

**OPTN/UNOS Operations and Safety Committee**  
**Report to the Board of Directors**  
**June 25-26, 2012**  
**Richmond, VA**

**Summary**

**I. Action Items for Board Consideration**

- None

**II. Other Significant Items**

- The Committee reviewed a data analysis on extra vessels disposition reporting and proposed policy changes. (Item 1, Page 3)
- The Committee reviewed safety data trends and patterns and proposed enhancements to the safety situation reporting system. (Item 2, Page 4)
- The Committee reviewed blood type verification policies; compliance data associated with the policies, and discussed development of a standardized documentation. (Item 3, Page 5)
- The Committee discussed ISBT 128 as a potential standard for implementation of real time organ tracking and traceability. (Item 4, Page 6)
- The Committee considered applicable public comment proposals that were distributed on March 16, 2012. (Item 8, Page 8)

**Report of the  
OPTN/UNOS Operations and Safety Committee  
to the Board of Directors  
June 25-26, 2012  
Richmond, Virginia**

**Phillip C. Camp, Jr., M.D. – Chair  
Jean Davis – Vice Chair**

*This report represents the OPTN/UNOS Operations and Safety Committee's (OSC) discussions and deliberations during its meeting held in Chicago, Illinois on April 4, 2012.*

1. **Vessel Recovery, Storage, and Transplant.** The Committee reviewed the Board of Director's discussions from the November 2011 meeting on the Committee's proposal to restrict the storage of hepatitis B surface antigen and hepatitis C antibody positive extra vessels. After the review of the Board's resolution to the proposal, it was discussed that many surgeons in the community did not approve of the Board's decision. The approval made an important statement about patient safety in the use of extra vessels from an organ donor.

The Committee discussed its continued efforts to re-design the system for tracking extra vessels that will include a safe process for storing all vessels in the future. A data analysis was reconsidered by the Committee that highlighted problems in compliance with extra vessels disposition reporting (**Exhibit A**). The data indicate more than 20,000 extra vessels were recovered with kidney, liver, pancreas, or intestine deceased donor recoveries during the years of 2008 through 2010. In 2008 through 2009, 50 percent of extra vessels had disposition reported to the Organ Procurement and Transplantation Network (OPTN) as being unknown at the time of organ transplant. At the end of 2010, more than 55 percent of vessels recovered and sent did not have disposition reported. More recent data from 2011 identified over 3,000 recipients removed from the waiting list with vessel disposition unknown. The same data shows over 400 (40.7 percent) of pancreas and kidney/pancreas transplants in which extra vessels were reported as not used. The Committee discussed the inaccuracy of the data as most pancreas transplants must utilize extra vessels to complete the transplant procedure therefore there must be issues in communicating vessel use or misunderstanding of what an extra vessel is. The data analysis also identified several liver, kidney, kidney/pancreas, and thoracic programs that may have good practices for reporting vessel disposition to the OPTN.

Based on the data, outlier kidney, kidney/pancreas, liver, heart, and lung programs were identified. Outliers were defined as programs having greater than 50 transplants or 50 percent of their transplants with extra vessels disposition outstanding. These programs received a letter highlighting their programs disposition reporting data and a survey to collect information regarding vessel recovery, storage, and transplant processes within the program. An analysis of the survey responses is being reviewed by the committee's Vessel Policy Work Group (VPWG). From the survey analysis the work group will attempt to identify programs that can provide useful input in the re-design of the OPTN's extra vessels disposition tracking and reporting system.

The Committee reviewed its proposal currently out for public comment, that would require transplant centers to report extra vessels used or disposed of within five days. Regional and center specific responses to the proposal were discussed. The proposal is consistent with Organ Procurement Organization (OPO) requirements for reporting extra vessels sent and would align organ and extra vessels data collection. The Committee requested data to identify the number of proven disease transmission events for which extra vessels disposition was pending at the close of the case review.

These data would provide additional support for the proposal and could be shared during regional meetings.

- 2. Review of Safety Data and Trends.** The Committee reviewed the 301 safety situations that were voluntarily reported to the OPTN from April 2006 through January 2012 (**Exhibit B**). The Committee believes the number of reports under-represents safety events occurring in the field day to day. However, reporting has increased over the last three years, and the database continues to mature. It was discussed that the increase in reporting may be due to efforts within the community to heighten awareness of safety and training provided by UNOS staff on the types of safety events members should report. The two most reported safety events were data entry and organ labeling errors. Other events reported were packaging and shipping issues as well as communication and documentation errors. Trend charts of the data were reviewed to assess increases in the types of events reported and external events that may positively or negatively affect reporting. Current trends show an increasing number of reported events by year. The Committee discussed the increase in reporting and that trends should be interpreted cautiously due to small sample sizes.

