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

Prepared for:
Operations & Safety Committee
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EXECUTIVE SUMMARY

The OPTN Operations and Safety Committee (OSC) has requested an update to a standing committee request to analyze trends and patterns in patient safety situations reported to or identified by UNOS. As with the last update presented on April 30, 2013, this report includes a more granular summarization of safety situations than had been presented previously. As before, this report also 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 2013, as 63 safety situations were entered into the system. An additional 73 safety situations from other reporting pathways (such as emails/letters to UNOS) were also included in the analysis (**Figure 1**).

This report summarizes safety situations reported into the IPS or other pathways by the 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 nearly 23% of safety situations involved a **breakdown in communication**. Many other safety situations involved **testing issues** (16%), **organ allocation/placement issues** (15%), **data entry issues** (11%), and **labeling issues** (10%). (**Figure 6**) The more granular subcategory analysis revealed that more than one in three communication issues pertained to inaccurate or insufficient information about a donor or organ/vessel. More than one in four recovery procedure/process issues involved an injury to an organ or vessels.

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), along with its Patient Safety Planning Development Subcommittee, previously reviewed de-identified, summarized patient safety situations (including both adverse events and near misses) submitted into UNet's Improving Patient Safety portal. Based on the narrative describing each event provided by members, the events reported through June 2013 have 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.

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 June 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 through June of 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 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 Situation Planning Development Work Group. Also, 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 proposed 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
- ☐ 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 proposed and approved for incorporation into the IPS.

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 86% of situations from 'other pathways' were classified into a single high-level category, while 14% 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 and Living Donor Adverse Events portals within the IPS.

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.

RESULTS

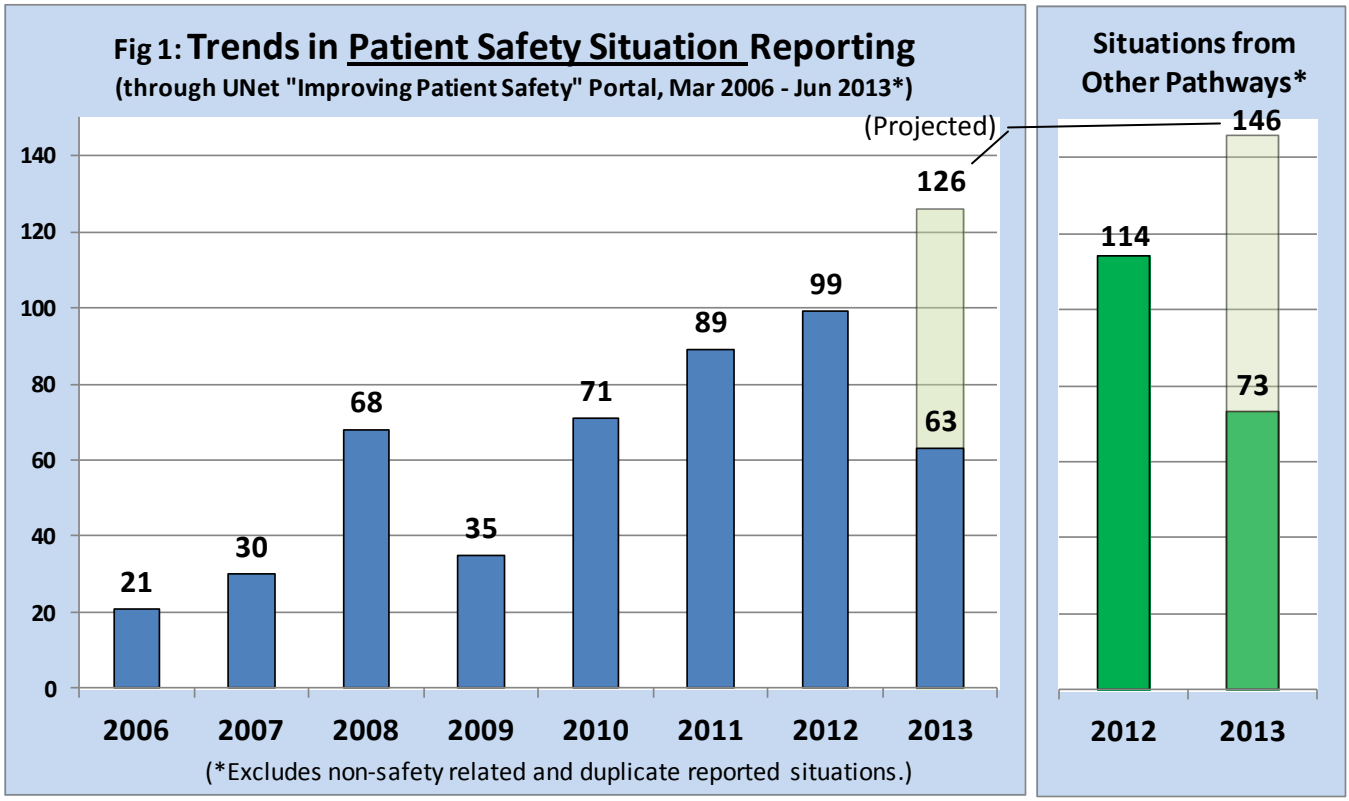
Overall Trend in Safety Situation Reporting

