

At-a-Glance

Proposed ABO Subtyping Consistency Policy Modifications

- **Affected/Proposed Policies:** Policy 2.6. B (Deceased Donor Blood Subtype Determination), Policy 5.3. C (Liver Acceptance Criteria), Policy 8.5. E (Allocation of Kidneys by Blood Type) (Not yet implemented), Policy 9.5.B (Points Assigned by Blood Type), Policy 13.7.A (Blood Type), Policy 13.7.B (A₂ and-A₂B Matching), Policy 14.4.A.i (Living Donor Blood Subtype Determination)

- **Operations and Safety Committee**

This proposal seeks to make all ABO subtype references consistent throughout OPTN policies. Current references use different terms, such as A₂ and non-A₁, which are intended to mean the same thing but may be confusing. The more technically accurate description uses the “non” preface as routine testing only detects the presence or absence of A₁ and other rare subtypes other than A₂ do exist. In 2011, the OPTN published guidance on this issue. The proposed changes will align references with this guidance using the terms blood type A, non-A₁ and blood type AB, non-A₁B.

- **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

- **Number of Potential Candidates Affected**

This proposed policy change will not directly impact any potential candidates

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

By standardizing policy language, this proposal supports the following strategic plan goal to promote the efficient management of the OPTN

- **Specific Requests for Comment**

None

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Operations and Safety Committee

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

Summary and Goals of the Proposal

This proposal seeks to make all ABO subtype references consistent throughout OPTN policies. Current references use different terms, such as A₂ and non-A₁, which are intended to mean the same thing but may be confusing. The more technically accurate description uses the “non” preface as routine testing only detects the presence or absence of A₁ and other rare subtypes other than A₂ do exist. In 2011, the OPTN published guidance on this issue. The proposed changes will align references with this guidance using the terms blood type A, non-A₁ and blood type AB, non-A₁B.

Background and Significance of the Proposal

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

This proposal will not change any allocation policy. It only makes all references to subtypes consistent to reduce any potential confusion. OPTN guidance published in June 2011 states, “It is important to know that the technically accurate term for A₂ and A₂B donors is “A₁-negative” or “A, non-A₁” because A₂ is not directly tested for and many other rare subtypes exist (e.g. A₃, A_{int}, etc.). Blood group “A, non-A₁” organs are transplanted in many centers into blood group O or B candidates, and blood group “AB, non-A₁B” organs into blood group B candidates.” Because routine subtyping does not detect results other than the presence or absence of A₁ or A₁B antigens, all references will be modified to reflect technically accurate terminology.

The alternative considered would be to use the terms A₂ and A₂B throughout policy and to add definitions that these terms include any non-A₁ or non-A₁B result. Current labels within the OPTN computer systems do use these shorthand terms and help text is being developed to clarify the definition. The Committee did not choose this alternative based on previous subcommittee work and deliberations. Experts with experience in blood subtyping helped develop and review the OPTN guidance. The proposal is consistent with that guidance.

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

Supporting Evidence/Modeling

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

Due to these issues regarding interpretation, business requirements were approved to add online help documentation in Waitlist, TIEDI, KPD and DonorNet. Help documentation will explain that “ A_2 ” is used throughout UNetSM as shorthand for any subtype of blood group A that is not A_1 . Similarly, “ A_2B ” is shorthand for any subtype of blood group AB that is not A_1B . Wherever A_2 or A_2B labels exist, hover text will appear clarifying that this represents any non- A_1 or non- A_1B result as appropriate. These changes are awaiting programming and implementation.

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

Expected Impact on Living Donors or Living Donation

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

Expected Impact on Specific Patient Populations

Specific patient populations will not be impacted.

Expected Impact on OPTN, Strategic Plan, and Adherence to OPTN Final Rule

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

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

Plan for Evaluating the Proposal

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

Expected Implementation Plan

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

Members will need to understand the meaning of the terms: blood type A, non- A_1 and blood type AB, non- A_1B , which have sometimes been referred to as A_2 and A_2B .

Communication and Education Plan

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

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

Notification of this change will be sent to members through the policy notice in December 2014, 30 days after approval by the board. A link to the policy notice will be included in the December Transplant Pro e-newsletter.

Compliance Monitoring

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

Policy or Bylaw Proposal

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

Note: Policy 8.5.E is approved by the Board but pending implementation. It is scheduled for implementation before this policy proposal would be implemented.

2.6.B Deceased Donor Blood Subtype Determination

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

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

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

5.3.C Liver Acceptance Criteria

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

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

1. The maximum number of mismatched antigens it will accept for any of its liver candidates
2. Minimal acceptance criteria for livers
3. If a blood type O candidate will accept a liver from a deceased donor with blood type A, non-

- A₁ blood type
4. For status 1A or 1B candidates, if they will accept a liver from a deceased donor with any blood type
 5. If a candidate with a Model for End-Stage Liver Disease (MELD) or Pediatric End Stage Liver Disease (PELD) score of at least 30 will accept a liver from a deceased donor with any blood type
 6. If a candidate will accept a liver for other methods of hepatic support
 7. If a candidate is willing to accept a segmental graft

8.5. E Allocation of Kidneys by Blood Type

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

Table 8-4: Allocation of Kidneys by Blood Type

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

9.5.B Points Assigned by Blood Type

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

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

13.7.A Blood Type

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

Table 13-1: Allocation by Blood Type

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

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

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

1. The candidate must have an IgG antibody titer value less than 1:8
2. The candidate's transplant hospital must report to the OPTN Contractor the candidate's titer value and date of the test.

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)~~ blood type A, non-A₁ or ~~non-A₁B (negative for A₁B)~~ blood type AB, non-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.