

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 2.15.B (New: Pre-Recovery Verification), 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 5.7 (New: Pre-Transplant Verification), Policy 5.7.A (New: Pre-Transplant Verification Prior to Organ Receipt), and Policy 5.7.B (New: Pre-Transplant Verification Upon Organ Receipt), 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 (Medical Evaluation Requirements for Living Donors), Policy 14.4.A (Living Donor Blood Type Determination), Policy 14.4.Ai (Living Donor Blood Subtype Determination), Policy 14.5 (Registration and Blood Type Verification of Living Donors before Donation), Policy 14.5.A (New: Living Donor Blood Type Determination), Policy 14.5.B (New: Living Donor Blood Subtype Determination) Policy 14.5.C (New: Reporting of Living Donor Blood Type and Subtype), Policy 14.7 (New: Living Donor Pre-Recovery Verification), Policy 14.9 (New: Living Donor Organ Check-In), Policy 14.10 (New: Living Donor Pre-Transplant Verification), Policy 16.1 (Organs Not Requiring Transport), Policy 16.4.C (Internal Labeling of Blood and Tissue Typing Materials)

- **Operations and Safety Committee**

This proposal seeks to:

1. Clarify requirements related to ABO blood type determination, reporting, and verification for donors and candidates
2. Strengthen current key system safety components to ensure the correct organ is transplanted into the correct recipient and that the match is ABO compatible or planned incompatible
3. Align OPTN/UNOS and Centers for Medicaid and Medicare Services (CMS) blood type requirements more closely

This proposal was originally released in the spring 2014 public comment cycle and has been modified to address concerns raised by the transplant community.

- **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 Goals and Final Rule**

This proposal supports the following strategic plan goals:

1. Promote transplant patient safety (through strengthening ABO policies to ensure that transplants are ABO compatible or intended incompatible)
2. Promote living donor safety (through strengthening ABO policies to ensure that transplants are ABO compatible or intended incompatible)
3. Promote efficient management of the OPTN (through clearly written policy, education and proficiency tools, improved electronic and automated tools to manage ABO reporting and verification processes, and reducing duplicative efforts through further alignment with CMS requirements)

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Operations and Safety Committee

Public Comment Response Period: January 27, 2015 - March 27, 2015

Summary and Goals of the Proposal

This proposal seeks to:

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2. Strengthen current key system safety components to ensure the correct organ is transplanted into the correct recipient and that the match is ABO compatible or planned incompatible
3. Align OPTN/UNOS and Centers for Medicaid and Medicare Services (CMS) blood type requirements more closely

This proposal was originally released in the spring 2014 public comment cycle and has been modified to address concerns raised by the transplant community.

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 planned 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. Generating to generate appropriate donor/candidate matches based on blood type using UNetSM computer programming
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 policy and programming safeguards to prevent future occurrences.

In addition to OPTN policy, the CMS maintains Conditions of Participation (CoPs) regulations for both Organ Procurement Organizations (OPOs) (42 CFR 486, Subpart G) and transplant hospitals (42 CFR 482, Subpart E) which mandate certain practices to assure ABO compatibility in transplants.

Although the current system contains safeguards, this proposal is necessary to address three areas.

- First, the proposal adds further clarity and consistency to requirements. OPTN policies were rewritten in 2013 incorporating plain language and improved formatting. Some sections, however, needed further clarification and modification beyond the original scope of the rewrite based on rewrite public comments, ABO work group feedback, and transplant community questions regarding interpretation.
- Second, while the current policies contain safeguards, the ABO work group and the Operations and Safety Committee identified remaining risks through a Failure Modes and Effects Analysis (FMEA). These risks were significant enough to merit the proposed policy and programming changes. Where risks are targeted for action, proposed changes will use core safety principles and improve their consistent application.
- Third, the transplant community has requested better alignment between OPTN and CMS requirements. Compliance with policies covering ABO reporting and verification has been noted as problematic from both the OPTN and CMS. This proposal will further align the two sets of rules to enable better compliance. There are areas where OPTN policy will be consistent with CMS, yet safer. Other proposed OPTN policy changes address issues out of scope for CMS regulations, such as subtyping that supports allocation policy an area of policy exclusive to the OPTN.

Significant efforts have been ongoing to address these three issues. An ABO verification work group with representatives from several Committees, including Transplant Coordinators and Transplant Administrators, has met to identify the issues and solutions since early 2012. Prior to this proposal, OPTN and CMS representatives jointly worked to produce an educational webinar, a verification documentation template, and a crosswalk between OPTN and CMS policies in 2012. These efforts addressed some but not all issues. The Operations and Safety Committee and ABO work group engaged consultants in patient safety and human factors engineering to examine ABO processes through a FMEA approach to map existing steps and identify points of risk, and prioritize areas that needed further changes. This exercise was conducted to examine all aspects systematically and be proactive in preventing problems versus being reactive to adverse events. Strategies to lessen these risks were developed by the work group and endorsed by the Operations and Safety Committee. The Operations and Safety Committee consulted with the Living Donor and Organ Procurement Organization Committees on these proposed requirements. In addition, the Committee has incorporated feedback from the spring 2014 public comment cycle and the OPTN/UNOS Board of Directors into these proposed changes.

This proposal contains the following strategies to improve ABO determination, reporting, and verification include:

Proposed policy changes:

- Several substantive policy changes are proposed to reduce risks and align requirements with CMS where possible. In some cases, proposed OPTN policy will be safer but will also comply with CMS timing. Substantive changes are outlined in Table 1.

Table 1: Summary of Substantive Proposed Policy Changes

Requirement		Current	Proposed	Align CMS
Timing Changes	Two ABO results must be obtained for deceased and living donors	<ul style="list-style-type: none"> • Prior to incision • Prior to recovery 	<ul style="list-style-type: none"> • Prior to match run • Prior to generation of living donor ID 	Yes: OPTN Safer
	Living donor recovery verification must be conducted	Prior to leaving OR	Prior to general anesthesia for donor	Yes: OPTN Safer
Current Practice Expanded	Deceased donor recovery verification must be conducted	If organs remain in same OR suite	<ul style="list-style-type: none"> • Donor and organ info: All cases • Recipient info: When intended recipient is known 	Yes: OPTN Safer
	Living donor recovery verification must be conducted	If organs remain in same OR facility	All cases (Eliminates verification when leaving donor OR)	Yes
New Conditional Actions	Organ check-in	None	If organ arrives from different OR suite	No Rule
	Pre-procedure ABO verification	None	If recipient surgery starts prior to organ receipt	No Rule

- OPOs will no longer have the option to draw blood samples at one time and send to two different laboratories. This is proposed to reduce the FMEA identified failure mode that donor samples will be mislabeled and align with CMS. An exception clause for accelerated donations is proposed to avoid unnecessary organ wastage to meet policy rewrite and OPO Committee requests.
- OPOs, transplant hospitals, and recovery hospitals will need to have protocols meeting OPTN requirements for determination, reporting, and verification. Current protocol requirements are in policy sections addressing second user verifications. Protocols must include a process for resolving primary blood type conflicts and contain program-specific definitions for a qualified health care professional. Qualified health care professionals will be required for reporting and verification functions.

These proposed changes address all three goals. Protocols are required by CMS currently and OPTN policy will be further aligned. Having a process for resolving primary blood type conflicts will add consistency to current OPTN policy that addresses conflicting subtype results only. Using qualified health care professionals will assure some type of training and education to reduce the chance for occurrence of several FMEA risk points.

- Determination, reporting, and verification sections have been rewritten and reformatted to add further consistency and clarity. Many of these changes are not substantive but seek to address policy rewrite public comments and transplant community interpretation questions. These changes are applied consistently in sections for both deceased and living donation and between donors and candidates. Several definitions have been added.
- OPOs, transplant hospitals, and recovery hospitals will need to have protocols meeting OPTN requirements for determination, reporting, and verification. Current protocol requirements are in policy sections addressing second user verifications. Protocols must include a process for resolving primary blood type conflicts and contain program-specific definitions for a qualified health care professional. Qualified health care professionals will be required for reporting and verification functions. New verification requirements are explicit detailing information elements to be verified at pre-surgical points outlined in tables naming acceptable sources and required participants to reduce previous interpretation questions.

Where CMS requires transplant surgeon or licensed health care professional participation, similar OPTN policy is proposed to align the two regulations further.

- Because some ABO incompatible transplants are intended and allowable under OPTN policy, appropriate sections are modified to accommodate these cases. This adds clarity to current policies.
- Two proposed sections outline when a match must be re-executed to address a top FMEA failure mode and apply consistent core safety principles.
- In anticipation of TransNetSM use, proposed policy supports use of OPTN-approved electronic methods and will allow ABO results to be present on red top tubes sent with organs.

Proposed programming:

- The proposed programming changes are all independent of the proposed policy changes. Three proposed changes will address several FMEA failure modes and will assist with policy compliance.
- When liver candidates are registered as willing to accept an ABO incompatible (ABOi) organ, only one person is required to conduct data entry. A warning will be added when “yes” is checked for these candidates to address a top potential failure mode.
- The match run view will be modified to add candidate blood type and ABO compatibility status. This will provide a visual cue highlighting ABOi candidates and assist with verifications.
- Second user verification for donor subtypes will be programmed. The current system enforces second user verification of primary blood type for listing donors and candidates. Although current policy requires second user verification when reporting subtype, the system will allow one person to change a primary blood type to one with a subtype. This programming will strengthen safety by consistently applying second user verification for both primary blood type and subtype reporting.

