

Patient Safety Tip of the Week

March 20, 2018

Minnesota Highlights Lost Tissue Samples

Minnesota's Department of Health recently released its annual report [Adverse Health Events in Minnesota. 14th Annual Public Report](#). The category with a frequency of events that caught our eye was "Irretrievable Loss of an Irreplaceable Biological Specimen". That category has been included in its adverse event reporting system since 2014. It's, of course, of great concern since these represent incidents in which a biopsy or surgical specimen is lost, leaving a patient to not know whether he/she had cancer (or other serious condition) or a benign condition. Twenty-six of these events were reported during this fourth year of reporting, down slightly from the 31 events in 2016. Of those, 12 patients required additional monitoring or treatment as a result of the loss/damage to the specimen.

Specimens were lost during collection or obtaining the specimen in 54%, internal transport in 15%, and during lab processing during 31%. 77 percent of these specimens were lost, the rest being destroyed or damaged to the point that they could not be tested.

The majority of lost specimens were polyps obtained during a colonoscopy, but other types included placentas, masses/tumors, cervical tissue/cysts, and skin lesions.

Note that this category in adverse event reporting system does not include all lost specimens. To be reported, a specimen must both be lost and another procedure cannot be done to obtain a new specimen.

Inclusion of this category in the adverse event reporting system has led to changes ([Olson 2017](#)). Mayo switched to a standard container for specimens being sent to labs. Essentia Health added a computerized lab system, which uses bar-coding and other measures to track samples, to its northern Minnesota hospitals. Minneapolis-based Allina Health enacted policies governing the labeling, handling and transporting of hospital tissue samples. In addition, the Minnesota Hospital Association collaborated with multiple organizations to develop some excellent tools that we describe later.

There aren't any great statistics on how often surgical specimens are lost. One study ([Makary 2007](#)) looking at surgery in an outpatient clinic or a hospital operating room found 4.3 surgical specimen identification errors in every 1000 cases (and about 60% of those errors were in biopsies) but did not note cases of lost specimens. The Pennsylvania Patient Safety Authority did a Patient Safety Advisory "[Lost Surgical Specimens, Lost Opportunities](#)" in 2005. They had received at least 30 reports of lost surgical specimens through their patient safety reporting system but did not provide any denominator data so

the actual rates of lost specimens is unknown. Fortunately, these are probably rare events. However, they can be devastating to patients and staff when they occur.

We first highlighted the issue of lost lab specimens in our November 16, 2010 Patient Safety Tip of the Week “[Lost Lab Specimens](#)”. In that column we described participating in a **FMEA** (Failure Mode and Effects Analysis) after a near-miss where surgical biopsy specimens were temporarily misplaced (but fortunately found in a few days). Given the gravity of losing a specimen, we recommend organizations do their own FMEA of specimen management to identify vulnerabilities in their processes and procedures.

The process for specimen management begins well before the patient arrives in the OR. During **booking** onto the OR schedule one of the questions that should be asked is “Do you anticipate there will likely be surgical specimens to be sent to the lab?”. That is important since it can help facilitate having the correct specimen containers available before the case begins. Then, during the “**pre-op huddle**” or “**pre-op briefing**” that question should be asked again and all participants should verify that the correct specimen containers are present. Specimen containers come in different sizes and may or may not contain a preservative (eg. formalin), depending upon the size and nature of the expected specimen. Some organizations now utilize ways to further identify the nature (or destination) of the specimen by special means (eg. different colored lids).

We also advocate for including on your checklist during the **surgical timeout** an item to let all parties know that a specimen is expected (because more parties are in the OR than may have been at the pre-op huddle).

