

**OPTN/UNOS Operations and Safety Committee
Report to the Board of Directors
November 12-13, 2012
St. Louis, MO**

Summary

I. Action Items for Board Consideration

- The Board of Directors is asked to approve modifications to Policy 5.10.2 (Vessel Storage) that would require transplant centers to report extra vessels disposition every seven calendar days. (Item 1, Page 2)
- The Board of Directors is asked to approve programming of proposed enhancements to the safety situation reporting portal of the Improving Patient Safety electronic reporting system. (Item 2, Page 3)

II. Other Significant Items

- The Committee discussed developing an organ tracking and traceability system that would link organs allocated with donor risk that is identified. (Item 3, Page 3)
- The Committee reviewed and discussed ABO verification compliance and development of a standardized checklist. (Item 4, Page 6)
- The Committee reviewed patient safety data and reporting processes. (Item 5, Page 6)

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Jean Davis – Chair
Theresa Daly, M.S., RN, FNP – Vice Chair

This report represents the OPTN/UNOS Operations and Safety Committee's (OSC) discussions and deliberations during a LiveMeeting teleconference held on August 22, 2012 and its in-person meeting held in Chicago, Illinois on September 13, 2012.

1. Vessel Recovery, Storage, and Transplant – The Committee discussed its proposal to require transplant centers to report extra vessels disposition to the OPTN within five days of extra vessel use or disposal. The Vessel Policy Work Group (VPWG) Chair discussed with the committee extra vessels disposition data reviewed during the development of the proposal and alternative recommendations that were discussed prior to public comment. Feedback from public comment was reviewed along with responses to feedback from the VPWG and its decision to modify the proposal, based on public comment feedback, to require extra vessels disposition reporting every seven calendar days. The VPWG Chair explained that this change would allow transplant centers to develop a weekly reporting process that would assist in compliance with the proposed policy. In addition, the VPWG has requested to determine if an opportunity for electronic submission of the disposition fax form currently in use could be programmed into UNetsm. Providing electronic reporting in this manner would allow members to upload the dispositions directly into UNOS data systems thereby making the disposition data readily available to UNOS. The VPWG is awaiting further documentation and cost estimates to determine the feasibility and timing of the programming. The Committee agreed that the proposal for disposition reporting every seven calendar days should not be implemented until programming could be completed for electronic upload of extra vessels disposition data.

After careful review and discussion, the Committee voted 20 For, 0 Against, with 2 Abstentions to recommend the revised proposal to the Board of Directors for approval at its November 2012 meeting (**Exhibit A**).

*****RESOLVED, that Policy 5.10.2 (Vessel Storage) shall be modified as set forth below, effective pending programming and notice to the membership:**

5.10.2 Vessel storage

The Transplant Center must designate a person to monitor and maintain records, destroy, and notify the OPTN of outcome and/or use of vessels. This designated person must maintain information on all donor vessels including monitoring and maintaining all records relating to the use and management of donor vessels (e.g. subsequent positive serology testing, monitor inventory of stored ~~vascular conduits~~ extra vessels). This person must monitor the refrigerator, ensure records are up to date and available with the ~~conduits vessels~~, destroy the vessels when expired, and notify report the vessel's use or disposal to the OPTN within 5 days of when the Transplant Center uses or disposes of the vessel ~~of its use or disposal every 7 calendar days~~. [...]

2. Enhancements to Safety Situation Reporting – The Patient Safety Planning Development (PSPD) Subcommittee Chair updated the Committee on its work since the Committee’s April 2012 in-person meeting. Proposed enhancements to the Improving Patient Safety electronic reporting system in UNetsm (**Exhibit B**) were approved by the Committee to go to the Board for programming approval on April 12, 2012. The cost estimate and business requirements for programming will be reviewed during the PSPD subcommittee’s meeting in early November and will be made available to the Board. The Committee made the following recommendation:

*****RESOLVED, that the proposed enhancements to the Improving Patient Safety reporting portal for safety situations be programmed, effective pending notice to the membership.**

3. Linking Donor Risk with Organs, Tissues, and Blood – The Committee Chair reviewed with the Committee the Board’s recommendation to assess the prospect of adopting a uniform electronic system with the capacity to link all products of donor origin; such as cell, tissues, blood, and organs, with a specific focus on organ transplantation. The Committee discussed its efforts in identifying such systems and their particular interest in understanding how the Information Standard for Blood and Transplant (ISBT) Code 128 is currently being used in blood banking, the history of its development, and recommendations on how the standard could be used in the current system of organ donation and transplantation. As a result of these discussions, the Executive Director (ED) of the International Council for Commonality in Blood Banking Automation, Inc. (ICCBBA) was invited to talk to the committee about ISBT 128 and its current use in the blood banking environment.