Other recommendations to mitigate risks identified in the FMEA include education and collaboration strategies. The Committee plans to produce several educational products including simple one page overviews for various ABO steps, a guidance document with frequently asked questions and effective practices related to ABO processes, an updated version of the 2011

guidance document related to subtyping, and an e-learning proficiency module that can be used for training and assistance with compliance. In addition, existing templates and crosswalks will be updated in collaboration with CMS.

The Committee will continue collaborative efforts in developing TransNetsm to address failure modes and improve multiple areas of risk identified with ABO processes. 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. TransNetsm programming supports many core safety principles and mitigates risk for several failure modes. Additional programming will be planned to support all proposed changes should the proposal pass.

Feedback on Spring 2014 Public Comment Proposal

Alternatives in the [original spring 2014 public comment proposal](#) included consideration of multiple recommendations related to FMEA risk points. One alternative considered would be to focus solely on educational or programming efforts. While this could relieve some of the confusion regarding how to interpret the policies, it could not address vague language in in OPTN policy, further align OPTN and CMS requirements, or address substantive issues identified by the FMEA. Therefore, 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 unintended ABO incompatible transplant or organ wastage. This proposal contains many of these originally proposed changes with modifications as described based on public comment and OPTN/UNOS Board of Directors comments.

Several major themes emerged while the proposal was under consideration during spring 2014 public comment and at the November 2014 OPTN/UNOS Board meeting. Seven of the 11 regions voted in support of the original proposal. American Society of Transplant Surgeons (ASTS) supported the proposal. Association of Organ Procurement Organizations (AOPO) and American Society of Transplantation (AST) did identify areas of concern. AST supported all sections except the deceased donor verification requirements. At the OPTN/UNOS Board meeting, the proposal was tabled after lengthy discussion. Concerns and requests identified during either public comment or the OPTN/UNOS Board meeting were as follows:

1. Concerns related to requiring OPOs to conduct verification at recovery when the intended recipient is not known
2. Concerns over requiring the on-site recovering surgeon to participate in verification
3. Concerns that additional requirements were not needed given the infrequency of unintended ABO incompatible transplants
4. Concerns that the proposed policy was too prescriptive
5. Concerns that the entire process was redesigned
6. Requests to have no differences from CMS requirements
7. Requests for updated templates and electronic solutions
8. Requests to postpone policy requirements until after ETT (TransNetsm) implementation
9. Concerns about clarity of policy

The Committee has responded to these concerns and changes are proposed in this version to meet several key concerns.

1. Concerns related to requiring OPOs to conduct verification at recovery when the intended recipient is not known

The spring 2014 public comment version would have required a verification to be performed at all deceased donor organ recoveries. This requirement was proposed originally to address FMEA failure modes. Recovery is a surgical procedure that starts the chain of events, often involving handoffs, ending in transplantation. While the transplanting surgeon bears the ultimately responsibility, recovery is a critical point where if certain information is confirmed, then potential downstream adverse outcomes such as death, graft failure, or organ wastage are more likely to be averted. The Committee received comments about difficulties in conducting a verification when the intended recipient is not known. The Committee subsequently amended the proposal. The version sent to the OPTN/UNOS Board in November 2013 limited this verification to “when the intended recipient is known.” In addition to addressing the operational concerns, it is also further aligned with CMS language.

2. Concerns over requiring the on-site recovering surgeon to participate in verification

The 2014 public comment version would have required the on-site recovering surgeon to participate in verifying information. The Committee received numerous comments against the scope including verification of recipient information; therefore, the Committee subsequently limited the role to confirming that the intended recipient was on the match run. This change was not acceptable to some in the OPO community. Several OPTN/UNOS Board members voiced concerns about allowing OPOs to define that role or having the surgeon participate in verifying recipient information even when the intended recipient is known.

The Committee maintains that this verification is important. It is the start of a complex surgical process involving hand-offs and transfer of information. The recovering surgeon is an important part of the recovery team. In the current version of the proposal, the Committee has proposed that the Donor ID, Donor ABO, and organ information be verified in all cases with recovering surgeon participation. In cases when the intended recipient is known, OPO staff will verify additional information regarding the recipient. This second part will align with CMS. Both OPTN and CMS policies currently place the transplanting surgeon as the party ultimately responsible for ensuring medical suitability prior to transplant acknowledging that the recipient may change after the recovery verification.

3. Concerns that additional requirements were not needed given the infrequency of unintended ABO incompatible transplants

It is true that unintended ABO incompatible transplants are very rare events. Unintentional ABOi transplants that have occurred since the well-known 2003 event may not be as well known within the transplant community. Since 2006, there have been two unintended ABOi kidney transplants both leading to hyperacute graft rejection and three unintended ABOi liver transplants. These involved several different root causes including lab, documentation, communication, and verification errors.

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

The relative infrequency of events is not indicative of the chance for occurrence. The proposed substantive changes will add steps to avoid adverse events including unintended ABOi transplantation as well as wrong-organ/wrong-patient procedures. Strengthening safety is one part of the proposed changes. The infrequency of ABOi transplants, however, is not relevant to the other two key purposes that are to add clarity to policy and to align more closely with CMS rules.

4. Concerns that the proposed policy was too prescriptive

In some areas, the transplant community provided comments that the proposal was too prescriptive, yet others asked for more clarity in requirements. During the 2013 plain language policy rewrite, previous collaborative OPTN/CMS efforts, the FMEA, and policy development, it became clear that there was significant confusion in the current policies. These issues contributed to inconsistent interpretation and ultimately poor compliance rates. Questions have continuously surfaced since the project's inception related to the timing, what information must be verified, and number of pre-transplant verifications. Other areas of confusion included source documentation requirements, acceptable verification sources, and blood collection requirements. The language developed was more specific with these repeatedly identified concerns in mind. This current version contains explicit instructions with tables to address potential misunderstanding over requirements.

The proposal also seeks to strike a balance between individual organization-specific practices (e.g. requirement of individual protocols) while addressing identified safety and transplant community concerns. This method of policy development sets member goals that can be monitored but also will allow flexibility to accommodate local practices. This method has been used effectively in other areas of OPTN/UNOS policy.

5. Concerns that the entire process was redesigned

While the proposed language changes may seem extensive, most of the language changes either clarify existing requirements or make language consistent across donation types as well as between donors and candidates. The core principles of the existing process have not been redesigned. Some of these core principles will be more uniformly applied. This will result in scope timing and/or changes in four steps. Two conditional checks, which are being performed already in many places as a best practice or Joint Commission (JCAHO) requirements are added to this comprehensive system. The core principles remain unchanged and their applications have been strengthened to improve overall safety.

6. Requests to have no differences from CMS requirements

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

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

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

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

- Removal of option to draw blood sample and send to two different labs (deceased donors)
- Verification requirements at deceased donor organ recovery
- Timing and scope for verification requirements at living donor recovery
- Requirement of protocols related to ABO processes
- Requirement of transplanting surgeon and licensed health care professionals to conduct pre-transplant verification

The Committee worked to ensure that OPTN and CMS requirements are not in conflict but rather work in harmony. CMS participated in the ABO workgroup. Areas of difference were discussed. CMS agreed to assist with updating educational materials should this proposal pass. It became clear throughout the process that further education would be beneficial as some have misperceptions about what is actually required or allowed.

Finally, not all OPTN transplant programs are certified transplant providers under CMS. As of September 16, 2014, there were 104 organ specific transplant programs, including 12 kidney programs, that were not CMS certified (as of June 30, 2014) for transplantation. The proposed policies will provide rules for these programs that are not bound to CMS transplant-specific requirements.

7. Requests for updated templates and electronic solutions

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

In addition, the Committee is continuing to work on possible programming modifications to have the system align with requirements for second user subtype verifications that currently do not exist. The Committee also plans to work on an electronic solution to address issues that were uncovered during discussions of when the intended recipient changes or is unknown at recovery. The Committee will apply human engineering factors and tools to make it “easy to comply and hard to fail” with meeting the requirements.

8. Requests to postpone policy requirements until after ETT (TransNetsm) implementation

The Committee appreciates the assistance and improvement that the ETT (TransNetsm) will bring to the transplant community. This system will bring major advances for labeling, packaging, critical data verification including ABO, and assuring correct organ/correct recipient transplants. To wait for this system to be fully functional, however, would be a mistake. Currently, use continues to grow and a national OPO voluntary deployment is planned for March 2015. The transplant hospital piece is still under development with limited testing at this time. It is unknown how long it will be before widespread use or mandatory use might take place. Before mandatory use could be enacted, public comment and adoption by the OPTN/UNOS Board of Directors would be required. Some in the transplant community have stated they will have to develop a process now (e.g. for organ check-in) and modify it with ETT (TransNetsm) and that this is not efficient or desired.

