

Bx Switching and Misidentification Errors

Frequency of Occurrence, Detection Methods, and Prevention



JULY 2009

DIAGNOSTIC ID, LLC

5770 Decatur Blvd
Indianapolis, IN 46241



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I. BACKGROUND

There are approximately 11.3 million new cancer cases diagnosed annually world wide which translates to an estimated 38 million biopsy procedures. The U.S. represents approximately 14.5% of the world's total cancer incidence (1.4 million new cases and 4.8 million biopsies)¹ The process of collecting, handling, analyzing, diagnosing, reporting, and acting upon routine tissue biopsies is complex and involves many steps. Despite even the utilization of precise labeling systems, the opportunity for biopsy switching and/or misidentification errors persists.

A recent report from the Cleveland Clinic acknowledges the potential for error is ever-present. The article published by Cleveland Clinic's Dr. Mary Bronner, M.D., Section Head, Morphologic Molecular Pathology in the Department of Anatomic Pathology states (*note: numbers have been added by the author*):

“Considering the numerous medical professionals involved in processing a tissue sample from the patient to the pathologist reviewing it microscopically, it is truly a marvel that so few errors occur. Consider that from the patient, a biopsy sample or surgical resection specimen is initially (1) handled by the treating physician using carefully cleaned biopsy and surgical tools that have been used previously to obtain many other patients' samples. One or more nurses or other assistants assist the physician in (2) getting the tissue sample into a properly labeled specimen container. The specimen container is (3) batched with many other containers and (4) transported to the pathology laboratory. There, the specimen is (5) accessioned into the pathology computer system and is (6) assigned a unique surgical pathology identifier. Next, the paperwork and specimen container are (7) processed by a pathology assistant, resident, or pathologist who removes the specimen from the labeled container and examines and describes the tissue grossly. The tissue is (8) dissected by carefully cleaned instruments that also are used to dissect many other patients' samples. The specimen is (9) divided among a number of tissue cassettes, small plastic containers, which are (10) labeled individually with the surgical pathology number and a unique block number. The tissue cassettes have holes in them to permit flow of the various processing fluids required to process the tissue chemically into a final wax tissue block. Many hundreds of different patients' cassettes are (11) placed into a common chemical bath for this processing stage. Rarely, a tissue fragment from one patient can exit its cassette and enter through the cassette holes of another patient's block to become part of this second patient's block. A histotechnologist uses clean forceps, which are cleaned and used subsequently on many other patients' specimens, to (12) pick up the wax-infused tissue fragments from the processing cassettes and place them into the final wax tissue block that will be used to section the actual histologic slides. Another histotechnologist (13) sections 5 µm slices on a

¹ American Cancer Society, Cancer Facts and Figures 2008 and 2002 Study by the Agency For Research on Cancer



razor blade affixed to a microtome. These thin wax slices are (14) floated onto a carefully cleaned water bath, which has had many other patients' wax slices previously floating in it. Floating allows slices to flatten and be (15) transferred onto a glass slide, which has been hand-labeled by the histotechnologist. The slide later receives a permanent computer-generated slide label that is (16) affixed to the slide by another technician. Finally, all of the slides on any given patient's procedure are (17) assembled with the accompanying paperwork and (18) delivered to the pathologist for diagnostic interpretation. **A mistake leading to inadvertent tissue contamination can occur at any one of the above logistically complex processes.**²

² DNA Fingerprinting Analysis for Specimen Identification
<http://referencelab.clevelandclinic.org/DBSearch/TestDetail.asp?ID=2676>



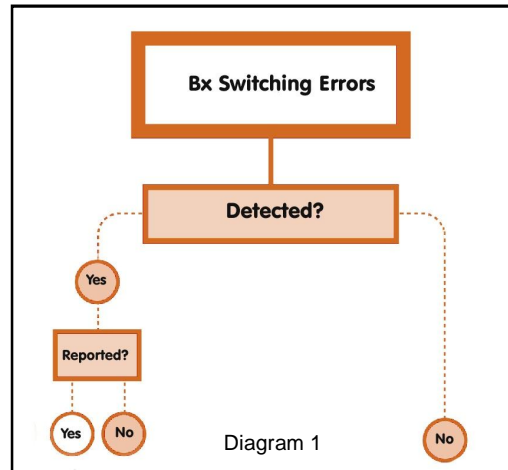
II. ERRORS ARE NOT UNCOMMON

“Misidentification errors are common in laboratory medicine...” according to the College of American Pathologists, whose extrapolation of reported errors from 120 recently studied pathology laboratories indicates that at least 2.9 million laboratory specimen misidentifications lead to more than 160,000 adverse patient events per year in the U.S.³

