

At-a-Glance

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

- **Affected/Proposed Policies:** Policy 1.2 (Definitions)

Policy 2.6 (Deceased Donor Blood Type Determination and Reporting), Policy 2.6.A (Deceased Donor Blood Type Determination), Policy 2.6.B (Deceased Donor Blood Subtype Determination), Policy 2.6.C (Primary Reporting of Deceased Donor Blood Type and Subtype), Policy 2.6.D. (Secondary Reporting of Deceased Donor Blood Type and Subtype)

Policy 3.3 (Candidate Blood Type Determination and Reporting before Waiting List Registration), Policy 3.3.A (Blood Type Determination before Registration on the Waiting List), Policy 3.3.B (Secondary Reporting of Candidate Blood Type)

Policy 5.4.B (Order of Allocation), Policy 5.5.A Receiving and Reviewing Organ Offers), Policy 5.6 (Blood Type Verification Upon Receipt), Policy 5.6.A (New: Host OPO Organ Recovery Verification, and Policy 5.6.B (New: Recovery and Transplant Hospital Organ Recovery, Check-In, and Pre-Transplant Verifications

Policy 13.6.A (Requirements for Match Run Eligibility for Candidates), Policy 13.6.B (Requirements for Match Run Eligibility for Potential KPD Donors)

Policy 14.4. (New: Living Donor Blood Type Determination and Reporting), Policy 14.4.Ai (Living Donor Blood Type Determination), Policy 14.4.A.ii (Living Donor Blood Subtype Determination), Policy 14.4.A.iii (formerly 14.6) (Registration and Blood Type Verification of Living Donors before Donation)

Policy 16.1 (Organs Not Requiring Transport)

Policy 16.4.C (Internal Labeling of Blood and Tissue Typing Materials)

- **Operations and Safety Committee**

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.

- **Affected Groups**

Directors of Organ Procurement
Lab Directors/Supervisors
OPO Executive Directors
OPO Medical Directors
OPO Coordinators
Transplant Administrators
Transplant Coordinators
Transplant Physicians/Surgeons
Transplant Program Directors
Organ Candidates
Living Donors

- **Number of Potential Candidates Affected**

ABO determination, reporting, and verification is required for all organ donors and candidates.

- **Compliance with OPTN Strategic Plan and Final Rule**

This proposal supports the following strategic plan goals:

1. Promote transplant patient safety (through strengthening ABO policies to assure that transplants are ABO compatible or intended incompatible)
2. Promote living donor safety (through strengthening ABO policies to assure that transplants are ABO compatible or intended incompatible)
3. Promote efficient management of the OPTN (through clearly written policy, education and competency testing, and improved electronic and automated tools to manage ABO reporting and verification processes)

- **Specific Requests for Comment**

The Committee wants to understand any concerns regarding implementing the proposed changes to ABO determination, reporting, and verification processes. The

Operations and Safety Committee seeks specific feedback on putting these changes into practice, and offers the following specific question for consideration:

What comments or suggestions would you offer regarding required verifications and responsibility for those verifications when the chain of custody and intended recipient changes among OPOs (e.g. Host OPO to importing OPO serving local DSA?) or among transplant hospitals?

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

Affected/Proposed Policies: Policy 1.2 (Definitions)

Policy 2.6 (Deceased Donor Blood Type Determination and Reporting), Policy 2.6.A (Deceased Donor Blood Type Determination), Policy 2.6.B (Deceased Donor Blood Subtype Determination), Policy 2.6.C (Primary Reporting of Deceased Donor Blood Type and Subtype), Policy 2.6.D (Secondary Reporting of Deceased Donor Blood Type and Subtype)

Policy 3.3 (Candidate Blood Type Determination and Reporting before Waiting List Registration), Policy 3.3.A (Blood Type Determination before Registration on the Waiting List), Policy 3.3.B (Secondary Reporting of Candidate Blood Type)

Policy 5.4.B (Order of Allocation), Policy 5.5.A Receiving and Reviewing Organ Offers), Policy 5.6 (Blood Type Verification Upon Receipt), Policy 5.6.A (New: Host OPO Organ Recovery Verification) and Policy 5.6.B (New: Recovery and Transplant Hospital Organ Recovery, Check-In, and Pre-Transplant Verifications)

Policy 13.6.A (Requirements for Match Run Eligibility for Candidates), Policy 13.6.B (Requirements for Match Run Eligibility for Potential KPD Donors)

Policy 14.4. (New: Living Donor Blood Type Determination and Reporting), Policy 14.4.Ai (Living Donor Blood Type Determination), Policy 14.4.A.ii (Living Donor Blood Subtype Determination), Policy 14.4.A.iii (formerly 14.6) (Registration and Blood Type Verification of Living Donors before Donation)

Policy 16.1 (Organs Not Requiring Transport)

Policy 16.4.C (Internal Labeling of Blood and Tissue Typing Materials)

Operations and Safety Committee

Public Comment Response Period: March 14, 2014-June 13, 2014

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.