The Committee discussed its prior method of safety data review. Reports were analyzed based on potential OPTN policy violations identified and event review by the Membership and Professional Standards Committee (MPSC). This process could identify some patterns in safety events but does not provide a broader view of events reported from all portals of entry within UNOS and is an incomplete picture of safety in the network. The Committee will continue to collaborate with UNOS to develop a system that will accommodate compilation of all safety events in one repository for accurate assessment of trends and patterns in safety.

The Patient Safety Planning Development Subcommittee reviewed a proposal to add data enhancements to the safety situation reporting portal in UNet<sup>SM</sup> (**Exhibit C**). Based on their review of safety data during the past two years, elements could be added to the system that would provide data for analysis in real time. Eight high-level categories were identified based on 301 events reported. Within each of the eight categories, subcategories were proposed to provide additional information related to the safety event being reported. The data enhancements would allow a reporter to select applicable events by category and subcategory rather than manually information within a text field. Consistent terminology and definitions in the reporting system was discussed. Terms like “Patient Harm” and “Patient Disadvantaged” would need to be defined and aligned with UNOS Evaluation and Quality (DEQ) event reviews, as well as the World Health Organization’s Technical Report of Conceptual Framework for the International Classification for Patient Safety published in January 2009.

After careful review, the Committee voted to accept the subcommittee’s recommended enhancements to the reporting system. Members voted in favor of the proposal: 21 For, 0 Against, 0 Abstentions.

RESOLVED, proposed enhancements to the Improving Patient Safety electronic reporting portal for safety situations in UNet<sup>SM</sup> should be programmed. Member use of enhancements will be pending programming and effective upon notice to the membership.

The Committee discussed the positive effects of reporting safety events to the OPTN. Safety reports identify problems in the system that the OPTN should be aware of to correct, or educate regarding, the issue. Transplant centers should focus on identifying gaps in the system, reporting and allowing the OPTN to correct them in a way that can have positive effects on patient outcomes. When patient outcomes are the concern of the center, safety situations can be identified and addressed quickly before an adverse event takes place. The Committee’s spring Patient Safety Newsletter will focus on this concept and encourage members to self report safety issues identified internally.

Transportation failure and near miss data provided by the Organ Center (OC) were reviewed by the Committee for the timeframe February 2011 – January 2012 (**Exhibit D**). These data focus on organs that were allocated and shipped through the OC. The data show 23 organ discards that were directly related to a transportation near miss or failure. A failure is defined by the OC as organs that do not make it to their original intended destination transplant center or those that arrive at the original intended destination but with a delay significant enough for the organ to be unacceptable for transplant. Failures fall into two categories; those that are ultimately transplanted (at an alternate center) and those that result in the organ being discarded. A near miss is defined as a delay of two or more hours from the original estimated time of arrival.

The Committee discussed that proposed enhancements to the Improving Patient Safety reporting system in UNet<sup>SM</sup> will provide a mechanism for OPOs to report transportation failures and near misses on a national level. Guidance on reporting and the importance of collecting this data will need to be shared. An abstract on the transportation failure and near miss data was submitted to American Transplant Congress for presentation in June 2012. The abstract highlights organ transport failures that are occurring at a higher rate than previously suspected, resulting in discards and increased cold ischemic times. It proposes that systems and human errors are the major causes of organ transportation issues.

3. **Blood Type Verification and Standardized Documentation.** The Committee reviewed blood typing and verification compliance data obtained for site surveys completed January 2007 through March 2011. These data show issues documenting ABO typing and verification processes as required by Policy. The Committee discussed the issue and that the Centers for Medicaid and Medicare Services (CMS) cites verification of blood type and other vital data between the organ donor and recipient as the most frequently cited condition-level deficiency during the transplant program surveys.

The individual steps and processes associated with identifying, reporting, and matching a potential recipient's blood type with that of a donor was reviewed. In 2003, the Operations Committee identified and documented four relevant steps in this process:

- Determining and reporting the potential recipient blood type
- Determining and reporting the deceased donor blood type
- Matching the compatibility of the donor blood type with medically suitable potential recipients on a match run
- Completing the processes and documentation in procuring, transporting and physically accepting a donor organ for a potential recipient

The Committee agreed that the above steps are still appropriate, safe, and relevant to current practice. It was discussed that standardized documentation alone would not increase compliance with these policies as current language is not consistent with current practice. Concerns were raised over a CMS document published in October 2011 that proposed to remove their requirement for blood type verification prior to the recovery of organs. The OPTN currently has no requirement for blood type verification prior to donor recovery, but the Committee discussed the need to propose such a policy to protect the donor. The ABO Verification Work Group is working to appropriately address these issues in a proposal to the committee. Once policy language and processes are agreed upon, a standardized checklist or documentation tool that includes all blood type verification requirements will be created for member use. The Committee is collaborating with other OPTN committees on this project and will provide a quality assurance and performance improvement tool to help members proactively audit themselves for compliance with the requirements.

