

## Preparing for ABO Determination, Reporting and Verification Policy Changes Webinar Script

Our speaker for today's webinar is Theresa Daly. Theresa is the Director of Clinical Operations for the Transplant Hospital at the New York Presbyterian Hospital – Columbia University. In this role she oversees clinical operations for heart, heart-lung, lung, liver, kidney, pancreas, and small bowel adult transplant programs. She is also the current Chair of the OPTN's Operations and Safety Committee.

By the end of today's webinar, you will be able to:

1. Explain upcoming changes to blood type determination, verification, and reporting policies.
2. And utilize tools and resources to prepare for policy implementation.

I would like to direct your attention to resources available in the ABO toolbox that was posted last month on the OPTN and TransplantPro websites. The resources were made available to give you a head start and begin preparing for the upcoming policy implementation. In the toolbox you will find:

- Frequently asked questions about the upcoming policy changes.
- A clean draft of the policy language to be implemented with programming. The implementation date will be no sooner than June 1, 2016.
- Two checklists, one for OPOs and one for transplant hospitals. The checklists include responsibilities and actions members should consider during preparations.
- And a draft of the UNOS compliance monitoring plan.

This toolbox will be updated periodically with additional resources as they become available and members will be notified through OPTN and TransplantPro postings. Be sure to review the monthly TransplantPro newsletters for highlights on communications regarding these resources and other instructional offerings.

To pin point the problem in the ABO system, the OPTN's Operations and Safety Committee performed a Failure Modes and Effect Analysis, or FMEA, in an effort to identify patient safety risks and gaps. The process helped us walk through the current ABO system, step-by-step, and identify all possible failures in the current design. Sixty-two potential fail points were identified in the current system for determining, reporting, and verifying ABO. The policy changes we will discuss today address only the top 10 fail points that posed the highest risk to the patient.

If you would like to review detailed information on the FMEA that was conducted and the report of findings, access the [public comment document](#) on the OPTN website.

The Committee had specific goals to achieve with the policy changes. They were to:

- Crosswalk OPTN and CMS rules to assess gaps and align OPTN policy and CMS requirements where possible – when and if it made sense, and assure that the two do not conflict.
- Improve clarity of what is expected from OPOs, transplant hospitals and living donor recovery hospitals.
- And, to fill the identified high risk patient safety gaps.

The Committee crosswalked OPTN policies with CMS conditions of participation and found misalignment in several places. There were also safety gaps and issues with continuity of language in OPTN policy. Requirements now align in related areas and provide a safer process for patients. Additionally, when the community is compliant with OPTN policies they will also be in compliance with current CMS conditions of participation.

## **Preparing for ABO Determination, Reporting and Verification Policy Changes Webinar Script**

We have heard from the community that the changes seem overwhelming. That's partly because ABO requirements are scattered throughout OPTN policy, touching seven policies and 23 sub-policies. That is why the changes seem so complex and large. At the end of the day, three items were added to policy, two were removed, and the timing on four existing items was changed. Today I will discuss the changes within the process and increase your confidence in complying with the policy changes.

A few clarifying definitions were added to the definitions section of policy. First, a definition is established for the term intended incompatible. It means that the donor and candidate primary blood types are biologically incompatible, but transplant is permissible according to OPTN policy. Second, a qualified health care professional is a person who is qualified to perform blood type reporting or verification requirements as defined in the OPO, transplant hospital, or living donor recovery hospital's written protocol. Lastly, source document is defined as an original record of results, or a photocopy or digital copy of the original record.

There are 5 basic steps in the ABO determination, reporting and verification process.

- Step 1 is blood type determination of the candidate, deceased or living donor.
- Step 2 is reporting the blood type of the candidate, deceased or living donor in UNet<sup>sm</sup>.
- Step 3 is UNet<sup>sm</sup> verification that the two blood type entries made by two independent individuals is the same.
- Step 4 is when UNet<sup>sm</sup> matches donors and potential recipients via match run.
- Step 5 is when blood type verifications take place prior to the transplant procedure.

