

**OPTN/UNOS Operations and Safety Committee  
Report to the Board of Directors  
June 1-2, 2015  
Atlanta, Georgia**

**Theresa Daly, MS, FNP, Chair  
David Marshman, Vice Chair**

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*This report reflects the work of the OPTN/UNOS Operations and Safety Committee from December 2014 through April 2015.*

**Action Items**

1. Proposal to Allow Collective Patient and Wait Time Transfers

*Public Comment:* [September 29-December 5, 2014](#)

The Operations and Safety Committee (OSC) developed this proposal in response to a request from the OPTN/UNOS Board of Directors to allow groups of patients and their wait times to be transferred when a transplant program enters long-term inactivity, closes, or is terminated. The current process is a manual one that requires each patient to be manually transferred. The proposal will authorize collective transfers to be done electronically after fulfilling the requirements developed. This will reduce potential errors associated with manual data transfer and more efficiently restore opportunities for transplant. This proposal was well received and supported during public comment.

The OSC made its final review of comments and proposed bylaws and policy language at their April 14, 2015 in-person meeting. Post public comment changes included allowing the agreement to specify that the closing program will inactivate patients if requested by the accepting program; allow the process to be used in other situations upon request; amend requirements for notification to include that an accepting program will conduct an evaluation and may have different selection criteria than the current program; authorize additional status update reports as needed; and require patient notification by the accepting program to inform patients what must be done to become an active patient at the new program. These changes were made in response to comments and requests during public comment.

The Operations and Safety Committee unanimously voted (18 in-favor) to adopt the proposal with the post public comment changes and send it to the OPTN/UNOS Board of Directors for consideration.

**RESOLVED, that Policies 3.6.C (Waiting Time Transfers) and 3.8 (New: Collective patient Transfers) and Bylaws K.3.B (Notice to the Patients of Long-term Inactive Status), K.4.B (Notice to the Patients), and K.6 (Transferred Candidates Waiting Time) are modified as set forth in Exhibit A, and are hereby approved, effective September 1, 2015.**

2. Proposal to Modify the Sterile Internal Vessels Label

*Public Comment:* [January 27 -March 27, 2015](#)

The Operations and Safety Committee developed this proposal in response to a recommendation from the Ad Hoc Organ Tracking Committee. Observations made during the discovery phase of the Electronic Tracking and Transport Project (TransNet<sup>sm</sup>) found numerous errors in completion of this label, which contains over 15 data fields that must be completed on a 2" by 4" label in a sterile field. The Committee developed a label in

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coordination with the OPO Committee that preserves the most critical fields (Donor ID, ABO, recovery date, PHS Increased Risk status, and whether the vessels are from a donor with positive results for HIV, HBV, or HCV). This label is not intended to be used for source documentation and the hang-tag poly plastic label which should always be on the outermost triple sterile barrier has not been changed. The data fields on this label should only be used in emergency situations if the hang-tag label is lost and not replaced.

This proposal was well received and supported during public comment. The Committee requested specific public comment feedback on how to display HBV results. HBV is different in that some results do not mean infection but can indicate immunity. Policy does not prohibit storage of vessels positive for HBcAb. Policy does prohibit storage of HbsAg or NAT positive vessels. Storage of HCV or HIV positive (any test result) vessels is prohibited. In order to not have vessels unnecessarily destroyed this label was modified post-public comment to separate out HBcAb results. This was done in response to multiple public comments, although the OPO Committee preferred no delineation of the specific HBV results.

The Operations and Safety Committee unanimously voted (18 in-favor) to adopt the proposal with the post public comment changes and send it to the OPTN/UNOS Board of Directors for consideration.

**RESOLVED, that Policy 16.4.D (Internal Labeling of Vessels) is modified as set forth in Exhibit B, and is hereby approved, effective September 1, 2015.**

### 3. Proposal to Modify ABO Determination, Reporting, and Verification Requirements

*Public Comment:* [March 14 – June 13, 2014](#)

*Public Comment:* [January 27 -March 27, 2015](#)

The Operations and Safety Committee developed this proposal to addresses three major goals:

1. Clarify requirements for ABO blood type determination, reporting, and verification and better assist members in complying with the requirements
2. Align OPTN/UNOS and Centers for Medicaid and Medicare Services (CMS) requirements
3. Strengthen current key safety components to ensure correct organ/correct recipient and blood type compatibility or planned incompatibility

This proposal was first released in spring 2014 and has been modified to address concerns raised by the transplant community and Board of Directors.

