OPO must document that two separate tests to determine the deceased donor’s blood type were performed.</p>	<p>The host OPO must ensure that each deceased donor’s blood type is determined by testing at least two donor blood samples prior to the match run.</p> <p style="text-align: center;">Donor blood samples must:</p> <ol style="list-style-type: none"> 1. Be drawn on two separate occasions 2. Have different collection times 3. Be submitted as separate specimens 4. Have results indicating the same blood type <p>The host OPO must establish and implement a written protocol for resolving conflicting blood type results. If the final ABO result is different from the initial ABO on the original match run, the host OPO must re-execute the match run and allocate based on the new match run.</p> <p>The host OPO must document that two separate tests to determine the deceased donor’s blood type were performed.</p>	<ul style="list-style-type: none"> • Clause added on how to handle discrepant blood type results. <p>Style changes:</p> <ul style="list-style-type: none"> • Removal of determination and reporting clauses as redundant in first clause (2.6) • Moved need to define qualified health care professional to 2.6.C as it applies to reporting • Clean up language for separate occasions • Put 2.6.A in list format • Other clean up language changes
<p>2.6.B Deceased Donor Blood Subtype Determination</p> <p>All of the following apply to subtype determination:</p> <ol style="list-style-type: none"> 1. Pre-transfusion blood samples must be used for all subtype testing. 2. Subtyping on blood type A must be completed if pre-transfusion samples are available. 3. Subtyping on blood type AB is optional if pre-transfusion samples are available. 4. If the blood samples are from the same blood draw, then the samples must be tested by two different laboratories. 5. Two subtype tests must be completed if subtyping results will be reported to the OPTN for allocation use including all blood type A, non-A1 and blood type AB, non-A1B results. 	<p>2.6.B Deceased Donor Blood Subtype Determination</p> <p>Host OPOs must complete subtyping on blood type A donors if pre-transfusion samples are available. Subtyping blood type AB donors is optional. If subtyping is completed and used for allocation, then testing must meet <i>all</i> of the following requirements:</p> <ol style="list-style-type: none"> 1. Pre-transfusion blood samples must be used. 2. A second subtype test must be completed if the first subtype result is <i>either</i>: <ul style="list-style-type: none"> • Blood type A, non-A₁ • Blood type AB, non-A₁B 3. Blood samples must be drawn on two separate occasions, have different collection times, and be submitted as separate specimens. 4. Two subtype tests must be completed and indicate the same subtype if results will be reported to the OPTN. 	

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<p>6. If two tests do not indicate the same subtype, then the donor must be allocated on primary blood type.</p> <p>The host OPO must document that blood subtype determination tests have been completed to determine the deceased donor’s blood subtype.</p>	<p>5. If there are conflicting subtype test results, the deceased donor must be allocated based on the primary blood type.</p> <p>For all blood type A donors, the host OPO must document that subtyping was completed and if not completed, the reason it could not be completed.</p>	
<p>2.6.C Reporting of Deceased Donor Blood Type and Subtype</p> <p>All of the following apply to reporting of deceased donor blood type and subtype:</p> <p>1.A. Blood Type: Two different qualified health care professionals must each make an independent report to the OPTN Contractor for blood type.</p> <p>B. Subtype: One qualified health care professional must report blood subtype to the OPTN Contractor if used for allocation. Report accuracy must be verified by a different qualified health care professional in accordance with the OPO’s protocol.</p> <p>2. Both qualified health care professionals must consult all source documents used for blood type and subtype determination.</p> <p>3. Each qualified health care professional must verify that the source documents:</p> <p>A. contain blood type and subtype (if used for allocation) results for the donor</p> <p>B. indicate two results with the same blood type and subtype (if used for allocation)</p> <p>The OPO must maintain documentation that reporting was completed according to the OPO’s protocol consulting source documents containing each blood type and subtype (if used for allocation) test result.</p>	<p>2.6.C Reporting of Deceased Donor Blood Type and Subtype</p> <p>The deceased donor is not eligible for a match run until the host OPO completes verification and reporting as follows:</p> <ol style="list-style-type: none"> 1. Two different qualified health care professionals, as defined in the Host OPO’s protocol, must each make an independent report to the OPTN Contractor for blood type. 2. If blood subtype is used for allocation, a qualified health care professional must report blood subtype to the OPTN Contractor. This report must be verified by a different qualified health care professional according to the OPO’s protocol. 3. Both qualified health care professionals must use all source documents used for blood type and subtype determination to verify they: <ol style="list-style-type: none"> a. Contain blood type and subtype (if used for allocation) results for the donor b. Indicate the same blood type and subtype (if used for allocation) on the two test results c. Match the result reported to the OPTN Contractor <p>The OPO must maintain documentation that reporting was completed according to the OPO’s protocol and above requirements.</p> <p>If donation must be accelerated to avoid organ waste, the OPO may instead complete these requirements prior to organ release to a transplant hospital for transplantation. The host OPO must document both of the following:</p>	

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<p>The deceased donor is not eligible for a match run until the host OPO completes two blood type and subtype (if used for allocation) determinations and two-person verification and reporting for two identical blood types and subtypes (if used for allocation).</p> <p>If circumstances require accelerating the donation process to avoid organ wastage, the OPO may proceed and complete these requirements prior to organ release from the operating room.</p> <p>In such an event, the host OPO must maintain documentation of all of the following:</p> <ol style="list-style-type: none"> 1. The reason that both blood type tests (and subtype if used for allocation) could not be completed, verified, and reported prior to the match run. 2. That the host OPO completed all required blood type and subtype determinations and two-person verification and reporting prior to organ release from the operating room. 	<ol style="list-style-type: none"> 1. The reason that both blood type tests (and subtype tests, if used for allocation) could not be completed, verified, and reported prior to the match run. 2. That the host OPO completed all required blood type and subtype determinations and two-person verification and reporting prior to organ release to a transplant hospital for transplantation. 	
	<p>2.15.B Pre-Recovery Verification</p> <p>Host OPOs must develop and comply with written protocols to perform a pre-recovery verification for each organ procured as required below.</p> <p>When the intended recipient is known prior to organ recovery, the host OPO must conduct a pre-recovery verification that meets <i>all</i> of the following requirements:</p> <ol style="list-style-type: none"> 1. Two qualified health care professionals, as defined in the host OPO’s protocol, must perform all verifications. 2. The on-site recovering surgeon must participate to verify that the intended recipient reported by the OPO is on the match run. 3. Verifications must occur prior to organ recovery. 	<ul style="list-style-type: none"> • Substantive change: Only covers “when the intended recipient is known” versus all cases as originally proposed. Done in response to public comment. Committee plans to work on electronic solution, which will address when the intended recipient is not known prior to recovery. • Substantive change: Timing is now prior to organ recovery due to use of only “when the intended recipient is known”. Timing had

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	<p>4. The host OPO must use at least one of the acceptable sources during the pre-recovery verification to verify all of the following information in Table 2.X below. Assistance using an electronic scanner is permitted.</p> <p style="text-align: center;">Table 2.X: Pre-Recovery Verification Requirements</p> <table border="1" data-bbox="846 516 1598 1084"> <thead> <tr> <th data-bbox="846 516 1213 574">Information to verify:</th> <th data-bbox="1213 516 1598 574">Acceptable Verification Sources:</th> </tr> </thead> <tbody> <tr> <td data-bbox="846 574 1213 654">Donor ID</td> <td data-bbox="1213 574 1598 654"> <ul style="list-style-type: none"> • Donor identification band • OPTN computer system </td> </tr> <tr> <td data-bbox="846 654 1213 734">Organ type and laterality (if applicable)</td> <td data-bbox="1213 654 1598 734"> <ul style="list-style-type: none"> • OPTN computer system </td> </tr> <tr> <td data-bbox="846 734 1213 834">Donor blood type and subtype (if used for allocation)</td> <td data-bbox="1213 734 1598 834"> <ul style="list-style-type: none"> • Donor blood type and subtype source documents </td> </tr> <tr> <td data-bbox="846 834 1213 914">Intended recipient unique identifier</td> <td data-bbox="1213 834 1598 914"> <ul style="list-style-type: none"> • OPTN computer system </td> </tr> <tr> <td data-bbox="846 914 1213 993">Intended recipient blood type</td> <td data-bbox="1213 914 1598 993"> <ul style="list-style-type: none"> • OPTN computer system </td> </tr> <tr> <td data-bbox="846 993 1213 1084">Donor and intended recipient are blood type compatible (or intended incompatible).</td> <td data-bbox="1213 993 1598 1084"> <ul style="list-style-type: none"> • Donor medical record • OPTN computer system </td> </tr> </tbody> </table>	Information to verify:	Acceptable Verification Sources:	Donor ID	<ul style="list-style-type: none"> • Donor identification band • OPTN computer system 	Organ type and laterality (if applicable)	<ul style="list-style-type: none"> • OPTN computer system 	Donor blood type and subtype (if used for allocation)	<ul style="list-style-type: none"> • Donor blood type and subtype source documents 	Intended recipient unique identifier	<ul style="list-style-type: none"> • OPTN computer system 	Intended recipient blood type	<ul style="list-style-type: none"> • OPTN computer system 	Donor and intended recipient are blood type compatible (or intended incompatible).	<ul style="list-style-type: none"> • Donor medical record • OPTN computer system 	<p>been prior to organ release. Modified language is consistent with CMS.</p> <p>Style changes:</p> <ul style="list-style-type: none"> • Section moved to OPO Chapter (previously in 5.6) done in response to public comment • Use “Pre-Recovery” instead of “deceased donor organ recovery” • Required verification info and acceptable sources put into table • Substitute “electronic” for “bar code” • Two person process can be assisted by electronic scanner (Not one person/not consistent with CMS) • Documentation clause specific to reduce confusion and not require documentation of which source used
Information to verify:	Acceptable Verification Sources:															
Donor ID	<ul style="list-style-type: none"> • Donor identification band • OPTN computer system 															
Organ type and laterality (if applicable)	<ul style="list-style-type: none"> • OPTN computer system 															
Donor blood type and subtype (if used for allocation)	<ul style="list-style-type: none"> • Donor blood type and subtype source documents 															
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Donor and intended recipient are blood type compatible (or intended incompatible).	<ul style="list-style-type: none"> • Donor medical record • OPTN computer system 															
	<p>The host OPO must document that the verifications were completed. The documentation must include date and time of verification, participants, and each information element verified according to the above requirements.</p>															
<p>3.3 Candidate Blood Type Determination and Reporting before Waiting List Registration</p> <p>The transplant program must: 1. Ensure that each candidate’s blood type is determined.</p>	<p>3.3 Candidate Blood Type Determination and Reporting before Waiting List Registration</p> <p>Transplant programs must develop and comply with a written protocol for blood type determination and reporting that includes a two-person verification and reporting process as required below.</p>	<ul style="list-style-type: none"> • <i>No substantive changes</i> • Clause added on how to handle discrepant blood type results. 														

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<p>2. Report the blood type to the OPTN Contractor. 3. Develop and comply with a written protocol for blood type determination and reporting that defines a qualified health care professional and includes a two-person verification and reporting process.</p>		<p>Style changes: • Parallel changes as with deceased donor determination and reporting</p>
<p>3.3.A Candidate Blood Type Determination before Waiting List Registration</p> <p>The transplant program must ensure that each candidate’s blood type is determined by testing at least two candidate blood samples prior to registration on the waiting list. Blood samples must be taken on separate occasions defined as samples drawn at two different times.</p> <p>The transplant hospital must document that two separate tests to determine the candidate’s blood type were performed.</p>	<p>3.3.A Candidate Blood Type Determination</p> <p>The transplant program must determine ensure that each candidate’s blood type is determined by testing at least two candidate blood samples prior to registration on the waiting list. Candidate blood samples must:</p> <ol style="list-style-type: none"> 1. Be drawn on two separate occasions 2. Have different collection times 3. Be submitted as separate specimens 4. Have results indicating the same blood type <p>The transplant hospital must establish and implement a written protocol for resolving conflicting blood type results.</p> <p>The transplant hospital must document that two separate tests to determine the candidate’s blood type were performed.</p>	
<p>3.3.B Reporting of Candidate Blood Type</p> <p>All of the following apply to reporting of candidate blood type:</p> <ol style="list-style-type: none"> 1. Two different qualified health care professionals must each make an independent report to the OPTN Contractor for blood type. 2. Both qualified health care professionals must consult all source documents used for blood type determination. 3. Each qualified health care professional must verify that the source documents: <ol style="list-style-type: none"> A. contain blood type results for the candidate B. indicate two results with the same blood type 	<p>3.3.B Reporting of Candidate Blood Type</p> <p>The candidate is not eligible for a match run until the transplant hospital completes verification and reporting as follows:</p> <ol style="list-style-type: none"> 1. Two different qualified health care professionals, as defined in the transplant hospital’s protocol, must each make an independent report to the OPTN Contractor for blood type. 2. Both qualified health care professionals must use all blood type determination source documents to verify they: <ol style="list-style-type: none"> a. Contain blood type results for the candidate b. Indicate the same blood type on the two test results c. Match the result reported to the OPTN Contractor 	