Three of the five steps are manually performed. Let's review the steps in detail to give you a better feel for the impact of the policy changes. Today I will discuss the process in a way in which you can understand where candidates, deceased donors, and living donors converge in requirements for blood type determination, reporting, and verification process. The presentation is arranged in a way as to mimic the pathway of donation and transplantation. First, ABO determination and reporting for the living donor, deceased donor and candidate; then the match run is generated; then there is a pre-recovery verification for deceased and living donors; then organ recovery occurs; then all other checks are on the recipient side.

### **Blood Type Determination and Reporting**

Determining and reporting the blood type of the candidate and the donor are the first two steps in the process. This is a very manual human process and the steps have not changed. However, new for all candidate, living donors, and deceased donors is that transplant hospitals, recovery hospitals, and OPOs must have a protocol for resolving situations where there are discrepant blood type results. Let's look at it more closely.

First let's review the candidate process for which there are no changes. For all candidates, policy outlines requirements for blood type determination that must occur before being registered on the waiting list. There were no specific changes to this process.

The transplant program must determine each candidate's blood type by testing at least two candidate blood samples prior to registration on the waiting list. Candidate blood samples must:

## **Preparing for ABO Determination, Reporting and Verification Policy Changes Webinar Script**

- Be drawn on two separate occasions. That means that there are two distinct collections. Each with an independent patient identification and specimen labeling procedure.
- The blood samples must have different collection times.
- The blood samples must be submitted as separate samples.
- Both blood type results must indicate the same blood type before entering the result in UNet<sup>sm</sup>.

Programs must document that blood type determination was conducted according to their protocol and OPTN policy requirements.

Policy currently outlines the requirements for candidate blood type reporting. However, new to the policy is that a transplant hospital must use qualified health care professionals to report blood type in UNet<sup>sm</sup> for system verification. The transplant hospital must also define the qualified health care professionals in their protocol and what makes them qualified. This requirement ensures that those entering blood type data have some minimum and standardized training.

The process of reporting itself is unchanged. First, the two different qualified health care professionals each make an independent report of the candidate's blood type in the system. Both qualified health care professionals must use all blood type determination source documents to verify that they:

- Contain blood type results for the candidate.
- Indicate the same blood type on the two test results.
- Both results match what the blood type reported in UNet<sup>sm</sup>.

Transplant programs must maintain documentation that the reporting verification was completed according to their protocol and policy requirements.

There will be a system enhancement added for liver candidates that are listed as willing to accept an incompatible liver. There is no two person verification, only a warning message that will be displayed to create awareness and to confirm that when listing the candidate as willing to accept an incompatible liver, it is intentional.

There have been two changes in the policy that addresses blood type determination of a deceased donor. Current policy requires the host OPO to ensure that each deceased donor's blood type is determined by testing two blood samples prior to donor incision. New in this step for deceased donors is that the host OPO must ensure that each deceased donor's blood type is accurately determined by testing two donor blood samples prior to executing the match run. This was a timing change.

Deceased donor blood subtyping must be completed for blood type A donors, but is optional for blood type AB donors. Two subtyping blood samples are to be tested on pre-red blood cell transfusion samples for subtyping to be used for allocation.

Therefore, deceased donor blood samples must:

1. Be drawn on two separate occasions - meaning two distinct collections that each have an independent patient identification and specimen labeling procedure.
2. Blood samples must have different collection times.
3. Blood samples must be submitted as separate samples.
4. Both results must indicate the same blood type.

## Preparing for ABO Determination, Reporting and Verification Policy Changes Webinar Script

5. Subtyping samples must be pre-transfusion.

The OPO must also document that blood type determination was conducted according to their protocol and the policy requirements.

For deceased donors there have been modifications to the reporting requirement. New policy for OPOs requires the use of two qualified health care professionals to report blood type in UNet<sup>SM</sup> before executing the match run. The OPO must also define the qualified health care professionals in their protocol. This requirement ensures that those entering blood type data have some minimum and standardized training.