Using data analysis, transplant community input, and recommendations from a Failures Modes and Effects Analysis (FMEA) done in response to the 2012 OPTN Strategic Plan, the Committee identified areas of need and proposed solutions appropriate to each.

Goal 1: Clarify requirements for ABO blood type determination, reporting, and verification and better assist members in complying with the requirements.

There are over a dozen current policies in place containing requirements for blood type determination, reporting, and verification for donors and candidates. This proposal will make each type of policy (e.g. determination) have the same structure and terminology for all types of donors and candidates wherever possible. Core principles (e.g. two blood typings prior to being active in OPTN system) will be applied uniformly and requirements made consistent wherever possible.

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To help members comply with requirements, the Committee has proposed several items including UNet<sup>sm</sup> programming. This programming is to support existing, not new, policy.

1. Adding a warning when registering liver candidates willing to accept ABOi organs
2. Adding recipient blood type and donor/recipient compatibility symbol to match run results
3. Adding second user verification for subtyping so that data entry supports current policy

The Committee will 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 a proficiency module that can be used for training and assistance with compliance. Existing templates and crosswalks will be updated in collaboration with CMS. The Committee will continue collaborative efforts in developing TransNet<sup>sm</sup> to help members comply with policy.

### Goal 2: Align OPTN/UNOS and Centers for Medicaid and Medicare Services (CMS) requirements

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. CMS representatives participated in the workgroup to clarify transplant community questions regarding their rules. This proposal will further align the two sets of rules to enable policy consistency, easier understanding, and better compliance.

OPTN policy does use blood type in increasing access and ensuring fair access to transplantation through allocation policy. While this proposal better aligns the two organizations, there will always be differences as allocation policy is out of scope for CMS. This proposal does not touch allocation but it does address areas such as subtyping which is used in allocation.

OPTN policy will be more consistent with CMS, yet safer. The decision to propose safer requirements (e.g. timing of verification) is based on findings from the FMEA. The FMEA is a proactive risk assessment. Proposed policy will help reduce prioritized areas of risk. Current OPTN policy does have areas that do place members out of compliance with CMS. Substantive proposed policy changes are outlined below. Complying with proposed OPTN policy will not place members out of alignment with CMS. **Table 2** below provides a summary.

**Table 2: Summary of Substantive Proposed Policy Changes**

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

Goal 3: Strengthen current key safety components to ensure correct organ/correct recipient and blood type compatibility or planned incompatibility

A Failure Modes and Effects Analysis (FMEA) was conducted with assistance from two experts with experience in quality management and human factors engineering. OSC chose to use the FMEA because the tool was named as a key strategy in the 2012 OPTN Strategic Plan. This exercise is a proactive, not reactive, process to identify risks and make recommendations to mitigate these risks.

The Committee identified 62 failure modes that can occur during determination, reporting, or verification steps. The OSC prioritized these failure modes and developed recommendations to address the top 10 most concerning failure modes. Failures often follow the “swiss cheese” model where it takes several errors (holes) lining up to result in a sentinel event. FMEA rankings and recommendations are based on existing data and transplant community real-life experiences.

Action items were included in the proposal to meet Goals 1 and 2 and they support reducing risks for top failure modes identified in the FMEA. These include:

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1. Programming enhancements as outlined in Goal 1
2. Timing changes, current practice expansion, and new requirements as outlined in Goal 2. FMEA findings guided the Committee's selection of certain requirements that align but are safer than those in CMS rules
3. Requiring the match to be re-run in certain situations to ensure candidates appear on a match run
4. Use of qualified health care professionals, as defined by OPOs and transplant hospitals, to conduct key steps
5. Working with TransNet<sup>sm</sup> to program verifications and organ check-in

The current system will not fundamentally change. This proposal is needed though to address the three areas as identified by the transplant community and Board of Directors. Since 2012, an ABO verification work group with representatives from several Committees, including Transplant Coordinators and Transplant Administrators, has met to define problems and propose solutions.

The proposal was originally developed and released during the Spring 2014 public comment cycle. The proposal generated significant debate and was ultimately tabled at the November 2014 OPTN/UNOS Board of Directors (BOD) meeting. The Committee reworked the proposal based on public comment and BOD feedback. Notably, the requirement to have the recovering surgeon participate in the verification at deceased donor organ recovery was dropped.