There should be **no pre-labeling** of specimen containers. **Labeling specimens** should take place **immediately** when the specimen is removed in the OR. Specimens are usually given to a nurse in the OR, who then puts the specimens in a container, or put directly into the container by the surgeon. Caution must be used if any instruments are used in order to avoid crushing the specimen or causing thermal injury. The nurse labels the container with the patient’s identification (at least 2 methods of patient identification), date/time taken, surgeon’s name, and description of the tissue (what it is and where it was taken from), any preservative used, and a requisition slip with similar information. Labels may also require a biohazard notification. Note that the labels should be generated in close proximity (in both space and time) to specimen procurement and are generated just prior to when they are placed on the specimen container. For those few facilities that do not have label printers in their OR/procedure rooms, make sure you inscribe using indelible ink that will not smudge and clearly and legibly print all information. Also, when using labels, take care to make sure the label is not positioned in a manner that it might be torn when the container lid is removed.

See also below for a great description the Minnesota Hospital Association suggests for the verbal communication that should take place at the time of specimen removal and transfer to containers (using “**hearback**” or “**readback**”) and the use of verification by two trained clinical professionals (eg. scrub and circulating nurse).

The **OR surgery/procedure documentation sheet should contain a section detailing what specimens were obtained** and sent to the laboratory. In fact, we recommend you also have a **check box for when no specimen is sent** and have the surgeon sign or initial that box when no specimens are sent.

Using forms or checklists may help remind people what to do with the specimen. If you use the World Health Organization's [Surgical Safety Checklist](#) the **Sign Out phase** is completed before the patient leaves the operating room. The Checklist coordinator verbally confirms the name of the procedure, the instrument and sponge counts, **correct labeling of any specimens**, any equipment problems, and key concerns for postoperative care and recovery. It is important this be conducted prior to any cleaning of the room. We've seen cases where a "missing" specimen is found on a table (or elsewhere!). Note that should never happen if you did appropriate communication and verification as the specimen was removed.

The **post-op debriefing** is also important. Yes, you should discuss specimen handling during the debriefing. But you also should discuss any problems you had with the instruments used for procuring or handling the specimens or the containers, so that future OR/ procedure cases do not experience similar problems. We recall a case where a spring-loaded instrument used for procuring a specimen malfunctioned, tossing the specimen off. Staff said "Oh. Dr. X had the same problem with that last time."!

One fortunate thing has come out of Minnesota's event reporting: the Minnesota Hospital Association has collaborated with multiple organizations to develop guidelines and tools to help prevent loss of specimens. In 2015 they put together a document "[Specimen Management in the Operating Room. Gap Analysis](#)" that includes a checklist for organizations to use to assess their compliance with best practices for specimen management. That has also been incorporated into the MHA's [Surgery Road Map](#).

It amplifies some of our above recommendations. For example, the huddle should review anticipated specimens, specimen containers, and any special considerations (e.g., research specimen, forensics, patient and family wishes). The process for generating a specimen label should produce only as many labels as needed and labels are generated just prior to when they are placed on the specimen container. It also suggests that pathology specimen containers have visual cues to make them more recognizable in the environment (e.g., all surgical specimens have a colored lid and/or colored specimen label). And during the post-op debriefing all specimens and orders are accounted for prior to clearing and cleaning the designated specimen area. And a reconciliation process should be in place for any specimen discrepancies noted before, during or after the procedure.

But the MHA Surgery Road Map has really good recommendations on communication during specimen management. It notes that as specimens are procured, the surgeon/proceduralist verbally communicates to the team:

- Type of specimen/anatomic designation
- Handling instructions
- Type of testing needed for the specimen

- Any special needs (e.g., inked margin examination, research protocol)

The circulator verbally confirms (**read back**) the specimen and handling instructions. Specimen containers are labeled as the specimen is placed in the container rather than before specimen is placed in container.