The process for reporting is the same. Both qualified health care professionals must use all blood type and subtype determination source documents to verify that they:

- A. Contain blood type and subtype results for the donor.
- B. Indicate the same blood type and subtype on the two test results.
- C. Both results match the blood type reported.

The OPO must maintain documentation that the reporting verification was completed according to their protocol and policy requirements.

To avoid organ wastage, new policy language was added for rare cases of accelerated organ allocation (i.e. a crashing donor clause). In these instances, the OPO may complete reporting

requirements after the match is run, but prior to organ release to a transplant hospital. The OPO must also document:

- 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.
- All required blood type and subtype determinations, verification, and reporting were completed prior to the organ being released to the transplant hospital.

If there are conflicting primary blood type test results, the host OPO must follow its protocol for resolving the discrepancy and re-execute the match run if the final ABO result is different from the initial ABO on the original match run.

For living donors, current policy requires the recovery hospital to 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, which is done through the Living Donor Feedback form. Blood subtyping in living donors is optional. There were no specific changes to this process, but let's review.

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.
5. Subtyping samples must be pre-transfusion.

## Preparing for ABO Determination, Reporting and Verification Policy Changes Webinar Script

Living donor recovery hospitals must document that blood type determination was conducted according to protocol and the policy requirements. For living donor VCA blood type reporting, requirements are to be recorded in the donor medical record since the process cannot currently be conducted in UNet<sup>sm</sup>.

For living donor blood type reporting, policy currently requires that the recovery hospital report and verify the living donor's blood type prior to recovery. Policy language was changed to require reporting prior to registration using the Living Donor Feedback form. The only new policy language is that two different qualified health care professionals, as defined in the living donor recovery hospital's protocol, make an independent report of the donor's blood type and subtype.

Both qualified health care professionals must use all blood type and subtype determination source documents to verify they:

1. Contain blood type and subtype results of the living donor.
2. The two test results indicate the same blood type and subtype.
3. Both test results match the blood type reported.

The living donor recovery hospital must document that this reporting process was completed according to their protocol. For VCA recoveries, this process of blood type and/or subtype reporting must be recorded in the living donor's medical record.

A system enhancement has been added for blood subtype verification. The system will require a second user verification when donor blood subtyping is entered. This is the same process as with primary blood type user verification. There was no change in the policy, just an enhancement added to the system.

Once independent blood type entries are made, UNetSM verifies that the blood type entries made by each independent user are the same.

Now that the system has verified the blood type entries, it will allow potential recipients to be matched with potential donors through a match run. System enhancements are being implemented to assist you identifying data critical on the match run for the safety of your patient.

Match list system enhancements include:

1. A warning message on the screen for incompatibles.
2. New column on the match list for each potential recipient's ABO to be clearly visible to the reader.
3. The donor ABO type is also more visible on the page.
4. And incompatible ABO matches will be highlighted.

These visual cues can help avoid potential miscommunication about ABO compatibility.

Now we move back to the manual human verification portion that completes the process. In this step, we are confirming that the donors and recipients are compatible, or intended incompatible, by blood type. There are two verifications in this step:

1. Pre-recovery verification which occurs in the living and deceased donor ORs.
2. Pre-transplant verification which happens at the transplant hospital.

## Preparing for ABO Determination, Reporting and Verification Policy Changes Webinar Script

Let's discuss the pre-recovery blood type verification first. OPTN policy requirements regarding deceased donor blood type verification are now more closely aligned with CMS requirements. Now policy requires that a pre-recovery verification take place. Host OPOs must have a written protocol for the pre-recovery verification process for each organ recovered from a deceased donor. The process must be conducted on-site by the recovering surgeon and a qualified health care professional, as defined in the OPO's protocol. Lastly, the OPO must document that the verifications were completed.

The three elements to be verified during the pre-recovery verification process by the recovery surgeon and a qualified healthcare professional are:

1. The donor's ID using the donor's identification band or OPTN computer system.
2. The organ to be recovered, and laterality if applicable, using the donor medical record or OPTN computer system.
3. The donor blood type and subtype, if applicable, using source documents.