And according to a study of switching errors performed at the Baptist Hospital of Miami, Miami, FL. in 2005 and 2006, “.....because of the relatively high number of cases received by this laboratory, **this problem [switching of biopsies] occurs several times each year**”.⁴

A Wall Street Journal article from June 2006 reports, “3 percent to 5 percent of the billions of specimens taken each year are defective be it a biopsy that doesn't extract the tumor cells, blood that isn't drawn correctly or a **mix-up with another patient's sample**”⁵.

It is difficult to know the extent of switching errors since not all errors are detected, that is, you don't “know” what is “unknown”. And of those errors that are detected, those which are **reported** are a small subset of all errors (*refer to diagram 1*). As such, estimates of the error rate which are calculated from that which is reported must surely underestimate the total number of errors that are actually made. A College of American Pathologists study cautions that the **true incidence of both errors AND resulting adverse events is much higher than can be presently measured**⁶.



³ Valenstein PN, Raab SS, Walsh MK. Identification errors involving clinical laboratories: a College of American Pathologists Q-Probes study of patient and specimen identification errors at 120 institutions. Arch Pathol Lab Med. 2006

⁴ Andrew A. Renshaw, MD, Richard Kish, MHS, and Edwin W. Gould, MD *The Value of Inking Breast Cores to Reduce Specimen Mix-up*

⁵ “Hospitals Move To Cut Dangerous Lab Errors” June 14, 2006 By Laura Landro *The Wall Street Journal*

⁶ Valenstein PN, Raab SS, Walsh MK. Identification errors involving clinical laboratories: a College of American Pathologists Q-Probes study of patient and specimen identification errors at 120 institutions. Arch Pathol Lab Med. 2006



PUBLISHED ESTIMATES OF SWITCHING ERRORS

Following are some published reports which try to estimate the number of known errors, but are only based upon those errors which have been detected AND reported.

1) AMENDED REPORTS IN SURGICAL PATHOLOGY AND IMPLICATIONS FOR DIAGNOSTIC ERROR DETECTION AND AVOIDANCE:

A College of American Pathologists Q-probes Study of 1,667,547 Accessioned Cases in 359 Laboratories.

Nakhleh RE, Zarbo RJ. Department of Pathology, Henry Ford Hospital, Detroit, Mich 48202

Arch Pathol Lab Med. 1998 Apr;122(4):303-9. Comment in: Arch Pathol Lab Med. 1998 Apr;122(4):301-2.

OBJECTIVES: To evaluate amended report rates relative to surveillance methods and to identify surveillance methods or other practice parameters that lower amended report rates.

DESIGN: Participants in the 1996 Q-Probes quality improvement program of the College of American Pathologists were asked to prospectively document amended surgical pathology reports for a period of 5 months or until 50 amended reports were recorded. The methods of error detection were also recorded and laboratory and institutional policies surveyed. Four types of amended reports were investigated: those issued to correct patient identification errors, to revise originally issued final diagnoses, to revise preliminary written diagnoses, and to revise other reported diagnostic information that was significant with respect to patient management or prognosis.

PARTICIPANTS: Three hundred fifty-nine laboratories, 96% from the United States.

RESULTS: A total of 3147 amended reports in all four categories from a survey of 1,667,547 surgical pathology specimens accessioned during the study period were issued by the participants. The aggregate mean rate of amended reports was 1.9 per 1000 cases (median, 1.5 per 1000 cases). Of these, 19.2% were issued to correct patient identification errors, 38.7% to change the originally issued final diagnosis, 15.6% to change a preliminary written diagnosis, and 26.5% to change clinically significant information other than the diagnosis. Most frequently, a request from a clinician to review a case (20.5%) precipitated the error detection. Although not statistically significant, a higher amended report rate (1.6 per 1000) for all error types



was associated with routine diagnostic slide review that was performed after completion of the surgical pathology report. This is compared to rates for institutions that had routine diagnostic slide review of cases prior to finalization of pathology reports (1.2 per 1000) and institutions that had no routine diagnostic slide review (1.4 per 100). Slide review of cases prior to completion of reports lowered the rate of amended reports issued for two types of amended reports: those in which the originally issued final diagnosis was changed and those in which information other than the diagnosis was changed for patient management or prognostic significance. Other laboratory practice variables examined were not found to be associated with the amended report rate.