During his presentation, the ED for ICCBBA discussed the following elements of ISBT 128:

- History of ISBT 128’s development
- Current status of ISBT 128’s use internationally and in the United States (US)
- ICCBBA as the not for profit organization that provides ongoing support and management of the standard
- Basics of ISBT 128
- ISBT 128 potential for implementation in the current system of organ transplantation

The trigger for the development of the ISBT 128 standard began during the Gulf War when blood was sent to the war from many different countries with no unique identification system and there was duplication of donation numbers. Therefore, multiple blood units for different countries were received with the same identification number. There were different products, with different names, in different languages, with different labeling systems making it difficult for users to understand. Some bar-coding was being used during that time, but the codes meant something different with each country the blood was received from. All this led to serious transfusion errors, inadequate traceability, and waste of a large amount of blood that could not be used. These issues were not unique to the war situation, but were also noted domestically in the healthcare environment when moving blood from state to state. As a result, the International Society of Blood Transfusion tasked its working group on automation and data processing to devise an international labeling standard and in 1994 the first version of ISBT 128 was released. In 1995, the ICCBBA was established to maintain ongoing support and management of the standard.

ICCBBA manages, develops and licenses ISBT 128. It maintains the standard, international databases for Facility Identification Numbers and Product Coding, supports documentation, and provides educational materials related to its use. ICCBBA brings together experts from clinical, scientific, technical, and informatics backgrounds to review and update the ISBT 128 Standard to ensure it continues to meet the needs of its users. There are several standards committees and technical advisory groups with over 180 volunteers participating.

The first country to begin using ISBT 128 was Estonia and in the late 1990s other European countries began to use the standard in blood banking. The first use of ISBT 128 in cell therapy was Duke University and the American Red Cross in 1998. In the United Kingdom ISBT 128 was first used for tissues in 1997. In 2006, there has been an increase in the use of the standard to over 4,000 facilities worldwide, over five continents, 60 countries, and is used to label more than 40 million medicinal products of human origin each year. ISBT 128 is accepted as the 'de facto' Standard for coding and labelling of blood components and is supported by the International Society of Blood Transfusion, European Blood Alliance and American Association of Blood Banking (AABB).

An International Cell Therapy Coding and Labeling Advisory Group was established to develop standard terminology for cell therapy and the terminology was published in 2007. It is now accepted as the industry standard and managed by ICCBBA with accreditation organizations. ISBT 128 is now being used in 388 licensed facilities in 44 countries for cell therapy and growing at a steady rate.

ICCBBA has brought together the six major eye banking organizations around the world to establish global terminology for ocular tissue and support for adoption of ISBT 128 by these associations. They have signed a consensus statement to adopt the standard for ocular therapy. Implementation of ISBT 128 has not moved as rapidly with tissue organizations but has been implemented in the United Kingdom and Poland. Implementation is progressing in other European countries with currently 84 licensed facilities. Groups are currently established to work on skin, tendons, cardio-vascular, and bone standardized terminology.

As a result of the World Health Assembly resolution, ICCBBA and the World Health Organization (WHO) formed a working relationship. The Standardized Organ Nomenclature Globally (SONG) project was one effort of this group and terminology for organ transplantation is in development. ICCBBA is ready to move forward with organ coding and labeling as soon as organ transplantation field is ready to start using ISBT 128. ICCBBA continues to work with the WHO to develop nomenclature for tissue and cell therapy in an effort to get effect denominator data for biovigilance efforts and investigations. These efforts are also to increase global awareness of the need for traceability and vigilance. Through its efforts with the WHO, ICCBBA is working on a European coding system for tissues and cells, through an Italian regulator under contract to the European Commission. In the US, the Food and Drug Administration (FDA) recently released a proposed rule on unique medical device identification. Some medical devices also contain human tissues. It would not be prudent for devices and tissues to be labelled and traced differently. ICCBBA is hoping for an exception to allow ISBT 128 to be used for tracking both the device and tissue in such instances.

Income sources are generated for ICCBBA through user license fees and vendor license fees. Current rates are:

- Blood costs are 1.3 cents per donation

- Cell therapy are 1.3 cents per donation
- Tissue therapy are 10 cents per graft issued
- Organ costs have not yet been established but are estimated at one dollar per recovered organ
- Vendors pay a fee of 1,100 to 5,500 dollars dependant on their size

There is a mechanism for reduced fees for users that have a low human development index.

ISBT 128 is an information standard for transfusion and transplantation and provides a globally unique identification of the donation and product. It also provides a database of facilities that assign the numbers as a traceability tool, standard terminology and definitions, an international product code database for codes to be written into an electronically readable form, and a platform independent for data transfer. It enhances patient safety by providing a standardized environment that provides traceability, retention of information, and supports movement of donor products between multiple facilities or countries in such a way that critical information is accurately, rapidly, and unambiguously communicated.

