Surgical Specimen Management

A Descriptive Study of 648 Adverse Events and Near Misses

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• ***Context.***—**Surgical specimen adverse events can lead to delays in treatment or diagnosis, misdiagnosis, reoperation, inappropriate treatment, and anxiety or serious patient harm.**

Objectives.—**To describe the types and frequency of event reports associated with the management of surgical specimens, the contributing factors, and the level of harm associated with these events.**

Design.—**A retrospective review was undertaken of surgical specimen adverse events and near misses voluntarily reported in the University HealthSystem Consortium Safety Intelligence Patient Safety Organization database by more than 50 health care facilities during a 3-year period (2011–2013). Event reports that involved surgical specimen management were reviewed for patients undergoing surgery during which tissue or fluid was sent to the pathology department.**

Results.—**Six hundred forty-eight surgical specimen events were reported in all stages of the specimen management process, with the most common events reported during the prelaboratory phase and, specifically, with specimen labeling, collection/preservation, and transport. The most common contributing factors were failures in handoff communication, staff inattention, knowledge deficit, and environmental issues. Eight percent of the events (52 of 648) resulted in either the need for additional treatment or temporary or permanent harm to the patient.**

Conclusions.—**All phases of specimen handling and processing are vulnerable to errors. These results provide a starting point for health care organizations to conduct proactive risk analyses of specimen handling procedures and to design safer processes. Particular attention should be paid to effective communication and handoffs, consistent processes across care areas, and staff training. In addition, organizations should consider the use of technology-based identification and tracking systems.**

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The management of surgical specimens, from collection on the sterile field through communication of results, involves multiple providers from different disciplines. Various preparation processes (eg, preservatives) and numerous handoffs (eg, from the surgeon to operating room personnel to transporting personnel and to the pathology personnel), place the process at risk for error. When surgical specimens are mislabeled, improperly preserved, or lost, the consequences can be serious, particularly when specimens are irreplaceable. Surgical specimen errors can lead to delays in diagnosis and treatment, misdiagnosis, inappropriate treatment, repeat procedures or reoperations, and emotional distress or physical harm.[1,2] In a survey of top safety issues identified by perioperative nurses, prevention of specimen management errors was identified as one of the highest-priority issues requiring additional quality-improvement efforts.[3]

Errors in the management of surgical specimens can occur in the prelaboratory or laboratory phases, and communication of errors can occur during the postlaboratory phase.[1,4–10] Studies in the prelaboratory phase have focused on specimen identification.[4,6,7] Errors can also occur during order entry, specimen collection, specimen preservation, and transport to the laboratory.[11]

Studies of the laboratory phase have primarily focused on errors in specimen labeling[6,8,12] and diagnostic accuracy.[13–19] However, other errors can also occur during accessioning and processing, including failures in the use of equipment, incorrect techniques, and cross-contamination.[18,20–22]

In the postlaboratory phase, errors can occur during the communication of results from pathologist to treating clinician. Failure may also occur when the receiving provider fails to review the results, misinterprets the results, or fails to communicate the results to another provider or to the patient. In a study of frozen section reports, 2.7% (8 of 300) of the reports involved miscommunication of findings,

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including surgeons' misinterpretation of nonstandard descriptive terminology; these events were frequently associated with deferred diagnoses.[9]

A better understanding of the spectrum of surgical specimen management errors is needed to inform the design of systems that are effective in preventing the occurrence of these errors. The purpose of this analysis was to describe the types and frequency of events (eg, mislabeling, delays in transport), contributing factors (eg, communication failure, staff inattention), and harm (eg, additional testing or treatment) associated with the management of surgical specimens. Review of these events prompts discussion of interventions to reduce or eliminate surgical specimen error.

MATERIALS AND METHODS

This descriptive study used a retrospective review of adverse events and near misses voluntarily reported to the University HealthSystem Consortium Safety Intelligence Patient Safety Organization. Participation in a patient safety organization is voluntary, and the data submitted may not represent all reports. Surgical specimen–related reports were obtained from more than 50 participating health care organizations, primarily academic hospitals and affiliates across the United States. The University of Iowa institutional review board determined that this study did not meet the regulatory definition of human subjects research, and approval was not necessary.

