OPTN/UNOS Operations and Safety Committee
Report to the Board of Directors
June 23-24, 2014
Richmond, Virginia

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

Contents

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This report reflects the work of the OPTN/UNOS Operations and Safety Committee from December 2013 through April 2014.

Action Items
None

Committee Projects

1. **Clarify requirements for blood type verification and align with CMS regulation where possible**

   Public Comment: *March 14 – June 13, 2014*

   Board Review: *November 2014 (estimated)*

   The Committee conducted a Failure Modes and Effects Analysis (FMEA) to examine all ABO blood type verification steps to identify failure points as well as potential system or process changes that could eliminate or manage these risks. This framework has been used in high-risk industries such as aerospace, nuclear energy and the military as well as health-care. The OPTN Strategic Plan calls for the use of systems engineering tools to identify potential failure points including applying FMEA or other process analysis tools to key processes in transplantation to identify potential policy changes, member education, communication, or compliance initiatives.

   Two patient safety consultants assisted the ABO verification work group, which included representatives from the Transplant Coordinators and Transplant Administrators Committees in the FMEA exercise. The work group documented 8 main and 28 sub-processes involved with ABO blood type verification. A total of 62 potential failure points were identified and ranked on measures related to severity, occurrence, and detectability. The Committee prioritized the list and developed modifications to policies to address the top 11 measures. (See Table 1, next page). Policy, programming, and education recommendations were developed to address these top fail points. A public comment proposal, distributed spring 2014, is the first product to address these FMEA recommendations. The Committee will continue to develop additional education materials (e.g. competency training) and programming proposals (e.g. improvements to ABO reporting and verification) to address other recommendations.

Table 1: Top Failure Modes ABO FMEA

Rank	Failure Mode
1	OPO releases organ to recipient not on match run
1	Blood type verification does not occur prior to implantation
2	Candidate erroneously listed as accepting an ABO incompatible (pediatric heart,
2	Wrong organ arrived-not checked at arrival to verify correct organ arrived for the correct potential recipient
2	If intended recipient surgery begins prior to arrival, no requirement for blood source documentation availability to confirm compatibility prior to anesthesia
3	Blood samples are mislabeled (candidate)
3	Verification occurs without both source documents for recipient and donor
4	One blood sample sent and tested twice
4	Only one sample drawn and tested prior to match (no ABO confirmation by second sample)
5	No pre-transfusion specimen is available for testing
5	Blood samples are mislabeled (donor)

The proposal addresses concerns about making policy clear and consistent among donation types and donors and recipients as well as to align OPTN requirements with CMS regulations where possible. Several items that will be better aligned with CMS are OPO responsibilities for deceased donor organ recovery; timing of living donor organ recovery verification; and having the transplanting surgeon be part of the final pre-transplant verification. The proposals contains a comparison between the current and proposed OPTN requirements and CMS regulations.

Committee members are presenting the proposal at various committee and regional meetings and collecting feedback for consideration before taking this proposal to the Board for consideration in November 2014. Overall, the proposal has received support with conditions that specific questions or issues be addressed. These include:

- questions surrounding the requirements for organ recovery verification; particularly if recipients are unknown
- support for the concept of organ check-in but concern that it may need to be more specific
- concerns that any deviation from CMS requirements or additions would be too much regulation
- questions regarding whether requiring a match be rerun when the organ is not allocated on the initial match would be in conflict with liver policy
- other miscellaneous comments related to labeling and source documents

The Committee will review all comments received and provide responses.

2. <u>Collective Wait Time Transfer</u>

Public Comment: *Fall 2014 (estimated)*

Board Review: *June 2015 (estimated)*

Current OPTN Policy provides a specific mechanism using an individual Wait Time Transfer Form when a transplant candidate wishes to transfer primary waiting time from one transplant hospital to another. When transplant programs go into long-term inactive status, close, or have their membership terminated, a significant cohort of patients needs to be transferred. With the individual transfer process, the OPTN Contractor manually processes individual forms, each taking up to 30 minutes to complete. This method may not be the most efficient or safe method. Individually transferring large numbers of patients creates a data entry backlog with potential for delayed entry, missing patient forms, and delayed transplant opportunities.

In one instance, a hospital and all its transplant programs closed in December 2011 leaving over 400 candidates without access to services. Subsequently, another hospital started transplant services in early 2012 to serve the area which otherwise had no providers without requiring travel to the U.S. mainland. To restore and expedite their opportunity for transplant, a request was made to process these candidates as a group rather than individually. Consents were obtained and documented by the active transplant hospital and list of these patients provided to the OPTN. An information technology solution to transfer these patients collectively was employed substituting the new program's 8-character OPTN center code (e.g., ABCD-TX1) from the closed program. This effectively and efficiently transferred the entire candidate record, including waiting time. The OPTN Executive Committee approved waiving a second registration fee at the new program. This situation required special considerations and highlighted the need to address these types of circumstances in policy. The Committee's proposal would codify the authority and requirements to perform collective transfers.

The Operations and Safety Committee has been leading a work group with representatives from the Transplant Administrators, Transplant Coordinators, and Patient Affairs Committees and staff from the Membership Department and Organ Center, which provide assistance during program closures, to address this concern. This work group also developed a resource tool kit to help answer common questions, share effective practices, and highlight current requirements when transplant programs inactivate long-term or close. A proposal to add policy authorizing large scale wait time transfers and to amend the bylaws section dealing with programs entering long-term inactive, withdrawal, and termination status has been drafted. The draft proposal would necessitate a written agreement between the closing and receiving transplant hospital with certain requirements and acknowledgements of specified responsibilities. The agreement would be provided to the OPTN contractor and a collective wait time transfer executed as opposed to processing forms individually.

The Committee presented the draft proposal to the MPSC in March 2014 to gather feedback. MPSC questions involved preserving patient choice, allowing for transfers to multiple programs, and managing appropriate patient status and need for medical evaluation at the receiving program.

At the most recent Committee meeting in April 2014, the Committee discussed these questions and the draft proposal in general. The draft language would require the closing hospital to meet existing requirements, which include written notification to patients advising of the option to transfer to another program. The Committee's intent has always been to allow bulk transfers of patients to more than one program, and

the draft language was modified to make that possibility clearer. The draft language specifies that the receiving hospital is responsible for evaluating the transferred patient to assure that the patient meets that program's criteria. This concept is also stressed in materials being developed for a tool kit to assist transplant hospitals and their patients.

The Committee debated how best to manage status at transfer and responsibility for placing candidates into an inactive status. Three options were posed including: whether this could be done by the closing center; by the OPTN Contractor if specified in the agreement; or by the accepting hospital post-transfer. It was noted that while the closing hospital may have more time, it was not desirable to give them responsibility. It was decided to keep the draft language as originally proposed, which would place this responsibility for placing candidates in an inactive status as appropriate with the receiving hospital.

The Committee discussed adding a timeliness component to assure appropriate medical evaluation occurs within a reasonable time frame. Difficulties in proposing a standard timeframe were mentioned as volume of transferred patients and capacity at the accepting hospital may substantially differ across closings. Cases were noted where patients have not been evaluated by a new transplant program in a timely fashion, or there have been significant differences in time to evaluation based on place of transfer. The Committee debated options on ways to provide some level of assurance by the closing transplant program that patients were being timely transferred, such as a monthly call or report to UNOS. Committee members agreed that requiring a status report be made to the OPTN Contractor would make transplant hospitals more cognizant of operations. The Committee proposed adding language requiring the receiving hospital to develop and submit a plan for evaluating the transferred patients and providing periodic status reports to the OPTN Contractor. Once this additional language is drafted, the Committee will reconsider the proposal at its June 2014 meeting.

3. <u>Modify or Eliminate Internal Vessel Label</u>

Public Comment: *Fall 2014 (estimated)*

Board Review: *Spring 2015 (estimated)*

Following a recommendation from the former Ad Hoc Organ Tracking Committee working on the Electronic Tracking and Transport (ETT) project, the Operations and Safety Committee is examining issues with vessels labeling. The sterile internal vessel label is frequently cited as a problem with the current labeling system. This very small label must completed in the sterile field where the sterile pen may run and make marking the label illegible. Up to 20 data fields must be handwritten. The internal label must be filled out in the sterile field using source documentation for infectious disease results is often not as accurate as the plastic vessel label on the outermost triple sterile barrier, which can be filled out in an easier setting. Policies require that vessels packaged separately from an organ be protected by a triple sterile barrier, one of which must be a rigid container. Both the container and outermost barrier must have the OPTN standardized label. This issue ranked as the 6th highest failure mode identified during the Failure Modes Effects and Criticality

Analysis (FMECA) conducted by Northwestern University on the current deceased donor organ procurement process as part of the ETT project.

The Operations and Safety Committee reviewed data related to vessels labeling and packaging safety situations, disposition of extra vessels, and site survey compliance. These data have been shared with the ETT subcommittee and internal vessels label subgroup. Eleven safety situations involving the packaging and labeling of extra vessels were identified between 2006 and 2013. Three events occurred prior to the policy change in January 2011 requiring use of a standardized vessels label. Two of the three events involved missing labels. One error involving erroneous HCV results occurred prior to the February 2012 policy change that required use of both the sterile container label and the poly-plastic internal label on the outermost triple sterile barrier. Errors post February 2012 involved improper packaging (n=4), missing labels (n=2), and transcription error on label (n=1).

The Committee reviewed data from a previously conducted study on vessels disposition from 2008-2010. Of 21,140 extra vessels recovered in this period, 12.5% were used in the same recipient that received the accompanying organ. Another 1.7% were transplanted into a secondary recipient. Over one-third (35.7%) were destroyed. Half (50.1%) of dispositions were not reported to the OPTN Contractor. Data updated in 2012 showed less missing disposition reports (42%) but the percentages transplanted into primary and secondary recipients remained the same. Approximately 120 vessels per year are transplanted into secondary recipients.

The Committee discussed data from the Department of Evaluation and Quality (DEQ) site survey audits (June 1, 2012-June 30, 2013). Out of 47 programs audited with extra vessels on hand at the time of survey, 42 (89%) demonstrated compliance. Issues related to vessels were missing rigid sterile container label (n=1) and missing internal (outer sterile bag) label (n=4).

The vessels ETT subgroup presented the following options in Table 2 (next page) to the full Operations and Safety Committee along with recommendations. The Committee concurred with preliminary recommendations from the sub group and added the last option during the meeting deliberations.

