TRENDS AND PATTERNS IN PATIENT SAFETY SITUATIONS REPORTED TO THE OPTN THROUGH JUNE 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. As with the last several updates, this report includes events reported to or identified by UNOS from pathways other than the "Improving Patient Safety" (IPS) online portal located in Secure Enterprise^{SM}.

The increasing trend in the number of reports submitted through the IPS continued in the first half of 2014, as 81 safety situations were entered into the system. An additional 50 safety situations from other reporting pathways (such as emails/phone calls to UNOS) were also included in the analysis, along with reporting projections for the second half of 2014 (**Figure 1**).

This report summarizes safety situations reported into the IPS or through other pathways by the high-level and detailed subcategories that have been included as checkboxes as part of the OPTN board-approved enhancements to the IPS. This summarization revealed that between 2012 and June 2014, 23% of safety situations involved a **breakdown in communication**. Many other safety situations involved **testing issues** (16%), **transplant process/procedure issues** (15%), **organ allocation/placement issues** (13%), **labeling issues** (11%) or **packaging/shipping issues** (11%). Events related to **data entry issues** (10%) were also not uncommon.

The more granular subcategory analysis revealed that nearly one in three communication issues pertained to delayed communication. Inaccurate or insufficient information about a donor (or organ/vessel) and miscommunication about the increased risk (formerly "high risk") status of a donor were also relatively common. Testing issues most often tended to involve either a hemodilution or HLA discrepancy. Errors in entering data into DonorNet, in particular for HLA, continue to be reported. Incorrectly labeled Donor IDs continue to be a problem, in particular on tubes used for shipping diagnostic materials (blood, nodes, or spleen).

The data included in this analysis is based on what the member or complainant reported in their initial contact with UNOS; it does not incorporate information from subsequent inquiry with the member and analysis of additional information obtained 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) previously reviewed de-identified, summarized patient safety situations (including both adverse events and near misses) submitted into the Improving Patient Safety (IPS) portal. Based on the narrative describing each event provided by members, the events reported from January 2012 through June 2014 have been categorized using relevant keywords (e.g., packaging & labeling, data entry

error, transportation). Previous reports have shown the distribution of reported 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 proactively take measures to prevent repeat occurrences.

Since this database is currently still maturing and undoubtedly suffers from some degree of underreporting, the purpose of analyzing this 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 regarded outcomes of reported adverse events or near misses in an effort to heighten awareness of safety within the transplant community.

COMMITTEE REQUEST

Patient safety situation trends and patterns: Perform trends and patterns analysis of patient safety situations reported to UNOS, using the categories and subcategories developed in previous analyses and discussions with the OSC and its Patient Safety Planning Development Work Group.

Updating this analysis has been a standing committee request. In September 2012, the committee requested that this analysis be updated and reported to the work group and full committee on a semi-annual basis.

As discussed in committee deliberations on April 8, 2014, this analysis was expanded to show the breakdown of patient safety events jointly by high-level category and by institution type (e.g. OPO, TXC, Lab).

DATA AND METHODS

Data Sources:

This long-term trend analysis included patient safety situations reported into the Secure Enterprise^{SM} Improving Patient Safety (IPS) portal between March 7, 2006 (IPS implementation date) and June 30, 2014. 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. Enhancements to the IPS portal implemented on May 29, 2014 have given reporters the ability to select meaningful event categories that will hopefully streamline future data analysis and tracking processes.

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 between 2012 and June 2014. 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 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 570 events was reviewed by a UNOS patient safety specialist and/or committee liaison, and a biostatistician and/or research analyst 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 committee. Also, as more events have been analyzed, new categories have been found to be needed. Further refinements will likely be necessary. The current nine "high-level categories" (plus "other") 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
- ☐ 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 has also been incorporated into the IPS in May 2014.

Each situation was categorized into one *or more* high-level categories, as well as possibly one or more subcategories. 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 4% of IPS situations fell into more than two high-level categories. About 80% of situations from 'other pathways' were classified into a single high-level category, while the remaining 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^{SM} 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. Subcategories with only one reported event from 2012 through July 2014 were reported together as a single group in Tables 1-11.

Living donor adverse events that are required reporting per OPTN policy are generally reported through the IPS's Living Donor Adverse Events portal. This includes living donor deaths; failure of native organ function; organ recovered but discarded; organ recovered but redirected to alternate recipient; and aborted recovery procedure. Some events also pertaining to living donors are also reported through the Safety Situation portal. This analysis includes both types of events. For the purposes of reporting high-level category events, we are considering Living Donor events as a separate category in this report. These events were previously categorized as "Other". Only those living donor events reported as a "patient safety situation" in the IPS are included in the overall IPS portal trends analysis (**Figure 1**).

Reporting the death of a living donor is required, even if the death is clearly not donation related. Many living donor deaths that are reported occurred years after the donation and were due to non-medical causes of death (e.g., motorcycle accident). For this analysis, only those living donor deaths that occurred within 30 days of the donation and with a cause of death medical in nature were included. Also, events for people who underwent donation surgery but ultimately did not donate an organ are included, even though such individuals are not technically donors.