The reworked proposal was released again during the Spring 2015 public comment cycle. It continued to generate debate. Seven regions approved the proposal. There were eleven comments which favored or contained some favorable comments on the proposal. Commenters though did have varying opinions on requirements for deceased donor organ recovery, living donor organ recovery, organ check-in, and pre-transplant verification if surgery starts before the organ arrives. The Committee has conducted outreach and considered all comments. The Committee developed several post public comment changes including dropping the requirement that the living donor verification take place in the OR. This change along with the rationale for conducting the verification prior to anesthesia was shared with CMS. CMS has some concerns where programs may be conducting the verification too far away from the OR and risking that there could be an error prior to arrival in the OR. The OSC and CMS representatives are working to align this requirement as much as possible as CMS is revising its Interpretive Guidelines.

The other post public comment changes simplified language and aligned organ check in requirements with other relevant OPTN policy.

The OSC made its final review of comments and proposed policy language at their April 14, 2015 in-person meeting. The Operations and Safety Committee unanimously voted (18 in-favor) to adopt the proposal with the post public comment changes and send it to the OPTN/UNOS Board of Directors for consideration.

**RESOLVED, that Policies 1.2 (Definitions), 2.6 (Deceased Donor Blood Type Determination and Reporting), 2.6.A (Deceased Donor Blood Type Determination), 2.6.B (Deceased Donor Blood Subtype Determination), 2.6.C (Primary Reporting of Deceased Donor Blood Type and Subtype), 2.6.D. (Secondary Reporting of Deceased Donor Blood Type and Subtype), 2.15.B (New: Pre-Recovery Verification), 3.3 (Candidate Blood Type Determination and Reporting before Waiting List Registration), 3.3.A (Blood Type Determination before Registration on the Waiting List), 3.3.B (Secondary Reporting of Candidate Blood Type), 5.4.B (Order of Allocation), 5.5.A Receiving and Reviewing Organ Offers), 5.6 (Blood**

**Type Verification Upon Receipt), 5.7 (New: Pre-Transplant Verification), 5.7.A (New: Pre-Transplant Verification Prior to Organ Receipt), 5.7.B (New: Pre-Transplant Verification Upon Organ Receipt), 13.6.A (Requirements for Match Run Eligibility for Candidates), 13.6.B (Requirements for Match Run Eligibility for Potential KPD Donors), 14.4 (Medical Evaluation Requirements for Living Donors), 14.4.A (Living Donor Blood Type Determination), 14.4.Ai (Living Donor Blood Subtype Determination), 14.4.B (Living Donor Medical Evaluation Requirements) 14.5 (Registration and Blood Type Verification of Living Donors before Donation), 14.5.A (New: Living Donor Blood Type Determination), 14.5.B (New: Living Donor Blood Subtype Determination) 14.5.C (New: Reporting of Living Donor Blood Type and Subtype), 14.7 (New: Living Donor Pre-Recovery Verification), 14.9 (New: Living Donor Organ Check-In), 14.10 (New: Living Donor Pre-Transplant Verification), 16.1 (Organs Not Requiring Transport), and 16.4.C (Internal Labeling of Blood and Tissue Typing Materials) are modified as set forth in Exhibit C, and are hereby approved, effective February 1, 2016.**

**FURTHER RESOLVED, that programming modifications to ABO incompatible liver registrations, match run displays for candidate blood type including compatibility status, and second user subtype verification as set forth in Exhibit D are hereby approved, effective pending programming and notice to the OPTN membership.**

## **Committee Projects**

### **4. Infectious Disease Verification**

Public Comment: August 2015 (Estimated)

Board Consideration: December 2015 (Estimated)

While there is a process for ABO verification to prevent accidental transplant of incompatible blood types, there is no similar process of verification related to infectious disease. Current policy requires verification of all infectious disease results prior to use of deceased donor extra vessels in secondary recipients or living donor recipients as well as for deceased donor organ transplants not on a match run. Policy for these organs specifies that the transplant hospital verify the medical suitability between the deceased donor organ and recipient prior to transplant. Current policy does not require this type of verification in all organ transplants.

There have been cases where positive serology results have been available but inadvertently missed resulting in preventable disease transmission or near-misses of preventable disease transmission. In March 2014, the MPSC referred this issue to the Committee and requested development of a policy proposal requiring infectious disease verification at two points during living donor procedures. This safety check will become increasingly important as the HIV Organ Policy Equity (HOPE) Act will allow use of organs from HIV positive donors in HIV positive candidates starting in November 2015 under approved research protocols. The HOPE Act safety sub group discussed this issue and recommended a process be developed. In June 2014, the full HOPE Act work group also recommended this issue be referred to Operations and Safety to develop a proposed process and policy.