In addition, it recommends that procure specimens are visualized by two trained clinical professionals (e.g., scrub and circulator) at the time of procurement, labeled, and placed in the container. They ensure:

- Label is correct
- Label matches patient identification information
- Tissue is in container
- Correct number of specimens are in container
- Correct order has been placed

Moreover, it emphasizes some of the specimen tracking methods that we suggested were coming in our November 16, 2010 Patient Safety Tip of the Week “[Lost Lab Specimens](#)”. It specifies that an automation and health information technology (HIT) is present within the specimen management process:

- The facility’s primary electronic health record (EHR) interfaces with the facility’s laboratory information system (LIS).
- The LIS transmits accurate and timely results to the EHR and the specified provider(s).
- The EHR transmits accurate and timely patient and order information to the LIS.
- The EHR generates or electronically transmits a specimen requisition.
- There is an automated labeling system (e.g., bar coding, RFID).

AORN best practices for specimen management ([Van Wicklin 2015](#)) include even more valuable pearls. Once the need for a specimen is identified, the perioperative nurse conducts an assessment including the following:

- personnel to be notified (eg, pathologist for frozen section)
- requirements for specimen collection and handling (eg, keeping the specimen moist until transfer from the sterile field)
- method of transfer (eg, using sterile technique)
- requirements for containment (eg, size of the container)
- method of preservation (eg, type of solution)
- transport needs (eg, availability of personnel)
- disposition of the specimen (eg, disposal, returned to the patient)
- documentation required (eg, noting the location of suture tags)

Van Wicklin notes that specimens must be labeled to communicate preservative and biohazard information. She also stresses the importance of prompt use of correct preservatives and avoiding air exposure that can desiccate the tissue. For example, dry surfaces (eg if the specimen is put on a towel) may adhere to the tissue, and this can result in loss of portions of the resection margins when the specimen is removed from the

dry surface. The Van Wicklin article also has a nice cartoon illustrating multiple things not to do regarding specimens in the OR.

The MHA Surgery Road Map really just describes specimen handling up to the point of specimens leaving the OR/procedure room. In our November 16, 2010 Patient Safety Tip of the Week "[Lost Lab Specimens](#)" our FMEA went on to follow specimens on their way to and through the pathology lab. When we did that column there was limited data available on the impact of new technologies (**barcoding, RFID's, etc.**) on tracking lab specimens. These obviously have the potential to significantly reduce the loss of specimens.

So what happens to specimens once the surgery/procedure has been completed? Each hospital needs to look at all the steps in that subsequent process and especially take into account how the steps might differ after-hours and on weekends. And you need to take into account how the process in clinic or outpatient settings differs from that in the OR or procedure rooms.

In general, the process goes something like this at most hospitals:

The containers with the specimens are generally placed in a receptacle in the "pick-up" area of the OR nurses' station and entered into a log book. The specimens are then taken by someone (that "someone" could be a nurse, a courier, or anybody who happened to be going to the lab). That person would sign the log book in the OR and take the specimens to the lab. At the lab they would sign a log book, as would the person receiving the specimens in the lab. After logged in at the lab the specimens are taken by the technician to the "grossing" section and the technician prepares cassettes to be matched to each specimen. The pathologist then does a gross examination (dictating his/her report) and places specimen parts into the labeled cassettes. From there the specimens are put into the "processing" machine overnight. A technician maintains the lab log and indicates on there how many cassettes the pathologist listed in his dictated report. However, sometimes the technician does not hear the dictation until the following morning. In the morning the technician removes the cassettes from the processing machine and takes them to the "embedding" machine (paraffin bath). From there they go to a microtome where slides are prepared and labeled. They then go to a warming oven to dry, then are cooled off, and stained. Once stained and dried the slides are placed in a slide holder and placed, along with the corresponding gross descriptions, on the pathologist's desk. The pathologist adds the microscopic examination to his report and the slides are put in a filing cabinet for storage. This is the process that takes place at most labs.