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.

RESULTS

Overall Trend in Safety Situation Reporting

Figure 1 shows that 314 events were reported into the IPS from March 8, 2006 - December 31, 2011, 99 in 2012, 118 in 2013, and 81 from January - June 2014. In general, the rate of reporting has been increasing, with the exception of a temporary decrease in 2009.

Figure 1 also shows that 114 additional events were identified in 2012, 95 in 2013, and 50 from January - June 2014 through other reporting pathways besides the IPS. For example, "other pathways" included emails, calls, or letters to UNOS, patient complaints, and incidents identified by other UNOS departments. Year 2012 was the first full year for which these situations from other pathways were categorized for Operations & Safety Committee review.

*Figure 1. Safety Situations Reported (March 2006 - June 2014) to the UNet
"Improving Patient Safety" Portal and Situations Identified through
Other Reporting Pathways since 2012*
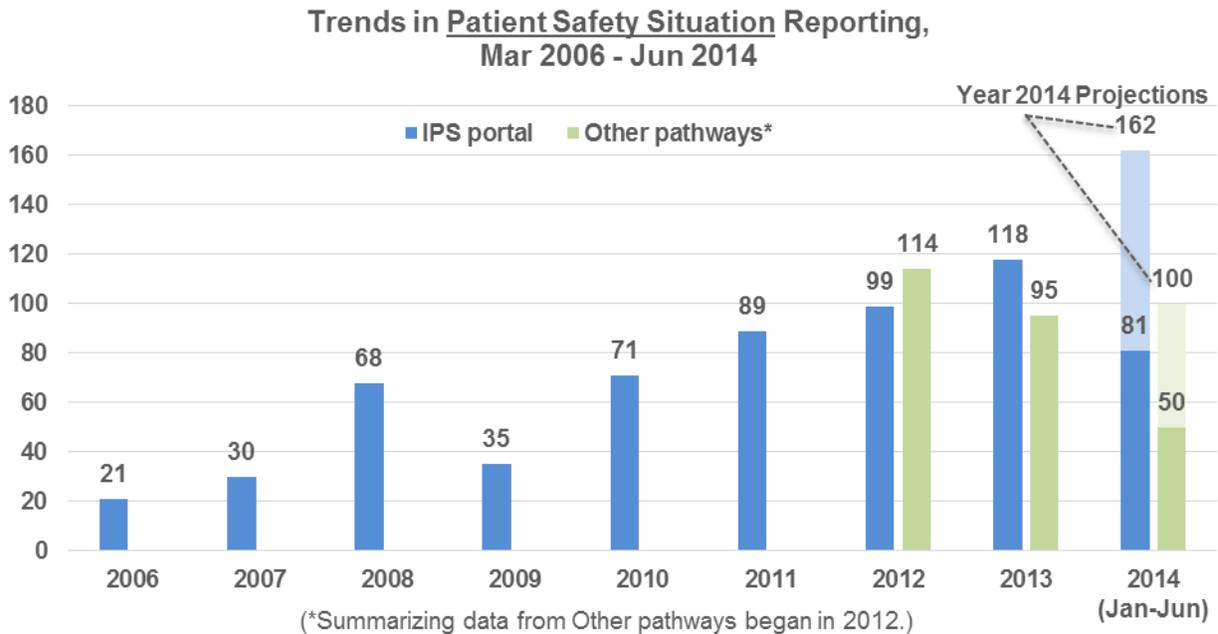
(Editor's note: Subsequent to the creation of this report, one additional event related to vessel sharing in June 2014 was identified.)

Reporting by Institution Type

Figure 2 reveals that during the first half of 2014, 50.6% of events reported to the IPS were reported by transplant hospitals, with OPOs accounting for 44.4% of reports, and labs the remaining 4.9%. By comparison, from 2012 - 2013, OPOs reported 48.4% of events and transplant hospitals 47%.

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 transplant hospitals' delayed communication regarding recipient status; likewise, transplant hospitals have reported concerns about the packaging and labeling of organs by the OPO.