Figure 1 shows that 314 events were reported into the IPS from March 8, 2006 – Dec 31, 2011, 99 in 2012, and 63 in the first half of 2013. In general, the rate of reporting has been increasing, with the exception of a decrease in 2009.

Figure 1 also shows that 113 additional events were identified in 2012 and 73 in 2013 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. 2012 was the first full year for which these situations from other pathways were categorized for review by the Operations & Safety Committee.

The projected number of safety situations for both the IPS and other pathways by the end – 126 and 146, respectively – portend a continued increase in the reporting rate for all of 2013.

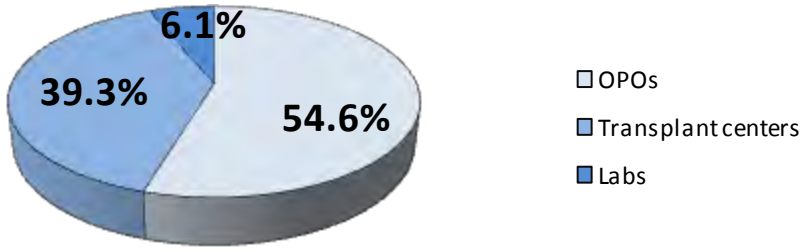
Figure 1. Safety Situations Reported (2006-June 2013) to the UNet "Improving Patient Safety" Portal and Situations Identified through Other Reporting Pathways since 2012



Reporting by Institution Type

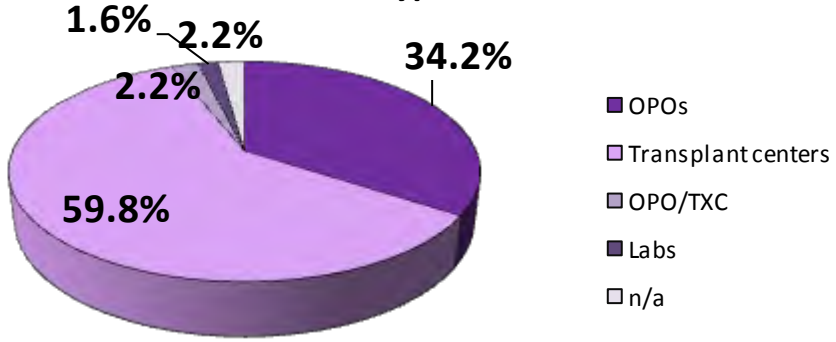
Figure 2 reveals that over half (54.6%) of the events reported to the IPS were reported by OPO's, with transplant centers accounting for 39.3% of reports, and labs the remaining 6.1%. Some events occurred at the institution reporting the event, whereas for other events, one institution reported about 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, 2006 -June 2013



Situations from other, non-IPS pathways were categorized by the type of institution involved, not by reporting institution. **Figure 3** reveals that for situations identified through other pathways, the majority (59.8%) involved a transplant center, while 34.2% 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



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

Figure 4 shows that between January 1, 2012 and June 30, 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 (22%), labeling issues (16%), and packaging/shipping issues (16%) were also relatively common in the first half of 2013.

Though 17% of reported safety situations in 2012 involved an electronic data entry issue, only 5% of reports related to a data entry issue in the first half of 2013. Other high level

categories and their 2013 proportions were as follows: organ allocation/placement (13%), recovery procedure/process (11%), transplant procedure/process (3%), and transportation (2%). About 11% of situations did not fall into one of these nine high level categories and were labeled as "other."