The Committee discovered that some organ check-ins are done already in many places. Postponing this requirement would not demonstrate good stewardship of a life-saving organ nor address risks proactively as identified through the FMEA. There have been at least ten wrong organ, wrong recipient or wrong organ delivered cases reported to the OPTN since 2006. Transplant hospitals having to develop a check-in can build their process with conversion to ETT (TransNetsm) in mind. In addition, while the ETT (TransNetsm) will address several areas where critical errors can occur (e.g. labeling), it does not address all facets covered in the proposal (e.g. both ABOs prior to match run).

9. Concerns about clarity of policy

Additional concerns about clarity of certain policy areas emerged post-public comment. These include areas such as subtyping requirements and clarification of the term “pre-transfusion”. The Committee has made additional style and language edits to address these concerns.

Strengths of the proposal include validation of the basic fundamental safety principles in place to maintain organ transplantation safety. Other strengths include meeting the proposal goals of making policy clearer, addressing existing risks identified through the FMEA, and aligning requirements more closely with CMS. The collective policy, programming, education, and collaboration with TransNetsm will strengthen the system and reduce chances of unintended ABOi transplantation.

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 and this could necessitate changing labs or other existing processes. OPOs will not be able to draw one blood sample and send to two different labs, however, that is not allowed under current CMS rules. While some transplant hospitals report currently performing organ check in and pre-procedure (anesthesia) verification, other transplant hospitals will need to develop protocols and practices to put these additional steps in place. This will require additional work, training, and documentation.

Additional Proposal Details and Supporting Evidence

Overall, the principles of using double checks, verifications, and computer assisted checking make for a robust system. Consultants working with the OPTN commented on the overall resiliency of the existing system. Unintentional ABOi transplants are considered “never events.” The occurrence is very low, yet devastating if it happens.

Since 2000, there have been six cases identified through OPTN data and patient safety situation reports of unintentional ABOi transplants. Table 2 shows five-year unintentional ABOi rates per 100,000 recipients using these known cases. Since patient safety situation reporting is voluntary, it is possible that other cases occurred, but were not identified as unintentional ABOi. Several of these cases involved livers where ABOi is permissible under policy but these cases were accidental not intentional.

Table 2: Five-Year Rates of Unintentional ABOi Transplants per 100,000 Recipients

Five-Year Time Period	2000-04	2005-09	2010-14
Unintended ABOi transplant rate per 100,000 recipients	0.8	1.4	2.2

One journal study estimated the probability of thoracic ABO incompatible transplant in the US to be 1.38 per 100,000 per donated organ prior to 2003. Following the changes made after patient death from an ABOi heart-lung transplant that added current redundancies in blood typing and reporting, the probability estimate was lowered to 0.308 per 100,000 donated organs. Additional changes made in October 2004 further reduced the probability to 0.022 per 100,000 donated

organs¹. Although limited to thoracic organs, this article predicted how changes to policy and practice could reduce risk.

Blood transfusion represents an area of medicine with some parallels to organ transplantation. The volume is significantly higher with an estimated 5,000,000 whole blood/red blood cell transfusion recipients in 2011. In 2011, there were 42 cases of acute hemolysis due to ABO incompatibility². This would equate to an approximate ABOi rate of 0.84 per 100,000 recipients. Between FY07 and FY13, 26 deaths were reported to the Food and Drug Administration due to hemolytic transfusion reactions by ABO antibody³. Given the extensive work to ensure blood safety, such as promoting hemovigilance and national incident reporting along with growing numbers of hospital transfusion safety officers, proposed OPTN improvements are reasonable. Although significant errors are relatively low, safety must be a continuous effort because “never events” significantly disrupt trust in the system.

Policy does not require mandatory reporting of all patient safety situations. Policy does mandate certain disease transmission and living donor events. The Improving Patient Safety portal launched in 2006 captures voluntary patient safety situation reporting as well as specified disease transmission and living donor events. The patient safety reporting component is a voluntary and confidential system that provides members the opportunity to report situations or activities that could have affected patient safety. These situations may be related to patient safety, organ placement/availability, communications, clinical information accuracy, or risk of disease transmission that was prevented. Situations that may not directly impact safety, availability, or utilization but cause concern from a transplantation, donation, and/or quality perspective may also be reported. Although safety situation reporting within the OPTN is largely voluntary, electronic patient safety situation reports have increased from 22 in 2006 to 99 in 2013.

These situations, however, are still thought to be significantly underreported. During 2012 and the first half of 2013, 64 reports were received in areas of labeling, testing, communication, data entry, transplant procedure, packaging/shipping, and transportation that could impact the possibility of an ABO incompatible transplant. In general, it is estimated that only about 5% to 15% of safety related events in a healthcare setting are typically reported through incident reporting systems^{4, 5}. In April 2014, UNOS staff conducted an analysis and estimated that only 13% of actual safety events are being reported to the OPTN. The [first public comment proposal](#) contains more information on this subsample of safety situation reports. The proposed actions will help reduce risk for these various types of errors.

¹ Cook, R. et al. Probabilistic Risk Assessment of Accidental ABO-Incompatible Thoracic Organ Transplantation Before and After 2003. *Transplantation* 2007; 84: 1602–1609.

² Whitaker, B. and Henry, R. The 2011 National Blood Collection and Utilization Survey Report accessed at <http://www.hhs.gov/ash/bloodsafety/2011-nbcus.pdf>.

³ Fatalities Reported to FDA Following Blood Collection and Transfusion: Annual Summaries for Fiscal Years 2016-2013. Accessed at: <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportProblem/TransfusionDonationFatalities/default.htm>

⁴ Levtzion-Korach, O. et al. Integrating incident data from five reporting systems to assess patient safety: making sense of the elephant. *Joint Commission Journal on Quality and Patient Safety / Joint Commission Resources*. 2010;36 (9):402-10.

⁵ Vincent, C. et al. Safety measurement and monitoring in healthcare: a framework to guide clinical teams and healthcare organisations in maintaining safety. *British Medical Journal of Quality and Safety*. 2014;23(8):670-7.

There have been at least ten cases involving either occurrences or near misses of wrong organ delivered or wrong organ/wrong candidate since 2006. In addition, there have been 21 switched kidney laterality cases since 2012 with four resulting in organ discard. Although this is not a risk for accidental ABOi transplant, it does represent unnecessary organ wastage. The proposed actions will help reduce risk for these events as well.

The Committee conducted a systematic and comprehensive FMEA to identify proactively areas where improvements could reduce risk. Conducting this 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 and corresponding sub-processes within each step that make up current OPTN requirements. Through the FMEA, 62 potential fail points were identified. Of these fail points, 11 were prioritized as highest risk based on available occurrence data, severity of risk, and detectability. See Table 3 below. The [first public comment proposal](#) contains more details on FMEA results. After examining these potential fail points and other “near miss” data, measures are proposed to strengthen the system and prevent unintended ABOi transplants as well as reduce risks for unnecessary organ wastage.

Table 3: Top Identified ABO Failure Modes

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

ABO Blood Type Determination:

Current Requirements and Core Principles:

ABO blood type determination is the first step conducted on all donors and candidates. There are two core safety principles associated with determination:

- Blood type and subtype results are based on two laboratory tests
- Blood samples drawn on different occasions. With each collection, a separate patient identification and labeling procedure is conducted prior to the blood draw

Current OPTN policy requires that all primary blood types and subtypes used for allocation be based on two laboratory tests reflecting the same result. This is consistent with the American Association of Blood Banks (AABB) standard requiring two blood type results for potential blood product recipients prior to releasing blood for transfusion.

CMS requires that laboratories maintain 100% proficiency for blood group testing. Proficiency testing results indicate that ABO mistypes occur in 1.4 (range 0.8 to 2.5 by blood group) per 1,000 typings. No subtyping proficiency benchmarks are required by CMS. The largest area of concern remains in accuracy of subtyping performed on blood type A patients where a 9.09% discrepancy rate has been cited for mistakenly resulting non-A₁ when the true result was A₁⁶.

The two blood typing results used must be from separate blood draws. Currently, OPOs only have the option to perform one blood draw and send the samples to two different labs. Transplant and recovery hospitals Separate blood draws involve two distinct collections that each have an independent identification and specimen labeling procedure.

This safety principle is critical as labeling errors or wrong blood in tube (WBIT) are the most frequent types of errors found. 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 errors⁷. Requiring double typings, however, is a safeguard that helps catch these errors. In one large study, 65% of WBIT errors were discovered through comparison to historical type and/or the double check test.⁸

Proposed Changes and Supporting Evidence:

Proposed changes to ABO determination sections include:

- Removing the OPO option to have one blood draw sent to two labs
- Requiring protocols to have a process when ABO primary types do not match

Four of the top 11 FMEA fail points identified relate to determination: 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). Supporting evidence includes over 100 patient safety situation reports related to mislabeling errors received by the OPTN since 2006.

Removing the OPO option to have one blood draw sent to two labs

The current option to perform one blood draw and send specimens to two different labs will be removed. OPOs will have to perform two separate draws. This is proposed to align further with CMS and reduce mislabeling risks associated with a collection that involves only one patient identification and labeling process.

