Patient Safety Tip of the Week

October 9, 2018 More on Lab Specimen Mixups

A report in the news earlier this year (Moore 2018) rekindled our interest in the issue of specimen mixups. A patient underwent a prostatectomy on the basis of a biopsy that showed an invasive, aggressive cancer. But it turned out that the removed prostate was healthy. The biopsy results that showed the cancer belonged to another patient. There had been a mixup. And this had occurred despite the fact that the patient, at the urologist's suggestion, had a DNA swab taken at the same time he had the biopsy. That should have made it nearly impossible to mix up test results among patients. But that's exactly what happened.

We've done several columns on lost surgical specimens or misidentification of surgical samples. In our March 24, 2015 Patient Safety Tip of the Week "Specimen Issues in Prostate Cancer" some of the estimates of switched or contaminated prostate biopsy specimens ranged from 1% to 2.5%. But those were largely estimates. A more realistic estimate comes from a recent clinical trial, the Reduction by Dutasteride of Prostate Cancer Events (REDUCE) prostate cancer risk reduction study. After three cases of biopsy sample misidentification were discovered in the first 2 years of that study, all protocol-mandated biopsy samples were DNA tested to verify biopsy identity (Marberger 2011). A total of 11,235 primary study biopsy samples were DNA identity tested. The results found that 27 biopsies were confirmed to be mismatched to the patient for whom they were originally submitted. In the first two years of the study, 0.4% of biopsies (n = 26) were found to be mismatched. After a rigorous improvement process, only a single biopsy was mismatched in the following two years.

The authors suggest some key strategies to address biopsy identification errors in clinical trials but several of them are pertinent to any setting:

1. Avoid scheduling two patients for biopsy back to back or having supplies for two patients in the same room at the same time.
2. Label pathology kits and requisitions at the time of the biopsy procedure, not in advance.
3. Have the patient verify accuracy of identifying information on his/her biopsy.
4. Consider DNA identity testing on all samples concurrent with, or immediately after, pathologic evaluation.

We've talked about doing DNA identity testing in several of our prior columns listed below and noted that there are some pathologists and urologists who have suggested such should be routine for all patients undergoing prostate biopsy. Note that a proposed bill, the Prostate Cancer Misdiagnosis Elimination Act of 2017, calls for Medicare to reimburse labs $200 for DNA testing that compares and matches the patient's biopsy tissue with cells from the inside the cheek that are taken with a cotton swab to ensure

both came from the same person (Mulcahy 2017). To our knowledge that bill has not yet progressed through Congress.

An analysis of closed pathology claims (Akland 2018) is very revealing. The majority of the claims were related to misreads, but in 38% of the claims there were systems issues that contributed. As we've seen with most "lab" errors, the majority occur in the pre-analytic phase. Specimen loss/mix-ups accounted for 78% of the systems issues. The other 22% involved specimen contamination (eg. floaters, carry-over artifacts and cross-contamination).

Errors may occur related to the handling practices of the submitting physician by his/her staff, But they may also occur within the lab related to transport and receiving the specimen, or related to accessioning and slide identification. Examples of errors include mislabeling, misidentification, sorting, routing and pour-off (decanting) errors.

Carolyn Akland provides several illustrative case descriptions and then offers the following excellent recommendations pertinent to labeling and identification issues:

1. In the operating room, labeling of bottles and request forms should be done at the time of the procedure. Mix-ups have occurred when labels have been affixed to containers prior to the biopsy. This practice should be prohibited as sometimes there is a change in the sequence of biopsies or another biopsy is added.
2. Check specimen bottles and request forms for completeness. The submitting physician/surgeon should be the one completing the request forms so that adequate information is provided.
3. Workplaces in the lab and in the pathologist's office should be tidy.
4. Standardization is key.
5. Have well documented and consistently used processes for accessioning.
6. If possible, have two individuals involved during accessioning of specimens in the lab; including unpacking, sorting and numbering of bottles and request forms.
7. Track any deficiencies by type and physician office.
8. Never allow files on two patients to be open at the same time as it increases the possibility that data from one patient may be interpreted or included for another patient.
9. Never have the specimen slides of two different patients on one tray.
10. Add color coding to the slides and paperwork.

