Lost Surgical Specimens, Lost Opportunities

At least 30 reports have been submitted to PA-PSRS involving surgical pathology specimens that were lost somewhere between specimen retrieval from the patient and processing in the laboratory. Some specimens can be repeated, such as a bowel biopsy to rule out inflammation or celiac disease. However, doing so places the patient at risk from the additional procedure and imposes a greater burden on the healthcare system through additional costs, time, and labor.

Of greater concern are specimens that cannot be replaced, such as fully excised tumors, skin lesions, or organs. The loss of such specimens may result in inappropriate or unnecessary treatment. Furthermore, lost specimens may delay diagnosis, increase patient anxiety, or be a source of potential litigation.

PA-PSRS Reports
The following examples of PA-PSRS narrative descriptions reflect the scope of the problem:

An OR specimen was transported to laboratory. The cutting room called to say there was no specimen in the container. The specimen was a completely excised ovary mass.

A patient underwent a liver biopsy. The pathology lab notified radiology that the patient’s specimen bottle was empty. It was discovered that another patient had two specimens in his bottle. The patient had a repeat biopsy performed.

A patient had two specimens excised from her breast. The specimens were sent to radiology for x-ray. The lab reported that only one specimen was received. Unable to locate the other specimen.

The surgeon dissected the patient’s ovary and tube and placed it in the cul-de-sac during a (laparoscopically assisted) vaginal hysterectomy. The ovary and tube were not ultimately removed from the cul-de-sac. Upon pathology review it was identified that the ovary and tube were missing. The patient returned to the OR, where the ovary and tube were located and removed.

Specimen was lost for 5 days. Specimen was left in the cooler. Specimen was discarded during clean up and was not sent to Pathology as requested.

The Process
The handling of specimens before reaching the pathology laboratory is referred to as the preanalytic phase. It involves many healthcare workers. Surgical pathology involves processing multiple specimens collected and labeled by numerous people. There may be little or no automation in the preanalytic phase. The persons handling the specimens have various levels of training. As a result, there is great potential for error. Specimens are more likely to be misplaced, mislabeled, or never collected in the first place, rather than lost in transit.

Getting a specimen to the laboratory for analysis involves the following steps:

1. Correctly identifying the patient.
2. Correctly identifying all the tissue/lesion in the patient.
3. Collection/biopsy/excision of the tissue.
4. Placing the specimen in an appropriate container.
5. Placing the specimen in an appropriate preservative/fixative.
6. Correctly labeling, recording of the specimen.
7. Completing a requisition slip that accompanies the specimen.
8. Transporting the specimen from the procedure and specimen drop-off area to the pathology department.

Systems Approach
Attempting to reduce risk using the traditional, person-oriented approach views lost specimens as being caused by aberrations in an individual’s performance. Attributing errors to apathy, distraction, or inattention results in corrective interventions such as retraining the “guilty” party or taking disciplinary action.

In contrast, a systems approach views errors in a complex system as being expected. Error analysis focuses on what safeguards can be put into place to reduce the risk of error in a flawed system—a system
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that may set up healthcare workers for error.\(^2\)

While the proximal cause of an adverse event may involve human lapses/omissions (sharp end of the patient care process), the origins of the error are more likely to be founded upon the organizational (blunt) end of the system’s process—institutional, regulatory, cultural, technological, and managerial factors.\(^2\)

Risk Reduction Strategies
Making a flow chart of your facility’s specimen collection system is a great way to begin looking at the process—from the time the specimen is obtained until it is received in the pathology department.\(^1,2\) Interviewing healthcare providers directly involved in the process is valuable in determining what actually occurs, rather than what the procedure manual indicates.\(^1\) Such interviews can also identify problems with the existing process and areas of potential improvement.\(^4\) Looking at workarounds in the system may provide insights into how to make the system more reliable. Interventions can then be piloted and outcomes measured to determine the extent of improvement.\(^2\)

Specimen Retrieval
Putting the specimens on the field in sterile containers and labeling the containers immediately when specimens are delivered to any container (on or off the field) makes it more likely that they will not get lost during clean-up. Verbal confirmation of patient/specimen information between the physician and the nurse also can help to ensure that the specimen is retrieved and secured.\(^4\)

Reducing Reliance on Memory
Relying on memory for complex tasks promotes inconsistency and variation in human performance. Pre-printed forms (checklists and daily logs/requisition slips) indicating data to be entered can reduce the need to rely on memory and also can help to ensure that all required information for specimen processing is obtained.\(^5\) Posting a chart of proper handling/fixative procedures associated with each type of commonly retrieved specimen may encourage staff to refer to written protocols, rather than to base their actions upon imperfectly recalled information.