The patient safety organization database incorporates the Agency for Healthcare Research and Quality (Rockville, Maryland) Common Format, version 1.1, and reporting organizations use a common taxonomy of event types and harm scales.[23] Event types are depicted in Tables 1 and 2. Harm is categorized as no harm, emotional distress or inconvenience, additional treatment, permanent harm, severe permanent harm, or death.[23] The interrater reliability of the Common Format Harm Scale has been found to be moderate ($\kappa = 0.51$).[24] Reporters described events that reached the patient and did or did not cause harm as well as those events that did not reach the patient (near misses). Managers (or their designees) of the reporting units (eg, operating room, pathology) and safety departments reviewed the accuracy of the harm scores and identified contributing factors (eg, communication, staff inattention) and costs incurred (eg, delay in care, additional cost, additional testing) from categories in a standardized list. Contributing factors are listed in Table 3. More information about the Agency for Healthcare Research and Quality common formats, including event types and harm scales, are available at https://www.psoppc.org/psoppc_web/publicpages/commonFormatsV1.1.

All event reports identifying an issue with a surgical specimen sent from the operating room for pathology, cytology, or culture from January 1, 2011, to December 31, 2013, were included. Reports that did not identify the type of specimen as a surgical specimen were excluded. A series of queries and text searches was conducted to assemble a comprehensive sample. First, events meeting the following search criteria were identified: (1) adverse laboratory event or near miss, or (2) location identified as laboratory/pathology departments and/or operating room; and (3) not including the word "blood" in the narrative. Next, additional events were selected based on the following criteria: (1) surgical events entered under "wrong patient," "wrong procedure," "wrong side/site," and "other surgical events"; (2) location laboratory/pathology departments and/or operating room; (3) the narrative description included the word "label," "report," "sample," "specimen," and/or "pathology"; and (4) the narrative did not include the word "blood." Events that were an integral part of the surgical procedure, such as an intraoperative parathyroid hormone test, were included.

Surgical specimen events were classified by specimen type and event type. Multiple classifications could be selected, as appropriate, for each event reviewed.

Table 1. Surgical Specimen Events by Category

Surgical Specimen Taxonomy, Level 1	Events,[a] No. (%), n = 648
Specimen labeling	319 (49)
Specimen transporting and/or storing	247 (38)
Specimen collecting	156 (24)
Specimen processing	55 (8)
Specimen quality	42 (6)
Ordering	40 (6)
Reporting of results	19 (3)
Analysis of specimen in the laboratory	8 (1)

[a] An event may appear in more than one category.

RESULTS

Our search initially yielded 1430 event reports. Of these, 54.7% (782 of 1430) did not meet our inclusion criteria. The remaining 648 events were included in this analysis. Surgical specimen errors were reported in all stages of the surgical specimen management process, with the most common errors reported in the prelaboratory phase during specimen labeling (49%; n = 319), specimen transport or storage (38%; n = 247), and specimen collection (24%; n = 156). Some reports described events in more than one stage of the process (Table 1).

The reporter identified his or her role in 518 of the 648 event reports (80%). Of these, more reports were completed by laboratory/pathology coordinators, supervisors, or technicians (39%; 202 of 518), likely because issues or errors were discovered when the specimen reached the laboratory. Other disciplines included nurses (30%; n = 155), managers (15%; n = 78), physician assistants (6%; n = 31), other/not specified (6%; n = 31), and physicians (4%; n = 21). The clinical service involved in the event was identified in about one-half of the surgical specimen reports (n = 331). Of these, general surgery (28%; n = 93), obstetrics/gynecology (11%; n = 36), and orthopedic surgery (9%; n = 30) were most frequently involved.

Prelaboratory Phase

Most of the 648 event reports (93%; n = 603) involved an error in the prelaboratory phase, when orders were entered or transcribed, specimens were collected, containers or requisitions were labeled, and/or specimens were transported to the laboratory (Table 2). Some event reports described errors in more than one laboratory phase.

Orders and Transcriptions.—Of the 648 events, 40 (6%) involved orders. In some events, orders were not entered or were cancelled because of a software programming issue, and the laboratory staff did not receive the order. Other errors occurred when the order was entered incorrectly or the incorrect order was delivered to the laboratory. In a few reports, orders were entered into the wrong patient's electronic health record, wrong encounter, or an inactive record.

