



At a glance

Title: Modify Blood Type Determination and Reporting Policies

Sponsoring Committee: Operations and Safety

What is current policy and why change it?

Currently, host Organ Procurement Organizations (OPOs) must ensure two donor blood type samples are used to determine blood type. They also must develop and comply with written procedures to resolve any conflicts with results and to verify key information prior to organ recovery.

Recent reports of events affecting patient safety led to the decision to re-evaluate the requirements for blood type determination.

What's the proposal?

- Require host OPOs, transplant programs, and recovery hospitals (for living donors) to include a process in their written **protocols** for addressing **indeterminate blood typing results**.
 - Require host OPOs to **document all blood products** the donor received since admission to the donor hospital.
 - **Align** deceased donor, candidate, and living donor **policies**.
-

What's the anticipated impact of this change?

- **What it's expected to do**
 - Trigger updates of written protocols to include plan for "indeterminate" results
 - Provide more thorough policy guidance to ensure patient safety
 - Changes to the candidate and living donor policies to provide consistency in policy language
- **What it won't do**
 - This proposal will not specify a comprehensive list of information that should be included in protocols and procedures for OPOs or transplant programs.

Themes to consider

- Living Donor Safety
- Recipient Safety
- Blood Type Verification

Terms you need to know

- **ABO Blood Type**: The classification of human blood into four groups: A, B, AB, and O.
- **Blood Products**: Any therapeutic substance prepared from human blood. This includes: whole blood, blood components, and plasma.
- **Conflicting**: Two blood tests from the same donor or candidate that show different blood types.
- **Indeterminate**: A blood test that does not provide a clear result.
- **Organ Procurement Organization**: An organization designated by the Centers for Medicare and Medicaid Services (CMS) and responsible for the procurement of organs for transplantation and the promotion of organ donation.
- **Protocol**: A predefined written procedural method.
- **Transplant Center**: A hospital that performs transplants, including qualifying patients for transplant, registering patients on the national waiting list, performing transplant surgery and providing care before and after transplant.
- [Click here to search the OPTN glossary](#)

Public Comment Proposal

Modify Blood Type Determination and Reporting Policies

OPTN Operations and Safety Committee

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Modify Blood Type Determination and Reporting Policies

<i>Affected Policies:</i>	<p>2.6.A: Deceased Donor Blood Type Determination</p> <p>2.6.B: Deceased Donor Blood Subtype Determination</p> <p>2.6.C: Reporting of Deceased Donor Blood Type</p> <p>3.3.A: Candidate Blood Type Determination</p> <p>3.3.B: Reporting of Candidate Blood Type</p> <p>14.5.A: Living Donor Blood Type Determination</p> <p>14.5.B: Living Donor Blood Subtype Determination</p> <p>14.5.C: Reporting of Living Donor Blood Type and Subtype</p>
<i>Sponsoring Committee:</i>	Operations and Safety
<i>Public Comment Period:</i>	January 22, 2020 – March 24, 2020

Executive Summary

The OPTN Operations and Safety Committee is charged with ensuring the safety of the organ donation and transplantation process. The Committee periodically reviews transplant and donation-related adverse events and near misses reported to the OPTN by the transplant community. The Committee uses the information to identify potential improvements and policy revisions that may prevent future such occurrences.

Recent reports of events affecting patient safety led to the decision to re-evaluate the requirements for blood type determination. The Committee agreed to re-evaluate the ABO policies and determine the best strategy to address recent concerns. The Committee agreed to develop both a guidance document and policy proposal. This proposal addresses the policy language aspect of this effort while a separate guidance document is proposed. The Committee initially focused on deceased donor policies; however, during the review of OPTN policies it was determined that changes should also be proposed for the candidate and living donor policies. These additional changes will provide consistency.

This proposal seeks to:

1. Require host OPOs, transplant hospitals, and recovery hospitals (for living donors) to include a process in their written protocols for addressing indeterminate blood typing results. Current policy only references conflicting results
2. Require host OPOs to document all blood products the deceased donor received since admission to the donor hospital
3. Align deceased donor policies with candidate and living donor policies.