Improving Information Access
Making clinical information easily accessible can be accomplished by computerized medical record information or the availability of the paper medical record when requisitions are completed.\(^5\)

Forcing Functions
Forcing functions apply constraints to the number of options by which a process can be completed. These include barcoding, preprinted supplies that improve labeling, supplies to prevent specimen mishandling, procedures requiring audible verification (read back) of patient identification and specimen type, hand-offs between personnel or departments at points of specimen transfer.\(^2,4\)

Decreasing Reliance on Vigilance
Both built-in internal checks and pathways can reduce dependence on human vigilance when all personnel use them. Bar codes and remote order entry into a computer system may help track specimens.\(^5\) Chain of custody documentation may help track specimens from the point of specimen generation to its entry into the pathology department.\(^2\)

Chain of Custody
Chain of custody is a process whereby a specimen is tracked from collection, through the steps of handling and transport, to the final disposition. Chain of custody is designed to maintain the integrity of the specimen and to ensure that the specimen and results are correctly matched to the person from whom the specimen was removed.

Chain of custody has been used in law enforcement/forensics to track evidence and to protect evidence from loss and tampering. In the healthcare environment, chain of custody documentation has been used to track such things as police-requested blood alcohol specimens and pre-employment, employment, school drug testing. Chain of custody concepts are also used by blood banks to ensure that the correct blood product is administered to the correct patient.

Chain of custody can also be used in tracking pathology specimens from procurement to arrival in the pathology department. This process may be especially valuable for irreplaceable excisional diagnostic biopsy specimens. In its Sample Protocol for Safe Specimen Handling in the OR, the Association of Perioperative Registered Nurses (AORN) states:

*Establish mechanisms for chain of custody to ensure accountability. Consistent communication patterns should be established between personnel at change of shift or relief.\(^4\)*

Information captured on a chain of custody form/log may include: persons and departments releasing the specimen, persons and departments/couriers receiving the specimen, release dates and times, patient identification, specimen number, specimen description, and purpose of the hand-off. If a specimen does not reach pathology, the chain of custody form/log may be helpful as the search is conducted and the
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error is analyzed for system improvement.

Standardizing Language and Tasks
The development of written policies and procedures, clear specimen acceptability standards, and easily available references provides a two-fold benefit by reducing guesswork concerning the specimen handling process in general, as well as promoting consistency in handling/preserving specific types of specimens.

Procedures for responding to specimen handling errors and near misses are incorporated into the system improvement/patient safety monitoring and analysis process.

Reducing the Number of Hand-Offs
Usually there are multiple hand-offs of specimens until the specimen arrives in pathology – each one a potential source of error. Reducing the number of hand-offs and using technology and chain of custody documentation to track specimens reduces complexity, and, thus, the potential for error.

System Design – Error Detection
Incorporating quality control monitors into the specimen handling process involves reviewing the chain of custody documentation and double checking when the specimen logs do not agree with specimens received in pathology. In addition, the pathology department might also consider reviewing OR schedules daily to determine what specimens are expected. Specimens expected can be compared with specimens received. Any discrepancies can be investigated and reconciled. With these approaches, specimens may be recovered if errors are caught in a timely fashion. Monitoring adherence to clearly defined policies and procedures for specimen handling will confirm competencies, ensuring that the right people are doing the right job.

Workload
Adjusting work schedules in the surgical setting and pathology department is an effective risk reduction strategy, particularly during times of fatigue, unexpected changes, or stress. This includes developing a pick-up/delivery schedule agreed upon by pathology and the perioperative area.

Environment
The physical environment where specimens are stored can be configured to reduce errors by providing dedicated, adequate space with good lighting, an appropriate area for documentation, and appropriate storage and delivery containers. Eliminating distractions during each step of the preanalytic phase promotes compliance with specimen handling procedures. The cultural environment – one based on a systems approach rather than individual blame – encourages identification of system issues, encourages problem solving, and reduces self-protective behavior in which errors are not reported. Some facilities have considered a free-standing pathology satellite department in the OR to handle specimens as they are generated.

Training
Providing appropriate training will help to ensure that responsibilities are clearly defined. Periodic observation of performance helps to confirm that competencies are maintained over time.

Success Story
In response to a lost specimen Sentinel Event, Slavin, et al.,2 flowcharted the specimen handling process, interviewed healthcare providers, and conducted multidisciplinary meetings involving representatives from administration, surgeons, nurses, pathology, and administration. The pathology department volunteered to assume responsibility for the specimen transport process. A designated pathology department staff person went to the operating rooms at regular intervals, collecting the specimens and ensuring that all specimens were accounted for and delivered to the laboratory for same-day processing. During the study period of one year, no specimens were lost, and there was a significant reduction in the number of specimen transport times longer than 24 hours.

Resources
The AORN has developed a guidance statement and sample protocol for safe specimen handling in the OR. The College of American Pathologists has a reference pertaining to error reduction: Quality Management in Anatomic Pathology: Promoting Patient Safety Through Systems Improvement and Error Reduction.

Notes
ECRI is an independent, nonprofit health services research agency dedicated to improving the safety, efficacy and cost-effectiveness of healthcare. ECRI's focus is healthcare technology, healthcare risk and quality management and healthcare environmental management. ECRI provides information services and technical assistance to more than 5,000 hospitals, healthcare organizations, ministries of health, government and planning agencies, and other organizations worldwide.

The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit organization dedicated solely to medication error prevention and safe medication use. ISMP provides recommendations for the safe use of medications to the healthcare community including healthcare professionals, government agencies, accrediting organizations, and consumers. ISMP's efforts are built on a non-punitive approach and systems-based solutions.