A work group with members of the HOPE Act safety sub group and additional representatives from the OPO, Transplant Administrators, and Transplant Coordinators Committees has been formed and is currently meeting monthly. Available data have been reviewed. There were five proven/probable viral disease transmission advisory cases between 2009 to the present related to this issue. Among these cases, 60% were from deceased donor organs

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and 40% were from living donor organs. In addition, three cases were related to donor HCV infection and two cases were related to donor CMV infection. Twelve recipients received infected organs and five recipients became infected following the transplantation. In addition, there have been two living donor and one deceased donor cases with similar process issues reported that were not classified as proven/probable transmission.

The work group has decided that a proposed verification would apply to all infectious diseases that would potentially screen a candidate off of a match run. This follows a recommendation sought from the DTAC on which infectious diseases should be included in a required verification. The group plans to overlay verification at recovery and pre-transplant where an existing verification exists or might exist. The group will finalize the recommendations once a decision has been made regarding proposed ABO time points. The group does not plan to recommend double testing or double data entry as is done currently for ABO. Work will continue to develop infectious disease verification requirements to enhance patient safety and protect candidates from accidental transmission of infectious disease.

### 5. Electronic Tracking and Transport Project/TransNet<sup>sm</sup>

*Public Comment: January 2016 (Estimated)*

*Board Consideration: June 2016 (Estimated)*

In March 2015, a voluntary national deployment of the OPO TransNet<sup>sm</sup> system was launched. The eight OPOs who have been using the application since field and beta testing are continuing to use the application. Each session can accommodate five OPOs. Participating OPOs have to send three staff members, including one management and one front line staff members, to training. It is expected that the OPOs will go back and train the rest of their staff following the UNOS training. All users will need to pass a proficiency test prior to using. OPOs will be expected to use the application on at least half of their donor cases. OPOs will purchase their own equipment. Ten additional OPOs have been trained in the March and April sessions. All ten OPOs successfully completed the training with all attendees (30) passing the required proficiency testing. A total of 18 OPOs are now using the system to some degree. The response has been overwhelmingly positive. An additional twenty OPOs are signed up for training through August 2015. As of May 6, 2015, TransNet has been used on 340 donors.

OPOs will provide the first level of support and then issues will be escalated to UNOS IT staff if the OPO cannot resolve them. TransNet<sup>sm</sup> programming has been brought in house with the UNOS IT department. UNOS staff programmed the version rolled out with the March deployment. UNOS IT is working on development for platforms other than Android. The goal is to have a version for use on other platforms (e.g. iOS) ready for July testing and possible September release. The in-house team is staffed to handle the rapid cycle development required to keep the project on its aggressive timeline.

TransNet<sup>sm</sup> project staff have started transplant hospital discovery. Transplant hospitals in New York, Chicago, and California have hosted visits. About 15 sites have been part of the discovery thus far. Two hospitals, Piedmont Hospital in Atlanta, Georgia and Henrico Doctors Hospital in Richmond, Virginia are actually testing the current version. The model they are using will probably be replicated in other transplant hospitals. During this discovery, transplant hospitals have welcomed being part of the development process. They have requested that the application include programming for assistance with vessel labeling and management as well as ABO verification in the OR. Project staff are getting a sense of what

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existing equipment (e.g. scanners and printers) that transplant hospitals currently have available for use with the system.

One issue will be how transplant hospitals integrate the system and process with their own electronic medical records (EMRs). It appears that printing recipient ID bands from DonorNet will not be an issue. Coordinators who work from home can print to network printers using Citrix. Transplant hospitals will need to develop their process for how the printed band will be put on the intended recipient.

Transplant hospitals see the value in using the system to meet and enhance ABO requirements and processes. TransNet<sup>SM</sup> staff had a meeting scheduled with CMS that had to be cancelled due to weather. This will be rescheduled and the purpose is to work together to make sure that the system can meet both OPTN and CMS requirements.

Transplant hospitals also see the potential for using the system to manage and document extra vessels. The system could calculate expiration dates and send notices when vessels need to be destroyed. If vessels are scanned upon storage and destruction, the system could create a log.