Purpose of the Proposal

Blood type is one of many factors used to match organ donors and recipients. Accurate determination, reporting, and verification of blood type is necessary to ensure that the correct organ is transplanted into the correct recipient and that the match is blood type compatible or intended planned incompatible. Failure to accurately determine blood type can result in significant adverse events, including graft failure or patient death. The purpose of this proposal is to increase patient safety by creating additional requirements that promote awareness about situations that could potentially affect the reliability of blood typing results.

Background

In 2014, the Operations and Safety Committee performed a Failure Modes and Effects Analysis (FMEA)¹, where all stages of ABO testing were extensively reviewed. Based on this analysis, there were ABO policy changes that were implemented² on February 1, 2016. At the time, when there was no pre-transfusion specimen available for testing, the Committee's response was to create a policy requirement for Organ Procurement Organizations (OPOs) to have their own protocol. Recent reports of events affecting patient safety led to the decision to re-evaluate the requirements for verifying deceased donor blood type.

One of the events that led to the development of this proposal was a case where massive transfusions in a donor affected the deceased donor blood typing results. The Committee agreed to take a holistic approach to address all factors that might influence blood typing results and not simply focus on massive transfusions. The Committee also believed that developing a comprehensive guidance document would be an appropriate first step instead of proposing significant policy changes. The intent of the policy changes outlined in this proposal is to establish additional requirements that create additional awareness that conflicting and indeterminate results need to be addressed prior to allocation to avoid adverse events related to incompatible donor and recipient matching.

The Committee formed a joint workgroup with representation from the following OPTN Committees: Operations and Safety, Membership and Professional Standards, Organ Procurement Organization, and Histocompatibility. The workgroup also included blood bank experts. The workgroup met monthly and concurrently worked on policy language and the guidance document.

Proposal

The Committee is proposing the following policy language modifications for blood type determination and reporting:

Indeterminate Blood Typing Results – Current OPTN policies include requirements for OPOs, transplant programs, and donor hospitals to develop and comply with written protocols for blood type determination and reporting. One of the requirements for the written protocols is to include a process for addressing conflicting primary and subtype results. The Committee is proposing the addition of

¹ November 12, 2014, OPTN Operations and Safety Committee Report to the Board of Directors. Available at <https://optn.transplant.hrsa.gov>

² Proposal to Modify ABO Determination, Reporting, and Verification Requirements. Available at <https://optn.transplant.hrsa.gov>

“indeterminate” to the policy language since this type of result should also trigger the use of written protocols.

Documentation of Blood Products – The use of blood products can potentially affect blood typing results. The Committee is proposing that host OPOs be required to document all blood products that the donor received since admission to the donor hospital. The rationale for this change is that when OPOs document all blood products received by the donor since admission to the donor hospital, it creates an awareness that blood typing results could be affected, especially if the potential donor received a significant amount of blood products.

Requirements for Blood Samples – OPTN Policies 2.6.A (Deceased Donor Blood Type Determination), 3.3.A (Candidate Blood Type Determination), and 14.5.A (Living Donor Blood Type Determination) address the requirements for deceased donor and candidate blood samples, which include two separate blood draws collected at different times and submitted as separate samples. An additional requirement is that the results must indicate the same blood type. The Committee determined that these policy sections address the process for blood type determination and do not focus on the actual reporting of the results. The reporting of blood typing results is addressed in Policies 2.6.C (Reporting of Deceased Donor Blood Type and Subtype), 3.3.B (Reporting of Candidate Blood Type), and 14.5.C (Reporting of Living Donor Blood Type and Subtype). The Committee determined that the language requiring blood samples to “have results indicating the same blood type” would make it impossible for members to comply with the policies if there are conflicting or indeterminate results. Therefore, the Committee is proposing the removal of the language in all three sections of the policies.