Table 2: Vessels Label Options

Option	Discussion	Recommendation
Change rigid sterile container label to identifying info only	• Option to include only Donor ID, ABO, date and omit infectious disease results. • Less writing but maintains identification for safety purposes. • Reduces chance of error for discrepant results between labels. • Concerns if poly plastic gets lost during transplant process re: lack of information for relabeling. • Concerns if not stored in triple sterile barrier and need in ER situation may not have time to access DonorNet for info • Not trusted as source documentation for infectious disease results	Under consideration
Package all vessels separately	• Vessels less likely to be unpackaged unless used • Organs may be shipped accidentally without vessels causing unavailability at surgery • Additional OPO time and packaging burden	Do not support this option
Education of storage of vessels	• Ongoing need regardless of solutions proposed • Need for OPOs to educate transplant hospitals on repackaging	Support this option
Eliminate rigid sterile container label	• Some type of label needed to reduce risk of inability to identify vessels especially if poly plastic label lost. • Storage in triple sterile barrier storage-in policy but not done always in practice.	Do not support this option
No changes	• Some changes needed	Do not support this option
Discard vessels if unpackaged in OR. Only store extra vessels that remain intact in triple sterile barrier	• Raised as possible option at OSC meeting • Difficulties in educating OR staff and effecting proper repackaging acknowledged • Need to distinguish chain of custody • Will continue to discuss within subgroup	Under consideration

4. <u>Electronic Tracking and Transport Project</u>

Public Comment: *Spring 2015 (estimated)*

Board Review: *November 2015 (estimated)*

The Electronic Tracking and Transport (ETT) Project is a task under the current OPTN Contract. The goal of this project is to create a stand-alone application used with a portable tablet and printer to facilitate labeling and tracking of organs. The

Operations and Safety Committee continues to be a resource providing feedback and guidance through both the ETT subcommittee and full Committee during project development. Voluntary usage will not require policy change; however, the Committee will consider development of proposed policy for mandatory use after beta testing is complete.

Five OPOs participated in the original pilot and the same organizations have been conducting field-testing on a staggered scheduled starting in August 2013. Participants include LifeNet Health (VA), Life Source (MN), California Transplant Donor Network (CA), LifeLink of Georgia (GA), and the Living Legacy Foundation (MD). Over 250 organs have been recovered using the ETT in field-testing. After each case, OPOs complete a survey giving feedback to ETT project staff.

Data related to preliminary findings from field-testing survey results were shared with the ETT subcommittee and the Operations and Safety Committee. The survey measures perceptions of ETT use and whether it makes processes safer and more efficient for the surgical recovery (OR) and donor management (ICU) phases. Out of 156 responses, 129 (83%) indicated that they strongly agree or somewhat agree that ETT makes the OR phase safer. There were 16 (10%) responses of strongly or somewhat disagree with this statement. The mean score on a scale of 1 (strongly disagree) to 5 (strongly agree) was 4.28 for this question. Out of 155 responses, 118 (76%) strongly or somewhat agreed that ETT was more efficient and 22 (14%) strongly or somewhat disagreed. The mean score was 3.98. Variability in scores was observed among the five participating OPOs with mean scores ranging from 3.2 to 5.0 (safer) and 2.9 to 5.0 (more efficient).

Out of 53 respondents, 49 (92%) strongly or somewhat agree that using ETT was safer than their regular process in the ICU phase. Forty-eight (48) or 91% strongly or somewhat agree that using ETT was more efficient in the ICU phase. There was less variability in OPO scoring on ICU phase surveys. Comments both positive (e.g. “much quicker and safer”) and negative (e.g. “had to wait for another (OPO) staff as hospital unwilling to be 2nd person for verification”) were reviewed. Results reflect survey data received as of February 21, 2014. Final data when available will be shared.

The ETT subcommittee debated requests on continued application use until beta testing starts. The majority of members supported not losing proficiencies gained between testing phases although one member had concern over potential risks associated with using a test product outside of field-testing. The subcommittee did recommend allowing continued use with the stipulation that a waiver be signed to acknowledge known and potential unknown bugs as well as responsibility for equipment. Field-testing will be extended on a voluntary basis and participating OPOs will sign waivers acknowledging potential risks and responsibilities.

Development of the ETT version for beta testing is now underway and expected to be complete by August 2014. Beta testing will start in September 2014 following training. Beta testing will involve the original five OPOs as well as three additional OPOs and associated transplant hospitals. Beta testing will include new testing components: transplant hospital printing of recipient ID bands, a bar code scan at organ check in and a bar code scan in the operating room between the recipient and

organ received. Following successful beta testing, an application is planned to be available for voluntary OPO national deployment.

5. Developing a System to Review and Share Safety Event Data

Project Approval: *June 2013*

Board Review *N/A*

The Committee continues to work on ways to systematically review, analyze, and share patient safety event data with the goal of sharing lessons learned, identifying and addressing systems issues, and preventing adverse events. The Committee is using multiple tools to present and share safety data including patient safety news articles, patient safety alerts for issues meeting specified criteria, presentations at professional society meetings, regional meeting presentations, and instructional events. The Committee continues to review aggregated safety situation event data every six months. Highlights from the data review along with a link to the full report are published in the Patient Safety News. The Patient Safety Advisory Group is also proceeding with development of a potential manuscript on the history of safety reporting within the OPTN.

The Committee presented this project to the Membership and Professional Standards Committee (MPSC) at its March meeting. After each MPSC meeting, members will be asked to refer safety topics to the Operations and Safety Committee. The Committee will work to develop educational strategies to address issues. Each year one instructional event will be devoted to a topic identified by the MPSC and one instructional event will address top safety reporting areas.

The Operations and Safety Committee most recently developed a Patient Safety News article and regional meeting slides devoted to the topic of safety in living donor evaluations following a request from the MPSC. Several living donation cases have occurred where infectious disease test results have been available but overlooked with resulting disease transmission or near-misses of disease transmission.

6. Patient Safety Newsletter

Projected Board Review: *N/A*

The Committee continues publishing “Patient Safety News” articles. Articles are now published on a real-time basis. These articles cover a variety of topics as relevant including features about patient safety situation reports, transplant hospital strategies to deal with common problems, timely changes such as the new PHS Guideline, and other focused topics such as extra vessels. The monthly Transplant Pro newsletter provides links to relevant articles. With 271 hits, “Patient Safety News” was the fifth most frequently accessed article link last year (2013). In April 2014, the article on living donor evaluation potential fail point which highlighted the need and possible solutions to avoid overlooking required test results had received 198 hits as of April 23, 2014.

Between December 2013 and April 2014, the following “Patient Safety News” articles and alerts were published in collaboration with OPTN Committees and staff:

- Apr 8, 2014: Patient Safety Alert: Hospira recall of irrigation/drainage sets
- Mar 26, 2014: Potential Failure Point Identified in the Evaluation of Living Donors
- Feb 26, 2014: 2013 PHS Guideline resource document available for transplant centers and OPOs
- Jan 27, 2014: DiaSorin EBV Testing Kit has Potential to Produce False Negatives

Committee Projects Pending Implementation

7. Modify Patient Safety Situation Reporting Portal

Public Comment: *N/A*

Board Approval: *November 2012*

Projected Implementation: *May 2014*

Enhancements to the patient safety situation portion of the Improving Patient Safety portal are in development. Enhancements include:

- More options to describe and provide specifics on reports
- Improved and increased high-level description categories (7 to 10)
- New subcategory description choices under each high level category
- Additional information will be collected relevant to the event including:
  - Who/what is involved (candidate/recipient, donor organs/extra vessels, or other)
  - Candidate/recipient or donor ID will be collected as appropriate
  - Specific organs impacted (all or choice of individual organs)
  - Impact of situation on organs (not recovered, delay in transplant, discard)
  - Whether root cause analysis has been done
  - Contact information
- Easier access for searches

8. Improvements to Vessels Disposition Reporting

Public Comment: *Spring, 2012*

Board Approval: *November 2012*

Projected Implementation: *April 2015*

When programming for the extra vessels disposition electronic reporting form is completed and released, then policy approved to require reporting within 7 days will go into effect.

9. Clarify Data Entry Screens for A2 and A2B in UNet[sm]

Public Comment: *N/A*

Board Approval: *November 2011*

Projected Implementation: *April 2015*

Implemented Committee Projects

None

Review of Public Comment Proposals

The Committee has finished its review of one of the 17 proposals released for public comment from March – June 2014. The Committee will continue reviewing proposals at its June meeting.

10. DTAC Public Comment Proposal: Proposal to Align OPTN Policies with the 2013 PHS Guidelines for Reducing Transmission of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C (HCV) Through Solid Organ Transplantation

The Committee heard a presentation on this public comment proposal. Issues regarding the balance of additional testing requirements (NAT) versus constricting the donor pool due to false positives, cost of additional testing, access to testing, and additional time required to complete testing that would be required by this proposal were noted. These issues were raised as requiring HCV NAT in all donors will likely result in NAT testing for all three infectious diseases (HCV, HBV, and HIV) due to real world practice and use of triplex testing.

The Committee voted to support the proposal (6 in favor, 2 opposed, 5 abstentions).

Other Committee Work

11. Patient Safety Data Review

The Operations and Safety Committee reviews aggregate data related to patient safety situation reports every six months to identify trends and patterns. The analysis guides recommendations to address gaps and systems issues identified that impact patient safety.

Data from the report "Trends and Patterns in Patient Safety Situations Reported to the OPTN through December 2013" are available in **Exhibit A.** In 2013, a total of 214 reports were received. An increase was observed in online reporting from 99 in 2012 to 119 in 2013. A decrease was observed in reports received through other pathways (e.g. email, phone) from 114 in 2012 to 95 in 2013. This resulted in a net increase of only one additional safety situation report between 2012 and 2013.

Overall, the most frequently reported events were related to communication (23%), testing (16%), organ allocation/placement (13%), transplant process/ procedure

(13%) and data entry (12%) issues. Table 3 (next page) outlines the most frequently occurring data by high level and subcategory level.

Table 3: 2013 High Level Category and Most Frequent Subcategory Reports (n > 3)

High Level Category	Subcategory	Number of reports
Communication	Delayed communication	17
	Inaccurate/insufficient donor or organ information	16
	Delay in potential disease transmission reporting	7
	Miscommunication of donor test results	4
	Increased risk (high risk) status of donor	4
Testing	HLA-discrepant results	8
	Infectious disease-hemodilution error or discrepancy	10
Allocation	Out of sequence allocation	8
Transplant process	Vessel sharing	10
	Complaint about listing practices	4
Data Entry	DonorNet-HLA	6
Labeling	Donor ID-incorrect ID	8
	Blood/nodes/spleen	8
	Switched laterality-kidney	4
Recovery process	Injury to organ or extra vessel	4
	Poor donor management	4
	Issue with recovering transplant team(s)	4
Packaging/shipping	Switched laterality-kidney	6
	Not packaged according to requirements	8
Other	Events related to a potential disease transmission	17
	Living donor issue (other)	8

Over 80% (47 of 58) of OPOs reported or were involved in a safety situation between 2012 and 2013. Among transplant hospitals, 44% (109 of 250) reported or were involved in a safety situation. An estimate of underreporting was prepared for this report based on a previous data request. Reviewed literature indicates that estimates of underreporting in safety systems range from 5% to 15%. Based on current reporting, it was approximated that as many as 3,300 transplantation-related safety events may have occurred during 2012-2013 and that the 427 events reported represent approximately 13% of what may be the true number of incidents.

Of the 56 safety situations reported through the online portal during the second half of 2013, at least 9 or 16% resulted in an organ discard according to information provided. Thirteen discards were noted in the Organ Center transportation data between October 2013 and March 2014. Three living donor organs were non-utilized but not all of these were due to process errors.