Background and Significance of the Proposal

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

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).

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 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.

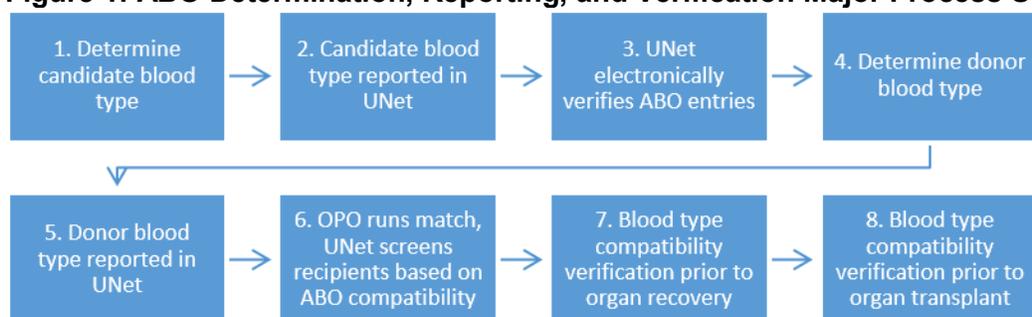
Supporting Evidence/Modeling

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. One 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.

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

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.

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 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.

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.

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).

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.

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.

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).

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,

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)

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 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 Strategic Plan, 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.

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

Compliance Monitoring

This section will describe proposed changes to the routine monitoring of members' compliance based on the proposed changes to policy.

Policy 2.6 Deceased Donor Blood Type Determination and Reporting – The monitoring plan may be updated as follows:

Upon site review of member OPOs, UNOS will review internal policies, protocols or procedures to verify the presence of:

- 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

Policy 2.6.A Deceased Donor Blood Type Determination – The monitoring plan may be updated as follows:

Upon site review of member OPOs, UNOS will review a sample of deceased donor records for:

- Source documentation of the results of two separate blood typing tests completed on two separate blood samples, and
 - Documentation showing that two different labs completed the two typing tests; or
 - If the same lab completed both typing tests, then
 - Documentation of the sample draws must include date and time for the draw of each sample used for the testing.

Policy 2.6.B Deceased Donor Blood Subtype Determination – No changes

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

The monitoring plan may be updated as follows:

Upon site review of member OPOs, UNOS will review internal policies, protocols or procedures to verify the presence of:

- A written protocol for the secondary reporting of blood type and subtype (if used for allocation) that includes a definition of a qualified health care professional, a process for consulting the source documents used by the initial reporter, and a process for confirming that the patient identification and test results match

Upon site review of member OPOs, UNOS will review a sample of deceased donor records for:

- Documentation showing that the secondary reporting process was carried out in a manner consistent with the OPO's internal protocol

Policy 3.3 Candidate Blood Type Determination and Reporting Before Waiting List Registration -

The monitoring plan may be updated as follows:

Upon site review of member OPOs, UNOS will review internal policies, protocols or procedures to verify the presence of:

- 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

Policy 3.3.A Candidates Blood Type Determination Before Waiting List Registration - The

monitoring plan may be updated as follows:

Upon site review of member transplant programs, UNOS will review a sample of candidate and recipient records for:

- The results of two separate blood typing tests completed on two separate blood draws, and

- Documentation of the sample draws must include date and time for the draw of each sample used for the testing
- The documented date and time of each sample draw must be no sooner than one minute apart

Policy 3.3.B Reporting of Candidate Blood Type

The monitoring plan may be updated as follows:

Upon site review of transplant programs, UNOS will review internal policies, protocols or procedures to verify the presence of:

- A written protocol for the secondary reporting of blood type that includes a process for consulting the source documents used by the initial reporter, and a process for confirming that the patient identification and test results match.

Upon site review of transplant programs, UNOS will review a sample of deceased donor records for:

- Documentation showing that the secondary reporting process was carried out in a manner consistent with the transplant program's internal protocol.

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

Upon site review of member recovery hospitals, UNOS will review living donor medical records, and any material incorporated into the medical record by reference, for documentation that:

- "Time outs" were performed prior to anesthesia of the living donor.

Policy 13.6.B Requirements for Match Run Eligibility for Potential KPD Donors – Monitoring Plan TBD

Policy 14.4.A Living Donor Blood Type Determination and Reporting - The monitoring plan may be updated as follows:

Upon site review of recovery hospitals, UNOS will review internal policies, protocols or procedures to verify the presence of:

- 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.