Source Documentation and Test Results – The policies addressing the verification and reporting of blood typing results state that two qualified health care professionals must use blood type and subtype source documentation to verify the blood type results. The Committee is recommending additional policy language to specify that “all known” blood type source documents be used to verify blood typing results. This provides an additional awareness of potential issues if there are inconsistencies noted in the source documents.

Candidate and Living Donor Requirements – The Committee initially focused on deceased donor policies; however, during the review of OPTN policies it was determined that changes should also be proposed for the candidate and living donor policies. These additional changes will provide consistency in OPTN policy. The policy changes addressed in this proposal address candidate and living donor blood type determination where applicable.

Implementation and Operational Considerations

OPTN Actions

This proposal will not require programming. Communication and educational efforts will be determined following public comment.

Member Actions

OPOs

OPOs will need to update their written protocols to address both indeterminate and conflicting blood typing results. OPOs will need to document that blood type determination was conducted according to

the written protocols. Finally, OPOs will need to document all blood products received by the donor since admission to the donor hospital.

OPOs will need to train their staffs on how to address both indeterminate and conflicting results as outlined in their written protocols.

Transplant Programs

Transplant programs will need to update their written protocols to address both indeterminate and conflicting blood typing results for candidates and living donors.

Transplant programs will need to train their staffs on how to address both indeterminate and conflicting results as outlined in their written protocols.

Post-implementation Monitoring

Member Compliance

Members will be expected to comply with the requirements in the proposed language. Site surveyors will continue to verify that OPOs, recovery hospitals, and transplant hospitals have written protocols for blood type determination of deceased donors, living donors, and candidates, respectively, and they will verify that the protocols include a process for resolving both conflicting and indeterminate primary blood types. Site surveyors will also continue to verify that OPOs and recovery hospitals have written protocols for blood subtype determination of deceased and living donors, respectively, and they will verify the protocols include only reporting primary blood type to the OPTN Contractor when the subtyping results conflict or are indeterminate.

Policy Evaluation

This policy will be formally evaluated approximately 6 months, 1 year, and 2 years post-implementation. The following metrics, and any subsequently requested by the Committee, will be evaluated as data become available. Appropriate lags will be applied, per typical OPTN conventions, to account for time delay in institutions reporting data to UNetsm (e.g., TIEDI forms may take 60+ days to be submitted). Metrics will be compared to an appropriate pre-policy cohort to assess performance before and after implementation of this policy:

- For all deceased donors, has the proportion with AB blood type increased?
- For deceased donors with over 10 transfusions during their terminal hospitalization, has the proportion of with AB blood type increased?
- How do the blood type distributions compare for deceased donors with no transfusions during their terminal hospitalization versus those with over 10 transfusions?
- Are there any reported patient safety events that are relevant to the policy?

Compliance with the Final Rule and OPTN Strategic Plan

This proposal addresses the following section of the OPTN Final Rule by ensuring accurate blood type determinations:

§121.6 Organ procurement.

The suitability of organs donated for transplantation shall be determined as follows:

- (a) Tests. An OPTN member procuring an organ shall assure that laboratory tests and clinical examinations of potential organ donors are performed to determine any contraindications for donor acceptance, in accordance with policies established by the OPTN.

This proposal also aligns with the OPTN Strategic Plan by “promoting living donor and transplant recipient safety.” The purpose of this proposal is to ensure accurate blood type determination by clarifying both conflicting and indeterminate blood typing results need to be addressed prior to organ allocation.

Potential Fiscal Impact of Proposal

The time and cost to implement these changes at transplant centers and OPOs are minimal.

Staff training on changes and center specific procedure or protocol will be necessary. This proposal does not change the process for confirming ABO blood type in donors and candidates in the event of discrepant or indeterminate results. If additional testing is required, these additional tests could cost between \$200-400 per test, which could be included in reimbursable payer items as part of transplant care. While overall current volume or center effort level to resolve discrepancies is unclear, the cost will be minimal if occurrence of discrepancy is infrequent.