We strongly encourage you to read Akland's analysis since she also has excellent recommendations regarding communication issues, using all available clinical information when rendering interpretations, avoiding interruptions and distractions, how to deal with and communicate amended reports, and others.

Lippi and colleagues (Lippi 2017a) recently published an article on patient and sample identification in the lab. They identified the following causes of identification errors in medical laboratory:

- Homonymy
- Incorrect patient registration

- Reliance on wrong patient data
- Error in order entry (incorrect or incomplete data entry)
- Order mistranscription
- Collection of biological specimens from the wrong patient
- Inappropriate labeling of specimens
- Specimens mislabeled
- Specimens partially labeled
- Specimens unlabeled
- Illegible label
- Inaccurate entry or transmission of test results in the Laboratory Information System

Homonymy, of course, refers to names sounding alike. They note that in one hospital district in Texas, 2488 patients were named Maria Garcia, and 231 of these (9.3%) also shared the same date of birth (Lippi 2017a)!

They note that Joint Commission's National Patient Safety Goal NPSG.01.01.01 mandates that at least two patient identifiers should be used when collecting blood samples and other specimens for clinical testing, or when providing other treatments and procedures. Notably, the room number or physical location of the patient should not be used as identifiers, whereas containers used for blood and other specimens should be labeled in the presence of the patient.

Lippi et al. point out an important distinction between handling of blood samples compared to surgical specimens. Whereas we've emphasized you should **not** pre-label containers for biopsies or surgical specimens, they recommend the practice for blood samples should be pre-labelling of tubes. There apparently have been discrepancies in the recommendations amongst the several specialty organizations covering laboratories, but evidence apparently suggests that post-collection labeling of tubes carries a higher risk of identification errors (Lippi 2011).

Lippi et al. (Lippi 2017a) note that conventional or two-dimensional (2D) barcoded wristbands are indeed the most used approach for patient identification around the globe. But they go on to discuss the roles of technological solutions to the identification process, radio-frequency identification (RFID) tags, infrared (IR)-based patient tracking, wireless networks, patient smart cards and biometric technologies, each of which has its own advantages and limitations. They also talk about future developments, including an automated device based on four cameras which photographs the outside of a sample tube and then recognizes discrepancies between patient identity in the lab information system versus that on the blood tube label by means of optical character recognition (OCR). Another is a recently developed chip-size passive RFID tag also offers a locating capability and read range that are comparable to an active tag, but in a form factor and price that would allow to attach the tags to disposable labels.

In yet another paper by Lippi and colleagues (Lippi 2017b) note that the frequency of misidentification in vitro laboratory diagnostic testing may be relatively low compared to

that of other laboratory errors (i.e., usually comprised between 0.01 and 0.1% of all specimens received). But up to 10–20% of these errors translate into harm for patients and may impact other human and economic resources.

They state the healthcare system should be re-engineered to act proactively to address this important problem. The advocate the widespread use of more than two unique patient identifiers, the accurate education and training of healthcare personnel, the delivery of more resources for patient safety (i.e., implementation of safer technological tools), and the use of customized solutions according to local organization and resources and, as above, after weighing advantages and drawbacks, labeling blood collection tubes before and not after venipuncture as a safer practice for safeguarding patient safety and optimizing phlebotomist's activity.

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"
- March 20, 2018 "Minnesota Highlights Lost Tissue Samples"

References:

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Akland C. An Analysis of Pathology Closed Claims, SVMIC (State Volunteer Mutual Insurance Company) January, 2017 https://home.svmic.com/resources/newsletters/59/an-analysis-of-pathology-closed-claims (Akland 2018)

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