CONCLUSIONS: There is an association between lower amended report rates and diagnostic slide review of cases prior to completion of the pathology report. The level of case review and type of case mix that is necessary for optimal quality assurance needs further investigation.

Author's annotation: *Detected patient identification error rate...0.04%. No estimate was made of the number of undetected errors.*

2) SURGICAL PATHOLOGY SPECIMEN IDENTIFICATION AND ACCESSIONING:

A College of American Pathologists Q-Probes Study of 1,004,115 Cases From 417 Institutions.

Nakhleh RE, Zarbo RJ. Department of Pathology, Henry Ford Hospital, Detroit, Michigan, USA.

Arch Pathol Lab Med. 1996 Mar;120(3):227-33

OBJECTIVE: To examine and suggest improvements for deficiencies occurring in the specimen identification and accessioning process in the surgical pathology laboratory.

DESIGN: Using the College of American Pathologists' and the Joint Commission for Accreditation of Healthcare Organizations' requirements as the standard, each laboratory was asked to prospectively document deficiencies in specimen identification and accessioning for 4 months, or until a maximum of 4000 cases or 400 deficiencies were accrued.

PARTICIPANTS: Four hundred seventeen laboratories in the College of American Pathologists' voluntary quality improvement program, Q-Probes, participated in this study.

RESULTS: Identification and accessioning deficiencies were found in 60,042 (6%) out of a total 1,004,115 cases accessioned (median deficiency rate of 3.4%). Errors related to specimen identification accounted for 9.6% of these



deficiencies, discrepant or missing information items were present in 77%, and 3.6% involved specimen handling. The most common deficiency was "no clinical history or diagnosis present on the requisition slip," which represented 40% of all deficiencies. Deficiencies were most often detected by the person assigned to accessioning duties or by histology personnel. In 66% of cases, no action was taken to remedy the deficiency, but this varied dramatically according to the specific type of deficiency. An action was taken to remedy deficiencies in 69% of cases involving specimen identification errors, in 58% of specimen handling errors, and in 27% of cases with discrepant or missing information. Peer group stratifiers were associated with a lower deficiency rate. Laboratories with lower numbers (<15 000) of accessioned cases and laboratories with a formal written plan for the detection of errors in accessioning and specimen identification reported lower rates of deficiencies. Factors that correlated with a higher rate of deficiencies included submitting the specimen container and requisition slip in a unique secondary container (P<.005) and labeling the specimen container with only a patient's name or unique patient identification number (as opposed to both identifiers).

CONCLUSIONS: The majority of deficiencies occurring in surgical pathology specimen identification and accessioning are related to missing or inaccurate clinical information. Deficiencies are detected in multiple locations, including areas not typically thought of as quality check points, such as transcription. A variable amount of effort occurs to rectify deficiencies; this effort is largely dependent on the type of deficiency involved. Finally, laboratories with a formal error detection plan had fewer deficiencies.

Author's annotation: Detected patient identification error rate...0.33%). No estimate was made of the number of undetected errors.

3) IDENTIFICATION ERRORS INVOLVING CLINICAL LABORATORIES:

A College of American Pathologists Q-Probes Study of Patient and Specimen Identification Errors at 120 Institutions.

College of American Pathologists, Valenstein PN, Raab SS, Walsh MK.

Department of Pathology, St Joseph Mercy Hospital, Ann Arbor, Mich 48106-0998, USA. paul@valenstein.org

Arch Pathol Lab Med. 2006 Aug;130(8):1106-13.

CONTEXT: Misidentified laboratory specimens may cause patient injury, but their frequency in general laboratory practice is unknown.



OBJECTIVES: To determine (1) the frequency of identification errors detected before and after result verification, (2) the frequency of adverse patient events due to specimen misidentification, and (3) factors associated with lower error rates and better detection of errors.

DESIGN: One hundred twenty clinical laboratories provided information about identification errors during 5 weeks.