4. **Linking Donor Risk with Organs, Tissues, and Blood.** The Committee reviewed current organ tracking and traceability mechanisms provided within UNet<sup>SM</sup> and the Improving Patient Safety electronic reporting system. Although tracking of donor organs to recipients is provided within the UNet<sup>SM</sup> system, it does not provide a way to link a donor to all products allocated. Often organ donors are tissue donors. Tissue testing standards are more restrictive than organ standards at times revealing test result post organ transplant that may need to be communicated to an organ recipient center. The risks of transmission increases when there are multiple recipients from a common donor. As many as 100 tissues and organs can be recovered from a single donor. When a potential transmission event is identified in a tissue recipient, the current OPTN system does not link that tissue recipient with the organ donor and thus delaying communication of risk to an organ transplant center. The Committee discussed center practice for analyzing recipient and donor risk and recognized that it varies from center to center according to local practice. The Committee was concerned that the potential for disease transmission could go unrecognized due to lack of standardization.

The Committee discussed the International Society of Blood Transfusion barcode symbology code 128 (ISBT 128) and the information that has been learned about the process of using this standard. ISBT 128 has been in use in the blood banking industry for years and is accessible in many hospitals that provide blood processing capabilities onsite. Members of the Committee discussed that the American Association of Blood Banks (AABB) may require the use of ISBT 128 for blood bank certification in the near future. Standard licensing, software and equipment needed to operate the standard would be available to many hospitals with transplant programs if this requirement is enforced.

Bar coding associated with ISBT 128 was discussed and whether bar coding of organs could be accomplished outside of the ISBT 128 standard. The Committee discussed the challenges in programming and interfacing with software. To have all of the tracking and traceability capabilities of the ISBT 128 standard, UNOS data systems would be required to interface software associated with ISBT systems. The potential benefits of this system and how it could assist the OPTN with current challenges in tracking extra vessels and pancreas islet cells was discussed. Members of the Committee agreed that implementing the full capabilities of ISBT 128 tracking could also benefit the OPTN system by:

- Decreasing the number of transcription errors on donor and recipient charts and organ labels
- Assist with blood type verification at organ recovery, receipt, and prior to transplant
- Identify a wrong organ sent for a recipient before the time of transplant
- Real time identification of organs transplanted into a recipient for whom it was not accepted (e.g., if multiple organs are delivered to a center)
- Identify extra vessels transplanted into a recipient or those disposed of

5. **Effective Screening Impact Analysis.** The Committee reviewed the Effective Screening Work Group's (ESWG) kidney impact data analysis completed as part of the effective screening project (**Exhibit E**). The analysis focused on identifying programs that had accepted zero out of a large number of imported expanded criteria donor (ECD) organ offers. Letters with surveys were sent to 43 kidney programs identified in the analysis as having an apparent "conflict" between screening criteria entered and observed import organ acceptance practices. Letters were focused on highlighting a program's data and educating on the ability to change screening criteria in UNet<sup>SM</sup>. For each program that received a letter, screening criteria and acceptance data was reviewed before and after the letter. To track the impact of this initiative, a comparison of each program's use of screening criteria, acceptance rates for ECD organ imports, and volume of offers before and after receipt of the letter

was reviewed. Changes in these metrics were also evaluated for programs in which letters were not sent. The results of the impact analysis showed only one program of the 43 identified that changed their screening criteria. Thirty two of 36 respondents (89 percent) said the data provided was data helpful but cited significant obstacles to effective screening. The most frequent obstacles cited were:

- The philosophy of wanting to manually evaluate all offers (36 percent)
- Too time consuming to manage so many factors for each candidate (33 percent)
- Concern of donor data changing or needing correction after screening (31 percent)

Only one of the 43 programs made substantive changes to its screening criteria by decreasing for all candidates the maximum acceptable donor age from 70 to 60 for import organ offers. As a result, this program recognized a 62 percent decrease in import ECD offers per month and a 12% decrease in all import offers.