In addition to safety situation reports, other summary data related to transportation failures, living donor adverse events, and disease transmission were reviewed. The Committee is working to bring all types of safety data together to examine the big picture across data sources. Forty living donor adverse events reported to the Living Donor Adverse Event portal (2012-2013) were included in the report and presentation. A high-level summary of Disease Transmission Advisory Committee

(DTAC) cases was also presented although only a portion of these may involve actual process issues. Transportation data from the Organ Center was reviewed which tracks failures (did not make to original destination in time for intended recipient) and near misses (delays of two or more hours). During October 2013-March 2014, 984 organ transports were facilitated by the Organ Center resulting in 17 (1.7%) failures and 30 (3.1%) near misses due to various types of transportation issues.

Improving reporting quality, use, and participation continues to be discussed by the Committee. The need to perhaps distinguish between process and safety issues was debated. It was mentioned that using the term "safety" might cause an unnecessary flag on an event. One member noted that underreporting is likely tied to an institution's philosophy on reporting. Several members described ways that process or safety incidents are handled internally (e.g. review by internal medical advisory board, direct contact with OPO) and that members need a benefit to voluntarily reporting to the OPTN. Removing punishment and fear as part of the reporting system remains an important concern.

The need and benefit to giving data back to the community continues to be part of the Committee mission as reflected in the Sharing Patient Safety Data project. The Committee acknowledged the usefulness of the data and subcategories to stimulate internal quality process discussions. It was noted that no further cases of vessels use in non-transplant procedures have been reporting following the patient safety alert. No specific data alerts or trends were identified for further immediate action. The Committee will publish a Patient Safety News article with the most recent findings. The Committee will continue to use this analysis in Sharing Patient Safety Data project initiatives.

Meeting Summaries

The committee held meetings on the following dates:

- December 3, 2013
- January 7, 2014
- January 21, 2014
- April 8, 2014

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

FINAL REPORT

OPTN Operations & Safety Committee *Descriptive Data Request*

TRENDS AND PATTERNS IN PATIENT SAFETY SITUATIONS REPORTED TO THE OPTN THROUGH DECEMBER 2013

Prepared for:
Operations & Safety Committee
Committee Meeting
April 8, 2014

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EXECUTIVE SUMMARY

The OPTN Operations and Safety Committee (OSC) has a standing request for semi-annual updates to analyze trends and patterns in patient safety situations reported to or identified by UNOS. This report includes events reported to the "Improving Patient Safety" (IPS) online portal located in Secure Enterprise℠ and events reported to or identified by UNOS through other communication channels.

A total of 214 patient safety situation reports were received in 2013. The increasing trend in the number of reports submitted through the IPS continued in 2013, as 119 safety situations were entered into the system. An additional 95 safety situations came through other reporting pathways such as emails/letters to UNOS (**Figure 1**).

This report summarizes safety situations reported into the IPS or through other pathways using high-level and detailed subcategories that have been proposed as checkboxes as part of the OPTN board-approved enhancements to the IPS. This summarization revealed that 23% of safety situations involved a **breakdown in communication**. Many other safety situations involved **testing issues** (16%), **organ allocation/placement issues** (13%), **transplant process/procedure issues** (13%), and **data entry issues** (12%). Events related to **labeling** (10%) or **packaging/shipping** (10%) problems were not uncommon. (**Figure 6**)

The more granular subcategory analysis revealed that nearly one in three communication issues pertained to inaccurate or insufficient information about a donor or organ/vessel. Delayed communication and miscommunication about the increased risk ("high risk") status of a donor were also relatively common. Testing issues most often involved either a hemodilution or HLA discrepancy. Errors entering data into DonorNet, in particular for HLA, continue to be reported. Labeling issues became less prevalent, though incorrect Donor ID's continue to be a problem, in particular on tubes used for shipping diagnostic materials (blood, nodes, or spleen).

Data included in this analysis is based on what was reported to UNOS; it does not incorporate information from subsequent inquiry or investigation after the initial report by the member. Thus, this report should be considered an analysis of "front-end" data, not "back-end" data. For example, information about the root cause of each event and whether any policy violations actually occurred was not included in this analysis.

BACKGROUND/PURPOSE

The OPTN Operations and Safety Committee (OSC), along with its Patient Safety Advisory Group, previously reviewed de-identified, summarized patient safety situations (including both adverse events and near misses) submitted into UNet's Improving Patient Safety portal as a "safety situation." Based on the narrative provided, the events reported through December 2013 have been categorized using relevant keywords (e.g., packaging & labeling, data entry error, transportation). Previous reports have shown the distribution of reported

BACKGROUND/PURPOSE

events by category and subcategory, as well as time trends. The purpose of these analyses is to help the committee better understand where safety gaps may exist in the system and to proactively address high frequency and/or high impact events with system improvements. The committee also hopes to use this information to increase awareness of the types of safety situations that are happening in order to spur institutions and individuals to take proactive measures to prevent repeat occurrences.

Since this database is currently still maturing and undoubtedly suffers from some degree of underreporting, the purpose of analyzing these data at this time is not to estimate the true, underlying error rates but to determine if certain types of events are becoming more frequent and thus identify area(s) where the OPTN would benefit from system improvements. Consequently, this analysis is primarily intended to help the committee understand what is currently being reported, increase the transplant community's awareness of the types of safety events that are occurring, foster increased reporting by the transplant community, and guide evolving refinements to the IPS portal.

This request is an update to previous analyses and has becoming a standing, semi-annual request of the OSC.

WORK PLAN ITEM ADDRESSED

1) Develop and implement a system for review of de-identified adverse events or near misses reported to the OPTN in order to identify potential network improvements and policy revisions necessary to prevent future occurrences.

2) Explore ways to disseminate information to the transplant community regarding outcomes of reported adverse events or near misses in an effort to heighten awareness of safety within the transplant community.

COMMITTEE REQUEST

Perform trends and patterns analysis of patient safety situations reported to UNOS, using the categories and subcategories developed by in previous analyses and discussions with the Patient Safety Advisory Group and scheduled for implementation into the online Improving Patient Safety portal.

Updating this analysis on a semi-annual basis is a standing committee request of the OSC. The analysis will be updated in early 2014, to include all events reported through 2013, in advance of the Spring OSC meeting.

As discussed in committee deliberations on September 24, 2013, this analysis will be expanded to provide insights, where possible, into the degree of underreporting of different types of events, by:

COMMITTEE REQUEST

1. Analyzing rates of reporting by (deidentified) transplant programs and OPOs, to determine the number of institutions that have never reported any events, and whether a few institutions account for a disproportionate number of reports.
2. Consider certain subtypes of events – e.g., transportation failures, match not rerun after serology found to be positive – for which other, more complete data sources are available for comparison.

DATA AND METHODS

Data Sources:

This analysis included patient safety situations reported into the Secure Enterprise[SM] Improving Patient Safety (IPS) portal between March 7, 2006 (IPS implementation date) and December 30, 2013. Currently, reporters submit detailed information about the safety situation primarily by means of a free-form (unrestricted text) narrative. Often these narratives are quite lengthy. Reporters do not have the ability to select meaningful event categories that would streamline the data analysis and tracking process.

In addition to safety situations reported though the IPS portal, this analysis included review of safety-related issues identified via other reporting pathways to UNOS in 2012 and 2013. For example, such pathways included patient and member complaints sent by email, calls placed to the Patient Services line or Member Services line, and process or policy-related issues discovered during Disease Transmission Advisory Committee (DTAC) review of potential disease transmission cases. As with the IPS, these "other pathway" events were categorized by reviewing the narrative of each reported situation.

The narrative associated with each of the over 500 events was reviewed by a UNOS patient safety specialist and/or committee liaison and biostatistician to determine the keyword(s) and categories that best summarize the nature of the event. These categorizations and sub-categorizations have evolved and been refined over time, based on feedback from the Patient Safety Advisory Group. As more events have been analyzed, new categories have been found to be needed. Further refinements will likely be necessary. The nine "high-level categories" (plus "other") being developed as checkboxes for the IPS are as follows:

- ☐ Communication issue
- ☐ Data entry issue
- ☐ Transportation issue
- ☐ Packaging/shipping issue
- ☐ Labeling issue
- ☐ Recovery procedure/process issue
- ☐ Transplant procedure/process issue
- ☐ Testing issue

COMMITTEE REQUEST

- ☐ Organ allocation/placement issue
- ☐ Other

An extensive list of subcategories and sub-subcategories (e.g., Data entry issue → DonorNet® → ABO) under each of these high-level categories is being developed for IPS reporting.

Each situation was categorized into one *or more* high-level categories, as well as possibly one or more subcategories. Previous reports showed the high level categorization breakdown from 2006-2011; this report focuses on high-level and subcategorization of events submitted since January 2012. About 70% of the IPS situations fell into strictly one high-level category, while the remaining 30% were considered to belong to more than one category. Only 5% of IPS situations fell into more than two high-level categories. About 84% of situations from 'other pathways' were classified into a single high-level category, while 16% fell under two or three high-level categories.

This analysis excluded events reported through the IPS portal that were clearly not related to patient safety (e.g., user difficulty using UNet℠ that was resolved without impact on safety) or were duplicative of another entry (e.g., several OPOs reported a recall of the same chest tubing). This analysis did not include events reported to the Potential Disease Transmission portal within the IPS.

Living donor adverse events that are required reporting per OPTN policy are generally reported through the IPS's Living Donor Adverse Events portal. Some events also pertaining to living donors are reported through the Safety Situation portal. This analysis includes both types of events.

For tracking trends in event reporting over time (**Figure 1**), IPS events were sorted using the date the event was added to the system ("add date"). "Other pathway" events were sorted using the date the incident report was received by UNOS staff.

This report focuses on events reported since January 2012. Since only the events in 2012 and 2013 have been manually categorized using the latest iteration of the proposed categorization scheme for the enhanced IPS, trends by category/subcategory were not included in this report. Including such trends would require a manual re-review and re-categorization of all 300+ situations reported to the IPS from 2006-2011.

In the sub-analysis that assessed the degree of underreporting to the OPTN patient safety system, a few events involved errors at both an OPO and a transplant hospital and were thus included in both the OPO and transplant hospital analyses. Since less than 10% of events were reported by or involved other institutions, such as histocompatibility labs, inference on underreporting was not performed for events involving these other institution types.