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<p>Once the second report is made and two identical blood types are verified, then the candidate will be registered on the waitlist and eligible for match runs.</p> <p>The transplant program must maintain documentation that reporting was completed according to the program’s protocol consulting source documents containing each blood type test result.</p>	<p>Once the second report is made and two identical blood types are verified, then the candidate has met blood type requirements to appear on a match run.</p> <p>The transplant program document that reporting was completed according to the program’s protocol and the above requirements.</p>	
<p>5.4.B Order of Allocation</p> <p>4. If no transplant program on the initial match run accepts the organ, the host OPO may give transplant programs the opportunity to update candidates’ data with the OPTN Contractor. If the transplant program notifies the host OPO of updated candidate data, and the organ has not been accepted on the initial match run, then the host OPO must run an updated match run to allocate the organ.</p>	<p>5.4.B Order of Allocation</p> <p>4. If no transplant program on the initial match run accepts the organ, the host OPO may give transplant programs the opportunity to update candidates’ data with the OPTN Contractor. The host OPO must run an updated match run to allocate the organ.</p>	<ul style="list-style-type: none"> • <i>No substantive changes</i> <p>Style changes:</p> <ul style="list-style-type: none"> • Language clean up
<p>5.5.A Receiving and Reviewing Organ Offers</p> <p>Transplant hospitals must view organ offers and respond to these offers through the match system.</p> <p>The transplanting surgeon at the receiving transplant hospital is responsible for ensuring the medical suitability of organs offered for transplant to potential recipients, including compatibility or intended incompatibility of deceased donor and candidate blood types (and donor subtype, when used for allocation).</p>	<p>5.5.A Receiving and Reviewing Organ Offers</p> <p>Transplant hospitals must view organ offers and respond to these offers through the match system. The previous sentence does not apply to VCA transplants.</p> <p>The transplanting surgeon at the receiving transplant hospital is responsible for ensuring the medical suitability of organs offered for transplant to potential recipients, including whether deceased donor and candidate blood types (and donor subtype, when used for allocation) are compatible or intended incompatible.</p>	
<p>5.6 Organ Recovery, Check-In, and Pre-Transplant Verifications</p> <p>Transplant hospitals and host OPOs must each develop and comply with their own written protocol to perform verifications as outlined in this policy.</p>	<p>5.6 Organ Check-In</p> <p>Transplant hospitals must develop and comply with written protocols to perform organ check-ins as required below.</p>	<ul style="list-style-type: none"> • <i>No substantive changes</i> <p>Style changes:</p> <ul style="list-style-type: none"> • Previous table broken up into separate parts in response to public comment

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<p>A qualified health care professional as defined in the program’s written protocol must perform and document all verifications.</p> <p>Recovery and pre-transplant verifications must include a process to confirm that all of the following information is correct:</p> <ol style="list-style-type: none"> 1. Donor ID, organ type, and laterality (if applicable) 2. Donor blood type and subtype (if used for allocation) 3. Recipient unique identifier 4. Recipient blood type 5. That the donor and recipient are the intended pair for transplant 6. That the donor and recipient are blood type compatible (or intended incompatible) <p>Verifications must be done using a two-person or a one-person assisted by an automated information technology bar code scanning process. Verifications must include confirmation of required information from at least two of the following:</p> <ol style="list-style-type: none"> 1. Donor or recipient identification band 2. Donor or recipient medical record 3. OPTN computer system 4. Donor or recipient ABO blood type and subtype source documents 5. OPTN external labels (check-in verification only) <p>5.6.A: Host OPO Organ Recovery Verification</p> <p>Host OPOs must complete and document deceased donor organ recovery verifications according to Table 5.1 below.</p> <p>Table 5.1: Deceased Donor Organ Recovery Verification</p>	<p>The transplant hospital must complete an organ check-in any time an organ is recovered outside the operating suite where the transplant will take place. The organ check-in must be completed when the organ arrives at the recipient’s operating suite prior to opening the organ’s external shipping container.</p> <p>The transplant hospital must use the OPTN external organ label to confirm receipt of the expected organ by verifying:</p> <ol style="list-style-type: none"> 1. The expected donor ID 2. Organ type and laterality (if applicable) <p>Assistance using an electronic scanner is permitted.</p> <p>The check-in and pre-transplant time out according to <i>Policy 5.7 Pre-Transplant Verification</i> may be combined if <i>both</i> of the following occur:</p> <ol style="list-style-type: none"> 1. A member of the organ recovery team is accompanying the organ 2. The organ is immediately brought into the recipient operating room upon arrival to the transplant hospital <p>The transplant hospital must document that the organ check-in was completed.</p>	<ul style="list-style-type: none"> • Clean up language changes
	<p>5.7 Pre-Transplant Verification</p> <p>Transplant hospitals must develop and comply with a written protocol to perform pre-transplant verifications as required below.</p> <p>5.7.A Pre-Transplant Verification Prior to Organ Receipt</p> <p>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 <i>all</i> of the following requirements:</p> <ol style="list-style-type: none"> 1. Two licensed health care professionals must participate in the verification 2. The intended recipient must be present in the operating room 	<ul style="list-style-type: none"> • No substantive changes <p>Style changes:</p> <ul style="list-style-type: none"> • Previous table broken up into separate parts in response to public comment • Use two licensed health care professions to be consistent with CMS. • Clean up language changes consistent where applicable with deceased donor pre-recovery verification

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Requirement	Time	Place	3. The verification must occur: a. Prior to induction of general anesthesia b. If the patient has been receiving continuous general anesthesia prior to arrival in the operating room, then prior to incision 4. 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 in Table 5.X below. Assistance using an electronic scanner is permitted. Table 5.X: Pre-Transplant Verification Prior to Organ Receipt Requirements	<ul style="list-style-type: none"> • Use separate sections for “prior to” and “after” organ receipt-use receipt to be consistent with CMS • Documentation clauses specific to reduce confusion and not require documentation of which source used 																		
The host OPO in conjunction with the on-site	Prior to organ release to the transplant	Per OPO protocol																				
5.6.B: Recovery and Transplant Hospital Organ Recovery, Check-In, and Pre-Transplant Verifications Recovery and transplant hospitals must complete and document organ recovery, check-in, and pre-transplant verifications according to Table 5.2 below. Table 5.2: Organ Recovery, Check-In and Pre-Transplant Verifications			<table border="1"> <thead> <tr> <th colspan="2">Information to Verify:</th> <th>Acceptable Verification Sources:</th> </tr> </thead> <tbody> <tr> <td>Expected donor ID</td> <td></td> <td> <ul style="list-style-type: none"> • OPTN computer system • Recipient medical record </td> </tr> <tr> <td>Expected organ (and laterality if applicable)</td> <td></td> <td> <ul style="list-style-type: none"> • OPTN computer system • Recipient medical record </td> </tr> <tr> <td>Expected donor blood type and subtype (if used for allocation)</td> <td></td> <td> <ul style="list-style-type: none"> • Donor blood type and subtype source documents • OPTN computer system </td> </tr> <tr> <td>Recipient unique identifier</td> <td></td> <td> <ul style="list-style-type: none"> • Recipient identification band </td> </tr> <tr> <td>Recipient blood type</td> <td></td> <td> <ul style="list-style-type: none"> • Recipient blood type and subtype source documents • Recipient medical record </td> </tr> </tbody> </table>		Information to Verify:		Acceptable Verification Sources:	Expected donor ID		<ul style="list-style-type: none"> • OPTN computer system • Recipient medical record 	Expected organ (and laterality if applicable)		<ul style="list-style-type: none"> • OPTN computer system • Recipient medical record 	Expected donor blood type and subtype (if used for allocation)		<ul style="list-style-type: none"> • Donor blood type and subtype source documents • OPTN computer system 	Recipient unique identifier		<ul style="list-style-type: none"> • Recipient identification band 	Recipient blood type		<ul style="list-style-type: none"> • Recipient blood type and subtype source documents • Recipient medical record
Information to Verify:		Acceptable Verification Sources:																				
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Recipient blood type		<ul style="list-style-type: none"> • Recipient blood type and subtype source documents • Recipient medical record 																				
Table 5.2: Organ Recovery, Check-In and Pre-Transplant Verifications																						
	Requirement	Time	Place																			
Recovery: Living Donation	The recovery hospital must perform a living donor organ recovery verification with the donor present in the operating room.	Prior to anesthesia of living donor	Living donor operating room																			

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Check-In: Deceased and	<p>If the organ is received from a different recovery operating room suite, then the transplant hospital must check-in the organ.</p> <p>The external label or source documents accompanying the organ must be checked against expected donor ID, organ type, and laterality (if applicable) prior to opening the organ package.</p> <p>The check-in may be done in combination with the final verification if the organ is immediately brought into the recipient operating room upon arrival at the transplant hospital and chain of custody has been maintained.</p>	<p>When the organ becomes physically present at the recipient's operating room suite</p>	<p>Per transplant hospital protocol</p>	<p>Expected donor and recipient are blood type compatible (or intended incompatible).</p>	<ul style="list-style-type: none"> • OPTN computer system • Recipient medical record • Attestation following verification of donor and recipient blood types 	
	<p>If a pre-transplant verification was conducted prior to organ receipt, the transplant hospital must document that the verification was completed. The documentation must include date and time of verification, participants, and each information element verified according to the above requirements.</p> <p>5.7.B Pre-Transplant Verification Upon Organ Receipt</p> <p>Upon organ receipt in the operating room, the transplant hospital must conduct a pre-transplant verification with the following requirements:</p> <ol style="list-style-type: none"> 1. The transplant surgeon and another licensed health care professional must participate in the verification 2. The intended recipient must be present in the operating room 3. The verification must occur after the organ arrives in the operating room, but prior to anastomosis of the first organ 4. 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 Table 5.X below. Assistance using an electronic scanner is permitted. 					
Pre-Transplant: Deceased and	<p>If surgery will begin prior to organ arrival, the transplant hospital must perform an additional pre-procedure verification with the</p>	<p>Prior to anesthesia of intended recipient</p>	<p>Per transplant hospital protocol</p>	<p>Table 5.X: Pre-Transplant Verification Upon Organ Receipt Requirements</p>		
				<p>Information to Verify:</p>	<p>Acceptable Verification Sources:</p>	

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	intended recipient present*.			Donor ID		External and internal organ package labels Documentation with organ			
	The transplant hospital including the transplanting surgeon must always perform a final verification with the organ and the intended recipient present in the operating room.	Between time of organ delivery into intended recipient's operating room and first anastomosis	Recipient operating room	Organ (and laterality if applicable)		Organ received			
				Donor blood type and subtype (if used for allocation)		Donor blood type and subtype source documents			
				Recipient unique identifier		Recipient identification band			
<p>Once the organ has been released to the transplant hospital, if the intended recipient changes, then the verification is solely the responsibility of the final transplant hospital.</p> <p>*If the intended recipient is under anesthesia prior to reaching the operating room and the organ is not present, then the additional pre-procedure verification must be conducted prior to incision.</p>						Recipient blood type	Recipient blood type source documents Recipient medical record		
						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	
						Correct donor organ has been identified for the correct recipient		Recipient medical record OPTN computer system	
							The transplant hospital must document that the pre-transplant verification after organ arrival was completed. The documentation must include date and time of verification, participants, and each information element verified according to the above requirements.		
<p>13.6.A Requirements for Match Run Eligibility for Candidates</p> <p>The OPTN KPD program will only match candidates who comply with all of the following requirements:</p>				<p>13.6.A Requirements for Match Run Eligibility for Candidates</p> <p>The OPTN KPD program will only match candidates who comply with all of the following requirements:</p>			<ul style="list-style-type: none"> • No substantive changes • Style changes: • Updated Policy Names/References 		
				<p>1. The candidate's transplant hospital must comply with</p>					

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<p>1. The candidate’s transplant hospital must comply with Policies 5.5.A: Receiving and Reviewing Organ Offers and 5.6 Organ Recovery, Check-In, and Pre-Transplant Verifications</p>	<p>Policies 5.5.A: Receiving and Reviewing Organ Offers, 5.6 Organ Check-In, and 5.7 Pre-Transplant Verification.</p>	
<p>13.6.B Requirements for Match Run Eligibility for Potential KPD Donors The OPTN KPD program will only match potential KPD donors that comply with all of the following requirements:</p> <p>1. The transplant hospital registering the potential KPD donor must perform blood typing and subtyping as required by Policy 14.4.A: Living Donor Blood Type Determination and Reporting with the following modifications:</p> <p>a. The transplant hospital registering the potential KPD donor must report the potential KPD donor’s blood type to the OPTN Contractor b. A qualified health care professional, other than the qualified health care professional who initially reported the potential KPD donor’s blood type to the OPTN Contractor, must compare the blood type from the two source documents, and separately report the potential KPD donor’s blood type to the OPTN Contractor c. The potential KPD donor is not eligible for a KPD match run until the transplant hospital verifies and reports two identical blood types</p>	<p>13.6.B Requirements for Match Run Eligibility for Potential KPD Donors The OPTN KPD program will only match potential KPD donors that comply with all of the following requirements:</p> <p>1. The transplant hospital registering the potential KPD donor must perform blood typing and subtyping as required by Policy 14.5: Living Donor Blood type Determination and Reporting with the following modifications:</p> <p>a. The transplant hospital registering the potential KPD donor must report the potential KPD donor’s actual blood type to the OPTN Contractor b. A qualified health care professional, other than the qualified health care professional who initially reported the potential KPD donor’s blood type to the OPTN Contractor, must compare the blood type from the two source documents, and separately report the potential KPD donor’s blood type to the OPTN Contractor c. The potential KPD donor is not eligible for a KPD match run until the transplant hospital verifies and reports two identical blood types</p>	
<p>14.4.A Living Donor Blood Type Determination and Reporting The recovery hospital must:</p> <p>1. Ensure that each living donor’s blood type is determined. 2. Report the blood type to the OPTN Contractor.</p>	<p>14.5 Living Donor Blood Type Determination and Reporting Recovery hospitals must develop and comply with a written protocol for blood type determination and reporting that includes a two-person verification and reporting process as required below.</p>	<p>• <i>No substantive changes but must address VCA</i> VCA language added to require: double verification and reporting in living donor medical record for</p>