Policy 14.4.A.i Living Donor Blood Type Determination

Upon site review of recovery hospitals, UNOS will review a sample of living donor records for:

- The results of two separate blood typing tests completed on two separate blood draws, and
- Documentation of the sample draws must include date and time for the draw of each sample used for the testing

- The documented date and time of each sample draw must be no sooner than one minute apart

Policy 14.4.A.ii Living Donor Blood Subtype Determination – No monitoring planned

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

Upon site review of recovery hospitals, UNOS will review internal policies, protocols or procedures to verify the presence of:

- A written protocol for the secondary reporting of blood type that includes a process for consulting the source documents used by the initial reporter, and a process for confirming that the patient identification and test results match

Upon site review of recovery hospitals, UNOS will review a sample of living donor records for:

- Documentation showing that the secondary reporting process was carried out in a manner consistent with the recovery hospital's internal protocol

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~~ and
2. ~~report~~ Report the blood type to the OPTN Contractor, ~~and~~ 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 ~~in~~ 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 subtyping 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

	<u>Requirement</u>	<u>Time</u>	<u>Place</u>
<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-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 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:

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.

Rank #	Line #	Failure Mode	Step	Causes	Actions to Reduce Failure Modes
1	1	OPO releases organ to recipient not on match run	6. OPO runs match, UNet screens potential recipients based on ABO compatibility 6B. Match lists potential transplant recipients compatible (or planned incompatibility) with donor based on blood type (subtype)	Data: NOMR = ~60 per year Directed Donation (70%)/Avoid organ wastage (30%) Kidney = 88% Causes: <ul style="list-style-type: none"> • ABO not identical (kidney O donors not programmed to match with any non-O recipients although compatible) • Pt not on waitlist • On waitlist but need to modify donor acceptance criteria 	<ol style="list-style-type: none"> 1. Modify policy and programming to add kidney O donors- ABO compatible recipients to the end of match run (Memo to organ specific committees) 2. Change policy from “may” to “must” requiring OPO to rerun match post candidate data update
1	2	Blood type verification does not occur prior to implantation	8. Blood type verification prior to organ transplant 8B. Organ brought into OR, check organ is compatible with potential recipient prior to transplant	Data: 23% programs/53% records show compliance Causes: <ul style="list-style-type: none"> • Human error-person did not check prior to transplant • Documentation not present (Complex forms- paper may be lost or not properly documented) • Lack of policy clarity (confusion of one versus two times) 	<ol style="list-style-type: none"> 1. Clarify policy language to be more explicit on requirements on documenting time of organ arrival and time /type (s) of verification 2. ETT barcode scanning as documentation of organ arrival (future) 3. Promotion of CMS/OPTN developed verification documentation form 4. ABO guidance document with FAQs/reoccurring questions
2	3	Candidate erroneously listed as accepting an ABO incompatible (peds heart, liver)	2. Enter candidate blood type in UNet SM 2A. First user enters candidate blood type using source documents	Data: 2,400 ABOi liver registrations with 300 changes. Ped heart has titer requirement Causes: <ul style="list-style-type: none"> • Team miscommunication • Human error in data entry. • Radio button only. Listing not required to have double data entry/verification 	<ol style="list-style-type: none"> 1. Program warning for liver ABO incompatible listings 2. Warning notice/visual cue on match run results to highlight incompatible candidates
2	4	Wrong organ arrived- not checked at arrival to verify correct organ arrived for the correct potential recipient	8. Blood type verification prior to organ transplant 8A. Organ arrives at TXC, check organ received is organ accepted (match list followed)	<ul style="list-style-type: none"> • Could have wrong organs delivered • Could have mix up in OR • Misdirected in shipping by courier/transport mistake • No check prior to anesthesia • Uncertainty in policy language for one or two checks/arrival verification • Pick up wrong box at recovery center or OR 	<ol style="list-style-type: none"> 1. ETT barcode scanning to help verify correct organ for correct recipient (future) 2. Policy to require verification at time of organ arrival 3. Promote effective check-in and verification effective practices

