Patient Safety Tip of the Week

January 22, 2013

You Don't Know What You Don't Know

Everyone dreads the error where lab specimens get mixed up and a patient (or likely 2 patients) gets the wrong diagnosis and wrong treatment. We've done multiple columns on such errors and they are listed at the end of today's column.

But here's one type of lab error that is kind of scary: occult specimen provenance complications (**SPC's**). It's scary because it is **occult**, i.e. the error is not recognized because it is not identified by standard laboratory procedures. There are actually 2 types of such errors:

- Type 1 complete transposition between patients
- Type 2 contamination of a patient's tissue with that of one or more other patients

So I could have a prostate biopsy that either gets mixed up with someone else's biopsy or that gets contaminated by tissue from another patient and my specimen gets reported as showing cancer. I might end up getting a treatment for prostate cancer and all the side effects even though I don't have cancer. Or I actually could have cancer and my specimen gets interpreted as normal and I don't get any treatment.

Such errors usually only come to attention when a patient undergoes, for example, a mastectomy or prostatectomy after a biopsy was interpreted as showing cancer and the full surgical specimen removed shows no cancer.

In one of our earliest columns on lab errors (see our October 9, 2007 Patient Safety Tip of the Week "Errors in the Laboratory") we noted a paper (Suba 2007) that suggested we consider the "**DNA timeout**" akin to the surgical timeout where we ask the question "Is this the correct diagnosis for the correct patient?" before doing an invasive procedure.

Now one of the co-authors of that 2007 paper has done a study providing an estimate of how often such SPC's occur (Pfeifer 2013). They examined about 13,000 prostate biopsy specimens from a wide variety of urology practices and pathology laboratories using a DNA identification technology. They found the frequency of occult type 1 errors (a complete transposition between patients) was 0.26% and type 2 errors (contamination of the patient's tissue with 1 or more unrelated patients) was 0.67%. Overall, the mean

frequency of SPCs across practice settings was 0.22% for type 1 errors and 1.69% for type 2 errors.

Basically, it means that just under 1% of patients might be given an incorrect diagnosis that no one even suspects is incorrect!

Perhaps just as striking is the fact that virtually every lab or clinical setting they studied had at least one SPC identified.

The authors also point out that in many or most of these occult SPC's there may be 2 "victims", the one whose specimen this was thought to be and the one whose tissue it actually is because both patients may end up getting the wrong diagnosis and wrong treatment. So the clinical impact might be twice as high as the SPC rates they identified.

Keep in mind that SPC's, like most "lab errors" may actually have nothing to with the lab itself. From our many previous columns you'll recognize that most "lab errors" actually occur in the pre-analytical phase, i.e. before the specimen ever even arrives at the lab. In our March 6, 2012 Patient Safety Tip of the Week ""Lab" Error" we noted that the vast majority of "lab"errors really occur in the pre-analytical and post-analytical phases of laboratory evaluation. Such mixups can occur at the time the specimen is obtained and labeled. They can also occur when it first gets accessioned at the lab. But even during processing in the lab there can be carryover artifacts or cross-contamination of tissues.

Importantly, the authors of the Pfeifer study had no financial interest in the DNA testing kit or the company (nor do we!) and the company did not sponsor the study. So it truly appears to be an unbiased study in that regard. However, there may well be some selection bias in that the urology practices submitting specimens for DNA testing may not be representative of all urology practices. They may be more patient safety conscious or they may have experienced a prior patient identification error. And the cost-effectiveness is not yet known. The Pfeifer study had no data on patient outcomes so it is not known how many patients received an incorrect diagnosis or incorrect treatment.

So this is a new application of technology that shows great promise in reducing the chances a patient may get an incorrect diagnosis and treatment with serious implications. But there are lots of important unanswered questions. It needs to be tested in a randomized fashion in a variety of settings with collection of patient-specific outcome data and good analysis of cost (both costs of testing and potential cost savings from reduction of errors).

Other technologies do play a role in minimizing specimen labeling errors. In our April 2012 What's New in the Patient Safety World column "Specimen Labeling Errors" we noted such labeling errors may occur either before the specimen ever arrives at the lab or may occur in the lab itself. One report on laboratory errors (Snydman 2012) found that the top 2 errors were specimen not labeled (18.7%) and specimen mislabeled (16.3%) and concluded that many "lab" errors occur before the specimen ever reaches the lab and could be prevented by better labeling. Technological solutions such as barcoding and

RFID (radiofrequency identification) techniques may be helpful in reducing such errors. A paper from the Mayo Clinic (Francis 2009) discusses changes made after their gastrointestinal and colorectal surgery endoscopy units had experienced mislabeling or no labeling of specimens. They initiated a new specimen-labeling system that uses RFID technology, a paperless requisition process, and confirmation of the correct site and correct patient by 2 healthcare providers. They were able to document a substantial decrease in errors as a result of the new processes.

Labeling errors can also be reduced by good performance improvement projects or doing a FMEA (failure mode and effects analysis). A study on specimen labeling errors within a surgical pathology laboratory (Layfield 2010) found labeling errors occurred at a rate of 0.25% of cases and could involve either patient name or site of the specimen. The majority of the mislabelings occurred in the gross room. One theme they noted was that more errors occurred with small specimens that were similar in appearance and were batch processed. They also noted that batch processing had been previously identified in the literature as a root cause of labeling errors in the laboratory.

See our Patient Safety Tips of the Week for October 9, 2007 "Errors in the Laboratory" and November 16, 2010 "Lost Lab Specimens" for discussions on specimen identification, labeling, etc. And our October 11, 2011 Patient Safety Tip of the Week "LEAN in the Lab" describes use of LEAN principles to improve lab safety and efficiency.

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"

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