Public Comment (If adopted) Language does not contain strikethroughs and underlines	Post Public Comment (if adopted) Language does not contain strikethroughs and underlines	Summary of changes
<p>3. Develop and comply with a written protocol for blood type determination and reporting that defines a qualified health care professional and includes a two-person verification and reporting process.</p>		<p>blood type and reporting of subtype in medical record.</p>
<p>14.4.A.i Living Donor Blood Type Determination The recovery hospital must ensure that each living donor’s blood type is determined by testing at least two living donor blood samples prior to generation of the living donor ID. Blood samples must be taken on separate occasions defined as samples drawn at two different times.</p> <p>The recovery hospital must document that two separate tests to determine the living donor’s blood type were performed.</p>	<p>14.5.A Living Donor Blood Type Determination The recovery hospital must ensure that each living donor’s blood type is determined by testing at least two donor blood samples prior to generation of the living donor ID.</p> <p>Donor blood samples must:</p> <ol style="list-style-type: none"> 1. Be drawn on two separate occasions 2. Have different collection times 3. Be submitted as separate specimens 4. Have results indicating the same blood type <p>The recovery hospital must establish and implement a written protocol for resolving conflicting blood type results.</p> <p>The recovery hospital must document that two separate tests to determine the living donor’s blood type were performed.</p>	<ul style="list-style-type: none"> • Clause added on how to handle discrepant blood type results <p>Style changes:</p> <ul style="list-style-type: none"> • Section number changes • Parallel changes as with deceased donor determination and reporting
<p>14.4.A.ii Living Donor Blood Subtype Determination</p> <p>All of the following apply to subtype determination:</p> <ol style="list-style-type: none"> 1. Pre-transfusion blood samples must be used for all subtype testing. 2. Subtyping on blood type A and blood type AB is optional if pre-transfusion samples are available. 3. At least two blood samples must be taken on separate occasions defined as samples drawn at two different times. 4. Two subtype tests must be completed if subtyping results will be reported to the OPTN when used for transplant compatibility determination or allocation 	<p>14.5.B Living Donor Blood Subtype Determination</p> <p>If subtyping is used to ensure transplant compatibility or allocation, then testing must meet <i>all</i> of the following requirements:</p> <ol style="list-style-type: none"> 1. Pre-transfusion blood samples must be used. 2. A second subtype test must be completed if the first subtype result is <i>either</i>: <ol style="list-style-type: none"> a. Blood type A, non-A₁ b. Blood type AB, non-A₁B 3. Blood samples must be drawn on two separate occasions, have different collection times, and be submitted as separate specimens. 4. Two subtype tests must be completed and indicate the same 	

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<p>including all blood type A, non-A1 and blood type AB, non-A1B results.</p> <p>5. If two tests do not indicate the same subtype, then transplant compatibility or allocation must be based on primary blood type only.</p> <p>The recovery hospital must document that blood subtype determination tests have been completed to determine the living donor’s blood subtype when used for determining transplant compatibility or allocation.</p>	<p>subtype if results will be reported to the OPTN.</p> <p>5. If there are conflicting subtype test results, the living donor must be allocated based on the primary blood type.</p> <p>When subtyping is used to ensure transplant compatibility or allocation, the recovery hospital must document that blood subtype determination tests have been completed according to the above requirements.</p>	
<p>14.4.A.iii Reporting of Living Donor Blood Type and Subtype</p> <p>All of the following apply to reporting of living donor blood type and subtype:</p> <ol style="list-style-type: none"> 1. A. Blood Type: Two different qualified health care professionals must each make an independent report to the OPTN Contractor for blood type. B. Subtype: One qualified health care professional must report blood subtype to the OPTN Contractor if used for allocation. Report accuracy must be verified by a different qualified health care professional in accordance with the recovery hospital’s protocol. 2. Both qualified health care professionals must consult all source documents used for blood type and subtype determination. 3. Each qualified health care professional must verify that the source documents: <ol style="list-style-type: none"> A. contain blood type results for the living donor B. indicate two results with the same blood type and subtype (if used for transplant compatibility or allocation) <p>The recovery hospital must maintain documentation that reporting was completed according to the</p>	<p>14.5.C Reporting of Living Donor Blood Type and Subtype</p> <p>The living donor will not receive a donor ID until the recovery hospital completes verification and reporting as follows:</p> <ol style="list-style-type: none"> 1. Two different qualified health care professionals, as defined in the recovery hospital’s protocol, must each make an independent report to the OPTN Contractor for blood type. Recovery hospitals performing VCA recoveries must instead establish and implement a written protocol for two different qualified health care professionals, as defined in the recovery hospital’s protocol, to make an independent report to the living donor’s medical record. 2. If blood subtype is used for ensuring transplant compatibility or allocation, a qualified health care professional must report blood subtype to the OPTN Contractor. This report must be verified by a different qualified health care professional according to the recovery hospital’s protocol. Recovery hospitals performing VCA recoveries must instead establish and implement a written protocol for a qualified health care professional to report the blood subtype to the living donor’s medical record if the blood subtype is used for ensuring transplant compatibility or allocation. 3. Both qualified health care professionals must use all blood type and subtype determination source documents to verify they: <ol style="list-style-type: none"> a. Contain blood type and subtype (if used for ensuring transplant compatibility or allocation) results for the donor 	

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<p>program’s protocol consulting source documents containing each blood type and subtype (if used for transplant compatibility or allocation) test result.</p>	<p>b. Indicate the same blood type and subtype (if used for ensuring transplant compatibility or allocation) on the two test results</p> <p>c. Match the result reported to the OPTN Contractor</p> <p>The recovery hospital must document that reporting was completed according to the hospital’s protocol and above requirements.</p>			
	<p>14.8 Living Donor Pre-Recovery Verification</p> <p>Recovery hospitals must develop and comply with a written protocol to perform pre-recovery verifications as required below.</p> <p>The recovery hospital must conduct a pre-recovery verification that meets <i>all</i> of the following requirements:</p> <ol style="list-style-type: none"> 1. The recovery surgeon and another licensed health care professional must participate in the verification 2. The living donor must be present in the operating room 3. The verification must occur prior to the induction of general anesthesia 4. Recovery hospitals must use at least one of the acceptable sources during the pre-recovery verification to verify all of the following information in Table 14.X below. Assistance using an electronic scanner is permitted. <p style="text-align: center;">Table 14.X: Pre-Recovery Verification Requirements</p> <table border="1" style="width: 100%; margin-top: 10px;"> <tr> <td style="width: 50%; padding: 5px;">Information to verify:</td> <td style="width: 50%; padding: 5px;">Acceptable Verification Sources:</td> </tr> </table>	Information to verify:	Acceptable Verification Sources:	<ul style="list-style-type: none"> • <i>No substantive changes</i> <p>Style changes:</p> <ul style="list-style-type: none"> • Previous table broken up into separate parts. Previously in 5.6. Done in response to public comment • Moved to Living Donor Chapter • Clean up language changes • Required verification info and acceptable sources put into table • Documentation clauses specific to reduce confusion and not require documentation which source used • Other changes consistent with pre-transplant verification as appropriate
Information to verify:	Acceptable Verification Sources:			

Public Comment (If adopted) Language does not contain strikethroughs and underlines	Post Public Comment (if adopted) Language does not contain strikethroughs and underlines	Summary of changes														
	<table border="1"> <tr> <td data-bbox="846 289 1268 370">Donor ID</td> <td data-bbox="1268 289 1598 370"> <ul style="list-style-type: none"> • Donor identification band </td> </tr> <tr> <td data-bbox="846 370 1268 451">Organ type and laterality (if applicable)</td> <td data-bbox="1268 370 1598 451"> <ul style="list-style-type: none"> • OPTN computer system </td> </tr> <tr> <td data-bbox="846 451 1268 589">Donor blood type and subtype (if used for ensuring transplant compatibility or allocation)</td> <td data-bbox="1268 451 1598 589"> <ul style="list-style-type: none"> • Donor blood type and subtype source documents </td> </tr> <tr> <td data-bbox="846 589 1268 670">Intended recipient unique identifier</td> <td data-bbox="1268 589 1598 670"> <ul style="list-style-type: none"> • Recipient medical record • OPTN computer system </td> </tr> <tr> <td data-bbox="846 670 1268 751">Intended recipient blood type</td> <td data-bbox="1268 670 1598 751"> <ul style="list-style-type: none"> • Recipient medical record • OPTN computer system </td> </tr> <tr> <td data-bbox="846 751 1268 922">Donor and intended recipient are blood type compatible (or intended incompatible).</td> <td data-bbox="1268 751 1598 922"> <ul style="list-style-type: none"> • OPTN computer system • Recipient medical record • Attestation following verification of donor and recipient blood types </td> </tr> <tr> <td data-bbox="846 922 1268 1019">Correct donor organ has been identified for the correct intended recipient</td> <td data-bbox="1268 922 1598 1019"> <ul style="list-style-type: none"> • Donor medical record • OPTN computer system </td> </tr> </table> <p data-bbox="846 1052 1598 1182">The recovery hospital must document that the verification was completed. The documentation must include date and time of verification, participants, and each information element verified according to the above requirements.</p>	Donor ID	<ul style="list-style-type: none"> • Donor identification band 	Organ type and laterality (if applicable)	<ul style="list-style-type: none"> • OPTN computer system 	Donor blood type and subtype (if used for ensuring transplant compatibility or allocation)	<ul style="list-style-type: none"> • Donor blood type and subtype source documents 	Intended recipient unique identifier	<ul style="list-style-type: none"> • Recipient medical record • OPTN computer system 	Intended recipient blood type	<ul style="list-style-type: none"> • Recipient medical record • OPTN computer system 	Donor and intended recipient are blood type compatible (or intended incompatible).	<ul style="list-style-type: none"> • OPTN computer system • Recipient medical record • Attestation following verification of donor and recipient blood types 	Correct donor organ has been identified for the correct intended recipient	<ul style="list-style-type: none"> • Donor medical record • OPTN computer system 	
Donor ID	<ul style="list-style-type: none"> • Donor identification band 															
Organ type and laterality (if applicable)	<ul style="list-style-type: none"> • OPTN computer system 															
Donor blood type and subtype (if used for ensuring transplant compatibility or allocation)	<ul style="list-style-type: none"> • Donor blood type and subtype source documents 															
Intended recipient unique identifier	<ul style="list-style-type: none"> • Recipient medical record • OPTN computer system 															
Intended recipient blood type	<ul style="list-style-type: none"> • Recipient medical record • OPTN computer system 															
Donor and intended recipient are blood type compatible (or intended incompatible).	<ul style="list-style-type: none"> • OPTN computer system • Recipient medical record • Attestation following verification of donor and recipient blood types 															
Correct donor organ has been identified for the correct intended recipient	<ul style="list-style-type: none"> • Donor medical record • OPTN computer system 															
	<p data-bbox="846 1190 1226 1219">14.10 Living Donor Organ Check-In</p> <p data-bbox="846 1252 1556 1312">Transplant hospitals must perform organ check-ins as required by Policy 5.6: Organ Check-In.</p>	<ul style="list-style-type: none"> • New cross references 														
	<p data-bbox="846 1325 1356 1354">14.11 Living Donor Pre-Transplant Verification</p> <p data-bbox="846 1386 1549 1416">Transplant hospitals must perform pre-transplant verifications as</p>															

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	required by Policy 5.7: Pre-Transplant Verification.	
16.1 Deleted	16.1 Deleted	<ul style="list-style-type: none"> • No changes
<p>16.4.C Internal Labeling of Blood and Tissue Typing Materials</p> <p>Each separate specimen container of blood or tissue typing material must have a label that will remain secured to the container under normal conditions of transport. The label must include the donor ID and at least one of the following identifiers:</p> <ul style="list-style-type: none"> • Locally assigned unique ID • Donor date of birth • Donor initials <p>Additionally each specimen should be labeled with both of the following:</p> <ol style="list-style-type: none"> 1. The date and time the sample was procured 2. The type of tissue <p>The donor blood type and subtype, if used for allocation, should be included on tissue typing material and blood samples if known. If the donor ID or blood type is not available during the preliminary evaluation of a donor, a locally assigned unique ID and one other identifier for the transportation of initial screening specimens may be used. The OPO must document in the OPO donor record all unique identifiers used to label tissue typing specimens.</p>	<p>16.4.C Internal Labeling of Blood and Tissue Typing Materials</p> <p>Each separate specimen container of blood or tissue typing material must have a label that will remain secured to the container under normal conditions of transport. The label must include the donor ID and at least one of the following identifiers:</p> <ul style="list-style-type: none"> • Locally assigned unique ID • Donor date of birth • Donor initials <p>Additionally each specimen should be labeled with both of the following:</p> <ul style="list-style-type: none"> • The date and time the sample was procured • The type of tissue <p>The donor blood type and subtype, if used for allocation, should be included on tissue typing material and blood samples if known. If the donor ID or blood type is not available during the preliminary evaluation of a donor, a locally assigned unique ID and one other identifier for the transportation of initial screening specimens may be used. The OPO must document in the OPO donor record all unique identifiers used to label tissue typing specimens.</p>	

Business Requirements

Proposed ABO Blood Type Determination, Reporting, and Verification Policy Modifications

Operations and Safety Committee Version 1.0

Proposal Number: 60720

Shyni Mohan, Business Analyst

15 March 2013



United Network for Organ Sharing

700 N. 4th Street
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1 Introduction

1.1 Background Summary & Purpose

Link to the public comment document:

http://optn.transplant.hrsa.gov/PublicComment/pubcommentPropSub_341.pdf

1.2 Assumptions

The following are the assumptions made in regard to this proposal:

- There will be no changes to Tiedi and KPD applications
- There will be no changes to the existing security in UNet.

1.3 Scope of the Project

The following items are determined to be in scope of the project.

IN Scope	Out of Scope
<ul style="list-style-type: none"> • Adding a new warning message in Waitlist for listing of a liver candidate. • Updates to the online help documentation in Waitlist. • Add a new column “ABO” to the “Match Results” page. • Updates to the online help documentation in DonorNet. 	<ul style="list-style-type: none"> • Any changes to KPD and Tiedi • Any changes to the Match Allocation Algorithms

2 Business Requirements

2.1 Waitlist Modifications

2.1.1 Addition of new warning messages to the Add/Edit candidate pages while adding a Liver Candidate. This is applicable to adult and pediatric candidates.

New warning messages will be added to the Add/Edit pages in Waitlist for adding a new adult and pediatric liver candidate.

1) The first warning message will be displayed if the user selects “Yes” as the option in the field “Accept an Incompatible Blood Type?” (See Figure 1)

Content for the error message:

“You have indicated that the candidate is willing to accept an incompatible blood type. Are you sure?”

Figure 1- Screen shot from Waitlist

The screenshot shows the U-Net Waitlist interface. The main content area is titled "Clinical Information" and contains a warning message: "Policy requires you to review source documents from two separate ABO typings to verify that the ABO is correctly entered for this candidate." Below this, there are radio buttons for ABO typing: O, A, B, AB, A1, A1B, A2, and A2B. Two confirmation questions are highlighted in yellow: "Accept an Incompatible Blood Type?" with radio buttons for YES, NO, and N/A (where NO is selected), and "Accept an A2 donor?" with radio buttons for YES, NO, and N/A (where N/A is selected). At the bottom, there are input fields for Height (ft/in and cm) and Weight (lbs and kg), each with a "Date:" field.

