Patient Safety Tip of the Week

March 24, 2015

Specimen Issues in Prostate Cancer

Imagine getting surgery, radiation or chemotherapy for a condition you really did not have! In our January 22, 2013 Patient Safety Tip of the Week "You Don't Know What You Don't Know" we discussed the possibility that you might have a biopsy specimen which was either not yours or was yours but also had some tissue from another patient on the slide(s). Such errors are known as occult specimen provenance complications (**SPC's**). In that Tip we noted 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 around 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.

Now a new study in the Journal of Urology has estimated the economic impact of such errors (Wojno 2015). The researchers extracted data from published studies on specimen provenance complications (SPC) rates, prostate cancer treatment efficacy, treatment cost, litigation/settlement costs after false diagnoses of prostate biopsies and patient quality of life. They then estimated how many cases with SPC's would have their management impacted by the SPC. Note, for example, that a biopsy specimen of a patient with true prostate cancer whose specimen was cross contaminated with that of another patient with prostate cancer would probably not lead to inappropriate treatment of the patient. So they focused on those cases where an SPC would likely have a clinical implication, i.e. those receiving a false positive or false negative diagnosis.

They estimated that approximately 2.5% of the 800,000+ prostate biopsies done in the US annually would involve a specimen switch or contamination overall and that would result in 4,570 clinically meaningful false diagnoses. That would result in an estimated loss of 634 QALY's and an average cost impact of $3,776 per positive cancer diagnosis. The total estimated impact for the whole country would be $879.9 million annually!

Though no pathology lab was immune to SPC's in prior studies, rates do vary by site. Sensitivity analyses in this study showed their results were sensitive to the rate of transpositions at independent reference laboratories. Results were also sensitive to litigation/settlement costs.

A bit of concern is the fact that it appears all the authors of the current study have financial ties to a company that does the type of DNA analysis that would need to be done to avoid mistakes related to SPC's. However, the key previous study (Pfeifer 2013) that identified the SPC problem as widespread did not appear to have such a potential conflict of interest (see our January 22, 2013 Patient Safety Tip of the Week "You Don't Know What You Don't Know"). However, we noted there might be some selection bias in that the urology practices submitting specimens for DNA testing may not be representative of all urology practices.

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. One of the co-authors of that 2007 paper subsequently did the study providing an estimate of how often such SPC's occur (Pfeifer 2013).

The current study looked only a prostate biopsies. It could be anticipated that SPC's would likely occur with almost any other tissue specimens as well. Application of DNA identification techniques therefore shows promise in reducing the chances a patient may get an incorrect diagnosis and treatment with serious implications. But there 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) for each of the conditions assessed.

See also our prior columns, listed below, that deal with "lab" errors (most of which do not originate in the lab itself), lost lab specimens, specimen misidentification, labeling issues, and use of FMEA or LEAN techniques to improve safety and efficiency in laboratories.

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"

References:

Pfeifer JD, Liu J. Rate of Occult Specimen Provenance Complications in Routine Clinical Practice. Am J Clin Path 2013; 139: 93-100
http://ajcp.ascpjournals.org/content/139/1/93.abstract

Wojno K, Hornberger J, Schellhammer P, et al. The Clinical and Economic Implications of Specimen Provenance Complications in Diagnostic Prostate Biopsies. Journal of Urology 2015; Published online: November 13, 2014
http://www.jurology.com/article/S0022-5347%2814%2904864-2/abstract

Suba EJ, Pfeifer JD, Raab SS. Patient Identification Error Among Prostate Needle Core Biopsy Specimens—Are We Ready for a DNA Time-Out? J Urol 2007; 178(4): 1245-1248
http://www.jurology.com/article/S0022-5347%2807%2901423-1/abstract

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