Figure 4. Patient Safety Situation Reporting in Improving Patient Safety Portal, by Event Type (High-Level Category), 2012 vs. 2013

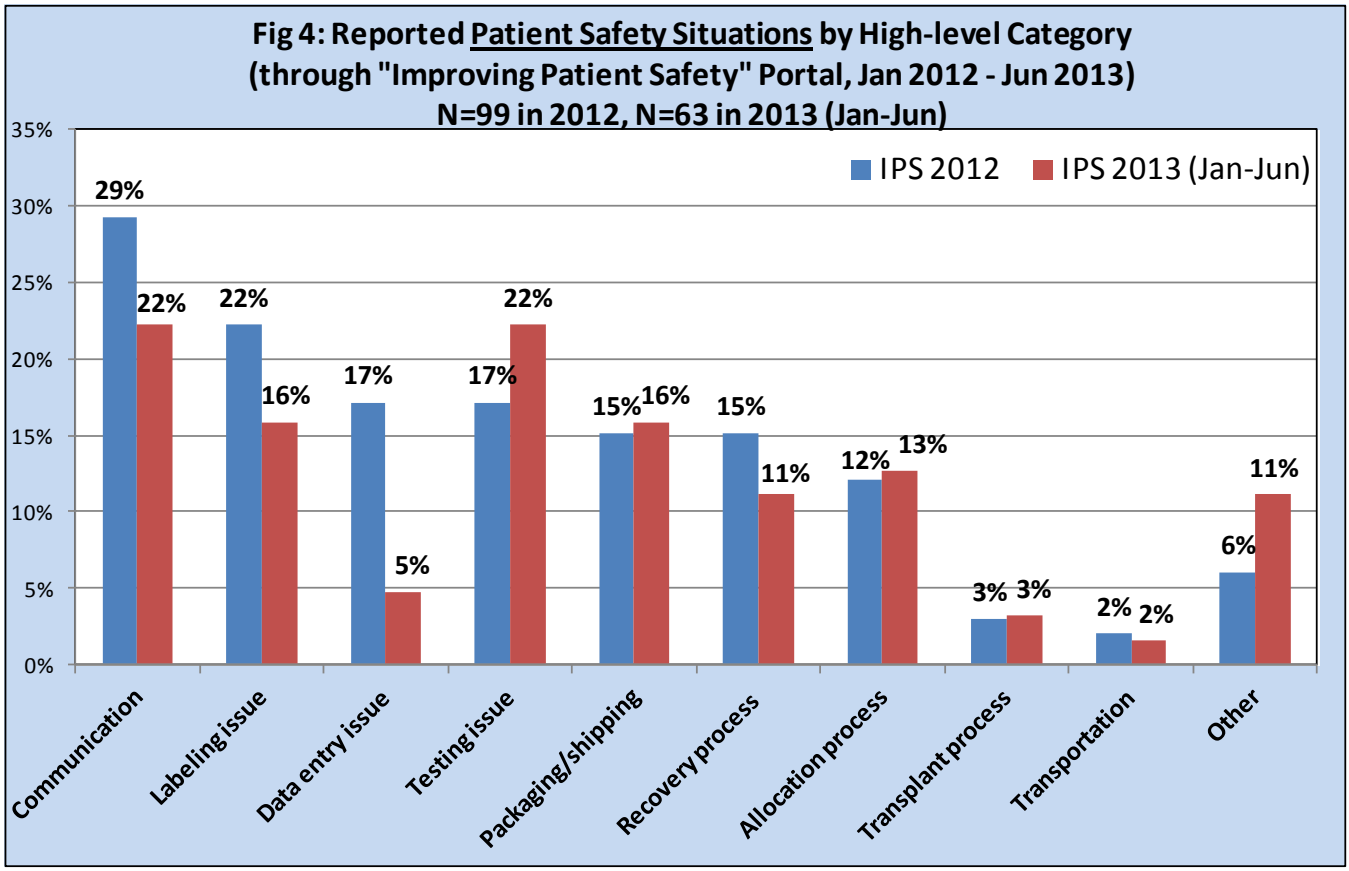


Figure 5 shows that, as with the IPS, the most common type of safety situation reported through "other pathways" in 2012 and 2013 were communication issues.