2) The second error message will be displayed if the user selects “No” as the option in the field “Accept an A2 donor?” while listing a candidate with blood type “O”.

Content for error message:

“Are you sure you want to list this candidate as willing to accept incompatible blood types except for A2?”

2.2 DonorNet Modifications
2.2.1 Modifications to the “Match Results” page

Currently, while reviewing the results for a match run, there is no functionality available to differentiate between candidates with an ABO that is identical or compatible with a donor and candidates with an ABO that is incompatible with the donor (or compatibility depends on the donor subtype and candidate eligibility).

This lack of differentiation among these types of candidates in the match run results can lead to a user unintentionally accepting an ABO incompatible organ for a candidate. Users need to be able to differentiate between these two categories.

- 1) The match results page will be modified to highlight the ABO’s that are:
 - Incompatible with the donor
 - Identical or compatible with the donor
 - The candidates that are identical or compatible with the donor will be highlighted differently than candidates with ABO’s that are incompatible with the donor.
- 2) A new column “ABO” will be added to the match results page ([See Figure 2](#))

Figure 2 – Screen shot of Match results page from DonorNet

The screenshot shows the DonorNet Match Results page. At the top, there are navigation options: "Electronically Notify" (highlighted in orange), "View all Provisional Acceptances >>", and "ABO". Below this, there are search filters: "Match ID: 900045 LI", "# Per Page: 100", and "Hide empty classifications". A pagination bar shows "Page 1 of 85".

The main content area displays two tables of candidates. The first table is titled "Regional LI MELD/PELD >= 40 - Adult and Pediatric Age 0-17". It has columns for Seq#, Center, Name, SSN, Age, LI seg, Donor Weight (lbs) (Min, Max), Score, Other Organs, Email/Fax Status, Offer Response, and ABO. Three candidates are listed:

Seq#	Center	Name	SSN	Age	LI seg	Min	Max	Score	Other Organs	Email/Fax Status	Offer Response	ABO
1	FLJM-TX1	Creary, Desmond	***-7-4636	9m	Y	10	150	40.0000				O
2	FLUF-TX1	Melendez, Julio	***-4-2231	54	Y	40	441	40.0000				O
3	FLUF-TX1	Trinckes, Debra	***-7-0028	51	Y	40	441	40.0000				AB

The second table is titled "Regional LI MELD/PELD = 39 - Adult and Pediatric Age 0-17". It has the same columns as the first table. One candidate is listed:

Seq#	Center	Name	SSN	Age	LI seg	Min	Max	Score	Other Organs	Email/Fax Status	Offer Response	ABO
4	FLTG-TX1	colon, josie	***-6-1963	42	N	75	300	39.0000				A

A yellow callout bubble with a speech bubble tail points to the "ABO" column header in the first table, containing the text: "A new column 'ABO' will be added to the Match Results page."

Note: The subtype compatibility will not be based on the logic used for allocation of organs, but on the biological ABO compatibility, as shown in the table below:

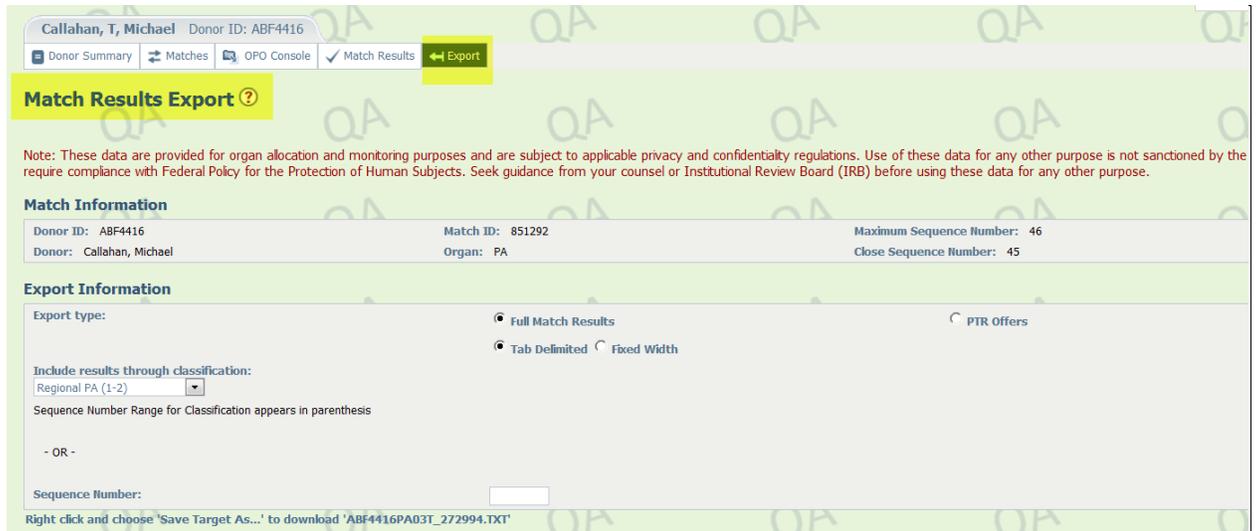
		Candidate's Blood Type			
		O	A/A1/A2	B	AB/A1B/A2B
Donor's Blood Type	O				
	A				
	A1				
	A2				
	B				
	AB				
	A1B				
	A2B				

Gray Cells = Incompatible ABO
 White Cells = Compatible ABO

2.2.2 Modifications to Match Results Export

The export match results functionality will need to be updated to reflect the modifications that are made to the match results page ([See Figure3](#))

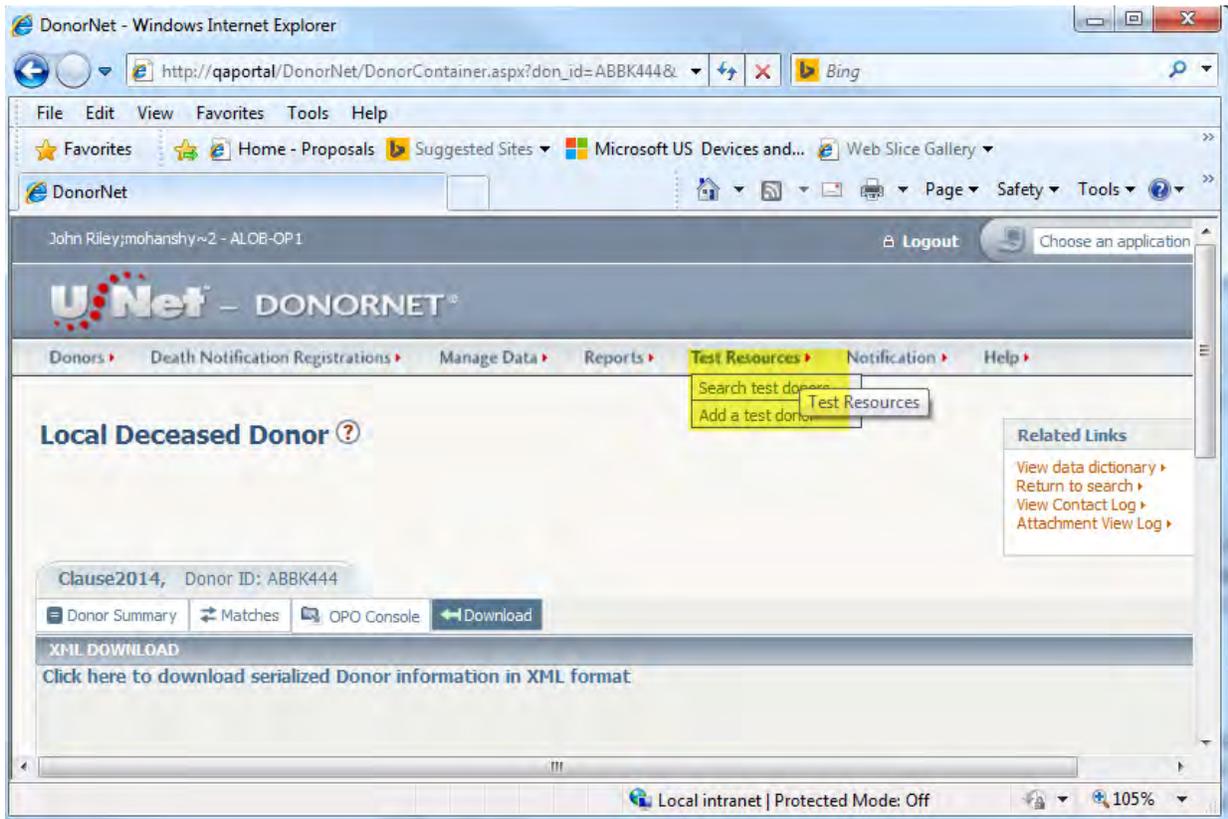
Figure 3 – Screen shot from DonorNet



2.2.3 Updates to the test resources page

The test resources page will need to be updated with the modifications that are made to the match results page (See Figure 4).

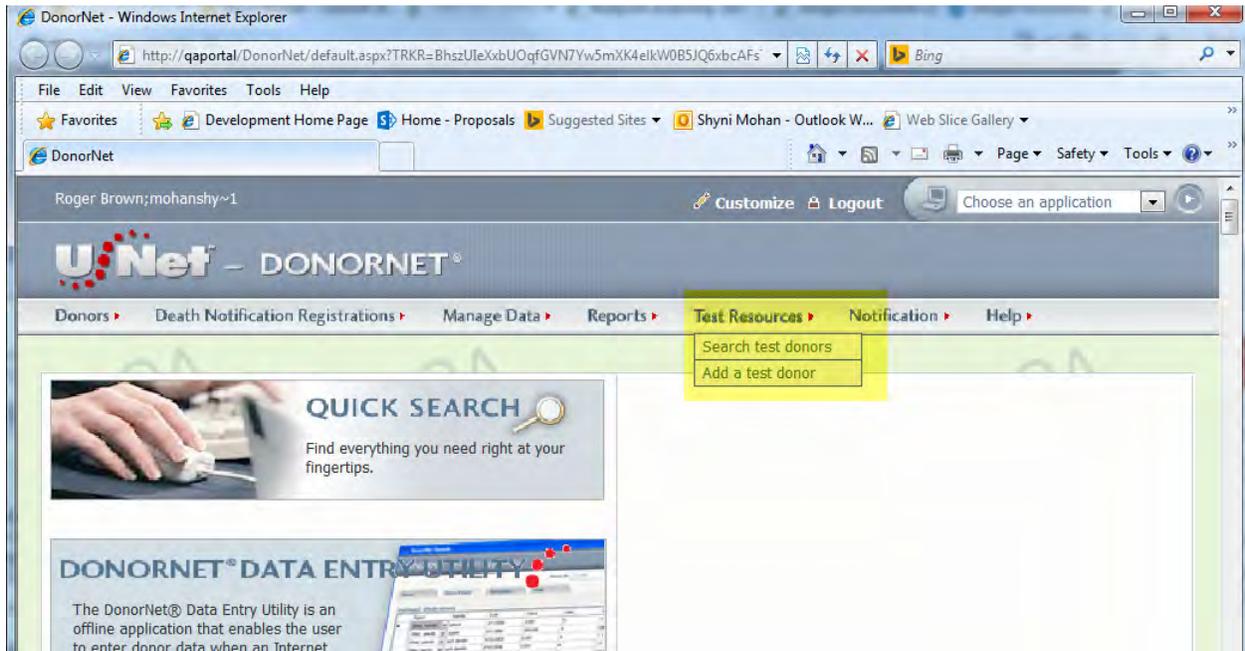
Figure 4 – Screen shot from DonorNet



2.2.4 Updates to the test resources page

The test resources page will need to be updated with the enhancements that are made to the match results page.

Figure 5 – Screen shot from DonorNet



2.2.5 Updates to the online help documentation in DonorNet

The online help documentation in DonorNet will be updated to reflect the modifications made to the match results page.

3 Security Requirements

Security requirements will continue as they exist today. No changes are proposed.

4 Impact Analysis

The following departments will need to be contacted to determine whether or not the proposed changes will impact the work area (tasks). If so, potential impact event(s) should be documented herein. For example, as a result of the proposed changes, the Communications Department may need to update the public websites.

Department	Contact	Comments	Approvals Received/Date Approvals Received
Corporate Counsel	Not Applicable		
DEQ	Elizabeth Miller		
Data Quality	Debra Ormond		
Policy	Shandie Covington		
Product Management	Carly Engelberger		
Regional Administration	Cliff McClenney Chrystal Oley-Graybill Betsy Gans Shannon Edwards		
Research	Sarah Taranto		
IT	TBD		

Approvals

Executive Sponsor

Approval Date

Executive Sponsor

Approval Date

Business Analyst

Approval Date

5 Revision History

Name	Date	Changes	Version

Proposal to Modify Subtyping Terminology References for Consistency

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Proposal to Modify Subtyping Terminology References for Consistency

Sponsoring Committee: Operations and Safety

Summary and Goals of the Proposal:

This proposal seeks to make all ABO subtype references consistent throughout OPTN policies. Current references use different terms, such as A_2 and non- A_1 , which are intended to mean the same thing but may be confusing. The more technically accurate description uses the “non” preface as routine testing only detects the presence or absence of A_1 and other rare subtypes other than A_2 do exist. In 2011, the OPTN published guidance on this issue. The proposed changes will align references with this guidance using the terms blood type A, non- A_1 and blood type AB, non- A_1B .

Background and Significance of the Proposal:

Certain OPTN allocation policies use subtyping to broaden the cohort of potential recipients. Blood type A or AB organs, in general, are not allocated to blood type O or B recipients. Certain subtypes of these primary groups, blood type A, non- A_1 and blood type AB, non- A_1B , however, can be allocated and successfully transplanted into certain blood type O or B recipients. This helps increase the probability of these recipients receiving organs in a timely manner.