Figure 2. IPS Safety Reports by Institution Type, 2012 - June 2014
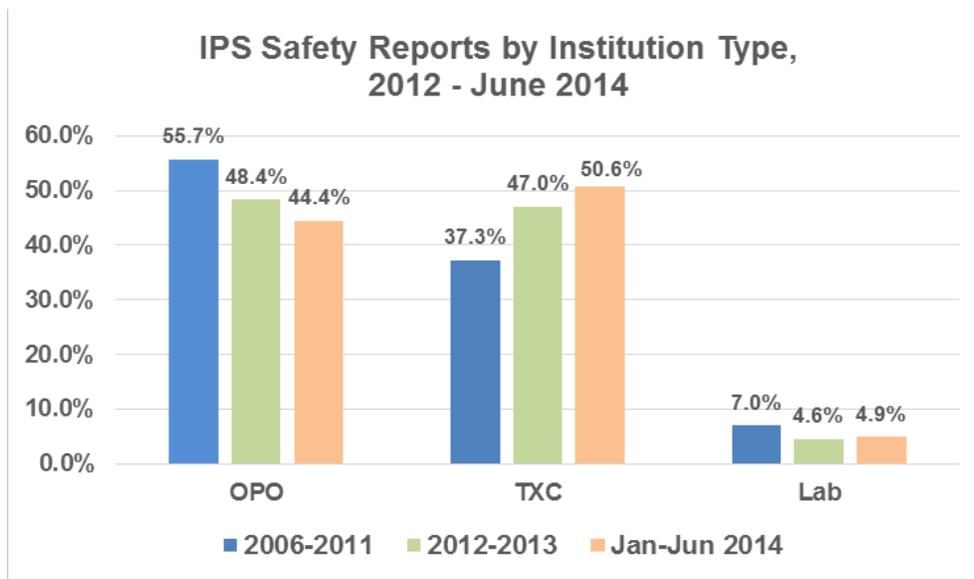
Reporting by Event Type (High-Level Category): 2012 – June 2014

Figure 3 shows the high-level category frequencies in 2012 - June 2014 for safety situations identified from both the IPS and other pathways combined.

During the first half of 2014, the most frequently reported events were related to communication issues (23%), transplant process/procedure issues (23%), packaging/shipping issues (18%), labeling issues (15%), testing issues (14%), recovery process/procedure issues (12%), and organ allocation/placement issues (11%).

Compared to the data from 2012 – 2013, the 2014 reported communication issues remained consistent, while there were increases in the reported transplant process/procedure issues,

packaging/shipping issues, and labeling issues, and slight increases in reported recovery process/procedure issues and transportation issues. Conversely, there were also slight decreases in reported data entry issues, testing issues, and allocation process/procedure issues. There was also a decrease in "Other" reports, which can be attributed in part to the new "Living Donor" category classification. Due to limited sample sizes, these differences may not be statistically significant.

Figure 3. Patient Safety Situation Reporting by Event Type (High-Level Category), 2012 - June 2014

Reported Patient Safety Situations by High-level Category (through both IPS and "Other Pathways"), 2012 - Jun 2014

2012 N=220
2013 N=218
2014 N=134

| Category	IPS + All Other (2012-2013)	IPS + All Other (Jan-Jun 2014)
Communication	23%	23%
Data entry	11%	7%
Transportation	1%	5%
Packaging/shipping	9%	18%
Labeling	9%	15%
Recovery process	8%	12%
Transplant process	13%	23%
Testing	16%	14%
Allocation	13%	11%
Living donor	6%	5%
Other	12%	5%
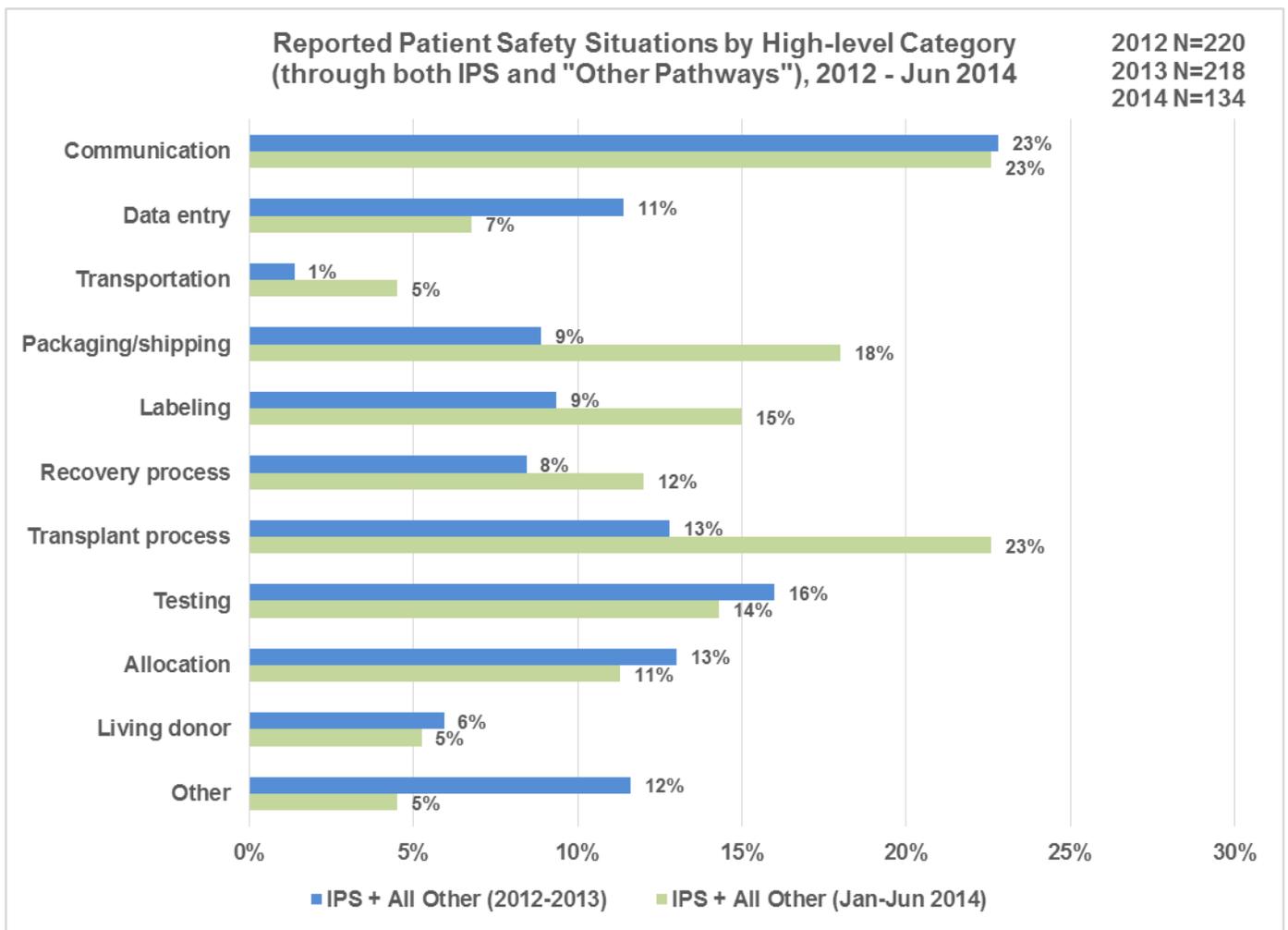
Figure 4 shows the high-level category frequencies from 2012 - June 2014 for safety situations identified from the IPS according to reporting institution type.