Rank #	Line #	Failure Mode	Step	Causes	Actions to Reduce Failure Modes
2	5	If intended recipient surgery begins prior to arrival, no requirement for blood source documentation availability to confirm compatibility prior to anesthesia	8. Blood type verification prior to organ transplant 8A. Organ arrives at TXC, check organ received is organ accepted (match list followed)	<ul style="list-style-type: none"> Intentional but desired to reduce ischemic time 	<ol style="list-style-type: none"> Change policy to push up verification to “prior to anesthesia or prior to incision” in policy (deceased and living donation) Better use of attachments in DonorNet (ABO results scanned/uploaded) Provide ABO guidance document ETT barcode scanning/website tracking to help verify correct organ on way (future)
3	6	Blood samples are mislabeled	1. Determine candidate blood type 1A. Test 2 samples taken on 2 occasions (2 draws, 2 samples, sent to 1 or 2 labs)	<ul style="list-style-type: none"> Human error/recklessness 	<ol style="list-style-type: none"> Clarity on timing of samples in policy and guidance
3	7	Verification occurs without both source documents for recipient and donor	8. Blood type verification prior to organ transplant 8B. Organ brought into OR, check organ is compatible with potential recipient prior to transplant	<ul style="list-style-type: none"> Reasons exist for not having source documentation for both Questions exist on what is a source document Tx program may not think they have to use lab results for donor ABO Human error/recklessness 	<ol style="list-style-type: none"> Clarify what is an acceptable source document- Guidance Define source document in policy Conduct verification using electronic means (w/out physical paper) Use physical comparison with hospital paper/EMR and Donor Net and add DonorNet statement that “I physically confirmed this ABO verification” to carry through process Better use of attachments in Donor Net (ABO results scanned/uploaded) Program ability to view ABO source documents on one screen side by side ETT project (future)

Rank #	Line #	Failure Mode	Step	Causes	Actions to Reduce Failure Modes
4	8	One blood sample sent and tested twice	1. Determine candidate blood type 1A. Test 2 samples taken on 2 occasions (2 draws, 2 samples, sent to 1 or 2 labs)	<ul style="list-style-type: none"> Miscommunication in blood bank- need to understand that you are sending two things-may do one on own decision Out of time/urgent listing Human error/disregard Blood bank mix up and tests same sample twice. 	<ol style="list-style-type: none"> Clarify in policy (and guidance) that one minute apart qualifies as separate draws Alternatives needed to address urgent situations
4	9	Only one sample drawn and tested prior to match (no ABO confirmation by second sample)	4. Determine donor blood type 4A. Test two samples of blood 1 draw, 2 samples, 2 labs OR 2 draws, 2 samples, 1 lab	<ul style="list-style-type: none"> Only 1 required prior to match run 	<ol style="list-style-type: none"> Change policy and (programming) to require both ABO results prior to executing match run with exception clause
5	10	No pre-transfusion specimen is available for testing	4. Determine donor blood type 4A. Test two samples of blood 1 draw, 2 samples, 2 labs OR 2 draws, 2 samples, 1 lab	<ul style="list-style-type: none"> Not controlled 	<ol style="list-style-type: none"> Put on lab orders to hold samples as additional testing may be needed (best practice) (This is often beyond OPO control)
5	11	Blood samples are mislabeled	4. Determine donor blood type 4A. Test two samples of blood 1 draw, 2 samples, 2 labs OR 2 draws, 2 samples, 1 lab	<ul style="list-style-type: none"> Human error-distraction/transposition of letters 	<ol style="list-style-type: none"> Control-double check manual label Use uniform ID; uniform donor ID Electronic generation of printed labels (ETT Project-future)

Overall Recommendations:

- 1.) Use human factors principles and usability testing for design of supplies, documentation forms, DonorNet interface and development of ETT.
- 2.) Build resiliency through competency based training and adaptive capacity.
- 3.) Provide training and information (website, handbook) on human factors and resiliency engineering strategies to transplant organizations and staff.

Exhibit B:

Safety Situations Reported to the OPTN Related to ABO Verification Policy Proposal*
43** Cases Reported through Voluntary Patient Safety System, Jan 2012 – June 2013

Category/Subcategory of Safety Situations	2012	2013*	Total
Labeling issue - donor id - incorrect id	13	5	18
Labeling issue - transcription error	10	1	11
Labeling issue - missing label	3	1	4
Labeling issue - donor id - missing id	2	0	2
Labeling issue - ABO	1	0	1
Testing issue - ABO - ABO subtyping error or discrepancy	3	1	4
Testing issue - ABO - ABO error or discrepancy	1	0	1
Testing issue - ABO - ABO subtyping misinterpretation	1	0	1
Testing issue - ABO - blood transfusion caused misleading results	1	0	1
Testing issue - ABO - switched source documents	1	0	1
Communication issue - other - ABO	1	0	1
Communication issue - other - donor id transcription error	0	1	1
Communication issue - missing documentation	4	2	6
Data entry issue - Waitlist - ABO	4	0	4
Data entry issue - DonorNet - ABO subtyping	2	1	3
Data entry issue - DonorNet - donor id	0	2	2
Tx procedure/process issue - donor/ recip. compatibility check not done	1	0	1
Packaging/shipping issue - other - wrong package sent	1	0	1
Transportation issue - other - courier took wrong package	1	0	1

* Categories Represent a Subset of Categories Included in Full Report, "Trends and Patterns in Patient Safety Situations Reported to the OPTN Through June 2013"

http://transplantpro.org/wp-content/uploads/Patient_Safety_report_09-2013.pdf

** Since some situations fall into multiple subcategories, the sum of the Total column is greater than the total number of events, which is 43.