This proposal will not change any allocation policy. It only makes all references to subtypes consistent to reduce any potential confusion. OPTN guidance published in June 2011 states, “It is important to know that the technically accurate term for A_2 and A_2B donors is “ A_1 -negative” or “A, non- A_1 ” because A_2 is not directly tested for and many other rare subtypes exist (e.g. A_3 , A_{int} , etc.). Blood group “A, non- A_1 ” organs are transplanted in many centers into blood group O or B candidates, and blood group “AB, non- A_1B ” organs into blood group B candidates.” Because routine subtyping does not detect results other than the presence or absence of A_1 or A_1B antigens, all references will be modified to reflect technically accurate terminology.

The alternative considered would be to use the terms A_2 and A_2B throughout policy and to add definitions that these terms include any non- A_1 or non- A_1B result. Current labels within the OPTN computer systems do use these shorthand terms and help text is being developed to clarify the definition. The Committee did not choose this alternative based on previous subcommittee work and deliberations. Experts with experience in blood subtyping helped develop and review the OPTN guidance. The proposal is consistent with that guidance.

The strength in this proposal is the consistency it will bring to policy references that will align with current OPTN guidance. If questions arise from the terminology changes, it could highlight other areas of educational need.

Supporting Evidence and/or Modeling:

The Operations and Safety committee has become aware of situations where OPOs have been reluctant to select subtype results referred to as A_2 as the donor subtype because technically the test results do not specify that the donor has subtype A_2 , but merely that the donor is non- A_1 . The proposed language will be consistent in use of blood type A, non- A_1 and blood type AB, non- A_1B to address these concerns. The terms “non- A_1 ” and “non- A_1B ” will not be used alone as comments received during the plain language policy rewrite indicated that this might be interpreted to mean any non- A_1 blood type such as O or B.

Due to these issues regarding interpretation, business requirements were approved to add online help documentation in Waitlist, TIEDI, KPD and DonorNet. Help documentation will explain that “A₂” is used throughout UNetSM as shorthand for any subtype of blood group A that is not A₁. Similarly, “A₂B” is shorthand for any subtype of blood group AB that is not A₁B. Wherever A₂ or A₂B labels exist, hover text will appear clarifying that this represents any non-A₁ or non-A₁B result as appropriate. These changes are awaiting programming and implementation.

The proposed policy changes will consistently use the technically correct language throughout all OPTN policies.

Expected Impact on Living Donors or Living Donation:

There is no substantive impact to living donors; however, there is a change in terminology in one living donor policy.

Expected Impact on Specific Patient Populations:

Specific patient populations will not be impacted.

Expected Impact on OPTN Key Goals and Adherence to OPTN Final Rule:

This proposal supports the following OPTN Strategic Plan Goal to promote efficient management of the OPTN.

This proposal promotes efficient management of the OPTN through using consistent terminology throughout OPTN policy.

Plan for Evaluating the Proposal:

Due to the nature of the proposal, there will not be an analytical evaluation.

Additional Data Collection:

No additional data collection will be required.

Expected Implementation Plan:

If approved by the Board of Directors, the proposal would go into effect May 1, 2015.

Members will need to understand the meaning of the terms: blood type A, non-A₁ and blood type AB, non-A₁B, which have sometimes been referred to as A₂ and A₂B.

Communication and Education Plan:

Communication and education regarding this proposal will be incorporated into overall education and competency training related to ABO policy and processes.

The Operations and Safety Committee is working on a guidance document, community education, and competency training related to all ABO policy and processes. Use and understanding of this terminology will be included in these efforts.

Notification of this change will be sent to members through the policy notice in December 2014, 30 days after approval by the board.

Compliance Monitoring:

No changes to compliance monitoring will be made if this proposal passes.

Policy or Bylaw Proposal:

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

At a meeting of the OPTN/UNOS Board of Directors convened on November 12, 2014 in St Louis, MO, the following resolution is offered.

A resolution to modify subtyping terminology references for consistency.

Sponsoring Committee: Operations and Safety

RESOLVED, that additions and modifications to Policies 2.6.B (Deceased Donor Blood Subtype Determination), 5.3. C (Liver Acceptance Criteria), 9.5.B (Points Assigned by Blood Type), 13.7.A (Blood Type), 13.7.B (A2 and A2B Matching), 14.4.A.i (Living Donor Blood Subtype Determination), and 8.5. E (Allocation of Kidneys by Blood Type) are modified as set forth below, effective May 1, 2015.

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2.6.B Deceased Donor Blood Subtype Determination

When a deceased donor is determined to be blood type A, then subtype testing must be completed. Subtype testing must be performed only on pre-transfusion blood samples. The host OPO may choose whether to perform subtype testing on deceased donors with blood type AB.

When deceased donor blood type A or AB is sub-typed and found to be ~~non-A1~~ blood type A, non-A₁ or ~~non-A1B~~ blood type AB, non-A₁B, the host OPO must complete a second subtype test. If the sample used for the second subtype test is from the same blood draw as the sample used for the first subtype test, the second sample must be tested by a different laboratory.

The host OPO must document that blood subtype determination tests have been completed to determine the deceased donor's blood subtype.

5.3.C Liver Acceptance Criteria

The responsible transplant surgeon must determine the acceptable deceased donor weight for each of its liver candidates, and the determined acceptable weight must be reported to the OPTN Contractor.

Liver transplant programs may also specify additional liver acceptance criteria, including *any* of the following:

1. The maximum number of mismatched antigens it will accept for any of its liver candidates
2. Minimal acceptance criteria for livers
3. If a blood type O candidate will accept a liver from a deceased donor with blood type A, ~~non-A₁ blood type~~
4. For status 1A or 1B candidates, if they will accept a liver from a deceased donor with any blood type
5. If a candidate with a Model for End-Stage Liver Disease (MELD) or Pediatric End Stage Liver Disease (PELD) score of at least 30 will accept a liver from a deceased donor with any blood type
6. If a candidate will accept a liver for other methods of hepatic support
7. If a candidate is willing to accept a segmental graft

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8.5. E Allocation of Kidneys by Blood Type

Transplants are restricted by blood type in certain circumstances. Kidneys will be allocated to candidates according to the blood type matching requirements in *Table 8-4* below:

Table 8-4: Allocation of Kidneys by Blood Type

Kidneys from Donors with:	Are Allocated to Candidates with:
Blood Type O	Blood type O. For offers made to candidates in zero mismatch categories, blood type O kidneys may be transplanted into candidates who have blood types other than O.
Blood Type A	Blood type A or blood type AB.
Blood Type B	Blood type B. For offers made to candidates in zero mismatch categories, blood type B kidneys may be transplanted into candidates who have blood types other than B.
Blood Type AB	Blood type AB.
Blood type <u>Types A, non-A₁</u> and <u>AB, non-A₁B</u>	Kidneys may be transplanted into candidates with blood type B who meet <u>all</u> of the following criteria: <ol style="list-style-type: none"> 1. The transplant program obtains written informed consent from each blood type B candidate regarding their willingness to accept a <u>blood type A, non-A₁</u> or <u>blood type AB, non-A₁B</u> blood type kidney. 2. The transplant program establishes a written policy regarding its program's titer threshold for transplanting <u>blood type A, non-A₁</u> and <u>blood type AB, non-A₁B</u> kidneys into candidates with blood type B. The transplant program must confirm the candidate's eligibility every 90 days (+/- 20 days).

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9.5.B Points Assigned by Blood Type

For status 1A and 1B transplant candidates, those with the same blood type as the deceased liver donor will receive 10 points. Candidates with compatible but not identical blood types will receive 5 points, and candidates with incompatible types will receive 0 points.

50 Blood type O candidates who will accept a liver from a ~~non-A1~~ blood type A, non-A₁ blood type
 51 donor will receive 5 points for blood type incompatible matching. Within each MELD or PELD
 52 score, donor livers will be offered to transplant candidates with blood types identical to the
 53 deceased donor first, then to candidates who are blood type compatible, followed by candidates
 54 who are blood type incompatible with the deceased donor.

55
 56 **13.7.A Blood Type**

57 The OPTN Contractor will only match candidates and potential donors who have identical
 58 or compatible blood types as defined in *Table 13-1* below.

59 **Table 13-1: Allocation by Blood Type**

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Donors with:	Are Matched to Candidates with:
Blood Type O	Blood type O Blood types A, A ₁ , A ₂ or A, non-A ₁
Blood Type A or A ₁	Blood types A, A ₁ , A ₂ or A, non-A ₁ Blood types AB, A ₁ B, or A ₂ B-AB, non-A ₁ B
Blood Type A ₄	Blood types A, A ₄ , A ₂ Blood types AB, A ₄ B, or A ₂ B
Blood Type A ₂ A, non-A ₁	Blood types A, A ₁ , A ₂ or A, non-A ₁ Blood types AB, A ₁ B, or A ₂ B AB, non-A ₁ B Blood type O or B if the candidate meets the requirements in <i>Policy 13.7.B: A₂ Blood Type A, non-A₁ and A₂B Blood Type AB, non-A₁B Matching.</i>
Blood Type B	Blood type B

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Donors with:	Are Matched to Candidates with:
	Blood types AB, A ₁ B, or A ₂ B-AB, non-A ₁ B
Blood Type AB	Blood types AB, A ₁ B, or A ₂ B-AB, non-A ₁ B
Blood Type A ₁ B	Blood types AB, A ₁ B, or A ₂ B-AB, non-A ₁ B
Blood Type A ₂ B-AB, non-A ₁ B	Blood types AB, A ₁ B, or A ₂ B-AB, non-A ₁ B Blood type B if the candidate meets the requirements in <i>Policy 13.7.B: A₂ Blood Type A, non-A₁ and A₂B Blood Type AB, non-A₁B Matching.</i>

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 65 **13.7.BA₂ Blood Type A, non-A₁ and Blood Type AB, non-A₁B A₂B Matching**

66 In order for a blood type B candidate to be eligible to be matched to a blood type A₂ A, non-A₁ or
 67 A₂B blood type AB, non-A₁B potential donor, or for a blood type O candidate to be eligible to
 68 match to a blood type A₂ A, non-A₁ potential donor in the OPTN KPD Program, the candidate
 69 must meet *both* of these conditions:

- 70
 71 1. The candidate must have an IgG antibody titer value less than 1:8

72 2. The candidate's transplant hospital must report to the OPTN Contractor the candidate's titer
73 value and date of the test.
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75 **14.4.A.i Living Donor Blood Subtype Determination**

76 The recovery hospital subtyping a living donor whose initial subtype test indicates the donor to be
77 ~~non-A1 (negative for A1) blood type A, non-A₁~~ or ~~non-A1B (negative for A1B) blood type AB, non-~~
78 ~~A₁B~~ must ensure a second determination test is performed prior to living donation to assess the
79 accuracy of the result. Blood samples for subtype testing must be taken on two separate
80 occasions, defined as two samples taken at different times. Samples tested must not be taken
81 after a blood transfusion. When the initial and second determination subtypings are the same
82 result, the result can be used to determine transplant compatibility with the intended recipient or
83 any other potential recipient. If the initial and second determination subtyping results are not the
84 same, the donor must be allocated based on the primary blood type, A or AB.
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Public Comment Responses**1. Public Comment Distribution**

Date of distribution: March 14, 2014
 Public comment end date: June 13, 2014

Public Comment Response Tally					
Type of Response	Response Total	In Favor	In Favor as Amended	Opposed	No Vote/ No Comment/ Did Not Consider
Individual	21	16 (76%)	0 (0%)	1 (5%)	4 (19%)
Regional	11	11 (100%)	0 (0%)	0 (0%)	0 (0%)
Committee	19	3 (16%)	0 (0%)	0 (0%)	16 (84%)

2. Primary Public Comment Concerns/Questions

There were no primary public comment concerns with the proposal.

3. Regional Public Comment Responses

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Meeting Format
1	5/5/2014	13 yes, 0 no, 0 abstentions		In person
2	3/28/2014	27 yes, 0 no, 0 abstentions		In person
3	5/30/2014	16 yes, 0 no, 1 abstention		In person
4	5/5/2014	17 yes, 5 no, 1 abstention		In person
5	6/12/2014	12 yes, 0 no, 2 abstentions		In person
6	5/16/2014	50 yes, 0 no, 0 abstentions		In person
7	5/9/2014	18 yes, 0 no, 0 abstentions		In person
8	4/4/2014	15 yes, 0 no, 0 abstentions		In person
9	5/21/2014	15 yes, 0 no, 0 abstentions		In person
10	5/15/2014	15 yes, 0 no, 0 abstentions		In person
11	5/30/2014	24 yes, 0 no, 0 abstentions		In person

There were no comments during the regional meetings as this proposal was on the consent agenda.

4. Committee Public Comment Responses

Membership and Professional Standards Committee:

The Committee did recommend any changes to the proposal.

Sponsoring Committee Response:

The Committee appreciates support of this proposal.

Pancreas Transplantation Committee:

The Committee voted in support of the proposal as long as the language coincides with the new Kidney Allocation policy. (13 yes; 0 no; 0 abstained)

Sponsoring Committee Response:

The Committee appreciates support of the proposal and language for all policies including the new kidney allocation policy will be modified if the proposal passes.

Patient Affairs Committee:

The Patient Affairs Committee voted in favor of this proposal.

Sponsoring Committee Response:

The Committee appreciates support of this proposal.

Transplant Coordinators Committee:

(Support 10, Oppose 0, Abstain 3)

The Committee received a presentation on the proposal and the following comments/questions were raised:

- a. A Committee member requested clarification that A2 sub-typing will not have to be reported and will only be required to report as A1-negative or A, non-A1?

Sponsoring Committee Response:

The Committee appreciates support of this proposal. In 2011, the Committee originally sought to have the labels used for reporting subtype in UNet to be changed to non-A₁ in order to be consistent with guidance issued. Labels will not be changed in UNet because of the effort and resources required. While the labels in UNet will not change, hyperlinked definition text will be added to indicate that reporting this result means non-A₁.

As discussed and noted above, help text will be hyperlinked to labels in UNet that explain the full definition.