Nearly 80% of issues reported by labs during this time period were either testing issues (50%) or data entry issues (29%). Transplant hospitals most often reported communication issues (32%), while OPOs most frequently reported testing issues (25%).

Figure 4. IPS Patient Safety Situation Reporting by Event Type (High-Level Category) and Reporting Institution Type, 2012 - June 2014

IPS Reported Patient Safety Situations by High-level Category and Institution Type, 2012 - Jun 2014

2012 N=106
2013 N=123
2014 N=84
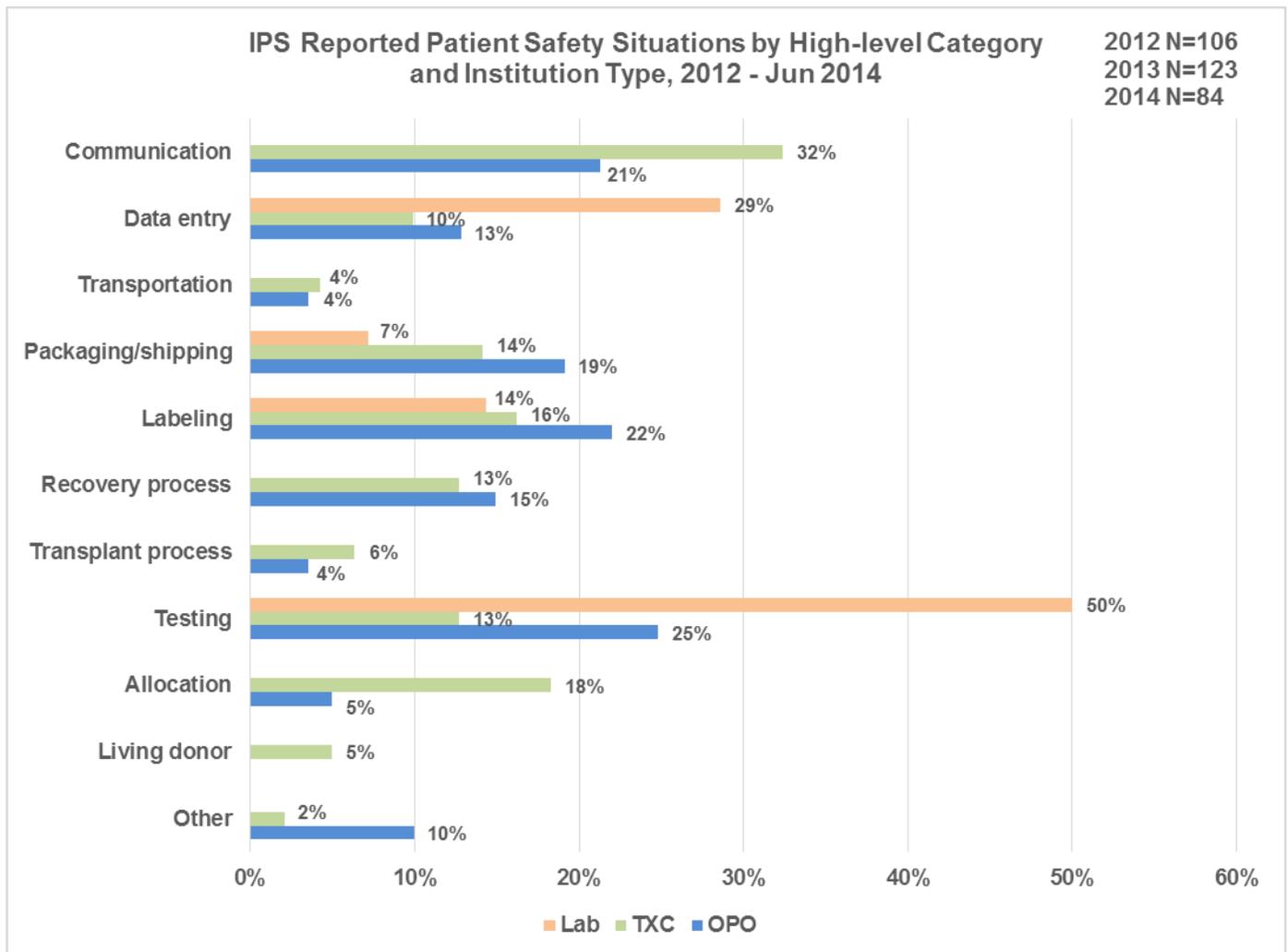
Reporting by Event Subcategory (2012 – June 2014)