Specimen Collections.—Nearly one-quarter of the 648 errors (n = 156) occurred during specimen collection. These errors mainly related to specimen solution (43%; n = 67), placement into containers (33%; n = 51), and collection technique (15%; n = 23). Solution/preservative errors involved not adding any solution, adding the incorrect

Table 2. Types of Surgical Specimen Issues by Stage of Specimen Management		
Stage in Process,[a] No. (%), n = 648	**Category Issue**	**Events,[a] No. (%), n = 648**
Ordering, 40 (6)	Orders not entered, cancelled by computer, not clarified	26 (4.0)
	Wrong test ordered and/or delivered to laboratory	8 (1.2)
	Order entered for wrong patient, encounter, inactive record, or provider	6 (0.9)
Specimen collection, 156 (24)	Not placed in specimen container, container empty, or specimen discarded	51 (7.9)
	No solution or preservative on specimen	44 (6.8)
	Incorrect technique used	23 (3.5)
	Incorrect solution on specimen or solution should not have been added to specimen	23 (3.5)
	More than one specimen in container	8 (1.2)
	Incorrect specimen container	7 (1.1)
Specimen labeling, 319 (49)	Label or requisition missing	96 (14.8)
	Mislabeled: wrong or missing patient identifiers	69 (10.6)
	Label or requisition inaccurate, incomplete, or illegible (eg, date/time, diagnosis)	67 (10.3)
	Mislabeled: wrong site or side	31 (4.8)
	Label does not match requisition	25 (3.9)
	Mislabeled: wrong tissue identified	17 (2.6)
	Mislabeled: tissue not identified	14 (2.2)
Transport and/or storage of specimen, 247 (38)	Delay	99 (15.3)
	Specimen lost or not received in laboratory or pathology department	77 (11.9)
	Delivered to or stored in wrong place	26 (4.0)
	Specimen not refrigerated	13 (2.0)
	Solution spilled or leaked out of container	12 (1.9)
	Transported through tube system instead of hand delivery, a pneumatic tube issue	8 (1.2)
	Delivered without communicating with the laboratory or pathology department	8 (1.2)
	Breakage or compromised specimen	4 (0.6)
Specimen processing, 55 (8)	Delay	31 (4.8)
	Error when logging in specimen	6 (0.9)
	Loss, breakage, or compromise in laboratory	6 (0.9)
	Failure of laboratory to enter or clarify order	5 (0.8)
	Test performed does not match order	4 (0.6)
	Mislabeled	3 (0.5)
Specimen quality, 42 (6)	Specimen quality compromised	27 (4.2)
	Quantity not sufficient	13 (2.0)
	Possible contamination	2 (0.3)
Analysis of specimen in the laboratory, 8 (1)	Incorrect technique	6 (0.9)
	Equipment error during analysis	2 (0.3)
Reporting results, 19 (3)	Delay in reporting of results	12 (1.9)
	Incorrect results reported	7 (1.1)

[a] An event may appear in more than one category or process stage.

solution, or adding solution when it should not have been added. About one-third of the collection issues involved specimens that were not immediately placed into the specimen container, resulting in temporarily misplaced or lost specimens. Some specimens were left on the surgical field and were, at times, accidentally discarded. Collection technique problems involved insufficient biopsy sample size, margins, or contents or incorrect specimen handling (eg, discarding a portion of specimen). Other collection issues included placing the specimen in the wrong container or type of container.

Specimen Labeling.—Almost one-half of the 648 surgical specimen events (n = 319) involved a specimen-labeling issue. In 96 of these events (30%), the specimen container was not labeled or the requisition form was not sent with the specimen. In the remaining 223 reports (70%), the specimen was labeled or had a requisition, but the information was incomplete, inaccurate, or illegible. In 67 of these 223 reports (30%), information such as date and time of collection, the patient's clinical information, or the diagnosis was missing or incorrect. In another 69 of the 223 reports (31%), the label did not have the required patient identifiers or the patient was incorrectly identified by name or number. The label or requisition identified the wrong side or site of specimen collection in 31 reports (14%). Mislabeling, in which the specimen label did not match the requisition, occurred in 25 reports (11%) and often misidentified the patient's name. In the remainder, the tissue was incorrectly identified (8%; 17 of 223) or not identified on the label or requisition (6%; 14 of 223).