CHANGES TO BLOOD TYPE ENTERED FOR CANDIDATES AND DONORS IN UNETSM

Prepared for:

ABO Verification Work Group of the
Operations & Safety Committee
August 27, 2013

By:

Darren Stewart, MS, Biostatistician
Bruce Shepperson, SAS Analyst
UNOS Research Department

Table of Contents

EXECUTIVE SUMMARY 2

BACKGROUND/PURPOSE 2

WORK PLAN ITEM (OR STRATEGIC GOAL) ADDRESSED 2

COMMITTEE REQUEST..... 2

DATA AND METHODS 3

RESULTS..... 5

 Waiting List Registrations with ABO Modified between Initial Entry and Verification 5

 Deceased Donors with ABO Modified between Initial Entry and Verification 5

 Duplicate Donors Added with a Change in ABO Subtype 5

EXECUTIVE SUMMARY

Of candidate registrations with blood type verified by a second-user, the ABO was changed prior to verification in only about 0.07% (n=153) cases from 2009-2012. The rate of ABO changes for deceased donors added to DonorNet[®] was only slightly higher at 0.24% (n=76 cases). These changes may represent “near misses,” in which the electronic second-user verification (or a user’s self-correction) prevented the creation of a candidate or donor record with an incorrect ABO.

Also during 2009-2012, in 100 instances, corrections were made to ABO subtype by creating a duplicate donor record. The most concerning types of changes – A2→A1, A2→A, and A2B→AB – accounted for 27% of the corrections; if corrections were not made in such cases, it is possible that an unintentional, incompatible transplantation event could have occurred in a blood type B candidate willing to accept an A2 or A2B organ.

These results highlight the importance of second-user verification of critical information such as ABO and are intended to help support the work of the ABO Verification Work Group.

BACKGROUND/PURPOSE

The Operations & Safety Committee has formed an ABO Verification Work Group and tasked the group with understanding the nuances of the process of verifying candidate ABO, donor ABO, and candidate-donor ABO compatibility. The work group is currently developing a process map and FMEA to formally document this process and identify potential failure modes.

On the March 28, 2013 teleconference, the group discussed how the computerized match system (in UNetSM), which automatically screens off candidates who are incompatible with the donor, is an important step in reducing the likelihood of an unintentional ABO incompatible transplant. They requested data that will help them understand how often this crucial step is bypassed, i.e., how often transplants are occurring in candidates who did not appear on a match run for the specific donor.

They also requested data involving DonorNet’s two-user ABO verification process for donors, to evaluate the frequency of the ABO (including subtype) being initially entered incorrectly and later changed.

WORK PLAN ITEM (OR STRATEGIC GOAL) ADDRESSED

Improve patient safety

COMMITTEE REQUEST

1. Tally the number of cases from 2009-2012 where the deceased donor’s ABO changed subsequent to the initial entry.

- Such changes may be indicative of the second-user verification process successfully preventing an erroneously entered ABO from being used for a match run.
- Show number of cases by year to assess recent trends.
- Show table of ABO changes (before/after matrix).

This request was appended by the Operations & Safety Committee during their April 30, 2013 meeting as follows:

Tally the number of cases from 2009-2012 where a waitlisted candidate's ABO changed subsequent to the initial entry.

- Such changes may be indicative of the second-user verification process successfully preventing an erroneously entered ABO from being used for a match run.
- Show number of cases by year to assess recent trends.
- Show table of ABO changes (before/after matrix).

2. Tally the number of cases from 2009-2012 where a deceased donor was re-added to DonorNet (i.e., a new Donor ID generated) with a change in the ABO subtype.

- DonorNet currently DOES NOT have a second-user verification process for the ABO subtype.
- Once the subtype is entered and saved (by a single user), it is locked and cannot be changed.
- Such cases may be indicative of either a data entry error, or the entry of the subtype based on a single test result, as opposed to two separate determinations.
- Show number of cases by year to assess recent trends.
- Show table of ABO subtype changes (before/after matrix).

DATA AND METHODS

This analysis includes candidates and donors added to UNetSM between January 1, 2009 and December 31, 2012. Results are based on the OPTN database as of August 9, 2013.

Tables 1a & 1b are based on registrations, not unique candidates, so it is possible that the same candidate is represented more than once in the tables by way of being registered more than once. Registrations without ABO verified electronically by a second user were excluded from the denominator when calculating the proportion of candidate records that had an ABO change. The same applies to donors (Tables 2a & 2b).

Only changes to the primary blood type (A, B, AB, O) were included in Tables 1a, 1b, 2a, and 2b. Changes involving the subtype but not the primary type (e.g., A2->A1, or A1->A) were not considered ABO changes.