As you can readily see, that's **a lot of handoffs** and handoffs are times of vulnerability to errors. "**Ownership**" becomes a key element. In one article ([Slavin 2001](#)), the pathology department decided that it would take ownership of the transport process from the OR to the lab. That effectively **reduced the number of handoffs**. Handoffs are always opportunities for errors to occur so anything that reduces the number of handoffs generally improves safety. In our own RCA/FMEA the OR staff decided to take ownership for the process when done after hours (taking the specimen to the lab, entering it into the log there, and putting it in formalin). This step basically says "**we will not**

assume that someone else will do it". Another example was our lab staff deciding to take over removal of the waste receptacles (rather than housekeeping) so they would have control in the event of a missing specimen.

Chain of custody is a term usually associated with precise tracking of forensic specimens or evidence in legal cases. Most labs at times do have to adhere to strict chain of custody procedures when they do handle items involved in litigation. Yet shouldn't every specimen be handled with the same level of scrutiny and security? We would certainly hope any specimen of ours were handled that way! Chain of custody is nicely described in the PPSA Patient Safety Advisory "[Lost Surgical Specimens, Lost Opportunities](#)". It usually involves logs containing the names/departments releasing the specimen, names/departments accepting the specimen, dates and times of such transfers, patient identification, specimen number, specimen description, and others.

One very simple intervention that should be done at all handoffs is a **specimen count**. If you knew you had 14 specimens or cassettes at Step B and you now have only 13 at Step D, you have at least isolated the locations where the specimen was most likely lost or misplaced. It's just like doing a sponge count when you are doing surgery. (Speaking of sponges...one cause of "lost" specimens is when tiny tissue specimens get attached to small sponges that may be put in specimen containers).

During the discussion with key stakeholders, **anecdotal items** tend to come out. In our original FMEA, it was brought out that sometimes the receiving person in the lab after hours did not always put the larger specimens in formalin. The pathologists also often grumbled that the surgeons weren't providing enough detail about the specimens.

What happens **after hours** probably differs from facility to facility. In our FMEA the OR nurse would deliver the specimen to the lab and turn it over to whoever was working in the lab that night (that might be someone other than the normal tissue lab technician). One must be certain that the person receiving specimens after hours is as fully trained in proper handling and processing of those specimens as your day staff are.

Specimens coming from outside the hospital via courier (eg. from offices) can be especially problematic. You may have little control over the labeling and handling that occur in those offices. And there are lots of anecdotes of such specimens never reaching the lab. It may make sense to have some communication from the offices to the lab ahead of time, notifying them that a specimen or specimens are on their way to the lab. In any event, the logbook and chain of custody procedures should take place every time a handoff takes place (eg. office-to-courier, courier-to-lab, etc.) and specimen counts should match.

One other caveat that comes from the literature on mislabeling of specimens: if you can avoid it, **don't batch!** Deal with specimens one at a time. Any time you are dealing with labeling multiple specimens at the same time you run the risk of transposing labels.

Having a **checklist “where to look for lost specimens”** may also help when the specimen is lost after leaving the OR. This should include places in the lab where previously misplaced specimens were ultimately found and should point staff to review the chain of custody logs to identify where the specimen was last recorded.

Prompt communication upon identifying a lost specimen is critical. That communication starts the search for the missing specimen, whether in the OR or the lab. Such cannot be delayed. For instance, if the specimen is in a trash can it may be gone and irretrievable by morning. Similarly, if your specimen count on arrival at the lab does not match what was in the logbook at the OR end, an immediate call to the OR is needed to avoid having a specimen discarded along with the other surgical paraphernalia.

A recent AHRQ WebM&M ([Heher 2017](#)) had a nice table showing factors affecting the likelihood that a specimen might be lost or misprocessed. It categorized these factors as below:

Ordering and transport factors

- Testing ordered by inexperienced provider
- Off-site and non-OR specimen procurement
- Batching during specimen transport
- Multiple transport handoffs

Laboratory factors

- Low or inexperienced staffing levels
- Lack of robust interface between LIS and EHR
- Lack of specimen tracking or chain of custody within lab
- Lack of specimen reconciliation

Test and patient factors

- Rare test ordered
- Test needs to be sent out of laboratory
- Specimen scant or minute
- VIP patient (SOP not followed)

Another study in an outpatient setting ([Sandbank 2010](#)) identified a critical point of specimen loss to be noninsertion of the specimen into the container by medical staff. The authors in that article and subsequent one ([Shalom 2013](#)) recommend strict guidelines, such as immediate insertion of the specimen into the container and signing on the container confirming that the specimen is in the correct labeled container at the end of the procedure.