COMMITTEE REQUEST

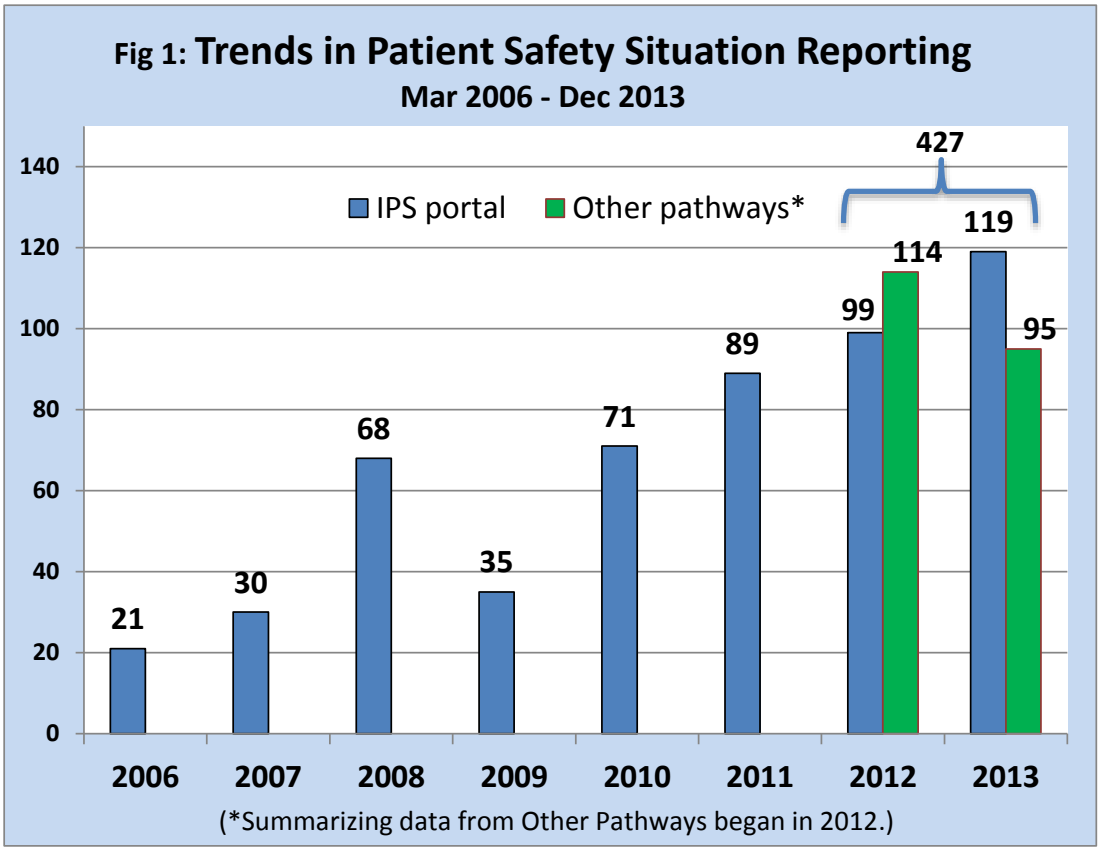
RESULTS

Overall Trends in Safety Situation Reporting

Figure 1 shows that 314 events were reported into the IPS from March 8, 2006 – Dec 31, 2011, 99 in 2012, and 119 in 2013. In general, the rate of reporting through the online portal has been increasing, with the exception of a decrease in 2009.

Figure 1 also shows that 114 additional events were identified in 2012 and 95 in 2013 through other reporting pathways besides the IPS. For example, "other pathways" include emails, calls, or letters to UNOS; patient complaints; and incidents identified by other UNOS departments. The Operations & Safety Committee started reviewing situations from other pathways in 2012.

Figure 1. Safety Situations Reported (2006-Dec 2013) to the UNet "Improving Patient Safety" Portal and Situations Identified through Other Reporting Pathways since 2012

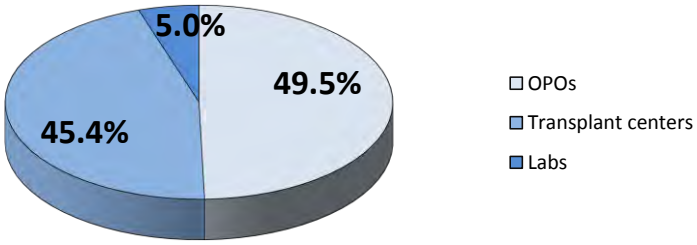


Reporting by Institution Type

Figure 2 reveals that just about half (49.5%) of the events reported to the IPS were reported by an OPO; transplant centers accounted for 45.4% of reports and labs the remaining 5.0%. By comparison, from 2006-2011, OPOs accounted for 55.7% of events and transplant hospitals 37.3%.

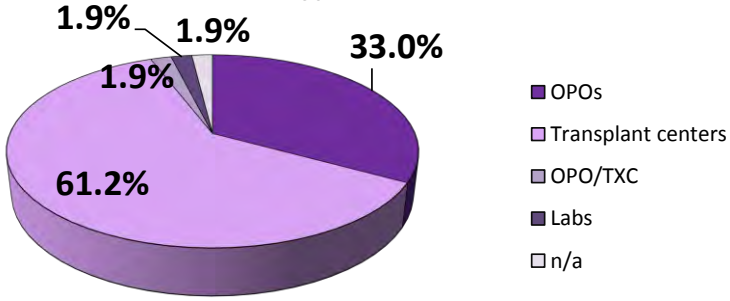
Some events occurred at the institution reporting the event, whereas for other events, one institution reported about an issue related to a different institution. For example, OPOs have reported concerns with a recovering transplant team; likewise, transplant centers have reported concerns about organ damage allegedly caused by an OPO during the recovery process.

Fig 2: IPS Safety Reports by Institution Type, 2012 - 2013



Situations from other, non-IPS pathways were categorized differently – by the type of institution involved, not by reporting institution. **Figure 3** reveals that for situations identified through other pathways, the majority (61.2%) involved a transplant center, while 33.0% involved an OPO. A small percentage of situations involved both a transplant center and an OPO, or a lab.

Fig 3: "Other Pathways" Safety Reports by Institution Type, 2012 - 2013



Reporting by Event Type (High-Level Category): 2012 – 2013

Figure 4 shows the high-level category frequencies in 2012-2013 for safety situations identified from both the IPS and other pathways.

Overall, the most frequently reported events were related to communication issues (23%), testing issues (16%), organ allocation/placement issues (13%), transplant process/procedure issues (13%), and data entry issues (12%).

Figure 4. Patient Safety Situation Reporting by Other Pathways, by Event Type (High-Level Category), 2012-2013

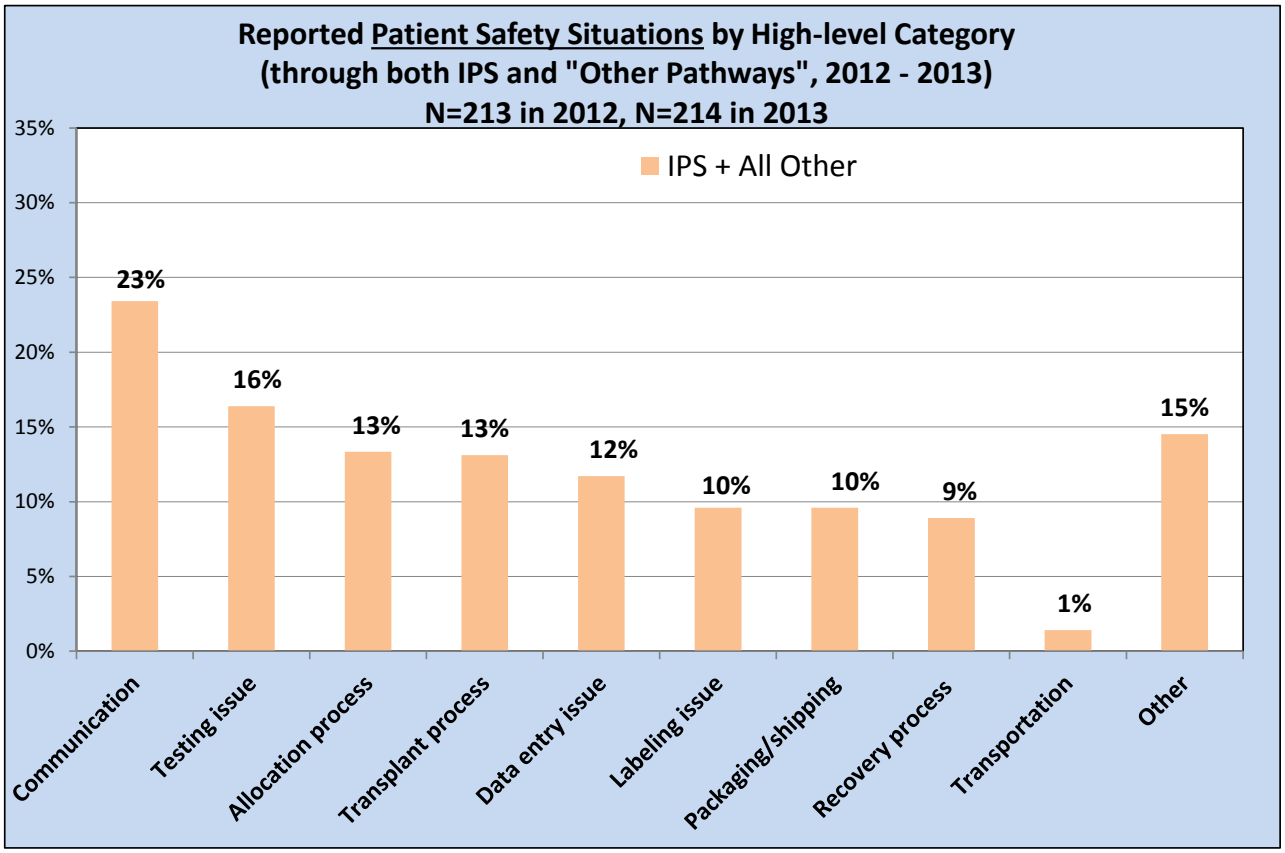


Figure 5 shows that between January 1, 2012 and December 31, 2013, the most common type of safety situations reported to the IPS were communication issues. In 2012, 29% of reported events involved a communication problem; this dropped modestly to 22% in 2013. Testing issues (21%), labeling issues (13%), and packaging/shipping issues (17%) were also relatively common in 2013.

Though 17% of reported safety situations in 2012 involved an electronic data entry issue, only 11% of reports related to a data entry issue in 2013. Other high level categories and their 2013 proportions were as follows: organ allocation/placement (10%), recovery procedure/process (10%), transplant procedure/process (7%), and transportation (3%). About 10% of situations did not fall into one of these nine high level categories and were labeled as "other."