The Committee discussed that many kidney programs are hesitant to rely on the automated screening features in UNet<sup>SM</sup> due to fear of missing out on an organ that may be a “hidden gem.” Potential system enhancements, such as refining the local/import distinction and adding the kidney donor profile index may help for more automated screening in the future. Monitoring acceptance patterns may be necessary to ensure programs are adequately meeting the needs of their listed patients and not slowing organ placement.

The ESWG also surveyed 23 liver programs identified as having donor screening parameters in an apparent conflict with observed organ acceptance practices, but an impact analysis was not completed. Thirteen liver programs received a letter indicating their program’s screening criteria and acceptance data. Seventy-seven percent of respondents indicated that the data was helpful; however, all respondents indicated there were obstacles to effective screening. The most frequently selected obstacle was “center philosophy of wanting to see all offers.” The survey data were provided to the Liver and Intestinal Organ Transplantation Committee’s Liver Utilization Group for consideration.

**6. Inactive Program Patient Transfers.** The Committee reviewed the process of candidate transfers from centers that have withdrawn their membership or inactivated a program indefinitely. Discussions of current policy 3.2.1.9 (Waiting Time Transferal) identified that the policy could not address situations where a center would need to transfer substantially all of their patients to another centers or program. The Committee agreed that a policy solution is needed to address these specific instances of large volume transfers. The current process can take several months to complete transfers limiting candidates’ access to transplant during the process. Wait-time transfer forms that are completed and signed by a candidate give permission to transfer waiting time from one center to another. Under some circumstances, the candidate may have no option but to transfer when the current program is closing. In the past, two options for accomplishing mass transfers have been utilized:

- Option One: Request the accepting center to add and verify the blood type of all candidates being transferred to their waiting list. Once that is complete, a wait-time transfer form must be signed by each candidate to transfer the patient from the closing center to the receiving one. This option requires that transfers are completed one by one, estimated to take a minimum of one month or more for centers with more than 300 candidates listed. This process would be compliant with the current OPTN policy for transferring patient waiting time from one center to another.
- Option Two: A utility was previously designed by Information Technology staff (IT) that would swap the center code candidates listed. With this option, both the closing and receiving

centers would agree to this process. To agree the centers would have to understand that the swap would require the receiving center to get each listing as-is, with correct or incorrect data. This process could easily transfer up to 400 candidates in approximately a week because wait-time transfer forms would still need to be completed and signed by each patient for transfer. This option is compliant with OPTN policy for transferring patient waiting time but would require IT resources for programming.

The Committee also discussed a third option in which IT staff could write a script to change the center code for all candidates listed at the closing center to the receiving center. This option would be the same as Option Two described above, but would allow all candidates to be transferred at once. This option would require IT programming and all wait-time transfers forms completed, signed and submitted to UNOS before the transfer. To waive the requirement of a transfer form would require review by the OPTN/UNOS Executive Committee unless the committee proposes policy to address large volume patient transfers. It was agreed that additional policy requirements should be implemented to ensure that the transfers take place in a manner that promotes the safety of transplant patients and living donors.

7. **Re-run of Match When Donor Serology Changes.** The Committee discussed issues concerning when a match run is generated before all donor serology results are available. UNOS staff has noted organ allocations involving blood borne pathogens that were not identified on the original match but were later available for a transplant center's review. The concern was of serology results that would result in screening a potential candidate off the match when listed as not willing to receive a positive organ for the pathogen. The Committee will work with the Disease Transmission Advisory Committee and OPO committee to provide assistance from an operational and safety standpoint.
8. **Public Comment Review.** – The Committee considered current proposed policies, which were to be released for public comment on February 3, 2012 and March 16, 2012. The Committee's opinion is shown below for the selected proposals considered within its purview:
  - **Proposal to Require Reporting of Unexpected Potential or Proven Disease Transmission Involving Living Organ Donors – (Living Donor Committee)** - The Committee offered the following comments:
    - The Committee questioned whether requiring reporting of potential or proven disease transmission for up to two years post donation and transplant was an adequate time frame for reporting. The Committee would have liked to have seen data that would provide evidence for this timeframe requirement but supports the intent of the proposal.

The Committee voted: 20 For, 0 Against, 0 Abstentions.

- **OPTN Bylaws Substantive Rewrite of Appendix A: Application and Hearing Procedures for Members and Designated Transplant Programs (Living Donor Committee)** – The Committee is opposed to the proposal and the new option of deferred disposition:
  - Many safety issues reported to the OPTN do not warrant disciplinary action. They may be lesser harm or near misses that when reported help the network to address policy gaps and process concerns to prevent future occurrences. Lesser harm, no harm, and near miss events must be managed in a different way to allow members to proactively address issues in real time, provide action plans, quality improvement initiatives, and self monitoring results to the OPTN when there is noncompliance identified.
  - Monitoring of patient outcomes and progress reports appears to only be applicable to members that are being considered for adverse action. Monitoring of outcomes and

progress reports of members that report lesser harm events could be implemented to assess for trends that may trigger further review of the member.