One of the features of ISBT 128 standard is the flexibility. The level of detail that is encoded into the electronically readable information can vary. The standard provides an international reference table of product names and definitions. The terminology model established must support both basic and detailed descriptions based on the concept of a product class and multiple product attributes. An organ example could be:

- Class: Kidney
- Attribute: anatomical position – left

The product code database is maintained by ICCBBA. Each product is represented by a five character product description code. The standard provides for a simple and rapid process to requesting and providing new codes. Regular updates are published by ICCBBA on its website approximately ten times each year. ISBT 128 also provides a standardized means to encode many other pieces of important information relevant to a donation. Blood Groups data structure carries ABO and Rh information. If dimensions data were important, the structure allows for coding of specifics such as counts, lengths and diameters. Infectious disease markers may also be provided related to screening results.

The Committee discussed possible implementation options. The ED of ICCBBA suggested that ISBT 128 be adapted to organ transplantation rather than making the blood, tissue or cell therapy model fit for organs in a standardized way provides for traceability. It was discussed that a step wise approach could be taken to implementation. The first step would be to develop the globally unique bar coded identification number, then a basic organ description for bar coding, and lastly to think about other important information that should be bar-coded for electronic messaging. It was discussed that only a small amount of information would need to be extracted from existing systems to generate the ISBT 128 labelling. The donation number must be compatible with ISBT 128 and the UNOS system would have to tell the labelling system what the organ type and other important information is for coding. This information can be generated within the UNOS data system or passed to a labelling system that would pull the specified data and generate the label. Multiple vendors already generate labels for blood, cells, and tissue and would be willing to generate organ labels. Information Technology input doesn't have to be complex as long as an interface to the labelling system can be provided. Initially the retention of the UNOS donor identification

(ID) would be beneficial for mapping to an ISBT 128 identifier, with a long term view to move toward using ISBT 128 exclusively. The Committee discussed transcription errors and miscommunication of basic donor information as two issues that could be minimized by a system such as ISBT 128. The following questions would need to be addressed to determine how to move forward with this project:

- Who would assign the ISBT 128 numbers?
- How will the ISBT 128 numbers be generated?
- How will the labels be printed?
- What is the basic nomenclature needed for barcoding organs that are transported?
- Will portable scanners and printers be needed?
- How and who decides on web-based interfaces?

A work group will be created to begin these discussions and move forward with this project with representation from multiple committees within UNOS and external stakeholders as necessary.

4. ABO Verification Requirements and Documentation – The ABO Verification Work Group of the Committee is reviewing current policy requiring blood type checks and verification of donor and recipient blood type prior to donor organ recovery and organ implantation. At the last in-person meeting, the Committee reviewed data on compliance with these policies and noted that non-compliance with each of the policies continue to persist. The group also notes that the Centers for Medicaid and Medicare Services (CMS) also cites verification of blood type and other vital data between the organ donor and recipient as their most frequent condition-level deficiency identified during transplant program surveys.

The work group discussed documentation of critical steps in the process of blood type identification and verification, and their efforts to identify process and policy gaps during this process. A representative from CMS was invited to participate with the work group as they address concerns regarding:

- Misinterpretation of terminology within CMS regulation and OPTN policy
- OPTN policies that may be inconsistent with current practice
- OPTN policies that are not aligned with CMS regulation
- Lack of standardization of blood type verification processes due to organ specific logistics

The work group will continue its efforts with CMS input and will address the above concerns in during a 2013 public comment period.

5. Patient Safety Data Collections and Reporting – The Patient Safety Planning Development Subcommittee Chair updated the Committee on its continued work on proposed enhancements to the patient safety reporting system and efforts to work with UNOS staff to ensure that the data collected aligns with processes of investigation. Currently the subcommittee is awaiting cost estimates for programming and plans to review that information during its October teleconference.

The UNOS Director of the Department of Evaluation and Quality (DEQ) presented the Committee with data collected through incident handling over the past 18 months. (**Exhibit C**) After this presentation, the Committee requested that the PSPD Subcommittee continue

to work with DEQ to align the processes of safety data review and to consider how these data can be made available to the membership in a real-time and impactful way.

6. Inactive Program Patient Transfers – The Committee has been tasked with developing policy to address the process of candidate transfers from centers that have withdrawn their membership or inactivated a program indefinitely. Members discussed current Policy 3.2.1.9 that requires a wait-time transfer form be completed for every candidate that transfers from one transplant center to another. In some cases, candidates may not be voluntarily transferring but are being relocated due to an issue with a program or entire center. The Committee discussed the current process of transferring candidate and noted that the UNOS Organ Center (OC) staff manually process wait time transfer forms individually. The OC processes approximately 225 transfers a month. Concerns were raised regarding the transfer of substantial numbers of candidates when centers withdraw membership or programs inactivate indefinitely. It was discussed that the current manual process of wait-time transfer forms could take several months with large volumes of candidates to be transferred and thus creating a situation where candidates' could have delayed access to transplant.