Labeling issues accounted for less than 2% of events reported through other pathways, a stark contrast to the 16% of reported events involving labeling problems in the IPS in 2013. Organ allocation/placement issues and transplant procedure/process issue were relatively common in other pathway reporting.

Nearly 30% of other pathway events did not fall into one of the 9 high level categories and were labeled "other."

Figure 5. Patient Safety Situation Reporting through 'Other Pathways,' by Event Type (High-Level Category), 2012 vs. 2013

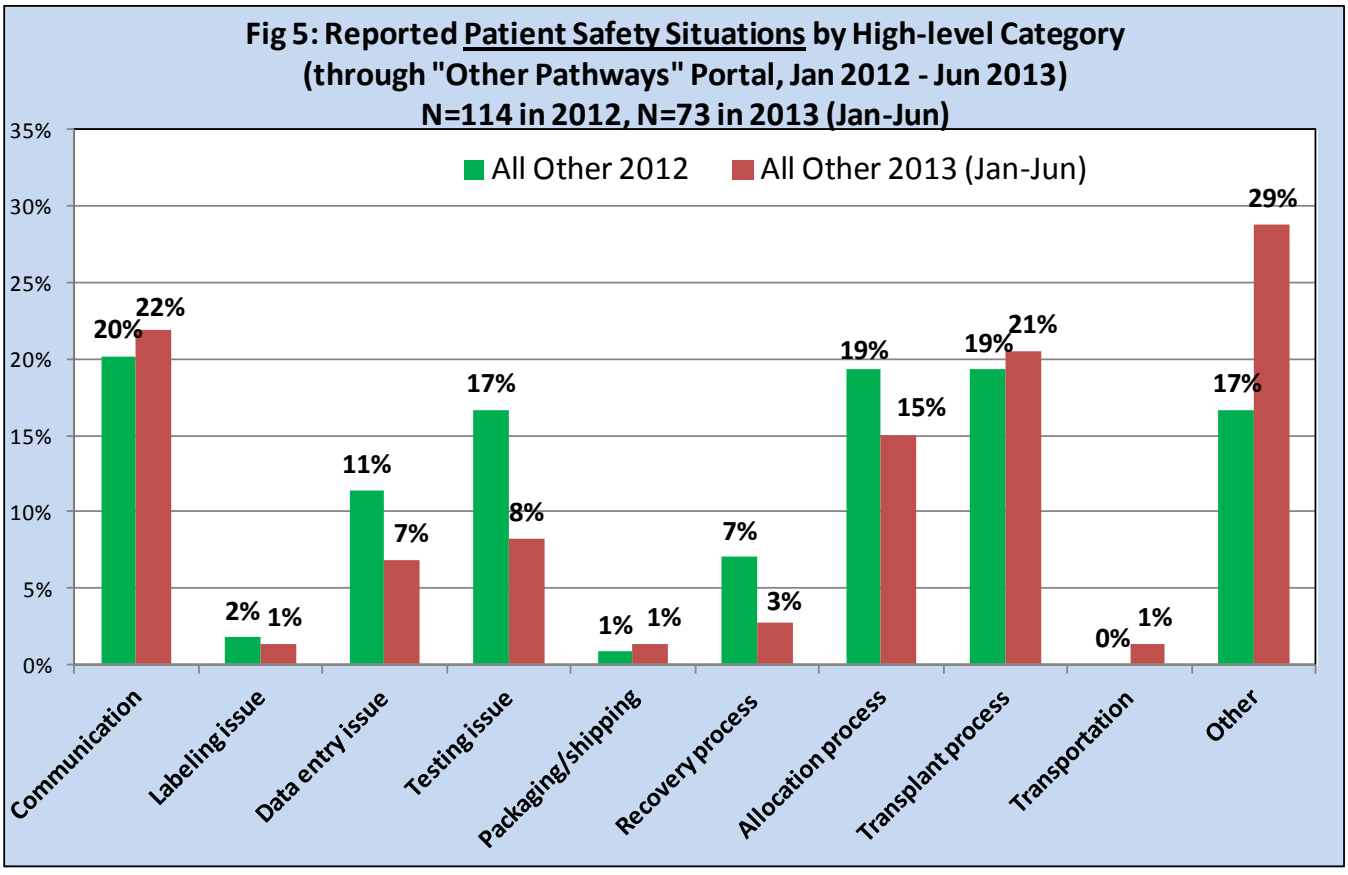
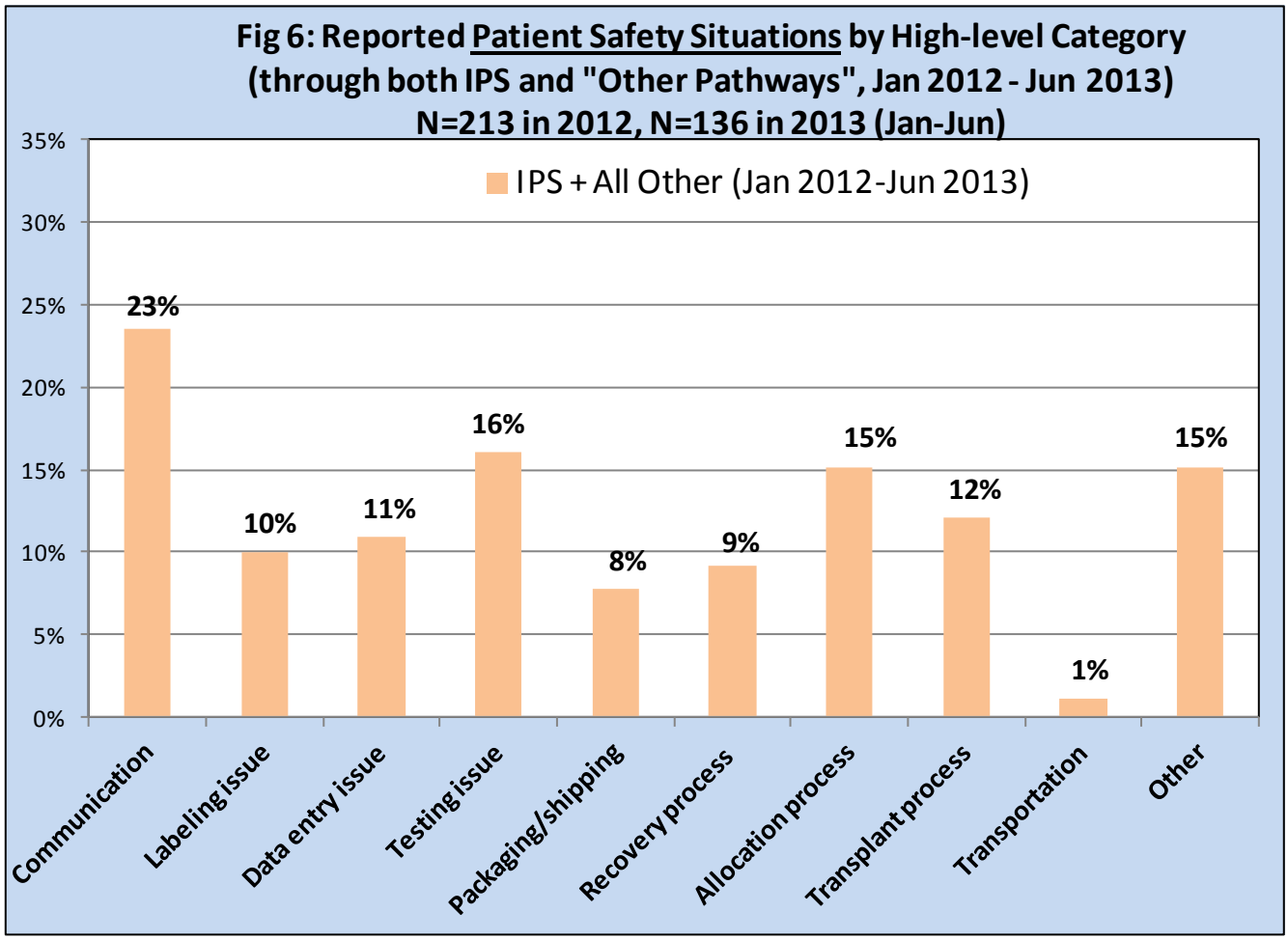