Requiring protocols to have a process when ABO primary types do not match

Protocols will be required to have a program-specific process for handling instances where blood type results conflict. Current policy does not allow use of subtype results if two results showed

⁶ Bryan, C. et al. Implications of ABO Error Rates in Proficiency Testing for Solid Organ Transplantation. *Transplantation* 2006; 82: 733–736.

⁷ 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.

⁸ 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.

conflicting results but is silent on conflicts found in primary types. This will add consistency and clarity to policy.

Other proposed changes make all determination sections consistent in style, format, and language. Following questions raised during policy development, subtyping sections have been rewritten for clarity although no substantive changes have been made. The changes address issues identified throughout the project and policy rewrite that transplant community members found unclear or subject to differing interpretations.

TransNetsm will provide significant assistance in reducing labeling errors. Currently, 40-70 labels may be handwritten in the donor management phase. TransNetsm will produce barcode 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 blood 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 TransNetsm.

ABO Reporting:

Current Requirements and Core Principles:

Following determination of blood type and subtype (if applicable), results must be reported to the OPTN. Reporting safeguards are based on the following core principles:

- Reports must be based on two lab results
- Source documents must be used for reports
- Reports must be entered independently by two different users and have the same result
- Reports must be completed prior to surgery or becoming active in OPTN system

For deceased and living donors as well as candidates, the OPTN computer system is built to require two different users to each make an independent report of blood type. If blood types reported do not match, the patient cannot proceed within the system for a match. When reporting blood type results, source documents must be used to assist in entering correct results. Source documents are an original or copy of the original result reported from the laboratory.

Currently OPOs can perform blood type reporting based on one test and execute a match-run. Current policy requires the second test be completed prior to incision. One person can complete subtype reporting only as the system currently functions. Policy requires second user verification but the workflow in UNetsm does not enforce this as it does with primary blood type.

Proposed Changes and Supporting Evidence:

The following changes are proposed for ABO reporting:

- Timing is made safer for deceased and living donors
- Must be done by “qualified health care professional” as defined in member’s protocol
- Exception clause for accelerated deceased donation cases
- Address living donor VCA reporting

Timing is made safer for deceased and living donors

For deceased donor blood type determination and reporting, both ABO typing procedures must be completed “prior to incision”. The match run, however, can be executed based on reported 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) was identified as one of the most problematic fail points. Anecdotal evidence was shared 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.

Proposed policy will require both 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. In these cases, the ABO determination and reporting must be completed prior to organ release. The proposed change will reduce the possibility of matches being performed on one possibly erroneous ABO typing procedure making for a safer process.

The same principle will be applied to living donors. The timing for reporting will be moved up from prior to recovery to prior to generation of the Donor ID. This will also assure that results used to determine compatibility are reported at a safer time. Because of the planned nature of living donation, this should not represent a significant change from current practice. All OPTN blood type reporting will now be done prior to any patient becoming active in the system.

Source documents must be consulted when reporting results in UNetsm. 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.

Must be done by a qualified health care professional as defined in the member’s protocol

Proposed policy will require that OPO and transplant hospitals have protocols for ABO determination and reporting and that the protocols contain a program-specific definition for a “qualified health care professional”. All blood type reporting will need to be completed by a “qualified health care professional” as defined in the programs’ protocol.

Requiring reporting by a qualified health care professional is supported by the volume of ABO blood type changes (2009-12) between first and second reports, and subsequent potential for patient harm. Deceased donor ABO type was changed in 76 deceased donors (0.24%) between the first and second data entry. An additional 100 donors had duplicate records created due to differences in subtype results. Candidate ABO type was changed in 153 cases (0.07%). The changes could indicate either data entry error or laboratory error. Ninety percent of all changes represent a possible “near miss” (e.g. non-A₁ changed to A₁) that could have led to an incompatible transplant. Details on blood type report changes are available in the [first public comment proposal](#). Data support the need for double typing and reporting prior to being an active OPTN participant by a qualified health care professional required to have some level of proficiency. This will make the system safer.

Exception clause for accelerated deceased donation cases

In response to requests made during the policy rewrite and from the OPO Committee, determination and reporting requirements may be completed prior to organ release in cases in accelerated donation cases to avoid organ wastage. Reporting policy sections have been reformatted using consistent style and language across all donation types. Reporting requirements have been an area where questions have arisen with differing interpretations. Some have interpreted that one reporter could use one source document to report and the second person could use another one for verification. The proposed timing changes and rewritten language reflect the intent that each independent reporter compares both source documents and enters the result if both types match for the correct person.

Address living donor VCA reporting

In addition, policy is proposed to remove the VCA exemption from these requirements. These exemptions were passed as UNetsm cannot capture all VCA data, however, no one should be

completely exempt as this represents a safety risk. The proposal would require reporting in the patient's medical record and keep the other requirements. Second user verification will need to be documented in the record.

ABO Match Run:

Current Requirements and Core Principles:

The match run, also referred to as identification of potential transplant recipients, is a fundamental OPTN cornerstone to assure ABO compatible or intended incompatible transplants. The match run generates lists between potential donors and candidates according to numerous criteria including ABO type. 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.

Proposed Changes and Supporting Evidence:

Having an OPO release an organ to a patient not on the match run, (NOMR) is a number one prioritized FMEA risk point. Approximately 60 organs each year are transplanted into NOMR candidates. The 2003 ABOi case was in a NOMR patient. 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 NOMR cases by changing an option in existing policy language to a requirement that host OPOs re-execute the match prior to allocation if an organ has not been placed on the initial match run and candidate data is updated and reported to the host OPO. A sample of 20 NOMR (2012) shows this action may have added six candidates (30%) to the match run. Other NOMR cases involve blood type O or B organs that are transplanted into ABO compatible candidates that would never appear on a match run due to allocation policy. The [first public comment proposal](#) contains details on the NOMR analysis. Decreasing NOMR cases will improve transplant safety.

ABO Compatibility Verifications:

Current Requirements and Core Principles:

Current OPTN policy requires that the transplant hospital perform a blood type verification prior to transplant. In addition, time-outs to conduct blood type verification at recovery are required for deceased donor cases when the organ will remain in the same operating suite and living donor cases when the organ will remain in the same operating facility. Time outs must be done prior to the organ leaving the recovery operating room and repeated when the organ arrives at the recipient operating room. Blood type verifications are also required in NOMR cases and prior to extra vessels use in secondary recipients. The check is to ensure that the correct organ will be transplanted into the correct recipient and that blood types are compatible or intended incompatible. The core principle is that confirmation of information is done at critical hand-offs or points of risk.

The concept of verifying critical data using a time out process has become a widely accepted safety practice and promoted by various health care organizations such as The Joint Commission. Two 2014 Joint Commission hospital patient safety goals measured 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 include conducting the time out immediately before the starting the procedure or making the incision. [Medicare Compare](#) tracks which hospitals use a safety checklist to conduct a verification prior to anesthesia and prior to incision.

Proposed Changes and Supporting Evidence:

The proposed changes include:

- Changing format and language to provide clarity
- Changing the timing and scope of recovery verifications
 - Verification of donor and organ information at recovery in all deceased donor cases
 - Verification of recipient information at recovery in deceased donor cases when the intended recipient is known
 - Verification at recovery in all living donor cases
- Including the surgeon in certain verifications
- Adding two conditional requirements
 - Adding an organ check-in when organs will arrive from a different operating suite
 - Adding a pre-procedure verification when surgery will start prior to organ arrival

These changes will improve transplant safety and further align OPTN and CMS requirements. The policies are redesigned and rewritten to provide clarity for common questions that have been previously asked about verification requirements.

Four of the top 11 identified failure modes relate to verification issues. 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 second 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.

Changing format and language to provide clarity

This proposal clarifies verification requirements. Two current policy sections containing verification/time out requirements have been reworked into policy sections specific to the responsible party. The proposed policy spells out specific information to be verified, sources that can be used, timing, and participants in verifications. This is done in response to transplant community feedback on lack of clarity around verification requirements and low policy compliance rates.

Recent reviews for compliance with (former) Policy 3.1.2 (ABO verification upon receipt of the organ and prior to implantation) found that only 32 of 139 (23%) reviewed programs demonstrated compliance. Demonstrating the organ was present at the time of verification was identified as the most significant compliance challenge for transplant centers. Another relatively common issue was that site surveyors were unable to determine the donor and/or recipient ABO and/or UNOS ID was verified upon receipt and prior to implant. These data are from 147 programs audited up to nine months before April and July 2013 MPSC meetings. Random samples of records were examined from 3-year cohorts of transplants performed.

CMS surveys transplant hospitals as well. In 2011, CMS published responses to frequently asked questions about the verification of recipient and donor blood type and other vital data. This memo stated, “The verification of blood type and other vital data between the organ donor and recipient is currently the most frequently cited condition-level deficiency during the transplant program surveys⁹.”

⁹ Centers for Medicaid and Medicare Services. S&C: 11-29-Transplant Memo to State Survey Agency Directors. May 27, 2011. Accessed at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter11_29.pdf.

Low compliance may reflect issues with policy clarity, interpretation, and documentation. It could also be indicative of heightened areas of risk. UNOS and CMS have collaborated to produce a webinar on blood type compatibility requirements, a verification documentation template, and a crosswalk between the two organizations' requirements. This proposal is a critical step to address the numerous questions surfacing from the transplant community during these efforts.