Discussions continue on how to handle cases where the recipient is not on a match run. Currently, there are about 60 cases per year. Discussions are also continuing on whether to limit printing of recipient ID bands to the accepting recipient only and have OPOs authorize printing for alternate recipients. This issue will continue to be considered.

Requirements for a beta version to be used in transplant hospital testing are under development. The plan is to have a version ready by late summer 2015. There will be approximately 15 transplant hospitals participating in this testing. Site selection will be limited to areas where the OPO is also using the application.

The OSC and the TransNet<sup>SM</sup> subcommittee are discussing a possible public comment proposal for mandatory use. As part of these considerations, they will examine potential timelines, readiness factors, resources, and how would mandatory be defined. Voluntary efforts will continue to be promoted and reviewed. The OSC favors having all OPOs and transplant hospitals use the same system as well as have all derived from the benefits TransNet<sup>SM</sup> use will offer.

### 6. Developing a System to Review and Share Safety Event Data

*Public Comment: N/A*

*Board Consideration: N/A*

The Operations and Safety Committee prioritized safety situation data at their September 2014 in-person meeting. At this meeting, they developed a data request to obtain additional information regarding the selected situations delayed communication, insufficient communication, living donor organs recovered but not transplanted, and switched kidney laterality. They were particularly focused on the events that resulted in organ discard. An internal UNOS patient safety group has been meeting to figure out how to provide information without compromising medical peer review protections. This group is looking at delayed communication events that resulted in organ discard and attempting to define a process where additional information could be shared to enable the OSC to work on appropriate policy, education, guidance, or programming.

The Committee has also decided to reconvene the Patient safety Advisory Group. The group has been meeting monthly since January 2015. Two volunteers have developed case studies based on a compilation of professional experiences and assistance from the UNOS

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Instructional Innovations department. These case studies are being developed into a short media session in order to help educate the transplant community about prevention of errors. The session will focus on one switched laterality fictional event and one delayed communication fictional event. Both of these events will result in organ discard. The viewer will be prompted to reflect on whether this could occur at their program and what steps might be taken or effective practices put into place to event repeat occurrences.

### **Committee Projects Pending Implementation**

#### 7. Improvements to Vessels Disposition Reporting

*Public Comment:* [March 16 - June 25, 2012](#)

*Board Approval:* [November, 2012](#)

*Projected Implementation:* Third quarter 2015

When programming for the extra vessels disposition electronic reporting form is completed and released, then policy approved to require reporting within seven days will go into effect.

#### 8. Clarify Data Entry Screens for A2 and A2B in UNet

*Public Comment:* N/A

*Board Approval:* [November, 2011](#)

*Projected Implementation:* Fourth quarter 2015

This programming enhancement will add links to explain that A2 and A2B labels throughout UNet mean any blood type A, non-A<sub>1</sub> or blood type AB, non-A<sub>1</sub>B result to match policy.

### **Review of Public Comment Proposals**

The Committee reviewed seven of the eighteen proposals released for public comment from September 29 through December 5, 2014.

#### 9. Vascularized Composite Allograft (VCA) Implementation (VCA Committee)

The Committee requested a list of all exemptions for VCA in policy. Committee members did not have any opposing comments. The Committee supports this proposal.

#### 10. Quality Assurance Process Improvement Initiatives (Membership and Professional Standards Committee)

The Committee asked for and received clarifying comments that this proposal did not add any further requirements than what Centers for Medicaid and Medicare Services (CMS) currently requires. A crosswalk between the proposed OPTN and current CMS requirements was done to ensure that no new requirements would be added. It was further discussed that quality assurance requests would not be part of routine site surveying but would be used where the MPSC had concerns about ability to self-correct based on previous issues. The Committee asked if this proposal had been considered for only non-CMS programs, however it was clarified that the intent was for all programs.

No members expressed opposition to the proposal. The Committee supports this proposal.

#### 11. HIV Organ Policy Equity Act (OPO Committee-first proposal)

The OSC has members participating in the HOPE Act workgroup that developed this proposal.

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One Committee member clarified that this current proposal would only permit HIV positive to HIV positive transplantation among deceased donors and under an approved research protocol consistent with the Final Rule.

The Committee did discuss possible inclusion of living donors based upon draft NIH protocols discussed at the World Transplant Congress. It was noted that kidney surgeons and the physician with international experience in this type of transplant expressed vocal opposition to the possible inclusion of living donation.