The communication issues (N=130) in **Figure 3**, which includes situations reported since January 2012 through both the IPS portal and other pathways, are categorized more finely in **Table 1**. Forty (31%) of the one hundred thirty communication-related safety situations involved *delayed communication. Inaccurate or insufficient donor (or organ/vessel) information* (N=36) was the second most prevalent communication subcategory. Some examples of inaccurate/insufficient information include the following:
- missing intraoperative report
- incorrect vein and artery information
- missing organ anatomy information
- no documentation of cyst

Increased risk (high risk) status of donor (N=11) was third most prevalent. There were also eleven situations that involved *patient not informed adequately (or at all)*.

Table 2 shows testing issues (N=89) by subcategory. Sixteen (18%) of the eighty-nine testing-related situations involved a concern about donor hemodilution. Fourteen situations pertained to *discrepant HLA results*. Situations also related to the following: *infectious disease cultures not available or not done* (N=8), *inaccurate HLA results reported* (N=5), and *important or required infectious disease test(s) not done* (N=5).

Table 3 shows that 32 of the transplant procedure/process-related situations (N=84) involved *sharing of extra vessels* among transplant centers or OPOs. Ten complaints were made about *listing practices*. Five cases of an *extra vessel being used in a non-transplant patient* were reported in 2012, one case in 2013, and one case during the first half of 2014. Six 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. Some examples include the following:
- delays in listing a patient
- organ too large for patient
- medical staff availability
- surgical competency

Organ allocation/placement issues (N=72) reported since 2012 were broken down by subcategory in **Table 4**. The majority (N=23) were related to a concern about *out of sequence allocation*. Several pertained to *rescinded offers* (N=7), *recipient not on match list* (N=4), and *inaccurate donor data causing match to run incorrectly* (N=4). Several complaints that were categorized as *other* involved cases of delayed organ offers or late offer declines, some of which resulted in increased cold ischemia time.

Table 5 reveals that the most common labeling-related issues (N=61) involved an *incorrect donor ID* (N=23). Labeling issues pertaining to *unlabeled or mislabeled diagnostic materials (blood/nodes/spleen)* were also frequently reported (N=21). *Transcription errors* (N=13) were

also common. 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. There were also eleven reports of *missing labels*.

Table 6 shows that *switched kidney laterality* (N=17) cases were the most common type of packaging/shipping-related (N=63) safety situations.

Note that some switched laterality cases were classified as labeling issues (N=12, Table 5) and some as packaging/shipping issues (N=17, Table 6), while eight events fell under both high level categories. Consequently, there were a total of 21 *switched kidney laterality* cases reported between January 2012 and June 2014[1]. Both kidneys were successfully transplanted in 16 (76%) of these 21 cases, despite the mix-up. There was also one case of *switched lung laterality*, with both lungs being successfully transplanted.

In fifteen of the packaging/shipping situations, the *organs were not packaged according to requirements*. There were also seven reports of *insufficient or missing blood/nodes/spleen,* and six instances where the *sterile container/bag not properly closed.*

Data entry issues (N=59) were subcategorized in **Table 7**. 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=5), and *infectious disease test results* (N=4). In three cases, a patient was *removed or inactivated in error*.

Table 8 shows thirteen (25%) of the situations related to a recovery procedure/process issue (N=53) involved an *injury to the organ or extra vessels*. An additional 11 cases involved an *issue with the recovering transplant team(s)* (e.g. complaint of onsite transplant team declining organ due to size without entering the OR). There were also ten reports of *poor donor management*.