Changing the timing and scope of recovery verifications

Recovery is the first surgical step in the complex process of transplantation. It also represents the first place of hand-off or transition. Studies have shown that patient transitions require transfer of all relevant information, authority, and responsibility from one entity to the next. Concerns for patient safety can arise when any elements are not effectively transferred during a transition. Transitions may be influenced by poor communication, which has been identified as a factor influencing quality and safety of care. Poor transitions can have a negative impact, including adverse events. Although transitions have been shown to be critical points at which failure may occur, they may also be considered as critical points for identifying potential errors and preventing failures.¹⁰

The second most common concern for patient safety in health care organizations identified by the ECRI institute, a patient safety organization, is poor care coordination with the patient's next level of care. The third most common concern is test results reporting errors¹¹. These principles can be applied to organ recovery, as it is the first step in transition of an organ that will be transplanted into a patient. Human factors and communication have been among the top three root causes for sentinel events reported to The Joint Commission since 2012¹². Handover error is recognized as a potential hazard in patient care, and the information error rate has been estimated at 13%. Current literature examined in a meta-analysis does not confirm that any methodology reliably improves the outcomes of clinical handover, although information transfer may be increased¹³.

Root cause analysis of the 2003 ABOi transplant case that led to patient death found that lack of redundancy and failure to complete verifications at the recovery and pre-transplant phases contributed to this adverse event. The corrective action plan included instituting ABO verifications by the procuring surgeon, the transplant surgeon, and the transplant coordinator.¹⁴

While over a decade has passed since that event, there are other future factors supporting verifications. The HOPE Act will allow organs from HIV positive donors to be transplanted into HIV positive recipients under research studies meeting certain Final Rule requirements beginning in November 2015. This underscores the need to have verification processes at certain standing and multiple times during recovery and transplant procedures. Redundancy is major principle in human factors engineering to reduce error. Points may be repeated but different parties do them

¹⁰ Carayon, P and Wood, K. Patient Safety: The Role of Human Factors and Systems Engineering. National Institutes of Health-Public Access Author Manuscript accessed at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3057365/>. Published in final edited form as: *Student Health Technology Information*. 2010; 153: 23–46.

¹¹ ECRI Institute. Top 10 Patient Safety Concerns for Healthcare Organizations 2014. Accessed at <https://www.ecri.org/Press/Pages/Health-IT-Care-Coordination-and-Drug-Shortages-Lead-ECRI-Institute-2014-List-of-Top-10-Patient-Safety-Concerns.aspx>.

¹² The Joint Commission. Sentinel Event Data Summary 2014. Accessed at http://www.jointcommission.org/sentinel_event.aspx.

¹³ Robertson, E. et. al. Interventions employed to improve intrahospital handover: a systematic review. *British Medical Journal of Quality and Safety* 2014;23:7 600-607 Published Online First: 8 May 2014

¹⁴ Duke Medicine and News and Communications. Duke Releases Letter to UNOS Concerning Jessica Santillan. Accessed at http://corporate.dukemedicine.org/news_and_publications/news_office/news/6419.

at different times. Each is a critical piece at a vulnerable point in time where mistakes are more likely to be made.

Because of these safety factors and to better align with CMS, 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. For deceased donors, host OPOs will be responsible for conducting verification prior to organ recovery. Performing a verification after organ removal but prior to leaving the operating room is not the safest timing possible. The FMEA identified these areas where further safety improvements could reduce risk. Transplant community feedback regarding questions on this timing and policy compliance are two additional reasons for this change.

The scope of these verifications has also been addressed. Verification at living donor recovery is not currently required in OPTN policy for all cases. It is only required for those cases where the organ remains in the same facility and the timing of this verification is prior to leaving the operating room. This leaves a major safety gap. Nearly 500 living donor recoveries occur where an organ is shipped. Currently, these events would not be subject to a pre-recovery verification. Living donors usually do not have the benefit of the computer generated match run to check compatibility. Current OPTN policy timing does not match current CMS requirements. This is an area where proactive risk identification and action can reduce the likelihood of a future ABOi transplant through the policy changes proposed and align further with CMS that requires a verification before removal of the donor’s organ in all cases.

Including the surgeon in certain verifications

To promote safety and to align with CMS, this proposal specifies where the recovering or transplanting surgeon must participate during verifications. This is a safety issue as the surgeon is the leader of the transplant team. Correct information review and transfer is critical to make a hand-off and procedure as safe as possible. The recovering surgeon will participate in verifying donor and organ information at deceased donor recovery. The living donor recovery surgeon will participate in the proposed verification prior to recovery. Qualified health care professionals, as defined in program specific protocols will also participate in verifications to ensure training and increase chances of correct confirmation of information.

To align with CMS, the transplanting surgeon and another licensed health care professional will perform the pre-transplant verification upon organ receipt. In addition, one OPO staff member must participate in deceased donor verification as is currently required by CMS.

Adding two conditional items

Two other items are being proposed: a check-in at organ arrival and a pre-procedure verification done prior to induction of anesthesia. 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.

While prevention of accidental ABOi was the focus of the FMEA. These items will also address prevention of wrong-organ/wrong-recipient. Wrong-patient, wrong-site, wrong-procedure has been the most common reported sentinel event (n= 1,072) to The Joint Commission between 2004-June, 2014. This error represents 13% of the 8,275 sentinel events that were voluntarily reported. The most common root causes for this error were leadership (n=865), communication (n=726), and human factors (n=722)¹⁵. Events may have more than one root cause. In transplant, there have been at least ten cases involving wrong organ delivered, wrong-organ/wrong-

¹⁵ The Joint Commission. Sentinel Event Data. 2014. Accessed at: http://www.jointcommission.org/assets/1/18/Root_Causes_by_Event_Type_2004-2Q_2014.pdf.

candidate occurrences or near misses since 2006. These cases may have been prevented with a required check-in or pre-anesthesia verification requirement.

The check-in could assist in reducing organ wastage and unnecessary cold ischemic time. By the time 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. There have been 21 switched kidney laterality cases since 2012 with five resulting in organ discard. One report has been received for switched lung laterality. Approximately 70-80 kidneys were discarded in 2012 due to placement or systems issues. While existing data do not indicate when the issues surfaced, it is possible that some were impacted due to an organ not receiving an immediate check in. Although these situations are not risks for accidental ABOi transplant, they do represent unnecessary organ wastage.

Performing a pre-anesthesia verification will add to patient safety. If an accidental incompatibility is discovered after surgery has started, 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. Pre-anesthesia verification is also a Joint Commission requirement. Moving toward these additions is consistent with other national patient safety goals.

As the OPTN starts using TransNetsm including use of barcoding to scan and document organ receipt as well as to scan and match received organs with recipients, the ability to meet these proposed requirements will be enhanced significantly.

Appendix A contains a comparison of OPTN (current and proposed) and CMS requirements.

Proposed UNetsm programming changes:

This proposal contains three programming changes. Each of these are enhancements and independent of the proposed policy changes. The programming changes include:

- Adding a warning when registering liver candidates willing to accept an ABOi organ
- Adding candidate blood type and ABO compatibility status to the match run view
- Adding second user verification for subtype reporting

All three programming changes will improve safety for planned or intentional ABOi transplants. Not all ABOi transplants are accidents and they are permissible in policy. It is imperative to enhance programming safeguards and visual cues for these types of transplants.

Having a candidate erroneously listed as willing to accept an ABO incompatible transplant was ranked as a significant potential FMEA fail points. **Table 4** shows that between 2010 and June 2014, 142 ABO incompatible deceased donor transplants took place. All 61 heart recipients were between ages zero – two years. The four incompatible kidney transplants occurred in recipients at least 18 years old as part of multi-organ transplants with livers. All 77 incompatible liver transplants occurred in patients classified as either Status 1A/1B or with MELD/PELD scores of at least 30.

Table 4: ABO Compatibility, Deceased Donor Transplants, 1/1/2010 – 6/30/2014

	ABO compatibility type								Total N
	Identical		Compatible		Subtype compatible		Incompatible		
	N	%	N	%	N	%	N	%	
Organ Txed									
HL	110	82.7	23	17.3	0	0	0	0	133
HR	9,102	84.3	1,632	15.1	1	0.0	61	0.6	10,796
IN	481	87.0	72	13.0	0	0	0	0	553
KI	47,262	95.8	1,933	3.9	146	0.3	4	0.0	49,345
KP	3,412	96.4	125	3.5	1	0.0	0	0	3,538
LI	25,436	92.6	1,732	6.3	220	0.8	77	0.3	27,465
LU	7,592	92.7	600	7.3	0	0	0	0	8,192
PA	1,004	80.4	244	19.6	0	0	0	0	1,248
Total	94,399	93.2	6,361	6.3	368	0.4	142	0.1	101,270

Reports exist of erroneous listings or lack of confirmation for ABO incompatible candidates. One anecdote revealed where 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 patient safety situation 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.