5. Individual Public Comment Responses

Comment 1: ASTS supports this proposal designed to improve safety and consistency.
vote: Support
Date Posted:
06/17/2014

Committee Response:
The Committee appreciates support of the proposal.

Comment 2: NATCO supports this proposal as written.
vote: Support
Date Posted:
06/13/2014

Committee Response:
The Committee appreciates support of the proposal.

Comment 3: The AST supports this policy change which will correct inconsistencies that currently exist in the OPTN policy and create an accurate standardized method to report ABO subtyping.
vote: Support
Date Posted:
06/16/2014

Committee Response:
The Committee appreciates support of the proposal.

Post Public Comment Consideration:

The OSC met via teleconference on August 19, 2014 and in Chicago, IL on September 23, 2014, to review public comment feedback on this proposal.

The Committee voted unanimously (17 in favor, 0 opposed, 0 abstentions) to send the proposed policy language without changes for consideration by the OPTN/UNOS Board of Directors.

TRENDS AND PATTERNS IN PATIENT SAFETY SITUATIONS REPORTED TO THE OPTN THROUGH JUNE 2014

Prepared for:

Operations & Safety Committee
 Committee Meeting
 September 23, 2014

Revised 9/18/2014

By:

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 UNOS Research Department

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 Committee Liaison

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EXECUTIVE SUMMARY

The OPTN Operations and Safety Committee (OSC) has a standing request for semi-annual updates to analyze trends and patterns in patient safety situations reported to or identified by UNOS. As with the last several updates, this report includes events reported to or identified by UNOS from pathways other than the “Improving Patient Safety” (IPS) online portal located in Secure EnterpriseSM.

The increasing trend in the number of reports submitted through the IPS continued in the first half of 2014, as 81 safety situations were entered into the system. An additional 50 safety situations from other reporting pathways (such as emails/phone calls to UNOS) were also included in the analysis, along with reporting projections for the second half of 2014 (**Figure 1**).

This report summarizes safety situations reported into the IPS or through other pathways by the high-level and detailed subcategories that have been included as checkboxes as part of the OPTN board-approved enhancements to the IPS. This summarization revealed that between 2012 and June 2014, 23% of safety situations involved a **breakdown in communication**. Many other safety situations involved **testing issues** (16%), **transplant process/procedure issues** (15%), **organ allocation/placement issues** (13%), **labeling issues** (11%) or **packaging/shipping issues** (11%). Events related to **data entry issues** (10%) were also not uncommon.

The more granular subcategory analysis revealed that nearly one in three communication issues pertained to delayed communication. Inaccurate or insufficient information about a donor (or organ/vessel) and miscommunication about the increased risk (formerly “high risk”) status of a donor were also relatively common. Testing issues most often tended to involve either a hemodilution or HLA discrepancy. Errors in entering data into DonorNet, in particular for HLA, continue to be reported. Incorrectly labeled Donor IDs continue to be a problem, in particular on tubes used for shipping diagnostic materials (blood, nodes, or spleen).

The data included in this analysis is based on what the member or complainant reported in their initial contact with UNOS; it does not incorporate information from subsequent inquiry with the member and analysis of additional information obtained after the initial report by the member. Thus, this report should be considered an analysis of “front-end” data, not “back-end” data. For example, information about the root cause of each event and whether any policy violations actually occurred was not included in this analysis.

BACKGROUND/PURPOSE

The OPTN Operations and Safety Committee (OSC) previously reviewed de-identified, summarized patient safety situations (including both adverse events and near misses) submitted into the Improving Patient Safety (IPS) portal. Based on the narrative describing each event provided by members, the events reported from January 2012 through June 2014 have been categorized using relevant keywords (e.g., packaging & labeling, data entry

BACKGROUND/PURPOSE

error, transportation). Previous reports have shown the distribution of reported events by category and subcategory, as well as time trends. The purpose of these analyses is to help the committee better understand where safety gaps may exist in the system and to proactively address high frequency and/or high impact events with system improvements. The committee also hopes to use this information to increase awareness of the types of safety situations that are happening in order to spur institutions and individuals to proactively take measures to prevent repeat occurrences.

Since this database is currently still maturing and undoubtedly suffers from some degree of underreporting, the purpose of analyzing this data at this time is not to estimate the true, underlying error rates but to determine if certain types of events are becoming more frequent and thus identify area(s) where the OPTN would benefit from system improvements. Consequently, this analysis is primarily intended to help the committee understand what is currently being reported, increase the transplant community's awareness of the types of safety events that are occurring, foster increased reporting by the transplant community, and guide evolving refinements to the IPS portal.

This request is an update to previous analyses and has become a standing, semi-annual request of the OSC.

WORK PLAN ITEM ADDRESSED

- 1) Develop and implement a system for review of de-identified adverse events or near misses reported to the OPTN in order to identify potential network improvements and policy revisions necessary to prevent future occurrences.
- 2) Explore ways to disseminate information to the transplant community regarding outcomes of reported adverse events or near misses in an effort to heighten awareness of safety within the transplant community.

COMMITTEE REQUEST

Patient safety situation trends and patterns: Perform trends and patterns analysis of patient safety situations reported to UNOS, using the categories and subcategories developed in previous analyses and discussions with the OSC and its Patient Safety Planning Development Work Group.

Updating this analysis has been a standing committee request. In September 2012, the committee requested that this analysis be updated and reported to the work group and full committee on a semi-annual basis.

As discussed in committee deliberations on April 8, 2014, this analysis was expanded to show the breakdown of patient safety events jointly by high-level category and by institution type (e.g. OPO, TXC, Lab).

COMMITTEE REQUEST

DATA AND METHODS

Data Sources:

This long-term trend analysis included patient safety situations reported into the Secure EnterpriseSM Improving Patient Safety (IPS) portal between March 7, 2006 (IPS implementation date) and June 30, 2014. Currently, reporters submit detailed information about the safety situation primarily by means of a free-form (unrestricted text) narrative. Often these narratives are quite lengthy. Enhancements to the IPS portal implemented on May 29, 2014 have given reporters the ability to select meaningful event categories that will hopefully streamline future data analysis and tracking processes.

In addition to safety situations reported through the IPS portal, this analysis included review of safety-related issues identified via other reporting pathways to UNOS between 2012 and June 2014. For example, such pathways included patient and member complaints sent by email, calls placed to the Patient Services line or Member Services line, and process or policy-related issues discovered during DTAC review of potential disease transmission cases. As with the IPS, these “other pathway” events were categorized by reviewing the narrative of each reported situation.

The narrative associated with each of the over 570 events was reviewed by a UNOS patient safety specialist and/or committee liaison, and a biostatistician and/or research analyst to determine the keyword(s) and categories that best summarize the nature of the event. These categorizations and sub-categorizations have evolved and been refined over time, based on feedback from the committee. Also, as more events have been analyzed, new categories have been found to be needed. Further refinements will likely be necessary. The current nine “high-level categories” (plus “other”) checkboxes for the IPS are as follows:

- Communication issue
- Data entry issue
- Transportation issue
- Packaging/shipping issue
- Labeling issue
- Recovery procedure/process issue
- Transplant procedure/process issue
- Testing issue
- Organ allocation/placement issue
- Other

COMMITTEE REQUEST

An extensive list of subcategories and sub-subcategories (e.g., Data entry issue→ DonorNet® → ABO) under each of these high-level categories has also been incorporated into the IPS in May 2014.

Each situation was categorized into one *or more* high-level categories, as well as possibly one or more subcategories. This report focuses on high-level and subcategorization of events submitted since January 2012. About 70% of the IPS situations fell into strictly one high-level category, while the remaining 30% were considered to belong to more than one category. Only 4% of IPS situations fell into more than two high-level categories. About 80% of situations from ‘other pathways’ were classified into a single high-level category, while the remaining fell under two or three high-level categories.

This analysis excluded events reported through the IPS portal that were clearly not related to patient safety (e.g., user difficulty using UNetSM that was resolved without impact on safety) or were duplicative of another entry (e.g., several OPOs reported a recall of the same chest tubing). This analysis did not include events reported to the Potential Disease Transmission portal within the IPS. Subcategories with only one reported event from 2012 through July 2014 were reported together as a single group in Tables 1-11.

Living donor adverse events that are required reporting per OPTN policy are generally reported through the IPS’s Living Donor Adverse Events portal. This includes living donor deaths; failure of native organ function; organ recovered but discarded; organ recovered but redirected to alternate recipient; and aborted recovery procedure. Some events also pertaining to living donors are also reported through the Safety Situation portal. This analysis includes both types of events. For the purposes of reporting high-level category events, we are considering Living Donor events as a separate category in this report. These events were previously categorized as “Other”. Only those living donor events reported as a “patient safety situation” in the IPS are included in the overall IPS portal trends analysis (**Figure 1**).

Reporting the death of a living donor is required, even if the death is clearly not donation related. Many living donor deaths that are reported occurred years after the donation and were due to non-medical causes of death (e.g., motorcycle accident). For this analysis, only those living donor deaths that occurred within 30 days of the donation and with a cause of death medical in nature were included. Also, events for people who underwent donation surgery but ultimately did not donate an organ are included, even though such individuals are not technically donors.

For tracking trends in event reporting over time (**Figure 1**), IPS events were sorted using the date the event was added to the system (“add date”). “Other pathway” events were sorted using the date the incident report was received by UNOS staff.

COMMITTEE REQUEST

RESULTS

Overall Trend in Safety Situation Reporting

Figure 1 shows that 314 events were reported into the IPS from March 8, 2006 - December 31, 2011, 99 in 2012, 118 in 2013, and 81 from January - June 2014. In general, the rate of reporting has been increasing, with the exception of a temporary decrease in 2009.

Figure 1 also shows that 114 additional events were identified in 2012, 95 in 2013, and 50 from January - June 2014 through other reporting pathways besides the IPS. For example, "other pathways" included emails, calls, or letters to UNOS, patient complaints, and incidents identified by other UNOS departments. Year 2012 was the first full year for which these situations from other pathways were categorized for Operations & Safety Committee review.

Figure 1. Safety Situations Reported (March 2006 - June 2014) to the UNet "Improving Patient Safety" Portal and Situations Identified through Other Reporting Pathways since 2012



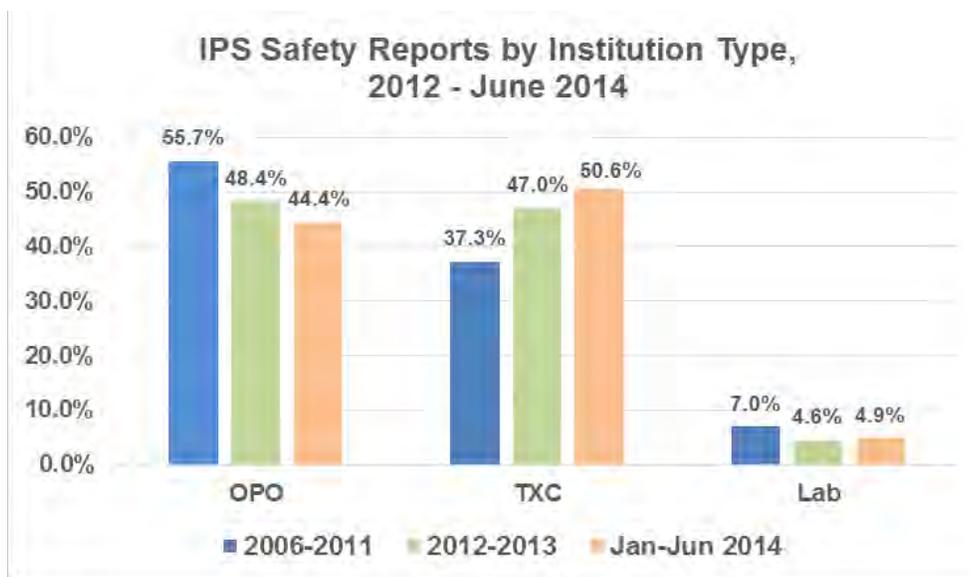
(Editor’s note: Subsequent to the creation of this report, one additional event related to vessel sharing in June 2014 was identified.)

Reporting by Institution Type

Figure 2 reveals that during the first half of 2014, 50.6% of events reported to the IPS were reported by transplant hospitals, with OPOs accounting for 44.4% of reports, and labs the remaining 4.9%. By comparison, from 2012 - 2013, OPOs reported 48.4% of events and transplant hospitals 47.0%.

Some events occurred at the institution reporting the event, whereas for other events, one institution reported about an issue related to a different institution. For example, OPOs have reported concerns with transplant hospitals’ delayed communication regarding recipient status; likewise, transplant hospitals have reported concerns about the packaging and labeling of organs by the OPO.

Figure 2. IPS Safety Reports by Institution Type, 2012 - June 2014



Reporting by Event Type (High-Level Category): 2012 – June 2014

Figure 3 shows the high-level category frequencies in 2012 - June 2014 for safety situations identified from both the IPS and other pathways combined.

During the first half of 2014, the most frequently reported events were related to communication issues (23%), transplant process/procedure issues (23%), packaging/shipping issues (18%), labeling issues (15%), testing issues (14%), recovery process/procedure issues (12%), and organ allocation/placement issues (11%).

Compared to the data from 2012 – 2013, the 2014 reported communication issues remained consistent, while there were increases in the reported transplant process/procedure issues, packaging/shipping issues, and labeling issues, and slight increases in reported recovery process/procedure issues and transportation issues. Conversely, there were also slight decreases in reported data entry issues, testing issues, and allocation process/procedure issues. There was also a decrease in “Other” reports, which can be attributed in part to the new “Living Donor” category classification. Due to limited sample sizes, these differences may not be statistically significant.