Table 9 shows 33 living donor issues. The most commonly reported types of living donor events were those that are required to be reported per OPTN policy: *organ recovered but not transplanted* (N=5), *failure of native organ function* (N=4), *organ redirected to another recipient* (N=4), and *aborted recovery* (N=3). Three events related to a *donor health issue,* including:
- perforated bowel with abscess
- retroperitioneal fibrosis post-donation with ureteric narrowing of solitary kidney
- metastatic cancer

Other living donor events, grouped as "*other*" since they occurred singly, included a complaint about a donor feeling pressured to donate, a living donor having difficulty finding care for complications, and a wrong laterality recovery "near-miss." Also, one living donor death was

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[1] One additional switched laterality event involved a data entry error, where the wrong anatomy charts were uploaded into DonorNet (Table 7, in "DonorNet (Other)").

reported where the death occurred within 30 days of the donation and the cause of death was medical in nature.

Twelve transportation-related issues, are shown in **Table 10,** four involving *airlines* and three involving *ground transportation/courier*. In one of these cases, an airline failed to board the organ at the airport. In another case, a courier transported tissue to a transplant center instead of the solid organ.

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 that didn't fall into one of the ten high-level categories were grouped together as other issues and are shown in **Table 11** (N=59). *Drug or product recalls* were reported in ten cases. *Extra vessels were not stored properly* in five of these other situations.

A large number of these situations (N=32) 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 or referred to DEQ due to a potential policy violation are included in this report.

Events Resulting in Organs Not Transplanted (2012 – June 2014)

Of the 572 events reported through both the IPS and other pathways, it was clear from the narrative that organ(s) were not transplanted as a result of the event in at least 64 (11%) cases. Organs were considered not transplanted if either an organ was recovered but discarded due to the event, or an organ was not recovered due to the event. Recent enhancements to the IPS portal require members to provide this information for each event reported. Some cases included switched kidney laterality, frozen organs, damage to organ during recovery, poor donor management, late organ declines, and equipment malfunctions.

Table 1: Communication-Related Safety Situations Reported from Jan 2012-Jun 2014 by OPTN Members into the UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory

Communication Issues, by Subcategory	2012	2013	Jan-Jun 2014	Total
delayed communication	9	17	14	40
inaccurate/insufficient donor (or organ/extra vessels) information	14	16	6	36
increased risk (high risk) status of donor	6	4	1	11
patient not informed adequately (or at all)	7	2	2	11
miscommunication of donor test results	3	4	0	7
other - delay in potential disease transmission reporting	0	7	0	7
missing documentation	4	2	0	6
other - complaint of unprofessional interactions	2	0	2	4
change in test results not reported	2	0	0	2
other - did not notify opo/OPTN of potential disease transmission	2	0	0	2
other - miscommunication re: organ refusal	0	0	2	2
other - transcription error	0	2	0	2
reliance on electronic instead of verbal communication	2	0	0	2
other	11	10	1	22
Number of unique patient safety situations*	52	48	30	130

*Events were categorized and (if applicable) sub-categorized by a UNOS staff review
of the descriptive narrative submitted for each safety situation.
* Since a patient safety situation may involve more than one subcategory, some situations may appear multiple times in this
table. Therefore, the sum of subcategory values may be larger than the actual number of unique events.
Safety situations may include near misses, 'no harm' events, and actual safety events.
Since reporting of most types of safety situations 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.*

Table 2: Testing-Related Safety Situations Reported from Jan 2012-Jun 2014 by OPTN Members into the UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory

Testing Issues, by Subcategory	2012	2013	Jan-Jun 2014	Total
infectious disease - hemodilution error or discrepancy	5	10	1	16
HLA - discrepant results	1	8	5	14
infectious disease - cultures not available or not done	2	3	3	8
HLA - inaccurate results reported	2	1	2	5
infectious disease - important or required test(s) not done	4	1	0	5
ABO - ABO subtyping error or discrepancy	3	1	0	4
infectious disease - discrepant results	1	1	2	4
infectious disease - wrong type of test used	3	0	0	3
HLA - required test not used	2	0	0	2
infectious disease - infectious disease test results not available prior to transplant	0	1	1	2
infectious disease - other - delayed culture results	0	0	2	2
other - important or required test(s) not done	2	0	0	2
other ABO or ABO subtyping related	4	1	0	5
other HLA related	1	1	1	3
infectious disease related	3	1	0	4
other	4	2	3	9
Number of unique patient safety situations*	36	34	19	89

Events were categorized and (if applicable) sub-categorized by a UNOS staff review of the descriptive narrative submitted for each safety situation.
* Since a patient safety situation may involve more than one subcategory, some situations may appear multiple times in this table. Therefore, the sum of subcategory values may be larger than the actual number of unique events.
Safety situations may include near misses, 'no harm' events, and actual safety events.
Since reporting of most types of safety situations 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.