OPOs implementation cost may include minor programming changes to allow for records of additional donor testing. Transportation of additional testing specimens to labs may also be necessary.

Any cost to transplant programs or OPOs would be worthwhile in order to prevent failed transplants and recipient harm.

Minimal impact to histocompatibility laboratories for additional infrequent testing.

Conclusion

Accurate determination, reporting, and verification of blood type is necessary to ensure that the correct organ is transplanted into the correct recipient. Patient safety should be considered during all aspects of the organ donation and transplant process. Failure to accurately identify donor blood type can lead to adverse events, such as graft failure or patient death. This proposal is part of an effort by the Operations and Safety Committee to create awareness of the importance of addressing all issues that might affect the accuracy of blood type determination. These policy changes, as well as the guidance document, will further educate the community and provide awareness of the importance of accurate blood type determination.

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

2.6 Deceased Donor Blood Type Determination and Reporting

Host OPOs must 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 determined by testing at least two donor blood samples prior to the match run. ~~The host OPO must include a process to address conflicting primary blood type results in their written protocol.~~

The ~~D~~ 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 include a process to address conflicting or indeterminate primary blood type results in their written protocol.

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

The host OPO must document:

1. That blood type determination was conducted according to the OPO’s written protocol and
2. A complete history of all blood products the deceased donor received since admission to the donor hospital in the deceased donor medical record.

2.6.B Deceased Donor Blood Subtype Determination

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

If the donor’s primary blood type is:	Then subtyping is	A second subtyping must be completed if the first subtype result is:
A	Required	Blood type A, non-A ₁
AB	Optional	Blood type AB, non-A ₁ B

35 Deceased donor blood samples for subtyping must:

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

40

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

45 For all blood type A donors, the host OPO must document *either* that subtyping was
 46 completed or the reason it could not be completed.

47 **2.6.C Reporting of Deceased Donor Blood Type and Subtype**

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

- 50 1. Two different qualified health care professionals, as defined in the host OPO's
 51 protocol, must each make an independent report of the donor's blood type to the
 52 OPTN Contractor.
- 53 2. If the donor's blood subtype will be used for allocation, a qualified health care
 54 professional must report the subtype to the OPTN Contractor. This report must be
 55 verified by a different qualified health care professional according to the OPO's
 56 protocol.
- 57 3. Both qualified health care professionals must use all known available blood type and
 58 subtype determination source documents to verify they:
- 59 a. Contain blood type and subtype (if used for allocation) results for the donor
 60 b. Indicate the same blood type and subtype (if used for allocation) on the ~~two~~ test
 61 results. If the results are conflicting or indeterminate, the host OPO must refer to
 62 their written protocol as outlined in *Policy 2.6.A: Deceased Donor Blood Type*
 63 *Determination*.
- 64 c. Match the result reported to the OPTN Contractor

65

66 The OPO must document that reporting was completed according to the OPO's protocol
 67 and the above requirements.

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

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

78 **3.3 Candidate Blood Type Determination and Reporting**
 79 **before Waiting List Registration**

80 Transplant programs must develop and comply with a written protocol for blood type
 81 determination and reporting that includes *all* of the requirements below.

82

83 **3.3.A Candidate Blood Type Determination**

84 The transplant program must ensure that each candidate's blood type is determined
 85 by testing at least two candidate blood samples prior to registration on the waiting
 86 list. ~~The transplant program must develop and comply with a written protocol to~~
 87 ~~resolve conflicting primary blood type results.~~

88

89 Candidate blood samples must:

90

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

95

96 The transplant program must include a process to address conflicting or
 97 indeterminate primary blood type results in their written protocol.