RESULTS: In aggregate, 85% of errors were detected before results were released; one quarter of laboratories identified more than 95% of errors before result verification. The overall rate of patient identification errors involving released results was 55 errors per 1,000,000 billable tests. A total of 345 adverse events were reported. Most of the adverse events caused material inconvenience to the patients but did not result in any permanent harm. **On average, adverse events resulted from 1 of every 18 identification errors. Extrapolating the adverse event rate observed in this study to all United States hospital-based laboratories suggests that more than 160,000 adverse events per year result from misidentification of patients' laboratory specimens.**

CONCLUSIONS: Identification errors are common in laboratory medicine, but most are detected before results are released, and only a fraction are associated with adverse patient events. Even when taking into consideration the design of this study, which used imperfect case finding, institutions that did a better job of detecting errors within the laboratory released a smaller proportion of results that involved specimen misidentification.

Author's annotation: Total detected identification error rate...0.03%. The portion not detected prior to release...0.01%. Estimated 161,000 adverse events per year in US result from misidentification of laboratory specimens. The estimates were based on known errors. No estimate was made of the number of undetected errors.

4) SURGICAL SPECIMEN IDENTIFICATION ERRORS:

A New Measure of Quality In Surgical Care

Martin A. Makary, MD, MPH Jonathan Epstein, MD, Peter J. Pronovost, MD, PhD, E. Anne Millman, MS, Emily C. Hartmann, MS, and Julie A. Freischlag, MD,

BACKGROUND: Communication errors are the primary factor contributing to all types of sentinel events including those involving surgical patients. One type of communication error is mislabeled specimens. The extent to which these errors occur is poorly quantified. We designed a study to measure the incidence and type of specimen identification errors in the surgical patient population.

METHODS: We performed a prospective cohort study that included all patients who underwent surgery in an outpatient clinic or hospital operating



room and for whom a pathology specimen was sent to the laboratory. The study took place during a 6-month period (October 2004 to April 2005) at an urban, academic medical center. The study's main end-points were the incidence and type of specimen labeling errors in the hospital operating room and the outpatient clinic. The specimen was the unit of analysis. All specimens were screened for "identification errors," which, for the purposes of this study, were defined as any discrepancy between information on the specimen requisition form and the accompanying labeled specimen received in the laboratory. Errors were stratified by the type of identification error, source, location, and type of procedure.

RESULTS: A total of 21,351 surgical specimens were included in the analysis. There were 91 (4.3/1000) surgical specimen identification errors (18, specimen not labeled; 16, empty container; 16, laterality incorrect; 14, incorrect tissue site; 11, incorrect patient; 9, no patient name; and 7, no tissue site). Identification errors occurred in 0.512% of specimens originating from an outpatient clinic (53/10,354 specimens) and 0.346% of specimens originating from an operating room (38/10,997 specimens). Procedures involving the breast were the most common type to involve an identification error (breast:11, skin:10, colon: 8); in addition, 59.3% (54/91) of errors were associated with a biopsy procedure. Follow-up was complete in all cases found to have an identification error.

CONCLUSIONS: Surgical specimen identification errors are common and pose important risks to all patients. In our study, these events occurred in 4.3 per 1000 surgical specimens or an annualized rate of occurrence of 182 mislabeled specimens per year. Given the frequency with which these errors occur and their potential effect on patients, the rate of surgical specimen identification errors may be an important measure of patient safety. Strategies to reduce the rate of these errors should be a research priority. (Surgery 2007;141:450-5.)

Author's annotation: Detected patient identification error rate...0.05%). No estimate was made of the number of undetected errors.



III. CONSEQUENCES OF UNDETECTED SWITCHING ERRORS

Most of switching errors are caught by the quality assurance systems in-place at collection sites and pathology labs prior to initiating treatments that result in adverse patient outcomes. Specimen switching errors that are not caught can result in misdiagnosis and mismanagement of patients with potentially catastrophic results. Patients may undergo radical surgery, radiation therapy, or chemotherapy for a cancer diagnosis that has been incorrectly assigned to a cancer-free patient. Moreover, the corresponding failure to treat a cancer patient at the earliest possible opportunity may also have undesirable consequences. Adverse patient outcomes also have both medical and legal consequences for every person and/or entity involved in the biopsy process.