Figure 5. Patient Safety Situation Reporting in Improving Patient Safety Portal, by Event Type (High-Level Category), 2012 vs. 2013

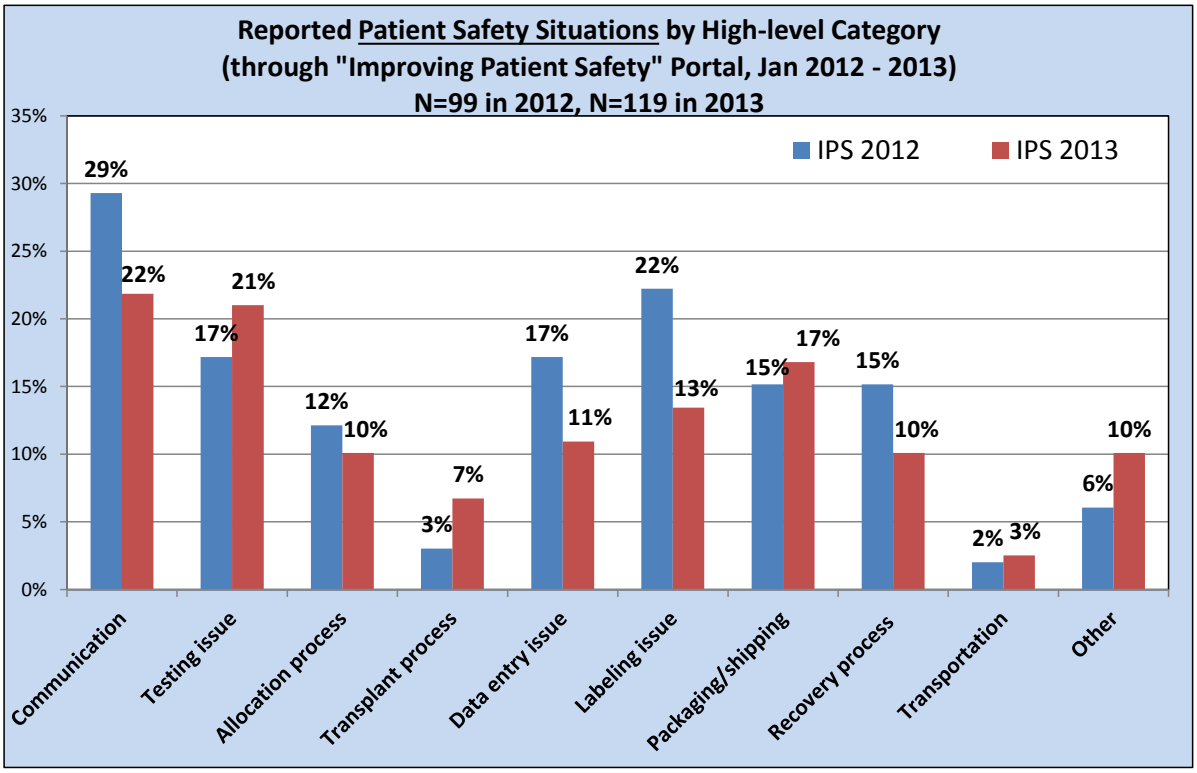
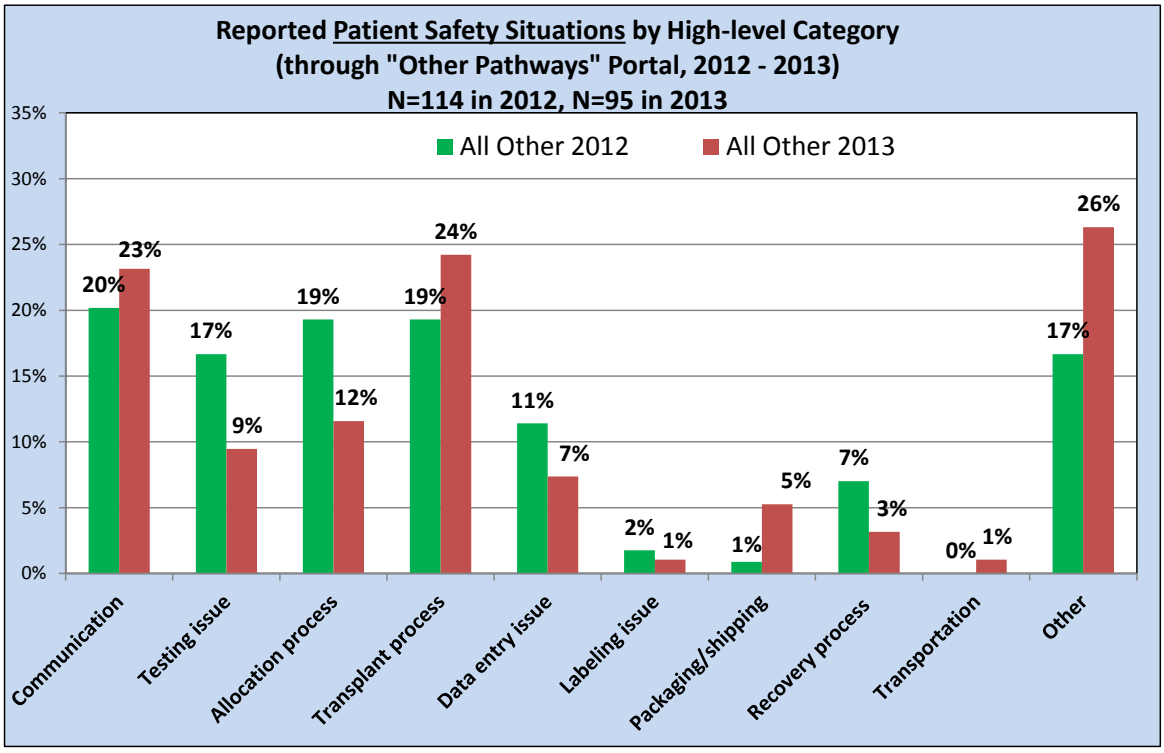


Figure 6 shows that, as with the IPS, the most common type of safety situation reported through "other pathways" in 2012 and 2013 was a communication issue.

Labeling issues accounted for just 1% of events reported through other pathways, a stark contrast to the 13% of reported events involving labeling problems in the IPS in 2013. Complaints about organ allocation/placement and transplant procedures/processes were relatively common in other pathway reporting.

Over a fourth of other pathway events did not fall into one of the 9 high level categories and were labeled "other."

Figure 6. Patient Safety Situation Reporting through 'Other Pathways,' by Event Type (High-Level Category), 2012 vs. 2013



Reporting by Event Subcategory (2012 –2013)

The communication issues (N=100) in **Figure 4**, which includes situations reported in 2012 and 2013 through both the IPS portal and other pathways, are categorized more finely in **Table 1**. (Note that since a single event can appear under multiple subcategories, the total number of events may be smaller than the high-level category total.) Thirty (30%) of the one hundred communication-related safety situations involved *inaccurate or insufficient donor (or organ/vessel) information*. Some examples of inaccurate/ insufficient information include the following:

- CT scan of donor kidney with lesion was not made available at time of offer
- stripped ureter not noted on the anatomy
- pumping data not shared
- non-documented capsular tear
- delayed documentation of blood product administration that could cause hemodilution
- information about whether donor was catheterized
- CMV status
- incorrect preservation fluid communicated verbally
- incorrectly communicated donor ABO
- IV track marks
- culture results
- kidney biopsy findings misinterpreted
- time kidney put on ice

Delayed communication (N=30) was the second most prevalent communication subcategory, with *increased risk (high risk) status of donor* (N=10) third most prevalent. Nine situations involved *patient not informed adequately (or at all)*.

Table 2 shows testing issues (N=70) by subcategory. Fifteen (27%) of the 56 testing-related situations involved a concern about donor hemodilution. In most cases, reports revealed that the sample should have been classified as hemodiluted, but the error was not discovered until after transplant, most often during a chart review. Nine situations pertained to HLA testing. Situations also related to the following: *infectious disease cultures not available or not done* (N=5), *important or required infectious disease test(s) not done* (N=5), or *ABO subtyping error or discrepancy* (N=4).

Organ allocation/placement issues (N=57) reported since 2012 were broken down by subcategory in **Table 3**. The majority (N=23) were related to a concern about *out of sequence allocation*. Several pertained to *rescinded offers* (N=5), *recipient not on match list* (N=4), *inaccurate donor data causing match to run incorrectly* (N=3), and *match not rerun once serology found to be positive* (N=2).

Table 4 shows that 21 of the transplant procedure/process-related situations (N=56) involved *sharing of extra vessels* among transplant centers or OPOs. In some cases, justification for the use of shared vessels was not provided by the member. Five cases of an *extra vessel being used in a non-transplant patient* were reported in 2012, with one additional case in

early 2013. Three reports were received about a *recipient not being promptly removed from the waitlist* after transplantation.

Many cases were unique and did not fall into any of the pre-determined subcategories. Several reports were complaints about transplant center practices and competency. Others included a sterile field breach, possible contamination, retained surgical instruments, and donor/recipient compatibility check not performed.

Data entry issues (N=50) were subcategorized in **Table 5**. The most prevalent type of data entry issue involved *entering donor HLA into DonorNet* (N=15). Several types of patient/candidate data entry issues were also relatively common: *inaccurate patient priority or* status (N=7), *ABO subtyping* (N=5), *increased risk (high risk) status of donor* (N=4), and *ABO* (N=4). In three cases, a patient was *removed or inactive in error*.

Table 6 reveals that the most common labeling-related issues (N=41) involved an *incorrect donor ID* (N=21). Oftentimes labeling issues pertained to *unlabeled or mislabeled diagnostic materials (blood/nodes/spleen)* (N=18). Labeling errors were commonly *transcription errors* (N=11). Many of the labeling situations were classified under multiple subcategories. For example, many of the situations with an incorrect donor ID were due to a transcription error on the label used for diagnostic materials.

In seven of the packaging/shipping situations (**Table 7**), the *organs were not packaged according to requirements*.

However, *switched kidney laterality* (N=12) cases were the most common type of packaging/shipping-related (N=27) safety situation. In one case in 2013, the visiting recovery surgeon failed to place a suture/tag on the left ureter to distinguish laterality per the OPO's usual practice. In another case, the courier picked up the wrong package (right instead of left) but there was no indication of a labeling error.

Note that some switched laterality cases were classified as labeling issues (N=6, Table 6) and some as packaging/shipping issues (N=12, Table 7), while two events were classified as both labeling and packaging/shipping issues. One additional switched laterality event involved a data entry error, where the wrong anatomy charts were uploaded into DonorNet (Table 5, in "DonorNet (Other)"). Consequently, there were a total of 16 *switched kidney laterality* cases reported between January 2012 and December 2013. Both kidneys were successfully transplanted in 12 (75%) of these 16 cases, despite the mix-up.

Nine (24%) of the situations related to a recovery procedure/process issue (N=38) involved an *injury to the organ or extra vessels*. An additional nine cases involved an *issue with the recovering transplant team(s)* (**Table 8**), and included the following types of complaints:

- Hand of perfusionist accidentally struck by recovering surgeon's scalpel
- Recovering surgeon accidentally lacerated the heart during recovery
- Surgeon refused to properly package and label organ before leaving OR
- Poor communication about anticipated arrival time for recovery
- Improper form completion

- Lack of cooperation with OPO attempting to photograph labels and packaging
- Pressure by one transplant team for the other to leave the OPO

Table 9 shows a total of only six transportation-related issues, two involving a commercial airline and four involving ground transportation/courier. In one of these cases, the courier took the wrong package. One 2013 report involved a kidney that was destroyed when the airport's pushback tractor ("tug") ran over a box containing a kidney.

Though few transportation-related events have been reported through the IPS or "other reporting pathways," the UNOS Organ Center audits all organ shipments it facilitates. About 3-4% of shipments have been found to be either failures (organ did not reach destination or with a long enough delay to cause the organ to be deemed unacceptable) or "near misses" (delay of 2+ hours but organ still acceptable at intended destination).

All situations not falling into one of the 9 high-level categories were grouped together as "Other issues" and are shown in **Table 10** (N=62). *Extra vessels were not stored properly* in 5 of these other situations.