Figure 3. Patient Safety Situation Reporting by Event Type (High-Level Category), 2012 - June 2014

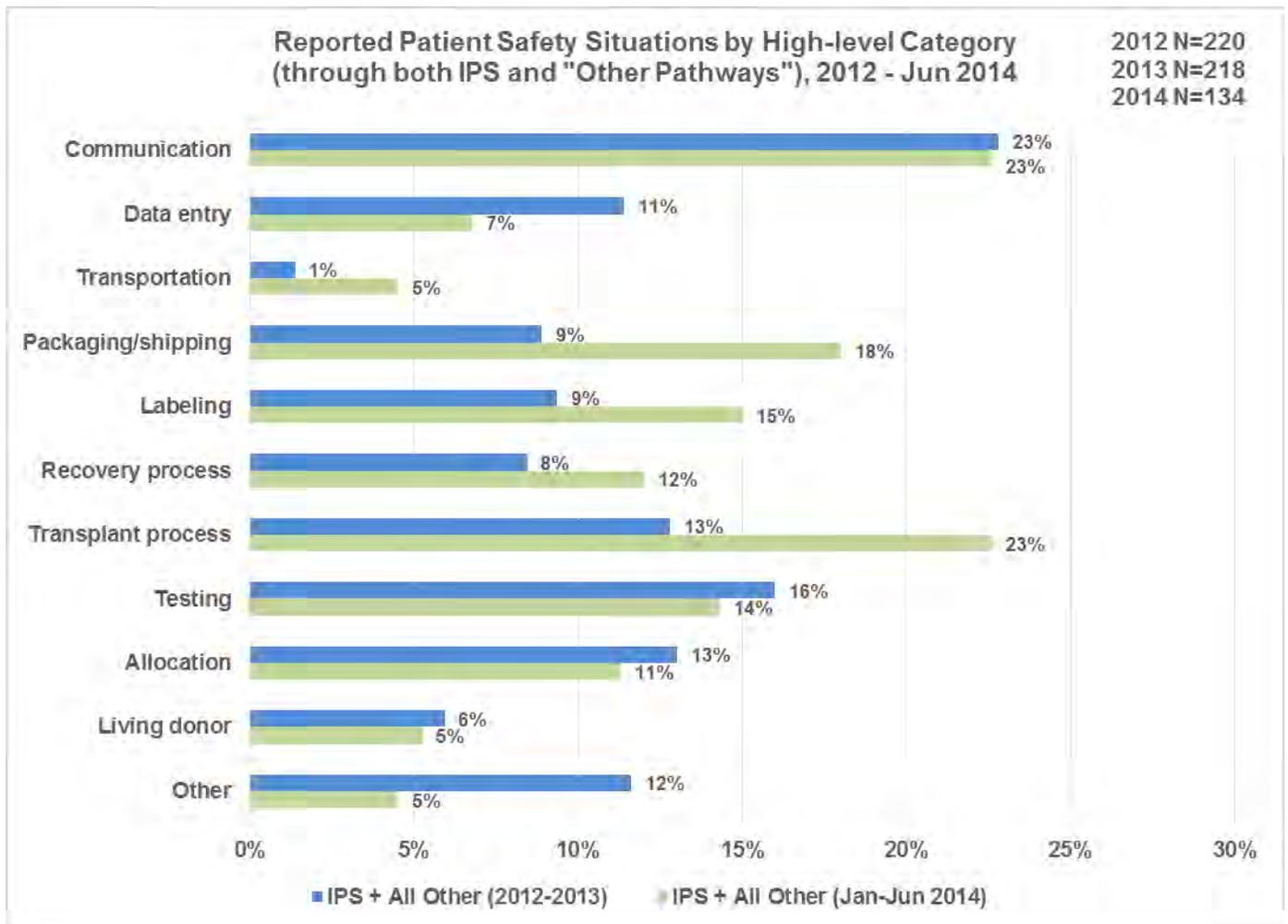
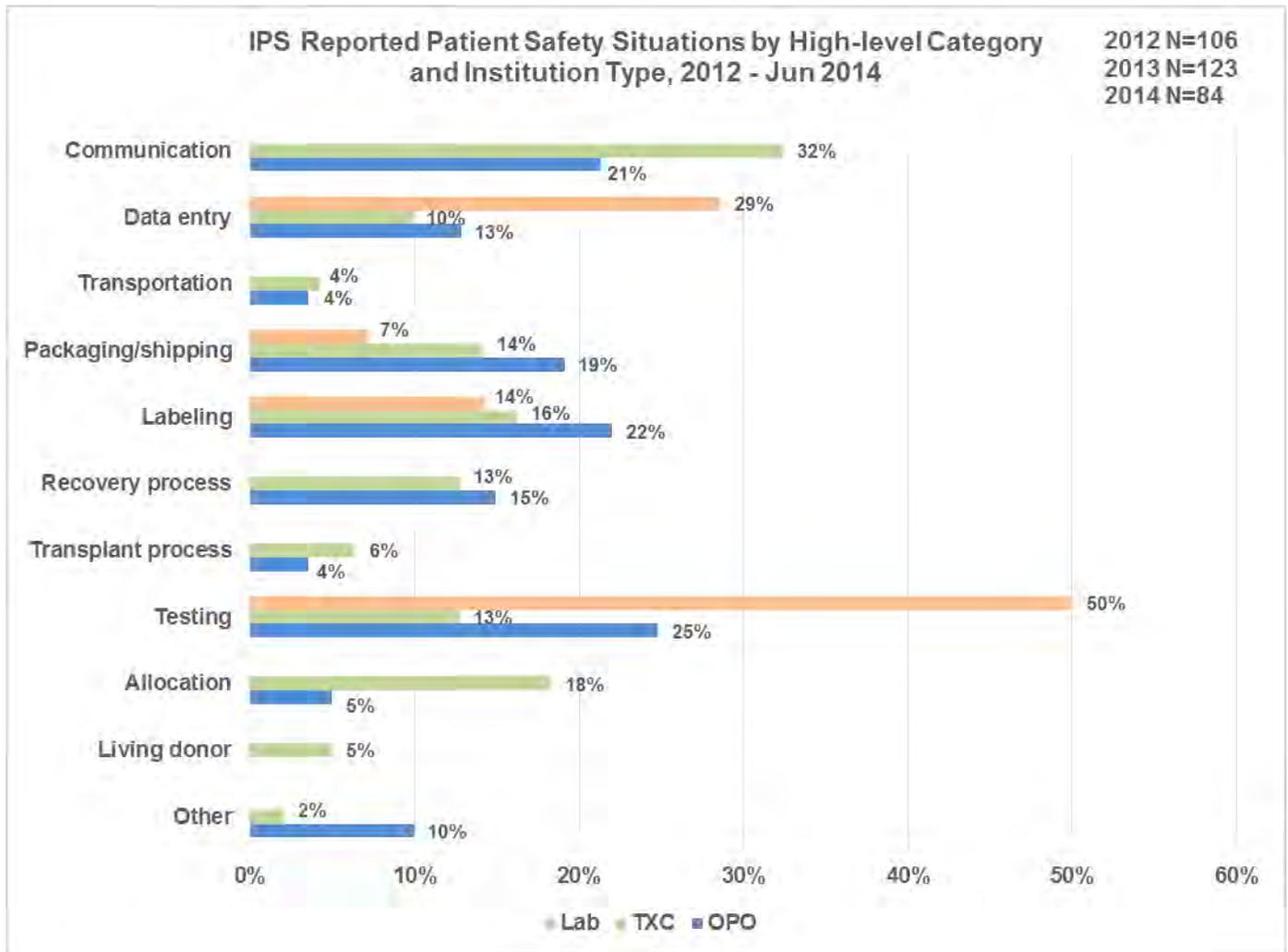


Figure 4 shows the high-level category frequencies from 2012 - June 2014 for safety situations identified from the IPS according to reporting institution type.

Nearly 80% of issues reported by labs during this time period were either testing issues (50%) or data entry issues (29%). Transplant hospitals most often reported communication issues (32%), while OPOs most frequently reported testing issues (25%).

Figure 4. IPS Patient Safety Situation Reporting by Event Type (High-Level Category) and Reporting Institution Type, 2012 - June 2014



Reporting by Event Subcategory (2012 – June 2014)

The communication issues (N=130) in **Figure 3**, which includes situations reported since January 2012 through both the IPS portal and other pathways, are categorized more finely in **Table 1**. Forty (31%) of the one hundred thirty communication-related safety situations involved *delayed communication*. *Inaccurate or insufficient donor (or organ/vessel) information* (N=36) was the second most prevalent communication subcategory. Some examples of inaccurate/insufficient information include the following:

- missing intraoperative report
- incorrect vein and artery information
- missing organ anatomy information
- no documentation of cyst

Increased risk (high risk) status of donor (N=11) was third most prevalent. There were also eleven situations that involved *patient not informed adequately (or at all)*.

Table 2 shows testing issues (N=89) by subcategory. Sixteen (18%) of the eighty-nine testing-related situations involved a concern about donor hemodilution. Fourteen situations pertained to *discrepant HLA results*. Situations also related to the following: *infectious disease cultures not available or not done* (N=8), *inaccurate HLA results reported* (N=5), and *important or required infectious disease test(s) not done* (N=5).

Table 3 shows that 32 of the transplant procedure/process-related situations (N=84) involved *sharing of extra vessels* among transplant centers or OPOs. Ten complaints were made about *listing practices*. Five cases of an *extra vessel being used in a non-transplant patient* were reported in 2012, one case in 2013, and one case during the first half of 2014. Six reports were received about a *recipient not being promptly removed from the waitlist* after transplantation.

Many cases were unique and did not fall into any of the pre-determined subcategories. Some examples include the following:

- delays in listing a patient
- organ too large for patient
- medical staff availability
- surgical competency

Organ allocation/placement issues (N=72) reported since 2012 were broken down by subcategory in **Table 4**. The majority (N=23) were related to a concern about *out of sequence allocation*. Several pertained to *rescinded offers* (N=7), *recipient not on match list* (N=4), and *inaccurate donor data causing match to run incorrectly* (N=4). Several complaints that were categorized as *other* involved cases of delayed organ offers or late offer declines, some of which resulted in increased cold ischemia time.

Table 5 reveals that the most common labeling-related issues (N=61) involved an *incorrect donor ID* (N=23). Labeling issues pertaining to *unlabeled or mislabeled diagnostic materials (blood/nodes/spleen)* were also frequently reported (N=21). *Transcription errors* (N=13) were

also common. Many of the labeling situations were classified under multiple subcategories. For example, many of the situations with an incorrect donor ID were due to a transcription error on the label used for diagnostic materials. There were also eleven reports of *missing labels*.

Table 6 shows that *switched kidney laterality* (N=17) cases were the most common type of packaging/shipping-related (N=63) safety situations.

Note that some switched laterality cases were classified as labeling issues (N=12, Table 5) and some as packaging/shipping issues (N=17, Table 6), while eight events fell under both high level categories. Consequently, there were a total of 21 *switched kidney laterality* cases reported between January 2012 and June 2014¹. Both kidneys were successfully transplanted in 16 (76%) of these 21 cases, despite the mix-up. There was also one case of *switched lung laterality*, with both lungs being successfully transplanted.

In fifteen of the packaging/shipping situations, the *organs were not packaged according to requirements*. There were also seven reports of *insufficient or missing blood/nodes/spleen*, and six instances where the *sterile container/bag not properly closed*.

Data entry issues (N=59) were subcategorized in **Table 7**. The most prevalent type of data entry issue involved *entering donor HLA into DonorNet* (N=15). Several types of patient/candidate data entry issues were also relatively common: *inaccurate patient priority or status* (N=7), *ABO subtyping* (N=5), *increased risk (high risk) status of donor* (N=5), and *infectious disease test results* (N=4). In three cases, a patient was *removed or inactivated in error*.

Table 8 shows thirteen (25%) of the situations related to a recovery procedure/process issue (N=53) involved an *injury to the organ or extra vessels*. An additional 11 cases involved an *issue with the recovering transplant team(s)* (e.g. complaint of onsite transplant team declining organ due to size without entering the OR). There were also ten reports of *poor donor management*.

Table 9 shows 33 living donor issues. The most commonly reported types of living donor events were those that are required to be reported per OPTN policy: *organ recovered but not transplanted* (N=5), *failure of native organ function* (N=4), *organ redirected to another recipient* (N=4), and *aborted recovery* (N=3). Three events related to a *donor health issue*, including:

- perforated bowel with abscess
- retroperitoneal fibrosis post-donation with ureteric narrowing of solitary kidney
- metastatic cancer

Other living donor events, grouped as “*other*” since they occurred singly, included a complaint about a donor feeling pressured to donate, a living donor having difficulty finding care for complications, and a wrong laterality recovery “near-miss.” Also, one living donor death was

¹ One additional switched laterality event involved a data entry error, where the wrong anatomy charts were uploaded into DonorNet (Table 7, in “DonorNet (Other)”).

reported where the death occurred within 30 days of the donation and the cause of death was medical in nature.

Twelve transportation-related issues, are shown in **Table 10**, four involving *airlines* and three involving *ground transportation/courier*. In one of these cases, an airline failed to board the organ at the airport. In another case, a courier transported tissue to a transplant center instead of the solid organ.

Though few transportation-related events have been reported through the IPS or “other reporting pathways,” the UNOS Organ Center audits all organ shipments it facilitates. About 3-4% of shipments have been found to be either failures (organ did not reach destination or with a long enough delay to cause the organ to be deemed unacceptable) or “near misses” (delay of 2+ hours but organ still acceptable at intended destination).

All situations that didn’t fall into one of the ten high-level categories were grouped together as other issues and are shown in **Table 11** (N=59). *Drug or product recalls* were reported in ten cases. *Extra vessels were not stored properly* in five of these other situations.

A large number of these situations (N=32) were classified as *events related to a potential disease transmission*. **This subcategory does not include all potential disease transmission events reported to the OPTN.** Rather, only those events involving a human/process error or referred to DEQ due to a potential policy violation are included in this report.

Events Resulting in Organs Not Transplanted (2012 – June 2014)

Of the 572 events reported through both the IPS and other pathways, it was clear from the narrative that organ(s) were not transplanted as a result of the event in at least 64 (11%) cases. Organs were considered not transplanted if either an organ was recovered but discarded due to the event, or an organ was not recovered due to the event. Recent enhancements to the IPS portal require members to provide this information for each event reported. Some cases included switched kidney laterality, frozen organs, damage to organ during recovery, poor donor management, late organ declines, and equipment malfunctions.