Specimen Transport.—Almost 40% of the 648 reported events involved issues in specimen transport to the laboratory and/or storage before receipt in the laboratory (n = 247). Of these 247 transport errors, 99 errors (40%) involved delays in transporting specimens. In 77 events (31%), specimens were misplaced or lost and did not reach

Table 3. Surgical Specimen Events by Contributing Factor

Contributing Factor	Events,[a] No. (%), n = 331
Communication issues, including handoffs	172 (52)
Staff inattention	162 (49)
Knowledge, training, experience	126 (38)
Environmental issues (distractions, interruptions, emergency, lighting)	56 (17)
Patient misidentification	36 (11)
Staffing issues (adequacy, staff mix, float/agency staff)	26 (8)
Accuracy or availability of test results	23 (7)
Order entry or other documentation problem	20 (6)
Policies/procedures lacking, unclear, or staff unaware	20 (6)
Repetitive task	17 (5)

[a] An event may have more than one contributing factor.

 Surgical Specimen Events. Chicago, IL: University HealthSystem Consortium, Safety Intelligence; 2015:1–11.

the laboratory/pathology department. Delays occurred when specimens were not immediately transported to the appropriate area. Operating room personnel set specimens aside or stored them temporarily on a counter, in collection boxes, in a refrigerator, or under a stretcher, or the specimen was held until the end of the case (individual or batched specimens) rather than taking or sending them directly to the laboratory. Other delays occurred when specimens were transported to the wrong location or area and had to be rerouted or were temporarily lost.

In some cases, the specimen was not stored properly in the refrigerator (13 of 247; 5%). In others, the preservative/solution leaked during transport when container lids were not sealed securely or breakage/compromise of the container occurred (12 of 247; 5%).

Laboratory Phase

Specimen Processing and Analysis in the Laboratory.—Errors in the laboratory phase were less commonly reported (63 of 648 reports; 10%). The most common issue involved delays in processing and analyzing specimens (31 of 63; 49%). Other specimen processing errors included errors logging in specimens (n = 6; 10%), lost or compromised specimens in the laboratory (n = 6; 10%), tests that were not completed or were incorrectly completed because orders were not entered or unclear orders were not clarified (n = 5; 8%), specimens in which the incorrect test was performed (n = 4; 6%), and specimens that were incorrectly labeled during the analysis (n = 3; 5%).

Only 8 reported events (13%) involved errors during specimen analysis. In 6 of these 8 events (75%), the laboratory/pathology staff analyzed the specimen using the wrong technique; for example, the tissue was oriented incorrectly. In other cases, the procedure setup was incorrect because important diagnostic information was unavailable. Two events (25%) were associated with an equipment malfunction.

Specimen Quality.—Of the 648 cases, 42 (6%) of the specimen quality issues were identified through the narrative descriptions and were typically reported by the laboratory. Most often, these were a result of improper specimen collection practices (27 of 42; 64%); for example, the tissue had dried because no solution or preservative had been added, or the specimen was placed in the wrong solution. In other cases, the quantity was inadequate (n = 13; 31%), or the specimen was compromised during handling; for example, the container broke and damaged the specimen or the specimen was contaminated.

Postlaboratory Phase

Problems surrounding the timeliness and accuracy of surgical specimen results were described in 3% (19 of 648) of the event reports. Delays in receiving the results were more common than incorrectly reported results. Some delays occurred with the patient still in the operating room; for example, the reporting of frozen section results was delayed.

Contributing Factors

Managers reviewing event reports identified contributing factors in 51% (331 of 648) of the event reports. Some events involved more than one contributing factor. The most common contributing factors reported in these 331 reports were failures in communication or handoffs (52%; n = 172); staff inattention (49%; n = 162); inadequate knowledge, training, and experience (38%; n = 126); and environmental issues (17%; n = 56), including distractions, interruptions, emergencies, and poor lighting (Table 3). These factors aligned with our review of the event descriptions.