Table 3, however, focuses on changes involving A or AB subtypes for deceased donors added to DonorNet. Whereas Tables 1a-2b examine changes made in the same candidate or donor's record prior to second-user verification, Table 3 enumerates cases in which a duplicate donor record was added in order to correct an ABO subtype. Since there is no electronic second-user verification of ABO subtype, and once a subtype is entered it cannot be changed, the only way to correct the subtype is to start over by creating a new record for the same donor. Each donor shown in Table 3 had ABO verified by two users on one of the duplicate records.

One ABO-verified donor actually had 2 duplicate ("suspended") records, and thus is counted twice in Table 3. Another ABO-verified donor had two duplicate records, but only one ABO change, and thus is counted once. Hence, a total of 99 distinct donors are included in Table 3. A suspended record is one that is not used for allocation and does not require further action by the OPO (such as submitting organ disposition/feedback or TIEDI data). A validated donor record is one in which the ABO has been second-user verified and for which a match can be run (assuming other required information has been provided).

Donors included in Table 3 are actually *potential* donors, as some of them may not have actually had any organs recovered or transplanted. These duplicates were identified two ways: (1) if the OPO reported to UNOS that a duplicate donor was added to the system, (2) if two donor records had the same date of birth, OPO, donor hospital, and were added within 7 days of each. About half of the cases were reported as duplicates by the OPO.

RESULTS

Waiting List Registrations with ABO Modified between Initial Entry and Verification

Table 1a reveals that the ABO was changed prior to being verified by a second user in 153 (0.07%) out of 219,117 candidate registrations between 01/01/09 and 12/31/12. A change in the ABO may be indicative of the electronic, second-user verification process, which displays a warning message if the second user selects a different ABO from the first user, successfully preventing the candidate from being registered with an incorrect ABO error. Changes in ABO can also occur due to the first user recognizing their own initial data entry error and self-correcting. Both scenarios likely represent “near misses” that could have resulted in a candidate being listed with the incorrect ABO.

The rate of candidate ABO changes has remained relatively steady, varying in what appears to be a random fashion (0.05% to 0.09%) from 2009 through 2012. The rate has decreased slightly, however, from the 0.10% rate from July 2004 through June 2009, as shown in a report presented to the Operations & Safety committee in September, 2009.

Table 1b shows that the most common types of ABO changes were O→A (n=68, 44%) and A→O (n=33, 22%), likely reflecting the fact that O and A are the most common blood types. In six cases, the initial ABO was entered as AB, while the corrected ABO was O; this type of discrepancy (and others as well), if not corrected, could obviously have led to serious consequences.

Deceased Donors with ABO Modified between Initial Entry and Verification

Table 2a indicates that the ABO was changed prior to being verified by a second user for 76 (0.24%) out of 32,233 donors entered into DonorNet[®] between 01/01/09 and 12/31/12. As with candidate ABO changes, these cases may indicate a successful error prevention by the electronic second-user verification process, or a self-correction by the initial user.

The rate of donor ABO changes varied in what appeared to be a random fashion (0.18% to 0.38%) between 2009 and 2012, with no apparent trend. The overall rate of donor ABO changes was about the same in this analysis as seen in a prior analysis covering July 2004 – June 2009, which showed a rate of 0.20%.

As seen with candidate ABO changes, O→A and A→O changes were most common (Table 2b).

Duplicate Donors Added with a Change in ABO Subtype

Unlike with primary blood type, a second-user verification step has not been implemented in DonorNet for electronically verifying the subtype. If, after the primary type has been second-user verified, a user enters an incorrect subtype and saves the donor record, the user is unable to correct the subtype; instead, he must start over by re-adding the donor. This results in duplicate records in DonorNet for the same donor. It also indicates potential “near misses,” where matches could have been run with an incorrect subtype (possibly

leading to an unintentional, incompatible transplantation event), had the correction not been made by creating a new donor record.

Table 3 shows that from 2009-2012, 100 duplicate donors were added to DonorNet with a change involving an A or AB subtype. With over 8,000 deceased donors added to DonorNet each year, 100 duplicates in 3 years represent a very small fraction of donors (<0.05%).

Though no clear time trend is evident, 2012 accounted for the most such cases (n=34, 34%). The three most common types of change (suspended → validated donor record) were A→A1 (n=22, 22%), A1→A (n=21, 21%), and A1→A2 (n=20, 20%).

If the correction had not been made in the third most common scenario (A1→A2), a subpopulation of candidates (those with blood type B) may have been disadvantaged. If the match was incorrectly run with A1 instead of A2, blood type B candidates listed as “willing to accept an A2 organ” would not have appeared on the match run and thus potentially would have missed an opportunity to accept a compatible, A2 organ.