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Table 1: Communication-Related Safety Situations Reported from Jan 2012-Jun 2014 by OPTN Members into the UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory

Communication Issues, by Subcategory	2012	2013	Jan-Jun 2014	Total
delayed communication	9	17	14	40
inaccurate/insufficient donor (or organ/extra vessels) information	14	16	6	36
increased risk (high risk) status of donor	6	4	1	11
patient not informed adequately (or at all)	7	2	2	11
miscommunication of donor test results	3	4	0	7
other - delay in potential disease transmission reporting	0	7	0	7
missing documentation	4	2	0	6
other - complaint of unprofessional interactions	2	0	2	4
change in test results not reported	2	0	0	2
other - did not notify opo/OPTN of potential disease transmission	2	0	0	2
other - miscommunication re: organ refusal	0	0	2	2
other - transcription error	0	2	0	2
reliance on electronic instead of verbal communication	2	0	0	2
other	11	10	1	22
Number of unique patient safety situations*	52	48	30	130

Events were categorized and (if applicable) sub-categorized by a UNOS staff review of the descriptive narrative submitted for each safety situation.

** Since a patient safety situation may involve more than one subcategory, some situations may appear multiple times in this table. Therefore, the sum of subcategory values may be larger than the actual number of unique events.*

Safety situations may include near misses, 'no harm' events, and actual safety events.

Since reporting of most types of safety situations is voluntary, the number of situations reported is believed to be an underestimate of the actual number of situations that have occurred.

Duplicate situations and reports not pertaining to patient safety were excluded.

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Table 2: Testing-Related Safety Situations Reported from Jan 2012-Jun 2014 by OPTN Members into the UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory

Testing Issues, by Subcategory	2012	2013	Jan-Jun 2014	Total
infectious disease - hemodilution error or discrepancy	5	10	1	16
HLA - discrepant results	1	8	5	14
infectious disease - cultures not available or not done	2	3	3	8
HLA - inaccurate results reported	2	1	2	5
infectious disease - important or required test(s) not done	4	1	0	5
ABO - ABO subtyping error or discrepancy	3	1	0	4
infectious disease - discrepant results	1	1	2	4
infectious disease - wrong type of test used	3	0	0	3
HLA - required test not used	2	0	0	2
infectious disease - infectious disease test results not available prior to transplant	0	1	1	2
infectious disease - other - delayed culture results	0	0	2	2
other - important or required test(s) not done	2	0	0	2
other ABO or ABO subtyping related	4	1	0	5
other HLA related	1	1	1	3
infectious disease related	3	1	0	4
other	4	2	3	9
Number of unique patient safety situations*	36	34	19	89

Events were categorized and (if applicable) sub-categorized by a UNOS staff review of the descriptive narrative submitted for each safety situation.

** Since a patient safety situation may involve more than one subcategory, some situations may appear multiple times in this table. Therefore, the sum of subcategory values may be larger than the actual number of unique events.*

Safety situations may include near misses, 'no harm' events, and actual safety events.

Since reporting of most types of safety situations is voluntary, the number of situations reported is believed to be an underestimate of the actual number of situations that have occurred.

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Table 3: Transplant Procedure/Process-Related Safety Situations Reported from Jan 2012-Jun 2014 by OPTN Members into the UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory

Transplant Procedure/Process Issues, by Subcategory	2012	2013	Jan-Jun 2014	Total
other - vessel sharing	11	10	11	32
other - complaint about listing practices	0	4	6	10
vessels used in a non - transplant patient	5	1	1	7
other - recipient not promptly removed from Waitlist	4	0	2	6
other - delay in listing a patient	0	2	1	3
other - organ too large for patient	0	1	1	2
other	3	12	4	49
Number of unique patient safety situations*	23	31	30	84

Events were categorized and (if applicable) sub-categorized by a UNOS staff review of the descriptive narrative submitted for each safety situation.

** Since a patient safety situation may involve more than one subcategory, some situations may appear multiple times in this table. Therefore, the sum of subcategory values may be larger than the actual number of unique events.*

Safety situations may include near misses, 'no harm' events, and actual safety events.

Since reporting of most types of safety situations is voluntary, the number of situations reported is believed to be an underestimate of the actual number of situations that have occurred.

Duplicate situations and reports not pertaining to patient safety were excluded.

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Table 4: Organ Allocation/Placement-Related Safety Situations Reported from Jan 2012-Jun 2014 by OPTN Members into the UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory

Organ Allocation/Placement Issues, by Subcategory	2012	2013	Jan-Jun 2014	Total
out of sequence allocation	15	8	0	23
rescinded offer	3	2	2	7
inaccurate donor data caused match to run incorrectly	2	1	1	4
recipient not on match list	2	2	0	4
organ allocation/placement issue - (no subcategory)	3	0	0	3
inaccurate patient priority or status	0	2	0	2
match not rerun once serology found to be positive	2	0	0	2
offer not made to secondary contact	2	0	0	2
other - complaint of influencing allocation	2	0	0	2
other - multiorgan sharing	0	2	0	2
other - no local backup	0	2	0	2
other	4	5	10	19
Number of unique patient safety situations*	34	23	15	72

Events were categorized and (if applicable) sub-categorized by a UNOS staff review of the descriptive narrative submitted for each safety situation.

** Since a patient safety situation may involve more than one subcategory, some situations may appear multiple times in this table. Therefore, the sum of subcategory values may be larger than the actual number of unique events.*

Safety situations may include near misses, 'no harm' events, and actual safety events.

Since reporting of most types of safety situations is voluntary, the number of situations reported is believed to be an underestimate of the actual number of situations that have occurred.

Duplicate situations and reports not pertaining to patient safety were excluded.

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Table 5: Labeling-Related Safety Situations Reported from Jan 2012-Jun 2014 by OPTN Members into the UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory

Labeling Issues, by Subcategory	2012	2013	Jan-Jun 2014	Total
donor id - incorrect id	13	8	2	23
blood/nodes/spleen	10	8	3	21
transcription error	10	1	2	13
switched laterality - kidneys	2	4	6	12
missing label	3	3	5	11
required information missing	3	0	1	4
donor id - missing id	2	0	0	2
other - opo did not provide labels	0	1	1	2
other	3	0	3	6
Number of unique patient safety situations*				
	24	17	20	61

Events were categorized and (if applicable) sub-categorized by a UNOS staff review of the descriptive narrative submitted for each safety situation.

** Since a patient safety situation may involve more than one subcategory, some situations may appear multiple times in this table. Therefore, the sum of subcategory values may be larger than the actual number of unique events.*

Safety situations may include near misses, 'no harm' events, and actual safety events.

Since reporting of most types of safety situations is voluntary, the number of situations reported is believed to be an underestimate of the actual number of situations that have occurred.

Duplicate situations and reports not pertaining to patient safety were excluded.

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Table 6: Packaging/Shipping-Related Safety Situations Reported from Jan 2012-Jun 2014 by OPTN Members into the UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory

Packaging/Shipping Issues, by Subcategory	2012	2013	Jan-Jun 2014	Total
switched laterality - kidneys	6	5	6	17
not packaged according to requirements	3	8	4	15
insufficient or missing blood/nodes/spleen	2	2	3	7
sterile container/bag not properly closed	2	3	1	6
frozen organ	0	1	1	2
ice melted	0	2	0	2
other	4	2	3	9
Number of unique patient safety situations*				
	15	24	24	63

Events were categorized and (if applicable) sub-categorized by a UNOS staff review of the descriptive narrative submitted for each safety situation.

** Since a patient safety situation may involve more than one subcategory, some situations may appear multiple times in this table. Therefore, the sum of subcategory values may be larger than the actual number of unique events.*

Safety situations may include near misses, 'no harm' events, and actual safety events.

Since reporting of most types of safety situations is voluntary, the number of situations reported is believed to be an underestimate of the actual number of situations that have occurred.

Duplicate situations and reports not pertaining to patient safety were excluded.

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Table 7: Data Entry-Related Safety Situations Reported from Jan 2012-Jun 2014 by OPTN Members into the UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory

Data Entry Issues, by Subcategory	2012	2013	Jan-Jun 2014	Total
DonorNet - HLA	9	6	0	15
Waitlist - inaccurate patient priority or status	5	2	0	7
DonorNet - ABO subtyping	2	3	0	5
DonorNet - increased risk (high risk) status of donor	2	2	1	5
Waitlist - ABO	4	0	1	5
DonorNet - infectious disease test result(s)	3	0	1	4
Waitlist - patient removed or inactivated in error	3	0	0	3
DonorNet - demographics	1	0	1	2
DonorNet - donor id	0	2	0	2
DonorNet - infectious disease testing results	0	1	1	2
DonorNet - labs	1	0	1	2
DonorNet - other	0	1	1	2
Waitlist - other	1	2	0	2
other	1	2	2	5
Number of unique patient safety situations*				
	30	20	9	59

Events were categorized and (if applicable) sub-categorized by a UNOS staff review of the descriptive narrative submitted for each safety situation.

** Since a patient safety situation may involve more than one subcategory, some situations may appear multiple times in this table. Therefore, the sum of subcategory values may be larger than the actual number of unique events.*

Safety situations may include near misses, 'no harm' events, and actual safety events.

Since reporting of most types of safety situations is voluntary, the number of situations reported is believed to be an underestimate of the actual number of situations that have occurred.

Duplicate situations and reports not pertaining to patient safety were excluded.

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Table 8: Recovery procedure/process-Related Safety Situations Reported from Jan 2012-Jun 2014 by OPTN Members into the UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory

Recovery Procedure/Process Issues, by Subcategory	2012	2013	Jan-Jun 2014	Total
injury to organ or extra vessels	5	4	4	13
issue with recovering transplant team(s)	5	4	2	11
poor donor management	3	4	3	10
sterile field breach or other sterility issue	2	0	1	3
OR time delayed	2	0	0	2
equipment malfunction	0	1	1	2
other - concerned about validity of brain death declaration	2	0	0	2
other - increased CIT	0	0	2	2
preservation fluid issue	1	1	0	2
other	4	5	3	12
Number of unique patient safety situations*	22	15	16	53

Events were categorized and (if applicable) sub-categorized by a UNOS staff review of the descriptive narrative submitted for each safety situation.

** Since a patient safety situation may involve more than one subcategory, some situations may appear multiple times in this table. Therefore, the sum of subcategory values may be larger than the actual number of unique events.*

Safety situations may include near misses, 'no harm' events, and actual safety events.

Since reporting of most types of safety situations is voluntary, the number of situations reported is believed to be an underestimate of the actual number of situations that have occurred.

Duplicate situations and reports not pertaining to patient safety were excluded.

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Table 9: Living Donor-Related Safety Situations Reported from Jan 2012-Jun 2014 by OPTN Members into the UNet(SM) 'Improving Patient Safety' (IPS) Portal, including Living Donor Adverse Event Portal, or Other Pathways, by Subcategory

(All living donor deaths are required reported, even if death was years after donation and not related to a medical condition.

(Only deaths within 30 days of donation and cause of death was medical in nature are included)

(Events for people who underwent donation surgery, but ultimately did not donate an organ, are included though they are not technically donors)

Living Donor Issues, by Subcategory	2012	2013	Jan-Jun 2014	Total
organ recovered but not transplanted	2	2	1	5
failure of native organ function	1	1	2	4
redirected organ	1	3	0	4
aborted recovery	0	3	0	3
donor health issue	2	1	0	3
other*	1	6	3	10
Number of unique patient safety situations**	10	16	7	33

**Includes one living donor death within 30 days of donation where cause of death was medical in nature. Events were categorized and (if applicable) sub-categorized by a UNOS staff review of the descriptive narrative submitted for each safety situation.*

*** Since a patient safety situation may involve more than one subcategory, some situations may appear multiple times in this table. Therefore, the sum of subcategory values may be larger than the actual number of unique events.*

Safety situations may include near misses, 'no harm' events, and actual safety events.

Since reporting of most types of safety situations is voluntary, the number of situations reported is believed to be an underestimate of the actual number of situations that have occurred.

Duplicate situations and reports not pertaining to patient safety were excluded.

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Table 10: Transportation-Related Safety Situations Reported from Jan 2012-Jun 2014 by OPTN Members into the UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory

Transportation Issues, by Subcategory	2012	2013	Jan-Jun 2014	Total
airline related	0	2	2	4
ground - courier/driver issue	2	1	0	3
ground - other	0	1	0	1
Number of unique patient safety situations*	2	4	6	12

Events were categorized and (if applicable) sub-categorized by a UNOS staff review of the descriptive narrative submitted for each safety situation.

** Since a patient safety situation may involve more than one subcategory, some situations may appear multiple times in this table. Therefore, the sum of subcategory values may be larger than the actual number of unique events.*

Safety situations may include near misses, 'no harm' events, and actual safety events.

Since reporting of most types of safety situations is voluntary, the number of situations reported is believed to be an underestimate of the actual number of situations that have occurred.

Duplicate situations and reports not pertaining to patient safety were excluded.

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Table 11: Other Safety Situations Reported from Jan 2012-Jun 2014 by OPTN Members into the UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory

Other Issues	2012	2013	Jan-Jun 2014	Total
events related to a potential disease transmission*	13	17	2	32
drug or product recall	5	1	4	10
vessels not stored properly	4	1	0	5
mishandling of confidential information	0	1	2	3
complaint about transplant program clinical competency	0	2	0	2
hospital failure to respond to DTAC investigation	2	0	0	2
living donor id generated after recovery	2	0	0	2
no patient safety contact	0	2	0	2
other	8	9	2	19
Number of unique patient safety situations**	26	27	6	59

**Does not include all potential disease transmission events reported to the OPTN, but only those reported as 'patient safety situations' through the IPS or through other pathways, such as a DTAC referral. Events were categorized and (if applicable) sub-categorized by a UNOS staff review of the descriptive narrative submitted for each safety situation.*

*** Since a patient safety situation may involve more than one subcategory, some situations may appear multiple times in this table. Therefore, the sum of subcategory values may be larger than the actual number of unique events. Safety situations may include near misses, 'no harm' events, and actual safety events. Since reporting of most types of safety situations is voluntary, the number of situations reported is believed to be an underestimate of the actual number of situations that have occurred. Duplicate situations and reports not pertaining to patient safety were excluded.*