Specimen collection errors occurred because surgical staff lacked knowledge, training, and experience with the procedures for handling specimens or communication was unclear about the preservative required. Specimens were lost or discarded because of improper handoffs. Factors contributing to labeling errors included staff inattention, environmental distractions, failure to follow procedures, and changes in staff. In some cases, the surgeon did not clearly communicate about, or miscommunicated, the specimen type, site or side, or quantity or the nurse misunderstood the directions.

Factors contributing to delays in transporting specimens included heavy workload, interruptions, batching specimens, and staff inattention. Errors during specimen transport were commonly due to lack of knowledge on policies and procedures for the delivery of specimens, often during "late hours" or "after hours." Failures in verbal and physical handoffs contributed to specimens being delivered to the wrong location or getting lost when they were delivered through the pneumatic tube system. In some cases, staff was unaware that surgical specimens were to be hand-delivered to the laboratory and that delivery via the pneumatic tube was in violation of policy. Often, laboratory staff was unaware that a specimen had been delivered because it was left on the counter without notice; therefore, the specimen sat unattended and was not processed. Delays in specimen analysis were caused by numerous factors, including failures in order entry, indirect handoff to laboratory staff, inadequate specimen quantity or quality, failures in specimen transport, miscommunication between the surgical staff and laboratory staff, availability of laboratory/pathology staff, and shift changes. In cases in which the specimens were lost in the laboratory, there was often more than one specimen and/or different sizes of specimens in the same container.

Harm

Most surgical specimen errors were discovered before the patient was significantly harmed. Of the 648 surgical specimen reports, most were either near miss events (43%; n = 279) or events that reached the patient and did not result in harm or only caused emotional distress or inconvenience (49%; n = 318). About 8% (n = 52) of all surgical specimen events resulted in either the need for additional treatment (7%; n = 45) or temporary or permanent harm to the patient (1%; n = 7).

Some errors resulted in delays, either intraoperatively or during processing and reporting. In cases in which a delay affected intraoperative interpretation, the error extended the duration of surgery and anesthesia. For example, when orders were not identified as "rapid" for intraoperative parathyroid hormone, delays occurred in obtaining results. When orders were entered into the wrong patient's electronic health record, wrong encounter, or an inactive record, orders were not seen by the laboratory staff and a delay in processing occurred.

In many of the events, operating room or laboratory personnel identified the error and took corrective action. About 54% of the identification/labeling errors (172 of 319) were caught after transport to the laboratory. Errors were also caught when laboratory staff discovered that labeled containers were empty or requisitions indicated that not all specimens were in the container, and the specimens were retrieved. In some of these cases, specimens were found in the operating room and/or garbage after staff conducted a search. Rarely, lost specimens resulted in additional surgery when it was necessary and possible; however, in some cases, the specimen could not be replaced.

Costs Incurred

Overall, managers reviewing reports indicated that the financial cost for surgical specimen-related events was low. Of the 648 events reported, the reporter categorized the costs incurred in 316 cases (49%), and most (212 of 315; 67%) reported no or minimal additional cost to the organization. Of the 316 reports, 70 (22%) indicated that the event caused delays in care, and 60 (19%) reported that the event caused pain, anxiety, or inconvenience to the patient. Additional laboratory or diagnostic testing or treatment (eg, ambulatory visits or drug therapy) was required in 13% (41 of 316) of the events; additional patient monitoring was needed in 5% (n = 16); extended length of stay, a higher level of care, or an admission was required in 3% (n = 9); and additional surgery was indicated in 1% (n = 3) of the cases.

DISCUSSION

This analysis examines a large, generalizable sample of errors reported in the management of surgical specimens and communication of results by more than 50 health care organizations nationally. Event reporting is voluntary, and the data do not represent all surgical specimen management events. In addition, the types of event reports submitted to the patient safety organization may vary across organizations and may not represent all reports.

Lack of documentation of specimen type did not allow inclusion of some potential events. Reports were reviewed by managers within facilities, and inconsistencies in the completion of reports may exist. Because data on the number of specimens accessioned at each organization were not available, we were unable to calculate the incidence rate of reported events.

However, the results provide a rich source of information on the types of errors that occur and the factors contributing to those errors. These events can have significant impact on patient care and outcome, including the need for additional testing, treatment, and patient monitoring, as well as an increased length of stay, a higher level of care, admission, or additional surgery. Although it is beyond the scope of this article to measure the cost of this additional care, it may be significant and is worthy of additional study.