Additionally, when the intended recipient is known prior to organ recovery two qualified health care professionals must verify:

1. The intended recipient by unique identifier.
2. The intended recipient's blood type.
3. That the donor and intended recipient are compatible or intended compatible by blood type.

The OPTN computer system can be used as a source for this portion of the verification.

Policy currently outlines requirements for living donor blood type verifications for all living donors. Recovery hospitals must have a written protocol to perform pre-recovery verifications. The recovery surgeon and another licensed health care professional must participate in the verification. What's new is the timing of the verification.

Pre-recovery verification must now occur prior to the induction of general anesthesia on the day of recovery. The need to verify has not changed. There must be verification of:

- The donor's ID using the donor's identification band.
- The organ to be recovered, and laterality (if applicable) using the OPTN computer system.
- The donor blood type and subtype using source lab documents.
- The intended recipient by unique identifier through the recipient medical record or OPTN computer system.
- The intended recipient's blood type using the recipient medical record or the OPTN computer system
- Donor and intended recipient compatibility or intended compatibility by blood type using the medical record or the OPTN computer system.
- And lastly, verify that the correct donor organ is identified for the correct intended recipient. Again using the donor medical record or the OPTN computer system.

You were all doing this already, it's now earlier in the process.

The living donor recovery hospital must document that the verification was completed to include how the elements were verified.

## Preparing for ABO Determination, Reporting and Verification Policy Changes Webinar Script

There are two pre-transplant blood type verifications required:

1. Blood type verification for when and only when surgery begins prior to organ arrival in the OR; and
2. Blood type verification when the organ arrives in the OR that occurs for all recipients.

If the recipient's surgery must begin before the organ arrives in the operating room, a pre-transplant verification must take place with two licensed health care professionals, not the surgeon, while the intended recipient is in the operating room. It must also occur before the induction of general anesthesia. This is for heightened awareness and to be able to potentially troubleshoot later. It also aligns with Joint Commission and will generally be seen in heart, liver, and lung transplant surgery. However, if the patient is receiving continuous sedation prior to arriving in the OR, this verification should be done prior to incision. This verification can be incorporated in the Joint Commission universal protocol which requires a time-out immediately before starting and invasive procedure or making the first skin incision. OPTN information to meet policy requirements can easily be added (i.e. expected donor ID, blood type and compatibility). Transplant hospitals must have a written protocol on how they will perform this verification process.

Pre-transplant verification in this instance must include:

1. Verification of the expected donor's ID using the OPTN computer system or the recipient medical record.
2. Verification of the expected organ and laterality using the OPTN computer system or the recipient medical record.
3. Verification of the expected donor blood type and subtype using source lab reports or the OPTN computer system.
4. Verify that the recipient is indeed the intended recipient using the recipient's ID band.
5. Verify the intended recipient's blood type using the recipient medical record or blood type and subtype source documents.
6. And lastly, verify that the donor and intended recipient are compatible, or intended compatible, by blood type using the recipient medical record or the OPTN computer system.

Before we move to the last step, let's discuss a new action within the policy that makes the system safer and helps to ensure that the right organ gets to the right recipient, organ check-in.

Transplant hospitals must develop and comply with a written protocol to perform organ check-ins any time an organ is recovered outside the facility where the transplant will take place. It must be completed upon organ arrival and prior to opening the organ's external transport container.

The transplant hospital uses the external organ label to confirm that the donor ID and organ type and laterality information provided is consistent with the offer accepted and documents that the check-in was completed. If identified that the organ arriving is not the one accepted, the hospital must notify the host OPO as soon as possible, but within one hour of the mix up. This will help to ensure that the right recipient gets the right organ without unnecessary accumulation of cold ischemia time.

## Preparing for ABO Determination, Reporting and Verification Policy Changes Webinar Script

What does organ check-in mean? It is not another ABO verification, but simply the same thing that the FedEx and Pizza man go through. They deliver their package and the receiver checks to make sure they received what they were expecting. For example: left kidney, UNOS ID ABCD123. Check.