The HOPE Act Work Group and the OPO Committee may consider addressing living donation in a second forthcoming proposal. Safety concerns such as HIV associated nephropathy were brought up with concerns that a living donor may give up an organ that they may later need. Another member expressed that with active retroviral therapy and good medical management that this concern may not be valid. Other medical concerns such as cardiomyopathy and metabolic syndrome were mentioned. One member shared that HIV-positive couples do present with one requesting the ability to donate to their partner with some regularity and that it would be beneficial to be able to meet these requests at some point in the future. Other members offered that patient safety was paramount and this may not be supported in the interest of safety.

Committee members did not express opposing comments, however, for the proposal under consideration. The Committee does support this current proposal.

### 12. Improving OPTN Policy Development Process (Executive Committee)

The Committee did ask how often it was anticipated that alternative processes might be used. Previous examples were shared. It was stated that while this may not be a frequent occurrence some routine items might apply if their language is approved to have an expedited option. One member also shared comments from their regional meeting where one person may anonymously submit four or five comments against a proposal and then stop a possible expedited process.

The Committee did not have any opposing comments. The OSC supports this proposal.

### 13. Clarify Definition of Organ Transplant and Transplant Date (Policy Oversight Committee)

The Committee questioned if the OPTN would make requests to update data retrospectively if this proposal passes. A definitive answer will be researched and provided. It was noted that it would not be likely as policy typically applies starting with its implementation date.

The Committee did not have any opposing comments. The OSC supports this proposal.

### 14. Clarification of Multi Organ Policies (Policy Oversight Committee)

The Committee did not have any opposing comments. The OSC supports this proposal.

The Committee reviewed four of the ten proposals released for public comment from January 27 to March 27, 2015.

### 15. Require another match run based on infectious disease test results (Ad Hoc Disease Transmission Advisory Committee)

The Operations and Safety Committee supports this proposal. Members asked some questions about the logic behind the proposal. While the first person to accept an organ on a match run executed while infectious disease results are pending will retain first right of refusal should the infectious disease test come back positive, the Committee understands that those further down the list would not have the same options. The Committee understands that this issue was debated and considered in-depth by the work group and DTAC. Requiring the

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match run to be re-executed if infectious disease results come back positive and the first candidate who accepted turns down the organ due to the new positive results represents a compromise to promote safety by eliminating manual analysis of the first match run without taking away a commitment to the first person who had accepted.

### 16. Improve reporting of aborted procedures and non-transplanted organs (Living Donor Committee)

The Operations and Safety Committee supports this proposal. The Committee believes that capturing data on both aborted procedures and living donor organs recovered but not transplanted is necessary

### 17. Clarify Policy Language and Process for Individual Wait Time Transfer (Patient Affairs Committee)

The Operations and Safety Committee supports this proposal. The Committee did ask for clarification on some questions related to waiting time and the new KAS rules.

### 18. Addressing the Requirements Outlined in the HIV Organ Policy Equity Act (OPO Committee)

Committee representatives participated in the HOPE Act work group. Research protocols have not yet been released for public comment. Once these are published there may be an additional public comment session. This proposal does address the HIV positive donation for living donors. The Operations and Safety Committee supports several safety measures including double verification for candidates willing to accept positive organs and requiring all allocations to be conducted from a match run.

## Other Committee Work

### 19. Trends and Patterns in Patient Safety Situations Reported to the OPTN

The Committee reviewed the last six months of patient safety situation data at their April 14, 2015 in-person meeting. The Committee did not prioritize these data as they are still awaiting fulfillment of a data request with additional information to guide next steps for the top situations selected at the September 2014 meeting. Details of the latest report can be found in **Exhibit D**. The Committee also prepared a summary of safety situation data that was accepted for a poster display at the American Transplant Congress in May 2015.

### 20. Transport of Living Donor Organs

The Committee is working with the Living Donor Committee to conduct a Healthcare Failure Modes and Effects Analysis (HFMEA) on the transport of living donor organs. Details on this project can be found in the Living Donor Committee Board Report.

### 21. Patient Safety News

Since November 2011, the Committee has published the *Patient Safety News* newsletter. In 2013, the Committee decided to publish stories on a real time basis on the OPTN and other websites as opposed to a quarterly publication.

## Meeting Summaries

The Committee held meetings on the following dates:

- December 2, 2014
- January 27, 2015
- February 24, 2015
- March 24, 2015

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- April 14, 2015
- April 28, 2015

Meetings summaries for this Committee are available on the OPTN website at:  
<http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=60>.