Figure 6 shows the high-level category frequencies in 2012-2013 for safety situations identified from both the IPS and other pathways combined.

Overall, the most frequently reported events were related to communication issues (23%), testing issues (16%), and organ allocation/placement issues (15%).

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



Reporting by Event Subcategory (January 2012 – June 2013)

The communication issues (N=82) in **Figure 6**, which includes situations reported since January 2012 through both the IPS portal and other pathways, are categorized more finely in **Table 1**. Twenty-seven (33%) of the eighty-two communication-related safety situations involved *inaccurate or insufficient donor (or organ/vessel) information*. Some examples of inaccurate/ insufficient information include the following:

- stripped ureter not noted on the anatomy
- pumping data not shared
- non-documented capsular tear
- no documentation of blood product administration that could cause hemodilution
- 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=18) was the second most prevalent communication subcategory, with *patient not informed adequately (or at all)* (N=8) third most prevalent. Six situations, though none in the first half of 2013, involved a problem communicating an *increased risk (or high risk) status of the donor*.

Organ allocation/placement issues (N=53) reported since 2012 were broken down by subcategory in **Table 2**. The majority (N=22) were related to a concern about *out of sequence allocation*. Several pertained to *rescinded offers* (N=5), *inaccurate donor data causing match to run incorrectly* (N=3), *recipient not on match list* (n=3), and *match not rerun once serology found to be positive* (N=2).

Table 3 shows testing issues (N=56) by subcategory. Eight (14%) of the 56 testing-related situations involved a concern about donor hemodilution. Seven situations pertained to HLA testing. Situations also related to the following: *important or required infectious disease test(s) not done* (n=5), *ABO subtyping error or discrepancy* (n=4), and *wrong type of infectious disease test used* (n=3).

Data entry issues (N=38) were subcategorized in **Table 4**. The most prevalent type of data entry issue involved *entering donor HLA into DonorNet* (N=11). Several types of patient/candidate data entry issues were also relatively common: *inaccurate patient priority or* status (N=8), *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 5 reveals that the most common labeling-related issues (N=35) involved an *incorrect donor ID* (N=18). Oftentimes labeling issues pertained to *unlabeled or mislabeled diagnostic materials (blood/nodes/spleen)* (N=14). 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.

Table 6 shows that 19 of the transplant procedure/process-related situations (N=42) 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 the first half of 2013. Three reports were received about a *recipient not being promptly removed from the waitlist* after transplantation.

Nine (28%) of the situations related to a recovery procedure/process issue (n=32) involved an *injury to the organ or extra vessels*. Seven cases involved an *issue with the recovering transplant team(s)* (**Table 7**), and included the following types of complaints:

- 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

In seven of the packaging/shipping situations (**Table 8**), the *organs were not packaged according to requirements*.

However, *switched kidney laterality* (N=10) 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.

Note that some switched laterality cases were classified as labeling issues (n=5, Table 5) and some as packaging/shipping issues (n=10, Table 8), while two events fell under both high level categories. Consequently, there were a total of 13 *switched kidney laterality* cases reported between January 2012 and June 2013. Both kidneys were successfully transplanted in 10 (77%) of these 13 cases, despite the mix-up.

Table 9 shows a total of only four transportation-related issues, one involving a commercial airline and three involving ground transportation or a courier. In one of these cases, the courier took the wrong package.

Though few transportation-related events are 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 9 high-level categories were grouped together as "Other issues" and are shown in **Table 10** (N=53). *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 or referred to DEQ due to a potential policy violation are included in this report.

Also, this report does not contain all living donor related events reported to the OPTN, but only those reported as a safety situation in the IPS. Other events involving living donors are reported through the Living Donor Adverse Event (LDAE) portal within the IPS. Data from this portal is analyzed under a separate process, per direction of the OPTN Living Donor Committee.

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Updated Patient Safety Situation Report, August 2013

Table 1: Communication-Related Safety Situations Reported from Jan 2012-Jun 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=27).

Total Number of Communication-Related Situations Reported from Jan 2012-Jun 2013: N=82

Communication Issues, by Subcategory	2012	2013*	Total
inaccurate/insufficient donor or organ/extra vessels information	14	13	27
delayed communication	9	9	18
patient not informed adequately (or at all)	7	1	8
miscommunication of donor test results	3	4	7
communication issue - (no subcategory)	5	1	6
increased risk (high risk) status of donor	6	0	6
missing documentation	4	2	6
other - delay in potential disease transmission reporting	0	6	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
reliance on electronic instead of verbal communication	2	0	2
misinterpretaton of test results	1	0	1
other	1	0	1
other - ABO	1	0	1
other - dialysis and TXC communication breakdown	0	1	1
other - donor id transcription error	0	1	1
other - inappropriate patient communication/privacy violation	0	1	1
other - incorrect donor dob per family	0	1	1
other - local backup confusion	1	0	1
other - opo and transplant center communication breakdown	0	1	1
other - patient complaint of impolite treatment	1	0	1
other - unsympathetic attitude toward patient and family	1	0	1

**** January through June, 2013***
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 2: Organ Allocation/Placement-Related Safety Situations Reported from Jan 2012-Jun 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=21).