Misidentification and specimen labeling errors are common and represent an important priority for quality-improvement efforts. Although most labeling errors were near misses, the potential consequences can be severe when specimens are misidentified or labeled with the incorrect patient's name or clinical information, which can be critical for correct interpretation of the specimen by the pathologist.

Other problem-prone processes in the prelaboratory phase were specimen collection, preservation, and transport. Of particular concern are the many specimens that were compromised when prepared with incorrect transport medium, fixative, or technique. Policies and procedures should be readily accessible for staff at the point of use. Discussion of planned specimens and their management during the presurgical briefing and verification of specimens during the postoperative debriefing adds additional layers of safety.

Commonly, reports indicated that specimens were not received in the laboratory, having been either temporarily or permanently lost. Lost and compromised specimens can have serious implications for diagnosis and treatment, particularly when they are irreplaceable. Technology-based solutions, such as wireless bar code tracking systems and radiofrequency identification, have been proven to reduce identification errors during all phases of the laboratory process[25–28] and should be explored for potential benefit.

Less than 10% of reports described issues in processing and analysis in the laboratory. These results are consistent with previous studies reporting errors in the laboratory ranging from 0.1% to 7.44% of the overall total errors.[5] It is possible that errors occurring in these phases are reported in other venues, such as internal laboratory quality committees, and may be underreported in our data set.

In our analysis, 43% (279 of 648) of the reports were near misses, suggesting that the processes for managing specimens catch many errors before causing clinical consequence to the patient. However, in 18% (117 of 648) of events reviewed by managers, surgical specimen errors resulted in the need for additional patient monitoring or treatment, including ambulatory visits. Four percent (12 of 316) of the events involved higher costs associated with hospitalization and reoperation. Our analysis did not quantify the cost of litigation, which can be substantial.

Results of this analysis serve as a starting point for identification of systems weaknesses within the context of the individual organization. Key recommendations for improving the safety of specimen management are listed in Table 4.

Most reported surgical specimen errors occur in the prelaboratory phase. This is consistent with other published studies.[21] In addition to mistakes in labeling and identification, errors occurred during specimen collection, preservation, and transportation. Common contributing factors involved failures in handoff communication, knowledge

Table 4. Key Recommendations	
Recommendation	**Details**
1. Conduct a proactive risk assessment	• Establish an interdisciplinary team. • Conduct a proactive risk assessment (eg, health care failure mode and effect analysis),[29] and identify processes that are at high risk of failure and in need of control. • Use results to improve specimen handling processes.
2. Enhance communication and handoffs	• Discuss anticipated specimens during the preoperative briefing, and verify all information during the postoperative debriefing. • Include verbal communication and read-back verification of the specimen type, location, and other relevant information during handoffs of specimens among the surgeon, scrub nurse, and circulating nurse.[2,30]
3. Develop effective policies and procedures	• Establish policies and procedures for the safe handling of surgical specimens. The AORN, with input from the ACS, provides a framework for these documents.[2] • Place specimens in containers as soon as possible after they are obtained. • Label each container with 2 unique patient identifiers, specimen type, and specimen site.[2] • Conduct double-checks and cross-checks of the labeling of containers, requisitions, and logs before transport of specimens.[2] • Establish safe processes for chain of custody, and ensure the specimens are physically delivered to laboratory personnel, and critical information is communicated.[2]
4. Educate staff	• Provide training on handling surgical specimens during orientation, annually and when policies and procedures are updated. • Discuss policies and procedures for specimen labeling, adding solutions/preservatives, handoffs, transport of specimens (including delivery during off-hours), and management of rarely collected specimens. • Provide documentation and rapid reference guides at the point of use.
5. Explore technology	• Consider developing electronic order sets specific to specimens collected in the operating room.[27] • Explore technology-based solutions, such as wireless bar code–based tracking systems and radiofrequency identification to reduce identification errors during all phases of the process.[25–28]

Abbreviations: ACS, American College of Surgeons; AORN, Association of Perioperative Registered Nurses.

deficits, and the work environment. Multidisciplinary teams should evaluate and take action to improve their identified error-prone processes.

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