98

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

101

102 **3.3.B Reporting of Candidate Blood Type**

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

- 105 1. Two different qualified health care professionals, as defined in the transplant
 106 program's protocol, must each make an independent report of the candidate's
 107 blood type to the OPTN Contractor
- 108 2. Both qualified health care professionals must use all known available blood
 109 type determination source documents to verify they:
 - 110 a. Contain blood type results for the candidate
 - 111 b. Indicate the same blood type on the ~~two~~ test results. If the results are conflicting or
 112 indeterminate, the transplant program must refer to their written protocol as
 113 outlined in *Policy 3.3.A: Candidate Blood Type Determination*.
 - 114 c. Match the result reported to the OPTN Contractor

115

116 The transplant program must document that reporting was completed
 117 according to the program's protocol and the above requirements.

118

119

120 **14.5 Living Donor Blood Type Determination and Reporting**

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

123
 124 **14.5.A Living Donor Blood Type Determination**

125 The recovery hospital must ensure that each living donor’s blood type is determined
 126 by testing at least two donor blood samples prior to generation of the living donor ID.
 127 ~~The recovery hospital must develop and comply with a written protocol to resolve~~
 128 ~~conflicting primary blood type results.~~

129
 130 Living donor blood samples must:

- 131
 132 1. Be drawn on two separate occasions
 133 2. Have different collection times
 134 3. Be submitted as separate samples
 135 ~~4. Have results indicating the same blood type~~

136
 137 The recovery hospital must include a process to address conflicting or indeterminate primary
 138 blood type results in their written protocol.

139
 140 The recovery hospital must document that blood type determination was conducted
 141 according to the hospital’s protocol and the above requirements.

142
 143 **14.5.B Living Donor Blood Subtype Determination**

144 Subtyping is optional for living donors.

145
 146 If the recovery hospital chooses to subtype *and* pre-red blood cell transfusion
 147 samples are available, then subtyping must be completed according to *Table 14-*
 148 *9*.

149
 150 **Table 14-9: Subtyping Requirements by First Subtype Result**

If the donor’s primary blood type is:	A second subtyping must be completed if the first subtype result is:
A	Blood type A, non-A ₁
AB	Blood type AB, non-A ₁ B

151
 152 Living donor blood samples for subtyping must:

- 153
 154 1. Be tested using pre-red blood cell transfusion samples
 155 2. Be drawn on two separate occasions
 156 3. Have different collection times
 157 4. Be submitted as separate samples
 158

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

163 If subtype is determined and reported, the recovery hospital must document that
164 subtyping was conducted according to the above requirements.
165

166 **14.5.C Reporting of Living Donor Blood Type and Subtype**

167 The recovery hospital must report and verify the living donor blood type prior to
168 registration with the OPTN Contractor using the *Living Donor Feedback Form* as
169 required below:
170

- 171 1. Two different qualified health care professionals, as defined in the recovery
172 hospital's protocol, must each make an independent report to the OPTN
173 Contractor for blood type. For VCA recoveries, the blood type verification and
174 reporting must be recorded in the living donor's medical record.
- 175 2. If blood subtype is used for ensuring transplant compatibility or allocation, a
176 qualified health care professional must report blood subtype to the OPTN
177 Contractor. This report must be verified by a different qualified health care
178 professional according to the recovery hospital's protocol. For VCA recoveries, the
179 blood subtype verification and reporting must be recorded in the living donor's
180 medical record.
- 181 3. Both qualified health care professionals must use all known available blood type
182 and subtype determination source documents to verify they:
 - 183 a. Contain blood type and subtype (if used for ensuring transplant
184 compatibility or allocation) results for the donor
 - 185 b. Indicate the same blood type and subtype (if used for ensuring transplant
186 compatibility or allocation) on the ~~two~~ test results. If the results are
187 conflicting or indeterminate, the recovery hospital must refer to their written
188 protocol as outlined in *Policy 14.5.A: Living Donor Blood Type Determination*.
 - 189 c. Match the result reported to the OPTN Contractor or VCA donor medical record

190
191 The recovery hospital must document that reporting was completed according to the
192 hospital's protocol and the above requirements.
193

194 #