Total Number of Allocation/Placement-Related Situations Reported from Jan 2012-Jun 2013: N=53

Organ Allocation/Placement Issues, by Subcategory	2012	2013*	Total
out of sequence allocation	15	6	21
rescinded offer	3	2	5
inaccurate donor data caused match to run incorrectly	2	1	3
organ allocation/placement issue - (no subcategory)	3	0	3
recipient not on match list	2	1	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 - broken agreement to share split liver	0	1	1
other - center not given laterality choice	0	1	1
other - complaint of opos blasting too many offers	1	0	1
other - consent not obtained	1	0	1
other - match not rerun after brain death became dcd recovery	0	1	1
other - match not rerun after dcd converted to brain death	0	1	1
other - opo not accommodating to TXC request for donor testing	1	0	1
other - pressure applied to direct donation to specific candidate	1	0	1

**** January through June, 2013***
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Table 3: Testing-Related Safety Situations Reported from Jan 2012-Jun 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=8).

Total Number of Testing-Related Situations Reported from Jan 2012-Jun 2013: N=56

Testing Issues, by Subcategory	2012	2013*	Total
infectious disease - hemodilution issue	5	3	8
HLA - discrepant results	1	6	7
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 - cultures not available or not done	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
ABO - ABO error or discrepancy	1	0	1
ABO - ABO subtyping misinterpretation	1	0	1
ABO - blood transfusion caused misleading results	1	0	1
ABO - switched source documents	1	0	1
HLA	1	0	1
HLA - switched samples	0	1	1
infectious disease - other - inability to distinguish cultures	1	0	1
infectious disease - required test not used	1	0	1
infectious disease - switched samples	1	0	1
other - biopsy misinterpretation	1	0	1
other - donor tests performed outside of required window	0	1	1
other - illegible reports	1	0	1
other - manufacturer shortage of test kits	1	0	1
other - misinterpreted results	0	1	1
other - requested test (biopsy) not done	1	0	1
other - required donor tests not performed within 24 hours of cross clamp	1	0	1
other - required test not performed	1	0	1

**** January through June, 2013***
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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.
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Duplicate situations and reports not pertaining to patient safety were excluded.

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Table 4: Data Entry-Related Safety Situations Reported from Jan 2012-Jun 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=11).

Total Number of Data Entry-Related Situations Reported from Jan 2012-Jun 2013: N=38

Data Entry Issues, by Subcategory	2012	2013*	Total
DonorNet - HLA	9	2	11
Waitlist - inaccurate patient priority or status	5	2	7
DonorNet - increased risk (high risk) status of donor	2	2	4
Waitlist - ABO	4	0	4
DonorNet - ABO subtyping	2	1	3
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 - demographics	1	0	1
DonorNet - labs	1	0	1
Waitlist - labs	1	0	1
other - living donor patient status	1	0	1

**** January through June, 2013***
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Table 5: Labeling-Related Safety Situations Reported from Jan 2012-Jun 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=18), which are often transcription errors (N=11), and often involve incorrect labeling of blood/nodes/spleen (N=14).

Total Number of Labeling-Related Situations Reported from Jan 2012-Jun 2013: N=35

Labeling Issues, by Subcategory	2012	2013*	Total
donor id - incorrect id	13	5	18
blood/nodes/spleen	10	4	14
transcription error	10	1	11
switched laterality - kidneys	2	3	5
missing label	3	1	4
required information missing	3	0	3
donor id - missing id	2	0	2
ABO	1	0	1
other	1	0	1
other - international/foreign language issue	1	0	1
other - opo did not provide labels	0	1	1

**** January through June, 2013***
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: Transplant Procedure/Process-Related Safety Situations Reported from Jan 2012-Jun 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=19), use of vessels in a non-transplant patient (N=6).