FOUR EXAMPLES OF ADVERSE (PATIENT) OUTCOMES FROM UNDETECTED SWITCHING ERRORS

1) MEDICAL MIX-UP, UNNECESSARY MASTECTOMY (excerpt) Cancer-Free Woman Underwent Double Mastectomy Because of Lab MixUp

Mike Celizic TODAYShow.com contributor updated 8:46 a.m. ET, Thurs., Oct. 4, 2007

Because of a mislabeled tissue sample that led to a misdiagnosis, Darrie Eason had both of her breasts removed to save her from a cancer that she never had.

No amount of money will make Eason whole again, but the Long Island, N.Y., woman hopes that her experience and a lawsuit she is pressing may help other women. "Maybe if people hear about my case, they'll know. Maybe somebody will do something differently next time," she told TODAY co-host Meredith Vieira during an interview Thursday. "I don't want this to happen to anyone else." Eason is a 35-year-old single mother who works in the accounts receivable department of a local community newspaper chain. She has a 15-year-old son. In 2006, she was told she needed to undergo a radical double mastectomy because she had an invasive form of breast cancer. "I just broke down and cried," she recalled of the moment she got the diagnosis. **Eason went to another doctor for a second opinion, and was again told she had cancer. The doctor relied on the same mislabeled tissue sample.**

"I was told I had lobular breast cancer, which everybody said would come back," she told Vieira. Armed with that information, she had both breasts removed and underwent the first phase of reconstructive surgery in May 2006. While waiting to heal so she could begin chemotherapy, her surgeon, who had submitted removed tissue to a lab for routine testing, told her that



something was wrong: **She didn't have cancer.** "You can't even explain it," Eason said of her emotions when she was told she had had both her breasts removed for no reason. An investigation by the New York State Department of Health would reveal that the lab that handled her biopsy samples **had mixed up her sample with that of another woman.**

The other woman, who actually did have breast cancer, was told she was cancer-free. Only when Eason's error was discovered did the other woman, who has not been identified, learn that she had cancer. "She has to live with the idea that she had breast cancer and hers was not diagnosed at the earliest possible time," said Eason's attorney, Steven Pegalis, of the other woman. The state report said "the most likely source of the error" was the technician engaging in a practice called "batching," which involves handling more than one specimen at a time. The state health department determined that the lab's error was isolated and found "no systemic problems and no deficiencies" at the lab. Eason's attorney, Steven Pegalis, told Vieira he's not so sure. "It may be one person, but personally I doubt it. One of the things we may learn is 'Was there a system failure, and if so, what can be done to improve the system?' Personally, I doubt this is a one-time event by someone who was careless for one time in his or her life," he said.

2) MAN SUES AFTER HE'S WRONGLY DIAGNOSED WITH CANCER; HAS RIGHT BREAST REMOVED

Thursday, May 14, 2009 NY Daily News AP

A suburban New York City man is suing a hospital and three doctors for performing a radical mastectomy on him even though he never had cancer.

Personal trainer Scott Aprile says that two weeks after the January surgery, one of the doctors told him his biopsy had been switched with another patient's and he never had cancer.

Nyack Hospital in Rockland County tells the Daily News it "regrets the circumstances leading to the misidentification" and says new preventive measure are in place. The hospital is also calling Aprile's allegations "inflammatory and factually inaccurate."

The 28-year-old Aprile says he's still in pain after having his right breast and three lymph nodes removed and doesn't know if he can go back to work.

3) MOTHER'S HEALTHY OVARIES REMOVED IN LAB MIX-UP

Mass Lawyers Weekly

Published: July 31, 2008

\$315,000 settlement

On May 27, 2005, a 48-year-old married woman and mother of a young child saw her obstetrician-gynecologist because of abnormal vaginal bleeding. An endometrial biopsy was performed to determine whether the bleeding was



cancer-related. She had previously suffered from breast cancer five years earlier and therefore was at risk for metastases.

One week later, she was told that the pathology report indicated she may have cancer. Consequently, on June 9, she underwent a total abdominal hysterectomy and ovary removal. A week after the operation, the surgeon told her that when he looked at her organs during the operation, he had not seen any cancer and that the pathology report from the surgery did not evidence any cancer cells.

When she asked him how the initial pathology report could have shown cancer if the post-operative report was negative, he told her he did not have an answer.