- This proposal makes it easier for a member being considered for an adverse action to get through due process but does not address member responsibility for continuous improvement. Members that identify, proactively address, and report such issues should have incentive for doing this. Such a process should be clearly defined within the Bylaws.
- Safety data reviewed by the Committee clearly show that there is under-reporting of safety events that are occurring in the field. This proposal discourages reporting of those lesser harm and near miss events because of its punitive language. The network will not be able to address gaps in policy or process without understanding where the gaps in the system are. With this proposal, members will be even more fearful to report as the language does not reflect process improvement but adjudicates penalty.

The Committee voted on this proposal: 0 For, 19 Against, 0 Abstentions.

- Proposal to Document All Locally Assigned Unique Identifiers in the Donor Record – (OPO Committee) - The Committee offered the following comments:
  - The Committee recommends that there be a standard for the second unique identifier rather than options. Multiple specimens may be received and sent to several labs including pathology, HLA, and core labs for processing. It is recommended that policy require the second unique identifier to be the OPO assigned unique ID rather than date of birth or donor initials that can be common among donors. Creating this standard links source documentation with donor specimens, removes ambiguity, and makes the process of searching for elements to verify more efficient.
  - It is the understanding of the Committee that approximately three OPOs do not utilize electronic records limiting their capability to generate unique identifiers, but these OPOs intend to implement electronic records soon to comply with national safety standards and may have other processes in place now to generate unique IDs.

The Committee voted: 18 For, 1 Against, 0 Abstentions.

- Proposal to Update Data Release Policies (Policy Oversight Committee) - The Committee approved this proposal: 18 For, 0 Against, 0 Abstentions.

9. **Future Meeting Date.** – The full Committee will next meet face-to-face on September 13, 2012, at O’Hare Hilton Hotel, Chicago, Illinois.

**OPTN/UNOS OPERATIONS COMMITTEE MEETING ATTENDANCE**

<b>Name</b>	<b>Position</b>	<b>Chicago, Illinois April 4, 2012</b>
Phillip C. Camp, Jr., MD	Committee Chair	x
Jean Davis	Committee Vice Chair	x
Sharon Bartley, MS, RN	Region 1 Representative	x
Alden Doyle, MD, MPH & TM	Region 2 Representative	x
Michael Angelis, MD	Region 3 Representative	x
Dean Henderson, MHA, BSMT, CHT	Region 4 Representative	By Phone
P.J. Geraghty, MBA, CPTC	Region 5 Representative	x
Kathy Jo Freeman, RN, MSN	Region 6 Representative	x
Glen Geditz	Region 7 Representative	x
Zoe Stewart, MD, PhD	Region 8 Representative	
Theresa M. Daly, MS, FNCP	Region 9 Representative	x
Ladora Dils, BSN, MHA, CPTC	Region 10 Representative	
Jerita Payne, APRN, BC	Region 11 Representative	x
Karen R. Cox, PhD, RN	At Large Representative	x
Sharon Alcorn, RN, BSN, CCTC	At Large Representative	x
Daniela P. Ladner, MD	At Large Representative	
J.T. Rhodes, CPANCREAS	At Large Representative	x
Kristin Delli Carpini, MPH	At Large Representative	x
Julia Hart, BS	At Large Representative	x
Linda Ohler, RN, MSN, CCTC, FAAN	At Large Representative	x
Darla Phillips, RN, MSN	At Large Representative	x
Helen (Gigi) Spicer, RN, BSN	At Large Representative	By Phone
Michael Hagan, DO, MHSA, CMQ	Visiting BOD Member	x
Lisa McMurdo, RN, MPH	Visiting BOD Member	x
Raja Kandaswamy, MD	SRTR	x
Raelene Skerda	Ex Officio/HRSA	x
Robert W. Walsh	Ex Officio/HRSA	

**UNOS staff attending:**

Franki Chabalewski, MSN, RN, Acting Director, UNOS Professional Services  
 Kimberlye Joyce, Assistant Director, UNOS Professional Services  
 Darren Stewart, Biostatistician, UNOS Research Department  
 Kimberly Taylor, RN, Senior Patient Safety Specialist, Committee Liaison  
 Ronald Brown, UNOS Support Technician