However, the fourth most common scenario – A2→A1 (n=18, 18%) – is the most concerning. Assuming the validated subtype (A1) is correct, if this correction had not been made by creating a second donor record, it is possible that matches could have been run with subtype incorrect indicated as A2. Blood type B candidates listed as “willing to accept an A2 organ” could have appeared on such a match list, and unintentional transplantation of an A1 organ into a B candidate (as happened in a living donor case in 2009) could have resulted in a hyperacute rejection event. This risk may also have applied to the eight A2→A and one A2B→AB cases. In total, n=27 (27%) of cases, if not corrected by creation of a new donor record, could conceivably have resulted in a match run with an incorrect A2 or A2B subtype.

The entry of duplicate donor records to correct the ABO subtype is not concentrated at one or even a small handful of OPOs. To the contrary, these 100 cases occurred across 41 different OPOs. Some OPOs accounted for just one case, while others had as many as eight.

Data is not available to indicate the number of times the ABO subtype *should have been* corrected by adding a new donor but was not.

TRANSPLANT RECIPIENTS NOT ON THE MATCH RUN (NOMR)

Prepared for:

ABO Verification Work Group of the
Operations & Safety Committee
August 27, 2013

By:

Darren Stewart, MS, Biostatistician
UNOS Research Department

Matt Belton, Manager, Organ
Allocation Analysis & Quality
Inspection (DEQ)

Table of Contents

EXECUTIVE SUMMARY 2

BACKGROUND/PURPOSE 2

WORK PLAN ITEM (OR STRATEGIC GOAL) ADDRESSED 2

COMMITTEE REQUEST..... 2

DATA AND METHODS 3

RESULTS..... 4

 Trends in NOMR Cases, 2009-2012 4

 Total Number of Deceased Donor Organ Transplants, 2009-2012..... 5

EXECUTIVE SUMMARY

The ABO Verification Work Group of the OPTN Operations & Safety Committee is interested in cases in which an organ recipient did not appear on the match run. In these cases, the electronic ABO verification safeguards inherent in UNetSM are bypassed, which may be a risk to patient safety.

A total of 240 transplants occurred from 2009-2012 in which the recipient did not appear on a match run for the organ(s) transplanted. About 70% of these cases were due to directed donation, while the other 30% were due to other scenarios, such as a center avoiding organ wastage by finding a compatible candidate after all other centers had refused the organ. Cases in which the recipient was not on a match run represented less than 0.3% of all transplants. Over 100 different transplant centers and 50 OPOs were involved in these cases.

BACKGROUND/PURPOSE

The Operations & Safety Committee has formed an ABO Verification Work Group and tasked the group with understanding the nuances of the process of verifying candidate ABO, donor ABO, and candidate-donor ABO compatibility. The work group is currently developing a process map and FMEA to formally document this process and identify potential failure modes.

On the March 28, 2013 teleconference, the group discussed how the computerized match system (in UNetSM), which automatically screens off candidates who are incompatible with the donor, is an important step in reducing the likelihood of an unintentional ABO incompatible transplant. They requested data that will help them understand how often this crucial step is bypassed, i.e., how often transplants are occurring in candidates who did not appear on a match run for the specific donor.

They also requested data involving DonorNet's two-user ABO verification process for donors, to evaluate the frequency of the ABO (including subtype) being initially entered incorrectly and later changed.

WORK PLAN ITEM (OR STRATEGIC GOAL) ADDRESSED

Improve patient safety

COMMITTEE REQUEST

1. **Tally the number of incidents from 2009-2012 in which a recipient of a solid organ transplant did not appear on any match run for that donor:**
 - As allowed by available data, separate these two types of cases:
 - One recipient accepted the organ, but subsequently the organ

was redirected (reallocated) to a different candidate who was not on the match run, vs.

- All other cases
- Show number of cases by year to assess recent trends.
- This data will be provided by DEQ, based on their match run quality assurance process.

DATA AND METHODS

This analysis includes all cases identified by UNOS Department of Evaluation and Quality (DEQ) as solid organ recipients not appearing on a match run (“NOMR”) between 2009 and 2012. Cases were either due to directed donation or other reasons. Directed donation NOMR cases occur when the deceased donor’s family requests organs to be donated to a particular candidate that is not on the match run but is still found to be medically suitable to accept the organ(s) for transplantation.

The transplant center at which the NOMR case occurred was readily available in only 211 (88%) of the 240 cases; though incomplete, this information was sufficient to assess whether NOMR cases occurred at only a few centers or were spread widely among many centers.

RESULTS

Trends in NOMR Cases, 2009-2012

Table 1 indicates that between 2009 and 2012, 240 recipients (60 per year) received a solid organ transplant but were not on a DonorNet match run. There did not appear to be an increasing or decreasing trend in the overall number of cases in the past 4 years. However, nearly 88% of NOMR cases in 2012 were explained by directed donation, compared to 65% of cases in 2009-2011.