A large number of these situations (N=30) were classified as *events related to a potential disease transmission.* **This subcategory does not include all potential disease transmission events reported to the OPTN.** Rather, only those events involving a human/process error, such as failure to report, or that were referred to DEQ due to a potential policy violation are included in this report.

Three of the "other" events involved extra vessels: vessels could not be located, vessels erroneously discarded, and vessels shared with a non-OPTN member hospital. Several involved concerns or complaints about a center's listing practices, outcomes, access to transplant, or ability to transfer care. Several others were drug or device recalls. One report involved an internet outage.

Reported Safety Situations by Institution

Figure 7 shows that over 80% (47 of 58) of OPOs reported or were involved in a safety situation between 2012 and 2013. Three OPOs accounted for 12 or more events, whereas eight OPOs reported or were involved in just one event.

Figure 7. Patient Safety Situations by OPO, 2012-2013
Includes both IPS and Other Pathway Events

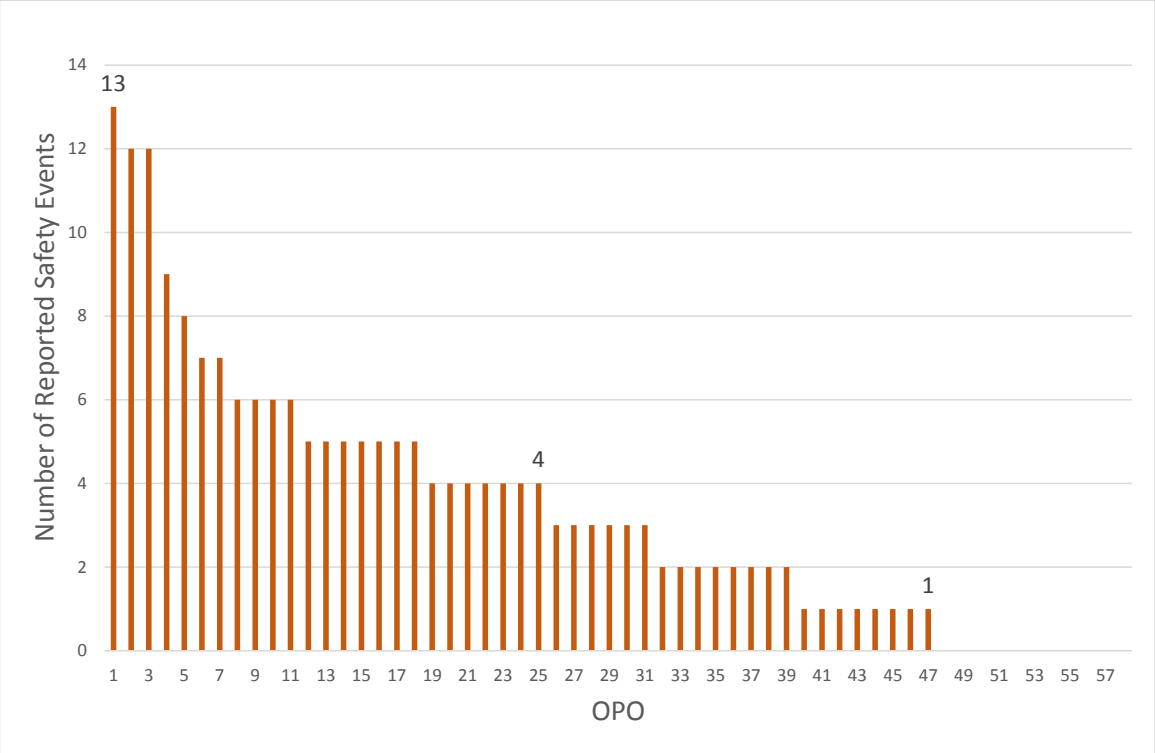
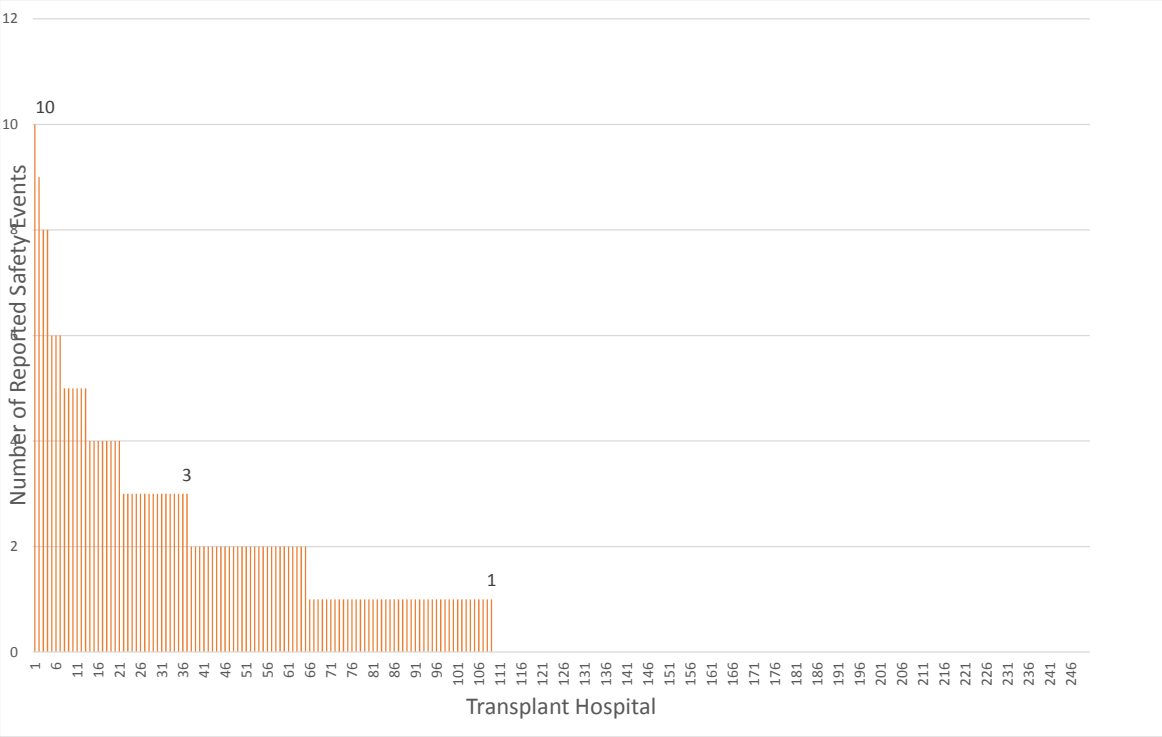


Figure 8 shows that only 44% (109 of 250) transplant hospitals reported or were involved in a safety situation between 2012 and 2013. Four hospitals accounted for eight or more events. Forty-four reported or were involved in just one event.

Figure 8. Patient Safety Situations by Transplant Center, 2012-2013
Includes both IPS and Other Pathway Events



Assessing the Degree of OPTN Patient Safety Situation Underreporting

Relative to the 30 year history of the OPTN, reporting of safety situations is relatively new, with the online reporting mechanism being introduced just 8 years ago. The broadening of the OPTN's role in improving patient safety, per HRSA's guidance, occurred within the last several years and is still evolving. With the exception of certain types of living donor adverse events and potential disease transmissions, reporting through this online portal is voluntary. Based on these and other factors, the Operations & Safety Committee believes that the number of events actually being reported to the OPTN represents a small fraction of the safety situations actually occurring in practice. In other words, the increasing trend in **Figure 1** most likely does not represent an increase in the number of actual safety events occurring in transplantation, but rather reflects increased awareness of the importance of reporting these events and an increased willingness to do so. In turn, the committee requested an assessment of the degree of underreporting of safety situations to the OPTN.

According to two reports[1,2] citing other studies, only about 5% to 15% of safety related events in a healthcare setting are typically reported through incident reporting systems. In the OPTN context, certain types of events may be more likely to be reported than others. For example, unusual and/or high harm events, such as "never events" (e.g., unintentional incompatible transplants; severe organ damage due to human error; wrong organ or laterality shipped) may be more likely to be reported than events considered to be more commonplace or a near miss (e.g., breakdown in communication; data entry error that was immediately corrected; transportation delay but organ still transplanted). Reporting may also be more complete for specific types of situations such as vessel sharing, since policy requires such cases to be reported.

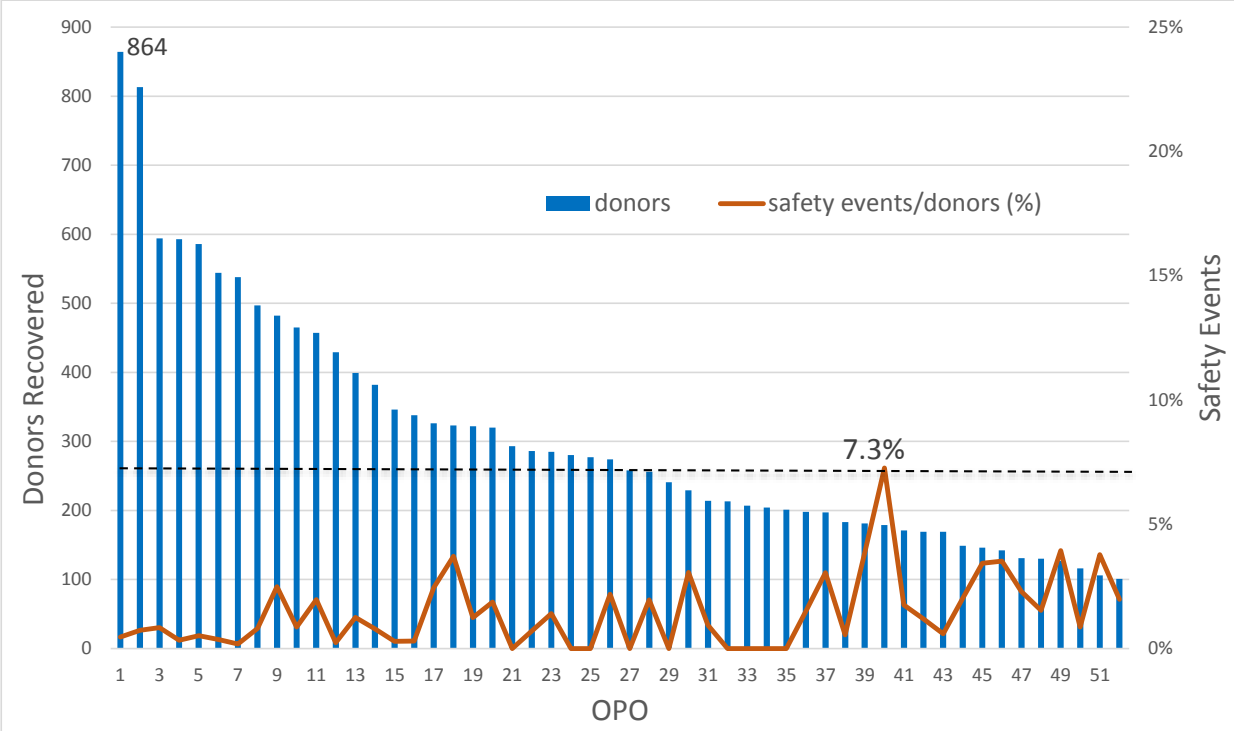
Figures 7 and 8 revealed wide disparities among OPOs and, in particular, transplant hospitals, in the number of events reported by (or involving) each institution. This data suggest that either some institutions have a much greater tendency to report safety situations than others, or some institutions are simply much safer than others and have had very few events. Given the aforementioned rationale for underreporting, and the unrealistic assumption that over 100 institutions have had *zero* safety related events within the last two years, this assessment of underreporting assumes that institutions with zero (or relatively few) reported events are not necessarily safer than others, but rather are unaware or reluctant to report these cases to the OPTN.