Intended ABO incompatible transplants are more common in living donation. Between 2005 and June 2013, there were 667 ABO incompatible transplants (kidney = 657; liver = 10) and 130 subtype compatible transplants (kidney = 126; liver = 4). In living donation, the match is not run except in kidney paired donation or non-directed altruistic donation.

Adding a warning when registering liver candidates willing to accept an ABOi organ

Only one person is required to list a candidate as willing to accept an ABO incompatible organ. Pediatric heart candidates must report certain titers before being 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 programming changes in UNetSM to warn users to verify that an ABO incompatible transplant is acceptable for liver registrations.

Adding candidate blood type and ABO compatibility status to the match run view

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 that are biologically incompatible (including subtype-compatible such as blood group 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 ABO candidate type and compatibility status as an additional visual cue to avoid potential miscommunication. This may also assist with verification requirements.

Adding second user verification for subtype reporting

Current policy requires second user verification of subtypes for deceased and living donors. The current functionality in all UNetsm systems, however, allows primary blood types A and AB to have a subtype added by only one user. Due to the number of subtype compatible transplants and the increases expected with the revised KAS, programming for second user verification of subtypes is proposed.

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 Program Goals, 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 unintentional 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 proficiency training and guidance to address frequently asked questions and promote effective practices. The proposal will help reduce duplicative efforts by further aligning OPTN with CMS requirements.

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 (TransNetSM) 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 proficiency 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 UNOS 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 June 2015. Implementation would be delayed until November 1, 2015 to allow adequate time for preparation, education, and training.

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

OPOs will need to complete two separate blood draws for deceased donor blood type determination.

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 include a process for resolving primary blood type conflicts in their determination and reporting protocols.

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. Donor and organ information will be verified with participation from the on-site recovering surgeon in all cases. When the intended recipient is known, the host OPO will verify additional information.

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 when surgery starts prior to organ receipt
- Verification once the organ is delivered into the operating room yet prior to first anastomosis for living or deceased donor organ recipients

Transplant hospitals will need to include a process for resolving conflicting primary blood types in their determination and reporting protocols.

ABO reporting and verifications will need to be performed by a qualified health care professional as defined by OPO and transplant hospital protocols. The transplant surgeon and a licensed health care professional will need to conduct the final pre-transplant verification to align with CMS regulations.

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 highlight planned ABO blood type incompatible matches. Second user verification for reporting subtype will be programmed to support existing current policy requirements. This will not require changes for member data entry but will require awareness of system changes.

Communication and Education Plan:

This proposal will require an instructional program and will be monitored for specific needs throughout the public comment and approval process. Specific communication efforts associated with the proposal will include:

- Policy notice
- System notice
- Updates to Help Documentation in UNetSM
- Patient Safety News articles
- Presentations at regional meetings

Compliance Monitoring:

Staff will continue reviewing all deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to OPTN requirements, and will continue investigating potential policy violations. Based upon the proposed language, monitoring will either be changed or continue as follows:

For this policy:	Monitoring will change as follows:	Site surveyors will continue monitoring as follows:
Policy 2.6 Deceased Donor Blood Type Determination and Reporting		At OPOs, site surveyors will review the OPO's internal policies, procedures and/or protocols to verify that they include a description of the process for: <ul style="list-style-type: none"> • Verification that the individual performing the secondary reporting consulted source documents from two blood type tests • If sub-type of non-A₁ or non-A₁B is reported: <ul style="list-style-type: none"> • Verification that two individuals separately reported the donor's blood type to the OPTN Contractor • Verification that both individuals consulted source documents from two blood type tests
Policy 2.6.A Deceased Donor Blood Type Determination	<i>If two tests were completed on blood drawn at the same date and time, then documentation showing that the tests were run by two different laboratories will no longer be permitted.</i>	At OPOs, site surveyors will review a sample of deceased donor records, and any material incorporated into the medical record by reference, to verify that: <ul style="list-style-type: none"> • There are identical results for two separate blood typing tests • Tests were completed on two separate blood samples • The draw times for the samples used for the two tests are at different times

For this policy:	Monitoring will change as follows:	Site surveyors will continue monitoring as follows:
Policy 2.6.B Deceased Donor Blood Subtype Determination	<p><i>If two tests were completed on blood drawn at the same date and time, then documentation showing that the tests were run by two different laboratories will no longer be permitted.</i></p> <p><i>Additionally, At OPOs, site surveyors will review a sample of deceased donor records when subtype is not reported for A donors, to verify that one of the acceptable reasons is documented.</i></p>	At OPOs, site surveyors will review a sample of deceased donor records when subtype is reported, to verify that: <ul style="list-style-type: none"> • There are identical results for two separate blood subtyping tests • Tests were completed on two separate blood samples • The draw times for the samples used for the two tests are at different times • Samples used were pre-red blood cell transfusion
Policy 2.6.C Reporting of Deceased Donor Blood Type and Subtype		Monitored as part of 2.6
Policy 2.15.B Pre- Recovery Verification	At OPOs, site surveyors will review a sample of deceased donor records, and any material incorporated into the medical record by reference, for documentation of a verification for each organ containing: <ul style="list-style-type: none"> • Donor ID • Organ • Organ laterality (if applicable) • Donor blood type • Participating individuals included: <ul style="list-style-type: none"> • On-site recovering physician • A second individual 	
Policy 3.3 Candidate Blood Type Determination and Reporting Before Waiting List Registration	At transplant hospitals, site surveyors will review internal policies, protocols or procedures to verify the presence of a written protocol for blood type determination and reporting that: <ul style="list-style-type: none"> ○ Includes a two-person verification and reporting process using two blood type source documents ○ Defines qualified health care professionals 	

For this policy:	Monitoring will change as follows:	Site surveyors will continue monitoring as follows:
Policy 3.3.A Candidates Blood Type Determination Before Waiting List Registration	<i>Additionally</i> , at transplant hospitals, site surveyors will review internal policies, protocols, or procedures to verify the presence of a written process for resolving conflicting blood type results.	At transplant hospitals, site surveyors will review a sample of medical records, and any material incorporated into the medical record by reference, to verify that: <ul style="list-style-type: none"> • There are identical results for two separate blood typing tests • Tests were completed on two separate blood samples • The draw times for the samples used for the two tests are at different times • Test results were available before the patient's registration on the waiting list
Policy 3.3.B Reporting of Candidate Blood Type		At transplant hospitals, site surveyors will review a sample of medical records to verify the accuracy of the reported blood type.
Policy 5.4.B Order of Allocation		Not routinely monitored on site.
Policy 5.5.A Receiving and Reviewing Offers		Not routinely monitored on site.
Policy 5.6. Organ Check-In	Review will be incorporated into the site survey review of Policy 5.7.B.	
Policy 5.7 Pre-Transplant Verification	At transplant hospitals, site surveyors will review internal policies, protocols, and procedures to verify the presence of a written protocol for pre-transplant verification.	
Policy 5.7.A Pre-Transplant Verification Prior to Organ Receipt	Not routinely monitored on site.	

For this policy:	Monitoring will change as follows:	Site surveyors will continue monitoring as follows:
<p>Policy 5.7.B Pre-Transplant Verification Upon Organ Receipt</p>	<p><i>Additionally</i>, at transplant hospitals, site surveyors will review a sample of medical records, and any material incorporated into the medical record by reference, to verify that:</p> <ul style="list-style-type: none"> • The transplant surgeon participated in the verification • A second licensed health care professional participated in the verification • The following were verified: <ul style="list-style-type: none"> ○ Organ ○ Laterality (if applicable) ○ Recipient identifier 	<p>At transplant hospitals, site surveyors will review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that:</p> <ul style="list-style-type: none"> • The following were verified between organ arrival and implantation: <ul style="list-style-type: none"> • Donor blood type • Recipient blood type • Donor ID • The following are documented: <ul style="list-style-type: none"> • Organ arrival time or documentation showing organ present at time of verification • Verification time • Anastomosis time or documentation showing verification occurred prior to implant
<p>Policy 13.6.A Requirements for Match Run Eligibility for Candidates</p>	<p>Monitored as part of referenced policies.</p>	
<p>Policy 13.6.B Requirements for Match Run Eligibility for Potential KPD Donors</p>	<p>Monitored as part of Policy 14.5.</p>	
<p>Policy 14.5 Living Donor Blood Type Determination and Reporting</p>	<p>At recovery hospitals, site surveyors will review internal policies, protocols, or procedures to verify the presence of a written protocol for blood type determination and reporting that includes a two-person verification and reporting process.</p>	

For this policy:	Monitoring will change as follows:	Site surveyors will continue monitoring as follows:
<p>Policy 14.5.A Living Donor Blood Type Determination and Reporting</p>	<p>At recovery hospitals, site surveyors will review internal policies, protocols, or procedures to verify the presence of a written process for resolving conflicting blood type results.</p> <p>At recovery hospitals, site surveyors will review a sample of medical records, and any material incorporated into the medical record by reference, to verify that:</p> <ul style="list-style-type: none"> • There are identical results for two separate blood typing tests • Tests were completed on two separate blood samples • The draw times for the samples used for the two tests are at different times 	
<p>Policy 14.5.B Living Donor Blood Subtype Determination</p>	<p>At recovery hospitals, site surveyors will review a sample of living donor records, and any material incorporated into the medical record by reference, when subtype is reported, to verify that:</p> <ul style="list-style-type: none"> • There are identical results for two separate blood typing tests • Tests were completed on two separate blood samples • The draw times for the samples used for the two tests are at different times 	
<p>Policy 14.5.C Reporting of Living Donor Blood Type and Subtype</p>	<p>At recovery hospitals, site surveyors will review a sample of medical records, and the hospital's internal policies, protocols or procedures, to verify that:</p> <ul style="list-style-type: none"> • Reporting was conducted: <ul style="list-style-type: none"> ○ By two qualified health care professionals, as defined in the hospital's protocol ○ Using two blood type source documents • The results on the source documents used match the reported type 	

