Studies Support DNA Testing On Biopsies To Prevent Misdiagnoses

Strand Diagnostics, LLC, maker of the know error@ system for breast and prostate biopsies, today announced the publication of two peer-reviewed studies that examine the use of DNA testing on biopsy samples as a means of reducing diagnostic mistakes. The first study, published in the *American Journal of Clinical Pathology*, found that up to 3.5 percent of patients initially diagnosed with cancer were subject to undetected specimen switches or contaminations which may have compromised the accuracy of their diagnosis.

The second, published recently in *Value in Health* concluded that performing a simple DNA test to confirm the provenance of malignant tissue samples is a cost-effective way to improve patient safety and diagnostic accuracy.

Specimen misidentification is a dangerous byproduct of the diagnostic testing cycle for cancer-a process that is performed millions of times annually for patients in the United States. The surgical biopsy process, which is most widely used for diagnosing cancers of the breast and prostate, typically involves nearly 20 steps and several medical professionals working in different locations. During this complex process, one individual's specimens are easily switched with or contaminated by specimens from another individual, which can lead to misdiagnoses for the patients involved.

The consequences of undetected SPCs can be severe, including healthy patients undergoing unnecessary chemotherapy, radiation and/or surgery, while undiagnosed cancer patients may miss the earliest opportunities to receive urgently needed treatment.

The first study examined the actual rate of occult SPCs among 13,000 prostate biopsies, processed in more than 50 pathology labs, for which DNA Specimen Provenance Assignment ("DSPA") testing was performed as part of routine clinical care. Each of the SPCs was classified as either a Type 1 error (a complete transposition between patients) or Type 2 error (contamination of the patient's tissue with one or more unrelated patients). The study observed that the mean percentage of undetected SPCs across all practice settings was 0.22 percent for Type 1 and 1.69 percent for Type 2 provenance errors, with a combined SPC rate as high as 3.51 percent measured in certain settings.

According to Dr. John Pfeifer, vice chairman for Clinical Affairs, Pathology and Immunology at Washington University in St. Louis, Missouri, and co-author on both studies, "The potential for misidentification of a patient's biopsy results is a real concern in anatomic and clinical pathology with potentially devastating consequences. While many physicians have long suspected that Specimen Provenance Complications occur, these results provide the first estimate of their frequency."

The second study evaluated the potential economic value of prospective DSPA testing as a solution to preventing misdiagnosis stemming from undetected SPCs. This study used a decision-analytic model developed to compare the benefits of DSPA testing of cancerous prostate biopsy specimens with the alternative of performing prostate biopsies with no provenance testing. Parameter values were chosen from published literature to calculate the expected costs of misdiagnosis, and incremental cost effectiveness of DSPA testing to avoid misdiagnosis. Results indicate that given certain conservative assumptions regarding the hypothetical rate of provenance errors and the price of DSPA analysis, testing of positive biopsy samples to rule out the presence of occult SPCs is likely a very cost-effective method for improving patient outcomes.

The know error@ system employs patient-specific bar coding and forensic chain-of-custody principles for the purpose of reducing SPCs, and a DSPA test that prevents SPCs from resulting in misdiagnosis and adverse patient outcomes. Through these combined features, the system ensures that surgical biopsy samples being evaluated belong exclusively to the patient being diagnosed, allowing physicians and patients to proceed confidently with the correct cancer treatment. For more detailed information, visit www.knowerror.com.

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