Obviously, this is a great topic for your organization to consider for a **FMEA** (Failure Mode and Effects Analysis). Flowcharting the entire process from pre-procedure through the entire pathology process will help you identify not only potentials for losing specimens but also those potentials for mislabeling specimens and mixing them up.

You begin by **flowcharting the entire process**. After you do your initial pass at flowcharting, you need to go back and ask questions like “**How is that handled after hours (at night or on weekends)?**”.

Key to doing a good RCA or FMEA is involving the **key players who are closest to the process**. They are the ones most likely to tell you where the problematic points are (and tell you the solutions!). You also need to visually **observe the entire process as it plays out in real time**. You will be surprised at how often you see things that others have come to accept as “normal”. And you’ll see the various “**workarounds**” that have crept into the process.

Having “outsiders” (i.e. people who do not ordinarily work in the pathology lab) observe the process also provides an opportunity to observe **the work environment**. That is where the little things, that escape the attention of the lab personnel, may be identified. For example, you might notice that the trash receptacles sit in locations where it might be possible to accidentally knock a specimen or cassette into them (don’t be afraid to ask them “Have you ever knocked a cassette into that trash can?”). Or you might notice that all the specimen containers and their matching cassettes are lined up like dominoes and vulnerable to being knocked over by an errant elbow!

Review of the work environment should include attention not only items like lighting and clutter but also workload issues. Mistakes tend to occur most often under stressful conditions, such as time pressures or deadlines, understaffing, fatigue, conflicting goals and incentives, etc.

Education, training and competency assessment are, of course, essential to quality in any laboratory setting. But don’t forget you also need to make sure everyone who might be in that laboratory, including your **housekeeping** staff, understand security of specimens.

So you haven’t had a lost specimen yet? Not yet. Just one critical lost specimen or mislabeling of specimens might lead to devastation for one of your patients and headlines in your local newspaper, not to mention costly litigation. Doing a FMEA on specimen handling will give you good insight into your vulnerability for lost specimens and mislabeled specimens, and may well help you identify other problems with efficiency in the OR, transport, or lab that are easily fixed.

If you can’t do a full FMEA, at least look at the Minnesota Hospital Association’s “[Specimen Management in the Operating Room. Gap Analysis](#)” that includes a checklist for organizations to use to assess their compliance with best practices for specimen management. Detailed guidelines for specimen handling and management are also available from the Association of Surgical Technologists ([AST 2008](#)) and the College of American Pathologists ([Lott 2015](#)).

Some of our other columns on errors related to laboratory studies:

- October 9, 2007 “[Errors in the Laboratory](#)“
- November 16, 2010 “[Lost Lab Specimens](#)”
- October 11, 2011 “[LEAN in the Lab](#)”
- March 6, 2012 “[“Lab” Error](#)”
- April 2012 “[Specimen Labeling Errors](#)”
- January 22, 2013 “[You Don’t Know What You Don’t Know](#)”
- April 15, 2014 “[Specimen Identification Mixups](#)”
- November 25, 2014 “[Misdiagnosis Due to Lab Error](#)”
- March 24, 2015 “[Specimen Issues in Prostate Cancer](#)”
- May 26, 2015 “[How Safe is the Lab You Use?](#)”
- March 29, 2016 “[Inappropriate Lab Testing](#)”
- September 27, 2016 “[Lab Errors Costly](#)”
- November 15, 2016 “[Surgical Specimen Mishaps](#)”

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