For this policy:	Monitoring will change as follows:	Site surveyors will continue monitoring as follows:
Policy 14.8 Living Donor Pre-Recovery Verification	<p><i>Additionally</i>, at recovery hospitals, site surveyors will review a sample of medical records, and any material incorporated into the medical record by reference, to verify that:</p> <ul style="list-style-type: none"> • The recovery surgeon participated in the verification • A second licensed health care professional participated in the verification • The following were verified: <ul style="list-style-type: none"> ○ Donor ID ○ Organ ○ Laterality ○ Donor blood type ○ Intended recipient blood type • The verification took place: <ul style="list-style-type: none"> ○ Before the induction of general anesthesia ○ After the donor arrived in the OR 	<p>Review the living donor recovery hospital's internal policies, procedures and/or protocols to verify that the hospital has developed and implemented written protocols that address:</p> <ul style="list-style-type: none"> • "Time outs" • That they include a process for verifying: <ul style="list-style-type: none"> • A unique identifier for the donor • A unique identifier for the recipient
Policy 14.10 Living Donor Organ Check-In	Monitored as part of Policy 5.7.B	
Policy 14.11 Living Donor Pre-Transplant Verification	Monitored as part of Policy 5.7.B	
Policy 16.4.C Internal Labeling of Blood and Tissue Typing Materials		Not routinely monitored on site.

Policy or Bylaw Proposal:

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

1.2 Definitions

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

Intended incompatible

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

Qualified health care professional

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

Source document

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

2.6 Deceased Donor Blood Type Determination and Reporting

~~The host Host OPOs must ensure that each deceased donor's blood type is accurately determined, report the blood type to the OPTN Contractor, and then verify that the correct blood type was reported develop and comply with a written protocol for blood type determination and reporting that includes *all* of the requirements below.~~

2.6.A Deceased Donor Blood Type Determination

~~The host OPO must ensure that each deceased donor's blood type is accurately determined by testing at least two donor blood samples prior to ~~insertion~~ the match run. The host OPO must develop and follow a process to resolve conflicting blood type results. ~~If the two samples are from the same blood draw, then the samples must be tested by two different laboratories.~~~~

Deceased donor blood samples must:

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

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

The host OPO must document that blood type determination was conducted according to the OPO's protocol and the above requirements.

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.

Deceased donor blood subtyping must be completed according to the *Table 2-1* and the requirements below.

Table 2-1: Subtyping Requirements by Primary Blood Type and First Subtype Result

<u>If the donor's primary blood type is:</u>	<u>Then subtyping is:</u>	<u>A second subtyping must be completed if the first subtype result is:</u>
<u>A</u>	<u>Required</u>	<u>Blood type A, non-A₁</u>
<u>AB</u>	<u>Optional</u>	<u>Blood type AB, non-A₁B</u>

Deceased donor blood samples for subtyping must:

1. Be tested using pre-red blood cell transfusion samples
2. Be drawn on two separate occasions
3. Have different collection times
4. Be submitted as separate samples

All subtype results reported to the OPTN Contractor must be from two separate tests indicating the same result. If there are conflicting subtype results, the subtype results must not be reported to the OPTN Contractor and the deceased donor must be allocated based on the primary blood type.

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

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

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

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

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

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

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

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

~~reporting of blood subtype that is completed by someone:~~

- ~~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~~

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

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

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

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

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

2.15 Organ Procurement

2.15.A Conflicts of Interest

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

- The potential deceased donor's attending physician at the time of death
- The physician who declares the time of the potential deceased donor's death

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

Host OPOs must develop and comply with a written protocol to perform a pre-recovery verification for each organ recovered as required below. Qualified health care professionals, as defined in the host OPO's protocol, must perform all verifications. At least one of the individuals performing a verification must be an OPO staff member.

The host OPO must conduct a verification prior to organ recovery according to *Table 2.1* below. Assistance using an OPTN-approved electronic method is permitted.

Table 2.1: Pre-Recovery Verification Requirements

<u>The host OPO must verify all of the following information:</u>	<u>Using at least one of these sources:</u>	<u>By the following individuals:</u>
<u>Donor ID</u>	<ol style="list-style-type: none"> 1. <u>Donor's identification band</u> 2. <u>OPTN computer system</u> 	<ol style="list-style-type: none"> 1. <u>On-site recovering surgeon</u> 2. <u>Qualified health care professional</u>
<u>Organ (and laterality, if applicable)</u>	<ul style="list-style-type: none"> • <u>Donor medical record</u> • <u>OPTN computer system</u> 	<ol style="list-style-type: none"> 1. <u>On-site recovering surgeon</u> 2. <u>Qualified health care professional</u>
<u>Donor blood type and subtype (if used for allocation)</u>	<ul style="list-style-type: none"> • <u>Donor blood type and subtype source documents</u> 	<ol style="list-style-type: none"> 1. <u>On-site recovering surgeon</u> 2. <u>Qualified health care professional</u>

When the intended recipient is known prior to organ recovery, the host OPO must verify all of the additional information according to Table 2.2 below.

Table 2.2: Additional Pre-Recovery Verification Requirements When the Intended Recipient is Known Prior to Organ Recovery

<u>The host OPO must verify all of the following information:</u>	<u>Using at least one of these sources:</u>	<u>By the following individuals:</u>
<u>Intended recipient unique identifier</u>	<ul style="list-style-type: none"> • <u>OPTN computer system</u> 	<u>Two qualified health care professionals</u>
<u>Intended recipient blood type</u>	<ul style="list-style-type: none"> • <u>OPTN computer system</u> 	<u>Two qualified health care professionals</u>
<u>Donor and intended recipient are blood type compatible (or intended incompatible).</u>	<ul style="list-style-type: none"> • <u>OPTN computer system</u> 	<u>Two qualified health care professionals</u>

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

2.15.BC Organ Procurement Procedures

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

3.3 Candidate Blood Type Determination and Reporting before Waiting List Registration

Transplant programs must determine and report each transplant candidate's actual blood type before registering them on the waiting list develop and comply with a written protocol for blood type determination and reporting that includes all of the requirements below.

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

The Transplant programs must ensure that each candidate's blood type is determined by testing at least two candidate blood samples prior to registration on the waiting list. The transplant program must develop and follow a process to resolve conflicting blood type

~~results. Transplant programs must test at least two blood samples from two separate blood draws taken at two different times.~~

Candidate blood samples must:

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

The transplant program must document that blood type determination was conducted according to the program's protocol and the above requirements.

3.3.B Secondary Reporting of Candidate Blood Type

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

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

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

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

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

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

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

5.4.B Order of Allocation

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

1. The match system eliminates candidates who cannot accept the deceased donor based on size or blood type.
2. The match system ranks candidates according to the allocation sequences in the organ allocation policies.
3. OPOs must first offer organs to potential recipients in the order that the potential recipients appear on a match run.
4. If no transplant program on the initial match run accepts the organ, the host OPO may give transplant programs the opportunity to update their candidates' data with the OPTN

Contractor. The host OPO ~~may must run an updated re-execute the match run and to allocate the organ according to the updated candidate data.~~

5. If no transplant program within the DSA or through an approved regional sharing arrangement accepts the organ, the Organ Center will allocate an abdominal organ first regionally and then nationally, according to allocation Policies. The Organ Center will allocate thoracic organs according to *Policy 6: Allocation of Hearts and Heart-Lungs* and *Policy 10: Allocation of Lungs*.
6. Members may export deceased donor organs to hospitals in foreign countries only after offering these organs to all potential recipients on the match run. Members must submit the *Organ Export Verification Form* to the OPTN Contractor prior to exporting deceased donor organs.

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

5.5 Receiving and Accepting Organ Offers

5.5.A Receiving and Reviewing Organ Offers

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

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

5.6 ~~Blood Type Verification upon Receipt~~ Organ Check-In

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

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

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

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

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

Assistance using an OPTN-approved electronic method is permitted. If the transplant hospital determines that the donor ID, organ type or laterality is incorrect, then the transplant hospital must notify the host OPO as soon as possible but within one hour of the determination.

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

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

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

5.7 Released Organs Pre-Transplant Verification

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

5.7.A Pre-Transplant Verification Prior to Organ Receipt

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

1. Two licensed health care professionals must participate in the verification
2. The intended recipient must be present in the operating room
3. The verification must occur *either*:
 - a. Prior to induction of general anesthesia
 - b. Prior to incision if the patient has been receiving continuous sedation prior to arrival in the operating room
4. Transplant hospitals must use at least one of the acceptable sources during the pre-transplant verification prior to organ receipt to verify all of the following information in *Table 5.1* below. Assistance using an OPTN-approved electronic method is permitted.