The Committee discussed two options that have been utilized in past years to address large volume candidate transfers from one center to another:

- A utility was designed by UNOS Information Technology (IT) that could “swap” the center code for the candidates. In this instance, both centers had to agree to this process. The receiving center received the candidates listing and records as currently noted in the UNetsm system. This process allowed for easy transfer of a large number of candidates in approximately one week while still fulfilling requirements of policy 3.2.1.9 for completion of wait-time transfer forms for each candidate transferred.
- In another instance the center receiving candidates would add and blood type verify all candidates and collect wait-time transfer forms to submit to OC staff for the transfer of wait-time.

The Committee agreed policy should address the process of candidate transfers more clearly to enhance the safety of candidates being transferred and to appropriately maintain their access to transplant. A multi-committee work group will be formed to address this concern.

7. Policy Rewrite Discussion – UNOS staff reviewed with the Committee the goals of the policy rewrite, new features of the policy document, significant changes in the look and feel of that document, and the next steps in responding to public comment feedback. It was also discussed that the policy rewrite proposal is planned to go to the Board for consideration at its November 12-13, 2012, meeting. The Committee reviewed each of the 18 policies proposed and provided comment on substantive changes that were recognized. The committee's review also focused on providing feedback related to the structure and usability of the new policy document as well as changes in language that clarified the policies' intent. It was agreed that the proposed changes are easier to read, understand, and the document is easier navigate for the member. Also, the policy change history was helpful for historical perspective and understanding of when policies were implemented.
8. Future Meeting Date – The next in-person committee meeting will take place on April 30, 2013, at O'Hare Hilton Hotel, Chicago, Illinois.

OPTN/UNOS OPERATIONS AND SAFETY COMMITTEE MEETING ATTENDANCE

Name	Position	LiveMeeting Teleconference August 22, 2012	Chicago, Illinois September 13, 2012
Jean Davis	Committee Chair	x	x
Theresa Daly, M.S., RN, FNCP	Committee Vice Chair	x	x
Sukru Emre, M.D.	Region 1 Representative		x
Alden Doyle, M.D., M.P.H. & TM	Region 2 Representative		x
Eric Gibney, M.D.	Region 3 Representative		x
Dean Henderson, M.H.A., BSMT, CHT	Region 4 Representative		x
P.J. Geraghty, M.B.A., CPTC	Region 5 Representative	x	x
Mark Menotti, RN, M.B.A.	Region 6 Representative		By Phone
Glen Geditz	Region 7 Representative		x
Nancy Long, RN, B.A., CCTC	Region 8 Representative	x	x
Colleen O'Donnell Flores, M.H.A.	Region 9 Representative	x	x
LaDora Dils, B.S.N., M.H.A., CPTC	Region 10 Representative	x	x
Laura Butler, FNP-BC	Region 11 Representative	x	x
Karen R. Cox, Ph.D., RN	At Large Representative		x
Sharon Alcorn, RN, B.S.N., CCTC	At Large Representative		
Dean Kim, M.D.	At Large Representative		x
Kathleen LeBeau	At Large Representative	x	x
Kristin Delli Carpini, M.P.H.	At Large Representative	x	x
David Marshman, B.S., CPTC	At Large Representative		By Phone
Linda Ohler, RN, M.S.N, FAAN, CCTC	At Large Representative	x	x
Darla Phillips, RN, M.S.N, CCTC	At Large Representative	x	x
Helen (Gigi) Spicer, RN, B.S.N.	At Large Representative		x
Timothy Pruett, M.D.	At Large Representative		x
Lisa McMurdo, RN, B.S.N., M.P.H.	Visiting BOD Member		x
Phillip Camp, Jr., M.D.	Ex Officio		
Raelene Skerda, R.Ph., BPharm	HRSA Ex Officio	x	By Phone
Chris McLaughlin	HRSA		x
Susan Leppke, M.P.H.	SRTR		By Phone

UNOS staff attending LiveMeeting teleconference:

Leigh Kades, Policy Editor, UNOS Policy Department
Darren Stewart, Biostatistician, UNOS Research Department
Kimberly Taylor, RN, Patient Safety Specialist, Committee Liaison
Shyni Mohan, Business Analyst, UNOS Policy Department

UNOS staff attending in-person meeting:

James Alcorn, Director, UNOS Policy Department
Darren Stewart, Biostatistician, UNOS Research Department
Kimberly Taylor, RN, Patient Safety Specialist, Committee Liaison
Lee Goodman, UNOS Support Engineer
Shyni Mohan, Business Analyst, UNOS Policy Department (By phone)
Elizabeth Miller, Policy Analyst, UNOS Evaluation and Quality (By phone)