Table 1: Solid Organ Transplant Recipients Not on a Match Run by Type, 2009-2012

	Directed Donation		All other cases		All	
	N	%	N	%	N	%
Donor Recovery Date						
2009	32	60.4	21	39.6	53	100.0
2010	51	68.0	24	32.0	75	100.0
2011	35	64.8	19	35.2	54	100.0
2012	51	87.9	7	12.1	58	100.0
All	169	70.4	71	29.6	240	100.0

Based on UNOS Department of Evaluation & Quality (DEQ) data as of July 12, 2013

NOMR cases not explained by directed donation are often the result of the following types of scenarios:

- Donor is blood group O, recipient is compatible but not identical to blood group O and also not a 0-ABDR mismatch. Hence the candidate did not appear on the kidney match run (which restricts O donors from going to non-O candidates except for 0-ABDR mismatches). Used in alternate candidate to avoid organ wastage.
- Organ refused by all other centers but accepted as an “open offer” to any compatible patient at a center, to avoid wasting the kidney.
- Expedited placement of a lower-quality liver that would otherwise have been discarded to a candidate not yet on the waitlist.
- Emergency listing of a lung candidate after the match was run. Lungs declined by all local and Zone A centers and utilized in candidate to avoid wasting the organs.

The 240 NOMR cases were not concentrated in one or a small number of OPOs. Fifty different recovering OPOs were involved in at least one case. Three OPOs, however, accounted for 30% of all cases and 34% of directed donation cases.

Over 100 transplant centers were on the receiving end of at least one NOMR case. At least 40 centers were on the receiving end of a NOMR transplant that was not due to directed

donation (“all other cases”). One center accounted for at least 7 of the “all other” NOMR cases.

Total Number of Deceased Donor Organ Transplants, 2009-2012

To put the number of NOMR cases into context, **Table 2** shows that 88,657 deceased donor transplants occurred between 2009 and 2012. The 240 NOMR cases during the same time period represent less than 0.3% of all transplants.

Table 2: Deceased Donor Solid Organ Transplants, 2009-2012

	N
Transplant Date	
2009	21,851
2010	22,101
2011	22,518
2012	22,187
All	88,657

Based on OPTN database as of August 16, 2013

Exhibit E: Comparison of Requirements

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	OPO must have protocol	DD,LD	DD
		Two separate blood type determination tests required	DD,LD	DD
		Blood samples must be drawn on separate occasions	LD	
		If samples are from same blood draw, then must go to different labs	DD	
Blood type A must be subtyped				
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 ¹	DD,LD
		Donor	Blood type tests must be completed and reported prior to:	
	• Organ recovery			
	• Incision		DD	
	• Match run		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	DD, LD ²	
Both persons must consult each source document with blood type and subtype test results when reporting				
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
		• All recoveries	DD, LD	LD
		Verification must be done:		
		• Prior to anesthesia	LD	
• Prior to organ recovery		DD,LD		
• Prior to organ release to the transplant hospital	DD			
• Before the organ leaves the operating room	DD, LD			
Organ Check In		When organ arrives from different operating room suite, transplant hospital must check in the organ	DD,LD	
		Requires confirmation of expected donor ID, organ type and laterality against external package label or source documents with organ		
		May be combined with final pre-transplant verification if organ will go immediately into OR with no break in chain of custody		
ABO Verification	Organ 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
		• "Between time of organ delivery into intended recipient's operating room and first anastomosis"	DD,LD	
• "Upon organ arrival and prior to transplantation"	DD,LD			
	Additional pre-procedure verification must be done prior to induction of anesthesia if surgery is scheduled to begin prior to organ arrival	DD,LD		

Exhibit E: Comparison of Requirements

Comparison of ABO Determination, Reporting, and Verification		OPTN	CMS	
ABO Verification	Both	Verifications must be done by:		
		• Two persons	DD,LD	DD,LD
		• One person assisted with bar code scanning automated	DD,LD	
		Verifications must be done by:		
		• Licensed health care professional (Step 8)		DD,LD
		• Qualified health care professional	DD,LD	
		• Transplant surgeon must participate (Step 8)	DD,LD	DD,LD
		Verification must confirm the following information: ³		
		• 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
		• 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	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

¹ If the current Living Donor Committee Proposal to [Require UNet Registration of all Living Donor Organ Candidates Prior to Transplant](#) becomes policy, then candidates for living donation will fall under these requirements.

² Reflects current and proposed living donor requirements and will apply to candidates for living donations if the current Living Donor Committee Proposal to [Require UNet Registration of all Living Donor Organ Candidates Prior to Transplant](#) becomes policy.

³ Requirements related to deceased donor organ recovery verification do not currently specify all of these elements.

⁴ 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 \(§ 482.92\)](#)