Table 3: Transplant Procedure/Process-Related Safety Situations Reported from Jan 2012-Jun 2014 by OPTN Members into the
UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory

Transplant Procedure/Process Issues, by Subcategory	2012	2013	Jan-Jun 2014	Total
other - vessel sharing	11	10	11	32
other - complaint about listing practices	0	4	6	10
vessels used in a non - transplant patient	5	1	1	7
other - recipient not promptly removed from Waitlist	4	0	2	6
other - delay in listing a patient	0	2	1	3
other - organ too large for patient	0	1	1	2
other	3	12	4	49
Number of unique patient safety situations*	23	31	30	84

Events were categorized and (if applicable) sub-categorized by a UNOS staff review
of the descriptive narrative submitted for each safety situation.
* Since a patient safety situation may involve more than one subcategory, some situations may appear multiple times in this table. Therefore, the sum of subcategory values may be larger than the actual number of unique events.
Safety situations may include near misses, 'no harm' events, and actual safety events.
Since reporting of most types of safety situations 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.

Table 4: Organ Allocation/Placement-Related Safety Situations Reported from Jan 2012-Jun 2014 by OPTN Members into the
UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory

Organ Allocation/Placement Issues, by Subcategory	2012	2013	Jan-Jun 2014	Total
out of sequence allocation	15	8	0	23
rescinded offer	3	2	2	7
inaccurate donor data caused match to run incorrectly	2	1	1	4
recipient not on match list	2	2	0	4
organ allocation/placement issue - (no subcategory)	3	0	0	3
inaccurate patient priority or status	0	2	0	2
match not rerun once serology found to be positive	2	0	0	2
offer not made to secondary contact	2	0	0	2
other - complaint of influencing allocation	2	0	0	2
other - multiorgan sharing	0	2	0	2
other - no local backup	0	2	0	2
other	4	5	10	19
Number of unique patient safety situations*	34	23	15	72

Events were categorized and (if applicable) sub-categorized by a UNOS staff review
of the descriptive narrative submitted for each safety situation.
* Since a patient safety situation may involve more than one subcategory, some situations may appear multiple times in this
table. Therefore, the sum of subcategory values may be larger than the actual number of unique events.
Safety situations may include near misses, 'no harm' events, and actual safety events.
Since reporting of most types of safety situations 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.

Table 5: Labeling-Related Safety Situations Reported from Jan 2012-Jun 2014 by OPTN Members into the UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory

Labeling Issues, by Subcategory	2012	2013	Jan-Jun 2014	Total
donor id - incorrect id	13	8	2	23
blood/nodes/spleen	10	8	3	21
transcription error	10	1	2	13
switched laterality - kidneys	2	4	6	12
missing label	3	3	5	11
required information missing	3	0	1	4
donor id - missing id	2	0	0	2
other - opo did not provide labels	0	1	1	2
other	3	0	3	6
Number of unique patient safety situations*	24	17	20	61

Events were categorized and (if applicable) sub-categorized by a UNOS staff review
of the descriptive narrative submitted for each safety situation.
* Since a patient safety situation may involve more than one subcategory, some situations may appear multiple times in this table. Therefore, the sum of subcategory values may be larger than the actual number of unique events.
Safety situations may include near misses, 'no harm' events, and actual safety events.
Since reporting of most types of safety situations 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.

Table 6: Packaging/Shipping-Related Safety Situations Reported from Jan 2012-Jun 2014 by OPTN Members into the UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory

Packaging/Shipping Issues, by Subcategory	2012	2013	Jan-Jun 2014	Total
switched laterality - kidneys	6	5	6	17
not packaged according to requirements	3	8	4	15
insufficient or missing blood/nodes/spleen	2	2	3	7
sterile container/bag not properly closed	2	3	1	6
frozen organ	0	1	1	2
ice melted	0	2	0	2
other	4	2	3	9
Number of unique patient safety situations*	15	24	24	63

Events were categorized and (if applicable) sub-categorized by a UNOS staff review of the descriptive narrative submitted for each safety situation.
* Since a patient safety situation may involve more than one subcategory, some situations may appear multiple times in this table. Therefore, the sum of subcategory values may be larger than the actual number of unique events.
Safety situations may include near misses, 'no harm' events, and actual safety events.
Since reporting of most types of safety situations 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.

Table 7: Data Entry-Related Safety Situations Reported from Jan 2012-Jun 2014 by OPTN Members into the UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory

Data Entry Issues, by Subcategory	2012	2013	Jan-Jun 2014	Total
DonorNet - HLA	9	6	0	15
Waitlist - inaccurate patient priority or status	5	2	0	7
DonorNet - ABO subtyping	2	3	0	5
DonorNet - increased risk (high risk) status of donor	2	2	1	5
Waitlist - ABO	4	0	1	5
DonorNet - infectious disease test result(s)	3	0	1	4
Waitlist - patient removed or inactivated in error	3	0	0	3
DonorNet - demographics	1	0	1	2
DonorNet - donor id	0	2	0	2
DonorNet - infectious disease testing results	0	1	1	2
DonorNet - labs	1	0	1	2
DonorNet - other	0	1	1	2
Waitlist - other	1	2	0	2
other	1	2	2	5
Number of unique patient safety situations*	30	20	9	59

Events were categorized and (if applicable) sub-categorized by a UNOS staff review
of the descriptive narrative submitted for each safety situation.
* Since a patient safety situation may involve more than one subcategory, some situations may appear multiple times in this table. Therefore, the sum of subcategory values may be larger than the actual number of unique events.
Safety situations may include near misses, 'no harm' events, and actual safety events.
Since reporting of most types of safety situations 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.