Total Number of Transplant Procedure/Process-Related Situations Reported from Jan 2012-Jun 2013: N=42

Transplant Procedure/Process Issues, by Subcategory	2012	2013*	Total
other - vessel sharing	11	8	19
vessels used in a non - transplant patient	5	1	6
other - recipient not promptly removed from Waitlist	3	0	3
complaint about program frequent pursuit of meld exceptions	0	1	1
donor/recipient compatibility check not performed	1	0	1
other - complaint about overaggressive acceptance of marginal organs	0	1	1
other - complaint about poor candidate selection that led to bad outcome	0	1	1
other - complaint of poor post - op patient care	1	0	1
other - complaint of poor quality organ used for transplant	1	0	1
other - delay in listing a patient	0	1	1
other - drug recall	1	0	1
other - immunosuppression drug recall	1	0	1
other - organ discarded due to no surgeon available	0	1	1
other - patient not listed promptly	0	1	1
other - recipient not removed promptly from Waitlist	1	0	1
other - stent left in too long	0	1	1
other - vessel destruction not documented	0	1	1
transplant procedure/process issue - (no subcategory)	0	1	1

**** January through June, 2013***
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: Recovery procedure/process-Related Safety Situations Reported from Jan 2012-Jun 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=7) and injury to organ or vessels(N=9)

Total Number of Recovery Procedure/Process-Related Situations Reported from Jan 2012-Jun 2013: N=32

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	2	7
poor donor management	3	3	6
OR time delayed	2	0	2
other - concerned about validity of brain death declaration	2	0	2
other - product recall	2	0	2
sterile field breach or other sterility issue	2	0	2
other - complaint about opo being unprofessional pursuing consent	1	0	1
other - donor family complaint about brain death declaration protocols	0	1	1
other - organ accidentally discarded	1	0	1
other - same surgeon for death declaration and recovery	1	0	1
other - undue pressure applied to obtain consent	1	0	1
other - violated dcd protocol	0	1	1
preservation fluid issue	1	0	1

**** January through June, 2013***
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 8: Packaging/Shipping-Related Safety Situations Reported from Jan 2012-Jun 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=10) and packaging not meeting requirements (N=7).

Total Number of Packaging/Shipping-Related Situations Reported from Jan 2012-Jun 2013: N=27

Packaging/Shipping Issues, by Subcategory	2012	2013*	Total
switched laterality - kidneys	6	4	10
not packaged according to requirements	3	4	7
insufficient or missing blood/nodes/spleen	2	2	4
sterile container/bag not properly closed	2	2	4
diagnostic materials from wrong donor	1	0	1
frozen organ	0	1	1
other - extra vessels	0	1	1
other - wrong package sent	1	0	1
packaging/shipping issue - (no subcategory)	1	0	1
preservation fluid issue	1	0	1

**** January through June, 2013***
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-Jun 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-Jun 2013: N=4

Transportation Issues, by Subcategory	2012	2013*	Total
airline (commercial) - airline misdirected	0	1	1
ground	0	1	1
ground transportation - courier/driver issue	1	0	1
other - courier took wrong package	1	0	1

**** January through June, 2013***
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 10: Other Safety Situations Reported from Jan 2012-Jun 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-Jun 2013: N=53

Other Issues	2012	2013*	Total
events related to a potential disease transmission*	13	17	30
vessels not stored properly	4	1	5
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
EMR system unavailable for extended period of time	1	0	1
complaint about transplant program lack of expertise	0	1	1
complaint of unethical/unlawful conduct	0	1	1
complaint that center refused to add patient to their list	1	0	1
concern about OPO showing favoritism to a TXC	1	0	1
concern about outcomes at a transplant center	1	0	1
concern about patient access to transplant	1	0	1
drug recall	1	0	1
ethical concerns about candidate evaluation/selection	0	1	1
internet outage	1	0	1
living donor issue* - aborted recovery	0	1	1
living donor issue* - concern about valuable consideration regulation breach	0	1	1
living donor issue* - donor felt pressured	0	1	1
living donor issue* - no ida consult	0	1	1
living donor issue* - pattern of errors and aborted recoveries	0	1	1
patient being hindered from transferring care	1	0	1
patient complaint about listing status	0	1	1
patient safety contact unclear of role	0	1	1
recall of chest tubing	0	1	1
vessels cannot be located	0	1	1
vessels erroneously discarded	1	0	1
vessels shared with non - OPTN member hospital	0	1	1

* Does not include all disease transmission or living donor related events reported to the OPTN.

**** January through June, 2013***
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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.