The woman proceeded to investigate on her own. In late July 2005, she sent her slides to the pathology departments at other hospitals to confirm the diagnosis of cancer on the original slides. When they confirmed the results, she pushed for DNA testing to determine whether the original slides showing cancer consisted of tissue from her body. Eventually, on March 9, 2006, she learned that the DNA testing confirmed that her slides had gotten "cross-contaminated" in the lab with those of another woman who had endometrial cancer. **The patient never had endometrial cancer.**

Due to this lab error, she had her entire uterus, cervix and ovaries removed unnecessarily. Following surgery, she was in extreme pain. In addition, the wound did not heal completely, and she had to return to the hospital to have a stitch removed that was protruding through her skin. She was left with a disfiguring bump on her stomach and a six-inch scar. She also went through emotional turmoil throughout the nine months that she believed she had endometrial cancer.

The devastating psychological impact of the mistake was compounded by the fact that she previously had suffered breast cancer. By 2005, she had managed to survive five years post-diagnosis and believed she was cancer-free. Her greatest concern, that the cancer would someday metastasize, was seemingly realized.

Type of action-Medical malpractice
Injuries alleged-Misdiagnosis and unnecessary operation causing pain, suffering and emotional anguish
Amount of settlement -\$315,000
Attorney-Jeffrey N. Catalano, Todd & Weld, Boston (for the plaintiff)
Date of Verdict or Settlement- 04-Aug-08

4) HUMAN ERROR BLAMED AFTER HOSPITAL REMOVES BREAST

The Standard
Beatrice Siu



Thursday, November 13, 2008

A cancer-free patient whose left breast was removed after a hospital mix-up over tissue samples was the victim of human error, health chief York Chow Yat-ngok admitted. But Chow stopped short of attributing blame, saying the Hospital Authority is in talks with the 36-year-old woman in an attempt to "settle the matter with a suitable arrangement." Secretary for Food and Health Chow was being quizzed by lawmakers yesterday over the blunder at North District Hospital in August. "An investigation was completed. It showed that human error was involved," he said. "The report also suggested that there was room for improvements in procedures." Chow said a report into the incident will be made public in the next one or two weeks. He said after the blunder the infirmary sent a report to the head office of the Hospital Authority and began an investigation. Chow said the hospital had immediately explained the error to the patient and her family and given them "suitable assistance." He insisted the existing complaints redress system is effective and that there is no need for another independent mechanism. He added that the authority would monitor and prevent the recurrence of medical blunders and be transparent in ensuring cases are handled fairly and impartially. After the patient had her breast removed, analysis of tissue samples revealed that she did not have cancer.



IV. ERROR REDUCTION SYSTEMS

A number of error reduction systems (i.e. quality improvements) have been suggested and/or utilized in an effort to reduce the number of identity errors.

BAR CODING

Probably the most common identification error reduction strategy in laboratory use today is simply to replace or supplement hand written identification with computer generated and computer read bar-codes. Though still not nearly as pervasive in laboratory settings as other industrial, retailing, and logistics arenas, bar-coding is a very cost effective means of tracking specimens and applying a degree of scientific precision to identification not possible from manual methods. Bar-codes are dramatically less susceptible to human error than any form of hand-written and visually interpreted identification.

INKING

One such error reduction method is the “inking” of specimens whereby at the time of grossing, each specimen is directly inked through the bag in one of 6 colors. The colors are always applied in the same sequence. The dissector writes the color used on the original requisition slip and dictates the color for the gross description. Each block is then routinely processed and entirely sectioned to produce at least 5 slides and 2 levels per slide. When the slides from the cases are reviewed, the pathologist compares the color of the ink in the tissue with that written in the gross description⁷

RFID

Yet another error reduction method is suggested by the Mayo Clinic. Mindful of their lab’s vast number of identity errors and the potential for adverse consequences, the Mayo Clinic recently adopted radio frequency technology in their GI lab in Rochester MN in an effort to determine and the reduce the incidents of identification errors.