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

<u>The transplant hospital must verify all of the following information:</u>	<u>Using at least one of these sources:</u>
<u>Expected donor ID</u>	<ul style="list-style-type: none"> • <u>OPTN computer system</u> • <u>Recipient medical record</u>
<u>Expected organ (and laterality if applicable)</u>	<ul style="list-style-type: none"> • <u>OPTN computer system</u> • <u>Recipient medical record</u>
<u>Expected donor blood type and subtype (if used for allocation)</u>	<ul style="list-style-type: none"> • <u>Donor blood type and subtype source documents</u> • <u>OPTN computer system</u>
<u>Recipient unique identifier</u>	<ul style="list-style-type: none"> • <u>Recipient identification band</u>
<u>Recipient blood type</u>	<ul style="list-style-type: none"> • <u>Recipient blood type and subtype source documents</u> • <u>Recipient medical record</u>
<u>Expected donor and recipient are blood type compatible (or intended incompatible).</u>	<ul style="list-style-type: none"> • <u>OPTN computer system</u> • <u>Recipient medical record</u> • <u>Attestation following verification of donor and recipient blood types</u>

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

5.7.B Pre-Transplant Verification Upon Organ Receipt

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

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

2. The intended recipient must be present in the operating room
3. The verification must occur after the organ arrives in the operating room, but prior to anastomosis of the first organ
4. Transplant hospitals must use at least one of the acceptable sources during the pre-transplant verification upon organ receipt to verify all of the following information in *Table 5.2* below. Assistance using an OPTN-approved electronic method is permitted.

Table 5.2: Pre-Transplant Verification Upon Organ Receipt Requirements

<u>The transplant hospital must verify all of the following information:</u>	<u>Using at least one of these sources:</u>
<u>Donor ID</u>	<ul style="list-style-type: none"> • <u>External and internal organ package labels</u> • <u>Documentation with organ</u>
<u>Organ (and laterality if applicable)</u>	<ul style="list-style-type: none"> • <u>Organ received</u>
<u>Donor blood type and subtype (if used for allocation)</u>	<ul style="list-style-type: none"> • <u>Donor blood type and subtype source documents</u>
<u>Recipient unique identifier</u>	<ul style="list-style-type: none"> • <u>Recipient identification band</u>
<u>Recipient blood type</u>	<ul style="list-style-type: none"> • <u>Recipient blood type source documents</u> • <u>Recipient medical record</u>
<u>Donor and recipient are blood type compatible (or intended incompatible)</u>	<ul style="list-style-type: none"> • <u>OPTN computer system</u> • <u>Recipient medical record</u> • <u>Attestation following verification of donor and recipient blood types</u>
<u>Correct donor organ has been identified for the correct recipient</u>	<ul style="list-style-type: none"> • <u>Recipient medical record</u> • <u>OPTN computer system</u>

The transplant hospital must document that the pre-transplant verification upon organ receipt was completed according to the hospital's protocol and the above requirements.

5.78 Released Organs

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

13.6 Matching within the OPTN KPD Program

13.6.A Requirements for Match Run Eligibility for Candidates

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

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

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

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

following requirements:

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

14.4 Medical Evaluation Requirements for Living Donors

~~14.4.A Living Donor Blood type Determination~~

~~The recovery hospital must ensure that blood typing of each living donor is performed on two separate occasions before the recovery. Two separate occasions are defined as two blood samples taken at different times, and sent to the same or different laboratories.~~

~~14.4.A.i 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.~~

14.4.BA Living Donor Medical Evaluation Requirements

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

14.5 ~~Registration and Blood Type Verification of Living Donors before Donation~~ Living Donor Blood Type Determination and Reporting

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

~~determination blood typing and subtyping source documents by an individual other than the person initially entering the donor's blood type data.~~

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

~~This policy does not apply to VCA transplants.~~

Recovery hospitals must develop and comply with a written protocol for blood type determination and reporting that includes all of the requirements below.

14.5.A Living Donor Blood Type Determination

The recovery hospital must ensure that each living donor's blood type is determined by testing at least two donor blood samples prior to generation of the living donor ID. The recovery hospital must develop and follow a process for resolving conflicting blood type results.

Living donor blood samples must:

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

The recovery hospital must document that blood type determination was conducted according to the hospital's protocol and the above requirements.

14.5.B Living Donor Blood Subtype Determination

Subtyping is optional for living donors.

If the recovery hospital chooses to subtype *and* pre-red blood cell transfusion samples are available, then subtyping must be completed according to *Table 14-2*.

Table 14-2: Subtyping Requirements by First Subtype Result

<u>If the donor's primary blood type is:</u>	<u>A second subtyping must be completed if the first subtype result is:</u>
<u>A</u>	<u>Blood type A, non-A₁</u>
<u>AB</u>	<u>Blood type AB, non-A₁B</u>

Living donor blood samples for subtyping must:

1. Be tested using pre-red blood transfusion samples
2. Be drawn on two separate occasions
3. Have different collection times
4. Be submitted as separate samples

All subtype results reported to the OPTN Contractor must be from two separate tests indicating the same result. If there are conflicting subtype results, the subtype results must not be reported to the OPTN Contractor and living donor transplant compatibility or allocation must be based on the primary blood type.

If subtype is determined and reported, the recovery hospital must document that subtyping was conducted according to the above requirements.

14.5.C Reporting of Living Donor Blood Type and Subtype

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

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

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

14.7 Living Donor Pre-Recovery Verification

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

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

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

Table 14.3: Pre-Recovery Verification Requirements

<u>The recovery hospital must verify <i>all</i> of the following information:</u>	<u>Using at least <i>one</i> of these sources:</u>
<u>Donor ID</u>	<ul style="list-style-type: none">• <u>Donor identification band</u>
<u>Organ type and laterality (if applicable)</u>	<ul style="list-style-type: none">• <u>OPTN computer system</u>

The recovery hospital must verify <i>all</i> of the following information:	Using at least <i>one</i> of these sources:
<u>Donor blood type and subtype (if used for ensuring transplant compatibility or allocation)</u>	<ul style="list-style-type: none"> • <u>Donor blood type and subtype source documents</u>
<u>Intended recipient unique identifier</u>	<ul style="list-style-type: none"> • <u>Recipient medical record</u> • <u>OPTN computer system</u>
<u>Intended recipient blood type</u>	<ul style="list-style-type: none"> • <u>Recipient medical record</u> • <u>OPTN computer system</u>
<u>Donor and intended recipient are blood type compatible (or intended incompatible).</u>	<ul style="list-style-type: none"> • <u>OPTN computer system</u> • <u>Recipient medical record</u> • <u>Attestation following verification of donor and recipient blood types</u>
<u>Correct donor organ has been identified for the correct intended recipient</u>	<ul style="list-style-type: none"> • <u>Donor medical record</u> • <u>OPTN computer system</u>

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

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

14.9 Living Donor Organ Check-In

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

14.10 Living Donor Pre-Transplant Verification

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

14.8-11 Reporting Requirements

16.1 Organs Not Requiring Transport

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

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

~~Time-outs must occur:~~

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

~~During these time-outs and before the transplant occurs, the transplant hospital must confirm and~~

document that a member of the transplant team identified the correct organ for the correct potential recipient prior to transplant according to *Policy 5.6: Blood Type Verification upon Receipt*.

16.4.C Internal Labeling of Blood and Tissue Typing Materials

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

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

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

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

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

Appendix A: Comparison of OPTN and CMS Requirements

Comparison of ABO Determination, Reporting, and Verification Requirements			OPTN	CMS
ABO Determination	Candidate	Transplant hospital must have protocol	DD,LD	DD,LD
		Two separate blood type determination tests required	DD,LD	
		Blood samples must be drawn on separate occasions		
	Donor	Must have protocol	DD,LD	DD
		Two separate blood type determination tests required	DD,LD	DD
		Blood samples must be collected on separate occasions	DD,LD	DD
		If samples are from same blood draw, then must go to different labs	DD	
Blood type A must be subtyped		DD		
Pre-transfusion blood specimens must be used for subtyping	DD, LD			
If first subtype result is blood type A, non-A ₁ or blood type AB, non-A ₁ B, then two separate subtype tests must be done				
ABO Reporting	Candidate	Blood type tests must be completed and reported prior to Waitlist registration	DD, LD	DD,LD
	Donor	Blood type tests must be completed and reported prior to:		DD
		• Organ recovery		
		• Incision	DD	
		• Match run	DD	
	• Generation of Donor ID	LD		
Both	Reports must be done by a qualified health care professional as defined in individual protocol	DD, LD		
	Two different persons must each independently report identical blood types to OPTN	DD, LD		

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

Comparison of ABO Determination, Reporting, and Verification Requirements		OPTN	CMS
	• OPTN external labels (check-in verification only)	DD,LD	

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

For more information on CMS regulations please see:

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

For more information on OPTN policies please see:

- Organ Procurement and Transplantation Network Policies at <http://optn.transplant.hrsa.gov/governance/policies/>