Figures 9 & 10 attempt to put the number of events reported (or involving) an OPO or transplant center into context by also showing the number of recovered donors and transplants (deceased + living), respectively, during this two-year time period. The number of recovered donors and transplants performed can be considered to approximate the number of opportunities for human or process errors to occur in an OPO and transplant hospital setting, respectively.

Figure 9 shows the number of recovered donors and the rate of safety event reporting relative to the number of donors for each OPO. (To avoid being misled by random variability due to small samples sizes, only OPOs with more than 100 recovered donors are shown.) The rate of reporting events relative to the number of donors recovered varied between 0% to approximately 7% across the 58 OPOs. This variation might be explained by differences in awareness and willingness to report safety situations, or differences in practices and protocols that may affect the likelihood of events occurring in the first place.

[1] Levtzion-Korach, et al, Integrating Incident Data from Five Reporting Systems to Assess Patient Safety: Making Sense of the Elephant, *The Joint Commission Journal on Quality and Patient Safety*, September 2010, Vol 36 (9).
[2] Vincent, et al, The Measurement and Monitoring of Safety, Health Foundation (UK), April 2013.

Figure 9. Patient Safety Situations and Recovered Donors by OPO, 2012-2013
Includes both IPS and Other Pathway Events

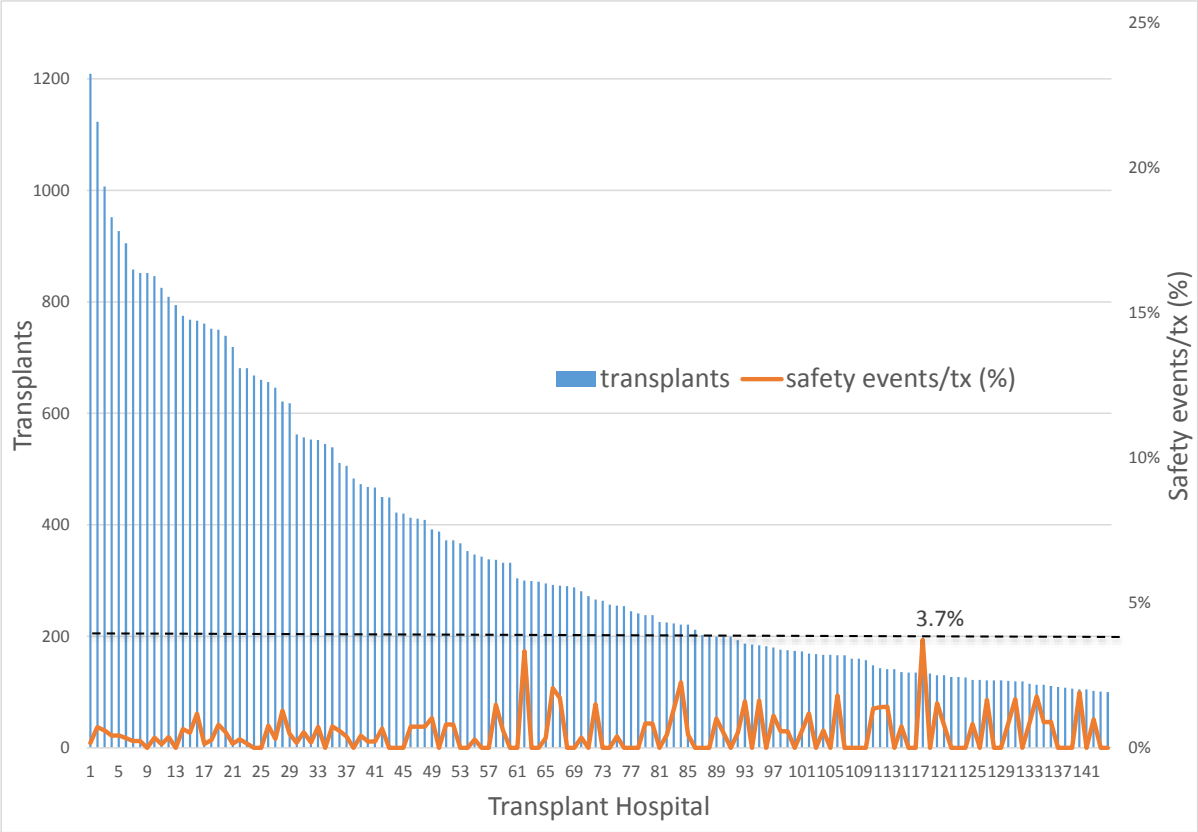


** To avoid being misled by random variability (noise) in safety event rates, only OPOs with more than 100 recovered donors are shown.*

Among OPOs with 100+ donors recovered, one stood out as having the most safety reports relative to the number of donors (7.3%). Under the assumptions that (a) this OPO is reporting all of its safety situations, and (b) all OPOs have approximately the same true error rate, we can infer the number of actual safety situations involving OPOs. Clearly, these assumptions may not be true; however, they are useful for performing this analysis, which is intended merely to approximate the number of events that may actually be occurring. A precise, high-confidence estimate of the number of events that go unreported is not possible.

This analysis was carried out by assuming this 7.3% relative event rate is the true event rate for each OPO, and multiplying the number of recovered donors at each OPO by 7.3%. Based on these assumptions, this analysis suggests that a total of 1,194 safety situations across all 58 OPOs may have actually occurred during this two-year time period. This estimate is a 6-fold increase over the 197 OPO-related events that were reported.

Figure 10. Patient Safety Situations and Transplants by Transplant Center, 2012-2013
Includes both IPS and Other Pathway Events



** To avoid being misled by random variability due to small sample sizes, only transplant hospitals with more than 100 transplants are shown.*

A similar approach was used for estimating the number of total events – reported and unreported – that may have occurred involving transplant centers. Among transplant centers having performed at least 100 transplants during 2012-2013, the highest rate of reported events relative to the number of transplants was 3.7% (Figure 10). Using the same assumptions as for OPOs and applying this 3.7% rate across all transplant centers yielded a total estimated number of safety situations of 2,104. This represents an 8-fold increase over the 263 events involving transplant centers reported during 2012-2013.

(Though the error rate assumed for this analysis was higher for OPOs (7.3%) than for transplant centers (3.7%), this does not in any way imply that OPOs have more safety situations than transplant centers. Rather, these percentages are strictly an artifact of the denominators chosen to approximate the number of error opportunities in an OPO and transplant hospital setting. One could just as easily justify using the number of *organs* recovered, instead of donors, to approximate the number of error opportunities for OPOs. This would markedly reduce the relative error rates but would not substantially alter the number of safety events estimated by this analysis.)

Combining both the OPO and transplant hospital estimates, this analysis suggests that as many as 3,300 transplantation-related safety situations may have occurred in the U.S. during 2012-2013, compared to the 427 safety situations actually reported during this time period. Thus, we estimate that approximately 13% of actual safety events were reported to the OPTN during this time period. Our estimate aligns with reporting rate estimates of 5% to 15% cited in the reports discussed earlier.[1,2] These reporting rates from the literature suggest that while 427 events were actually reported, between 2,800 and 8,500 transplantation-related safety situations may have actually occurred.

Events Resulting in Organ Discard (July – December 2013)

Of the 56 safety situations reported to the IPS in the second half of 2013 (July – December), it was clear from the narrative that organs were discarded as a result of the event in at least 9 (16%) cases. These cases included switched kidney laterality, ice melting during shipping, surgical error during recovery, poor donor management, equipment malfunction, airport pushback tractor ("tug") running over an organ, and difficulty with native organ removal.

Events Pertaining to Living Donors (2012 –2013)

Table 10 also shows several living donor related issues. Three involved an aborted recovery procedure. Eight other living donor related issues were reported either online through the IPS as "Patient Safety Situation" or through "other pathways" such as emails and calls to UNOS. However, other living donor related safety events are reported through the Living Donor Adverse Event (LDAE) portal, which is part of the IPS. Currently, the system is designed to allow reporting of two types of living donor events that are required to be reported per OPTN policy: living donor death, living donor failure of native organ function. Future enhancements to this portal will facilitate reporting of other types of events, such as living donor organ discards or redirections to a different recipient.

To supplement the information included in Table 10, the following table shows data submitted to the LDAE portal in 2012-2013, by event type.

Table A: Living Donor Adverse Events reported through IPS/LDAE Portal 2012-2013

	Donor Type		All	
	Kidney	Liver	N	%
Event Type				
Death	23	6	29	72.5
Redirected organ	3	0	3	7.5
Non-utilized organ	3	0	3	7.5
Other	3	0	3	7.5
Failure of native organ	1	1	2	5.0
All	33	7	40	100.0

It should be noted that most of the living donor deaths shown in Table A were clearly not donation related. (Note that events shown in Table A were not limited to those occurring within 2 years of donation.) Many were, for example, due to automobile or motorcycle accidents, or cancers such as cervical, lung, or pancreatic. For more complete information about living donor mortality, refer to the "Living Donor Deaths within 2 Years of Donation" reported prepared by UNOS for the OPTN Living Donor Committee.

The three redirected organs were cases involving recipient issues which caused surgery cancellation after recovery or shipment (e.g., KPD swap). One involved a case of renal cell carcinoma that was thought to confer a very small transmission risk which was acceptable to one patient but not the intended recipient.

The non-utilized kidney cases involved, for example, renal carcinoma found after recovery, as well as an inadvertent discard of a recovered kidney.

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Table 1: Communication-Related Safety Situations Reported from Jan 2012-Dec 2013 by OPTN Members into the UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory
Interpretation: The most common type of reported communication issue related to inaccurate or insufficient information about the donor (or organ/vessels) (N=30).

Total Number of Communication-Related Situations Reported from Jan 2012-Dec 2013: N=100

Communication Issues, by Subcategory	2012	2013	Total
inaccurate/insufficient donor (or organ/extra vessels) information	14	16	30
delayed communication	9	17	26
increased risk (high risk) status of donor	6	4	10
patient not informed adequately (or at all)	7	2	9
communication issue - (no subcategory)	5	3	8
miscommunication of donor test results	3	4	7
other - delay in potential disease transmission reporting	0	7	7
missing documentation	4	2	6
change in test results not reported	2	0	2
other - TXC complaint of unprofessional interactions with opo	2	0	2
other - did not notify opo/OPTN of potential disease transmission	2	0	2
other - transcription error	0	2	2
reliance on electronic instead of verbal communication	2	0	2
other	6	7	13

Events were categorized and (if applicable) sub-categorized by a UNOS staff review of the descriptive narrative submitted for each safety situation.
Some situations may appear multiple times in this table, falling under multiple subcategories.
Safety situations may include near misses, 'no harm' events, and actual safety events.
Since reporting to the IPS is voluntary, the number of situations reported is believed to be an underestimate of the actual number of situations that have occurred.
Duplicate situations and reports not pertaining to patient safety were excluded.