Now, when the organ arrives in the operating room, the transplant hospital must conduct a final pre-transplant verification for all recipients 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.

Again, you are already doing this. Transplant hospitals must have a written protocol on how they will perform this verification process, and document the following elements:

- Verification of the donor's ID using documentation that is received with the organ.
- Verification of the organ and laterality using the organ received.
- Verification of the donor blood type and subtype using source donor blood type documentation.
- Verify that the recipient is indeed the intended recipient using the recipient's ID band.
- Verify the intended recipient's blood type using the recipient medical record or blood type and subtype source documents.
- Verify that the donor and intended recipient are compatible or intended compatible by blood type using the recipient medical record or UNet<sup>sm</sup>. An attestation following the verification is acceptable if the surgeon is already scrubbed in for the surgery.
- And lastly, verify that the correct donor organ has been identified for the correct recipient using the recipient's medical record or UNet<sup>sm</sup>.

Let's summarize what you need to do to comply with the policy changes for blood type determination, reporting, and verification.

1. OPOs, Recovery Hospitals, and Transplant Hospitals need to have protocols that include a process for resolving primary blood type conflicts and define qualified healthcare professionals that will conduct blood type reporting and verification.
2. OPOs will need to complete both blood type determination and reporting prior to the match run based on two separate samples. They will need to conduct a pre-recovery verification for all donors.
3. Living donor recovery hospitals will need to complete both blood type determination and reporting by activating the donor through completion of the Living Donor Feedback form and conducting pre-recovery verifications on all living donors prior to general anesthesia.
4. Transplant hospitals will need to conduct an organ check-in and an additional pre-recovery verification if and only if surgery starts prior to organ arrival.

The Committee's ABO Implementation Work Group developed two checklists, one for transplant hospitals, which includes considerations for living donor recovery hospitals, and one for OPOs, to prepare you for implementation. These are available in the ABO toolbox on the OPTN and TransplantPro websites as previously mentioned. These checklists identify points of consideration for your organizations and outline steps to be successful in preparing for policy implementation.

## Preparing for ABO Determination, Reporting and Verification Policy Changes Webinar Script

Transplant hospitals and OPOs:

1. Develop a protocol that includes a process for resolving primary blood type conflicts.
2. Define who in your organization will serve as the “qualified health care professional” for entering blood type data in UNet<sup>sm</sup>. Ensure that staff have necessary training and permissions in the system to perform these functions (online help documentation is available).
3. Review and update internal policies and processes related to blood type determination, reporting, and verification for compliance with OPTN policies.
4. If you use electronic medical records, consider modifying your EMR systems to collect necessary fields for documentation of compliance.
5. Utilize UNet<sup>sm</sup> system training to develop and assess staff competency in using the system for blood type reporting and verification. This training will be available in spring 2016.

For Transplant Hospitals only:

1. Develop organ check-in procedure that include who will perform the organ check-in and what internal record will you use to document that the check-in was performed.
2. Determine how source documents will be made available for pre-organ arrival blood type verification in the recipient. Incorporate this information in policy for your organization.
3. Review and update pre-recovery blood type verification procedures for when surgery must start prior to organ arrival.
4. Develop a pre-recovery blood type verification process for living donors prior to initiation of general anesthesia.

For those interested in receiving credit, ABTC will award 1 CEPTC credit for this webinar. You must complete the assessment to receive the credit. Once you take and pass the assessment, you will receive a credit certificate within approximately one month. Access the evaluation and assessment here - [https://www.surveymonkey.com/r/Improvements\\_ABO](https://www.surveymonkey.com/r/Improvements_ABO).

The assessment will be open until June 8, 2016. If you do not wish to receive CEPTC credit you will not be required to take the assessment.

[UNOS Regional Administrators](#) are your first contact for direct questions about OPTN policies. Contact the Administrator for your region with questions.

For questions about educational or training events, contact UNOS Instructional Innovations at [education@unos.org](mailto:education@unos.org).