Table 8: Recovery procedure/process-Related Safety Situations Reported from Jan 2012-Jun 2014 by OPTN Members into the UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory

Recovery Procedure/Process Issues, by Subcategory	2012	2013	Jan-Jun 2014	Total
injury to organ or extra vessels	5	4	4	13
issue with recovering transplant team(s)	5	4	2	11
poor donor management	3	4	3	10
sterile field breach or other sterility issue	2	0	1	3
OR time delayed	2	0	0	2
equipment malfunction	0	1	1	2
other - concerned about validity of brain death declaration	2	0	0	2
other - increased CIT	0	0	2	2
preservation fluid issue	1	1	0	2
other	4	5	3	12
Number of unique patient safety situations*	22	15	16	53

*Events were categorized and (if applicable) sub-categorized by a UNOS staff review
of the descriptive narrative submitted for each safety situation.
* Since a patient safety situation may involve more than one subcategory, some situations may appear multiple times in this
table. Therefore, the sum of subcategory values may be larger than the actual number of unique events.
Safety situations may include near misses, 'no harm' events, and actual safety events.
Since reporting of most types of safety situations 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.*

Table 9: Living Donor-Related Safety Situations Reported from Jan 2012-Jun 2014 by OPTN Members into the UNet(SM) 'Improving Patient Safety' (IPS) Portal, including Living Donor Adverse Event Portal, or Other Pathways, by Subcategory

(All living donor deaths are required reported, even if death was years after donation and not related to a medical condition.
(Only deaths within 30 days of donation and cause of death was medical in nature are included)
(Events for people who underwent donation surgery, but ultimately did not donate an organ, are included though they are not technically donors)

Living Donor Issues, by Subcategory	2012	2013	Jan-Jun 2014	Total
organ recovered but not transplanted	2	2	1	5
failure of native organ function	1	1	2	4
redirected organ	1	3	0	4
aborted recovery	0	3	0	3
donor health issue	2	1	0	3
other*	1	6	3	10
Number of unique patient safety situations**	10	16	7	33

*Includes one living donor death within 30 days of donation where cause of death was medical in nature.
Events were categorized and (if applicable) sub-categorized by a UNOS staff review
of the descriptive narrative submitted for each safety situation.
** Since a patient safety situation may involve more than one subcategory, some situations may appear multiple times in this table. Therefore, the sum of subcategory values may be larger than the actual number of unique events.
Safety situations may include near misses, 'no harm' events, and actual safety events.
Since reporting of most types of safety situations 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.

Table 10: Transportation-Related Safety Situations Reported from Jan 2012-Jun 2014 by OPTN Members into the UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory

Transportation Issues, by Subcategory	2012	2013	Jan-Jun 2014	Total
airline related	0	2	2	4
ground - courier/driver issue	2	1	0	3
ground - other	0	1	0	1
Number of unique patient safety situations*	2	4	6	12

Events were categorized and (if applicable) sub-categorized by a UNOS staff review of the descriptive narrative submitted for each safety situation.
* Since a patient safety situation may involve more than one subcategory, some situations may appear multiple times in this table. Therefore, the sum of subcategory values may be larger than the actual number of unique events.
Safety situations may include near misses, 'no harm' events, and actual safety events.
Since reporting of most types of safety situations 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.

Table 11: Other Safety Situations Reported from Jan 2012-Jun 2014 by OPTN Members into the UNet(SM) 'Improving Patient Safety' (IPS) Portal or Other Pathways, by Subcategory

Other Issues	2012	2013	Jan-Jun 2014	Total
events related to a potential disease transmission*	13	17	2	32
drug or product recall	5	1	4	10
vessels not stored properly	4	1	0	5
mishandling of confidential information	0	1	2	3
complaint about transplant program clinical competency	0	2	0	2
hospital failure to respond to DTAC investigation	2	0	0	2
living donor id generated after recovery	2	0	0	2
no patient safety contact	0	2	0	2
other	8	9	2	19
Number of unique patient safety situations**	26	27	6	59

Does not include all potential disease transmission events reported to the OPTN, but only those reported as 'patient safety situations' through the IPS or through other pathways, such as a DTAC referral. Events were categorized and (if applicable) sub-categorized by a UNOS staff review of the descriptive narrative submitted for each safety situation.
** Since a patient safety situation may involve more than one subcategory, some situations may appear multiple times in this table. Therefore, the sum of subcategory values may be larger than the actual number of unique events.*
Safety situations may include near misses, 'no harm' events, and actual safety events.
Since reporting of most types of safety situations 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.