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Operations & Safety Committee
Updated Patient Safety Situation Report, February 2014

Table 2: Testing-Related Safety Situations Reported from Jan 2012-Dec 2013 by OPTN Members into the UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory
Interpretation: The most common type of reported testing issue related to hemodilution issues when testing for infectious disease (N=15).

Total Number of Testing-Related Situations Reported from Jan 2012-Dec 2013: N=70

Testing Issues, by Subcategory	2012	2013	Total
infectious disease - hemodilution error or discrepancy	5	10	15
HLA - discrepant results	1	8	9
infectious disease - cultures not available or not done	2	3	5
infectious disease - important or required test(s) not done	4	1	5
ABO - ABO subtyping error or discrepancy	3	1	4
HLA - inaccurate results reported	2	1	3
infectious disease - wrong type of test used	3	0	3
HLA - required test not used	2	0	2
infectious disease - discrepant results	1	1	2
HLA (other)	1	1	2
ABO (other)	4	0	4
infectious disease (other)	3	2	5
other	6	3	9

Events were categorized and (if applicable) sub-categorized by a UNOS staff review of the descriptive narrative submitted for each safety situation.
Some situations may appear multiple times in this table, falling under multiple subcategories.
Safety situations may include near misses, 'no harm' events, and actual safety events.
Since reporting to the IPS is voluntary, the number of situations reported is believed to be an underestimate of the actual number of situations that have occurred.
Duplicate situations and reports not pertaining to patient safety were excluded.

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Table 3: Organ Allocation/Placement-Related Safety Situations Reported from Jan 2012-Dec 2013 by OPTN Members into the
UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory
Interpretation: The most common type of reported allocation/placement issue was out of sequence allocation (N=23).

Total Number of Allocation/Placement-Related Situations Reported from Jan 2012-Dec 2013: N=57

Organ Allocation/Placement Issues, by Subcategory	2012	2013	Total
out of sequence allocation	15	8	23
rescinded offer	3	2	5
recipient not on match list	2	2	4
inaccurate donor data caused match to run incorrectly	2	1	3
organ allocation/placement issue - (no subcategory)	3	0	3
inaccurate patient priority or status	0	2	2
match not rerun once serology found to be positive	2	0	2
offer not made to secondary contact	2	0	2
other - complaint of influencing allocation	2	0	2
other - multiorgan sharing	0	2	2
other - no local backup	0	2	2
other	4	5	9

Events were categorized and (if applicable) sub-categorized by a UNOS staff review of the descriptive narrative submitted for each safety situation.
Some situations may appear multiple times in this table, falling under multiple subcategories.
Safety situations may include near misses, 'no harm' events, and actual safety events.
Since reporting to the IPS is voluntary, the number of situations reported is believed to be an underestimate of the actual number of situations that have occurred.
Duplicate situations and reports not pertaining to patient safety were excluded.

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Table 4: Transplant Procedure/Process-Related Safety Situations Reported from Jan 2012-Dec 2013 by OPTN Members into the
UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory
Interpretation: The most common type of reported transplant procedure/process issues related to use of extra vessels: sharing of vessels (N=21), use of vessels in a non-transplant patient (N=6).

Total Number of Transplant Procedure/Process-Related Situations Reported from Jan 2012-Dec 2013: N=56

Transplant Procedure/Process Issues, by Subcategory	2012	2013	Total
other - vessel sharing	11	10	21
vessels used in a non - transplant patient	5	1	6
other - complaint about listing practices	0	4	4
other - recipient not promptly removed from Waitlist	3	0	3
other - delay in listing a patient	0	2	2
other - drug recall	2	0	2
other	4	16	20

Events were categorized and (if applicable) sub-categorized by a UNOS staff review of the descriptive narrative submitted for each safety situation.
Some situations may appear multiple times in this table, falling under multiple subcategories.
Safety situations may include near misses, 'no harm' events, and actual safety events.
Since reporting to the IPS is voluntary, the number of situations reported is believed to be an underestimate of the actual number of situations that have occurred.
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Table 5: Data Entry-Related Safety Situations Reported from Jan 2012-Dec 2013 by OPTN Members into the UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory
Interpretation: The most common type of reported data entry issue related to HLA data entry (N=15).

Total Number of Data Entry-Related Situations Reported from Jan 2012-Dec 2013: N=50

Data Entry Issues, by Subcategory	2012	2013	Total
DonorNet - HLA	9	6	15
Waitlist - inaccurate patient priority or status	5	2	7
DonorNet - ABO subtyping	2	3	5
DonorNet - increased risk (high risk) status of donor	2	2	4
Waitlist - ABO	4	0	4
DonorNet - infectious disease test result(s)	3	0	3
Waitlist - patient removed or inactivated in error	3	0	3
DonorNet - donor id	0	2	2
DonorNet (other)	2	2	4
Waitlist - HLA	1	2	3
other - HLA	1	2	3

Events were categorized and (if applicable) sub-categorized by a UNOS staff review of the descriptive narrative submitted for each safety situation.
Some situations may appear multiple times in this table, falling under multiple subcategories.
Safety situations may include near misses, 'no harm' events, and actual safety events.
Since reporting to the IPS is voluntary, the number of situations reported is believed to be an underestimate of the actual number of situations that have occurred.
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Table 6: Labeling-Related Safety Situations Reported from Jan 2012-Dec 2013 by OPTN Members into the UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory
Interpretation: The most common type of reported labeling issues related to an incorrect Donor ID (N=21), which are often transcription errors (N=11), and often involve incorrect labeling of blood/nodes/spleen (N=18).

Total Number of Labeling-Related Situations Reported from Jan 2012-Dec 2013: N=41

Labeling Issues, by Subcategory	2012	2013	Total
donor id - incorrect id	13	8	21
blood/nodes/spleen	10	8	18
transcription error	10	1	11
missing label	3	3	6
switched laterality - kidneys	2	4	6
required information missing	3	0	3
donor id - missing id	2	0	2
Other	3	1	4

Events were categorized and (if applicable) sub-categorized by a UNOS staff review of the descriptive narrative submitted for each safety situation.
Some situations may appear multiple times in this table, falling under multiple subcategories.
Safety situations may include near misses, 'no harm' events, and actual safety events.
Since reporting to the IPS is voluntary, the number of situations reported is believed to be an underestimate of the actual number of situations that have occurred.
Duplicate situations and reports not pertaining to patient safety were excluded.

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Table 7: Packaging/Shipping-Related Safety Situations Reported from Jan 2012-Dec 2013 by OPTN Members into the
UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory
Interpretation: The most common type of reported packaging/shipping issues related to switched kidney laterality (N=12) and packaging not meeting requirements (N=11).

Total Number of Packaging/Shipping-Related Situations Reported from Jan 2012-Dec 2013: N=41

Packaging/Shipping Issues, by Subcategory	2012	2013	Total
switched laterality - kidneys	6	6	12
not packaged according to requirements	3	8	11
sterile container/bag not properly closed	2	3	5
insufficient or missing blood/nodes/spleen	2	2	4
ice melted	0	2	2
other	4	3	7

Events were categorized and (if applicable) sub-categorized by a UNOS staff review of the descriptive narrative submitted for each safety situation.
Some situations may appear multiple times in this table, falling under multiple subcategories.
Safety situations may include near misses, 'no harm' events, and actual safety events.
Since reporting to the IPS is voluntary, the number of situations reported is believed to be an underestimate of the actual number of situations that have occurred.
Duplicate situations and reports not pertaining to patient safety were excluded.

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Table 8: Recovery procedure/process-Related Safety Situations Reported from Jan 2012-Dec 2013 by OPTN Members into the
UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory
Interpretation: The most common type of reported recovery procedure/process issues related to problems with the recovering transplant team(s) (N=9) and injury to organ or vessels(N=9)

Total Number of Recovery Procedure/Process-Related Situations Reported from Jan 2012-Dec 2013: N=38

Recovery Procedure/Process Issues, by Subcategory	2012	2013	Total
injury to organ or extra vessels	5	4	9
issue with recovering transplant team(s)	5	4	9
poor donor management	3	4	7
OR time delayed	2	0	2
other - concerned about validity of brain death declaration	2	0	2
other - product recall	2	0	2
preservation fluid issue	1	1	2
sterile field breach or other sterility issue	2	0	2
other	4	6	10

Events were categorized and (if applicable) sub-categorized by a UNOS staff review of the descriptive narrative submitted for each safety situation.
Some situations may appear multiple times in this table, falling under multiple subcategories.
Safety situations may include near misses, 'no harm' events, and actual safety events.
Since reporting to the IPS is voluntary, the number of situations reported is believed to be an underestimate of the actual number of situations that have occurred.
Duplicate situations and reports not pertaining to patient safety were excluded.

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Table 9: Transportation-Related Safety Situations Reported from Jan 2012-Dec 2013 by OPTN Members into the UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory

Total Number of Transportation-Related Situations Reported from Jan 2012-Dec 2013: N=6

Transportation Issues, by Subcategory	2012	2013	Total
Ground – courier/driver issue	2	2	4
airline issue	0	2	2

Events were categorized and (if applicable) sub-categorized by a UNOS staff review of the descriptive narrative submitted for each safety situation.
Some situations may appear multiple times in this table, falling under multiple subcategories.
Safety situations may include near misses, 'no harm' events, and actual safety events.
Since reporting to the IPS is voluntary, the number of situations reported is believed to be an underestimate of the actual number of situations that have occurred.
Duplicate situations and reports not pertaining to patient safety were excluded.

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Table 10: Other Safety Situations Reported from Jan 2012-Dec 2013 by OPTN Members into the UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory

Total Number of 'Other' Situations Reported from Jan 2012-Dec 2013: N=62

Other Issues	2012	2013	Total
events related to a potential disease transmission*	13	17	30
vessels not stored properly	4	1	5
living donor issue* - aborted recovery	0	3	3
living donor issue* (other)	0	8	8
complaint about transplant program clinical competency	0	2	2
hospital failure to respond to DTAC investigation	2	0	2
living donor id generated after recovery	2	0	2
no patient safety contact	0	2	2
other	9	11	20

* Does not include all potential disease transmission or living donor related events reported to the OPTN, but only what was reported as a "patient safety situation" through the IPS or through other pathways.

Events were categorized and (if applicable) sub-categorized by a UNOS staff review of the descriptive narrative submitted for each safety situation.
Some situations may appear multiple times in this table, falling under multiple subcategories.
Safety situations may include near misses, 'no harm' events, and actual safety events.
Since reporting to the IPS is voluntary, the number of situations reported is believed to be an underestimate of the actual number of situations that have occurred.
Duplicate situations and reports not pertaining to patient safety were excluded.