⁷ Andrew A. Renshaw, MD, Richard Kish, MHS, and Edwin W. Gould, MD *The Value of Inking Breast Cores to Reduce Specimen Mix-up*



MAYO CLINIC STUDIES GI SUITE LABELING ERRORS

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<http://www.endonurse.com/>

Posted on: 10/07/2008

ROCHESTER, Minn. — Mayo Clinic researchers are recommending a new technologically-advanced labeling system aimed at reducing specimen labeling errors in high-volume gastrointestinal endoscopy centers. "The gastroenterology and colorectal surgery outpatient endoscopy unit at our facility yields over 30,000 specimen bottles that are sent for pathologic review every year," said Dawn Francis, MD, the lead author and a gastroenterologist at Mayo Clinic. "Over the past several years, Mayo Clinic identified some issues with mislabeling of tissue specimens in the units. Most labeling errors have been due to either the wrong patient label or no label being affixed to a specimen bottle. As a result, a quality improvement initiative was created to reduce the number of specimen-labeling errors." This study used a technology, radio-frequency identification (RFID), to track biopsy specimens taken during gastrointestinal endoscopic procedures and to automate identification. An RFID tag can be applied to or incorporated into an object so that it can be identified by using radio waves. Radio-frequency identification is used in other settings, such as libraries or passports, as an automated tracking system. This is its first application to track specimens in a healthcare setting. Researchers reviewed the number of specimen-labeling errors for the first three months of 2007, prior to the implementation of the initiative and the first three months of 2008, six months after the initiation of RFID specimen labeling. Specimen-labeling errors were categorized as Class 1 (only typographical with no potential patient care consequences), Class 2 (minor error, unlikely to have patient care consequences) and Class 3 (significant error that has the potential to detrimentally impact patient care). The endoscopy unit sent 8,231 specimen bottles to the pathology laboratory for evaluation during the first three months of 2007, and 8,539 bottles in the first three months of 2008. Compared to 765 errors in 2007, only 47 errors were noted in 2008. Overall, serious errors were low anyway, but the new labeling system reduced such errors even more, minimizing risk for patients. The two incidents of Class 3 errors in the first quarter of 2008 were recognized and corrected prior to specimen processing in the pathology laboratory." This system has provided us a great opportunity to enhance safety and quality efforts in specimen management. The RFID system has allowed us to reduce the number of data transcription points during the handling of these very important specimens," said Schuyler Sanderson, MD, a pathologist involved in the research study. "It appears that this quality initiative, with emphasis on correct data creation and transcription point reduction, has the potential to significantly improve our clinical practice." Previous Mayo Clinic research on RFID technology revealed that human error decreased dramatically as multiple checkpoints in specimen handling were eliminated.

Note that per the Mayo clinic study referenced above, in Q1 of 2008 AFTER implementing an error reduction program (i.e. state of the art RFID), 47 errors



were still made! The errors with which Mayo reported were only those that were detected (i.e. known), a subset of the actual number of errors (see Diagram 1). Since errors still can occur even after implementation of an “error reduction system”, patients remain exposed to the risk of overtreatment/undertreatment, and the hospital/physician reputation remains at risk.

Although error reduction systems such as those mentioned have the effect of reducing switching errors, there is still a possibility that some errors will remain undetected. Therefore a system to detect otherwise undetected switching errors (and thus prevent adverse patient outcomes) seems to be very desirable.



V. ONE METHOD TO DETECT SWITCHING ERRORS UNDETECTED BY QUALITY SYSTEMS

(both previously known, and unknown errors) i.e. to “know” what is not “known”

The use of forensic DNA to identify unknown tissues and match to a reference sample is one method by which undetected switching errors can be identified.

DNA “fingerprinting” analysis by polymerase chain reaction (PCR) is a highly accurate technique for determining patient identity for a tissue sample. This test is used in forensic pathology for criminal identification and can be useful in surgical and autopsy pathology when the patient identity of tissue samples is in question.

In the *Journal Of Urology* (October 2007), Drs. John Pfeifer, Stephen Raab, and Eric Suba suggested that the medical community may be ready for a “DNA Timeout”⁸ utilizing forensic DNA, an abstract of which follows :

Patient Identification Error Among Prostate Needle Core Biopsy Specimens

Are We Ready for a DNA Time-Out?

Eric J. Suba, John D. Pfeifer and Stephen S. Raab

From the Kaiser Permanente Medical Center (EJS), South San Francisco, California, Washington University Medical Center (JDP), Saint Louis, Missouri and University of Pittsburgh Medical Center (SSR), Pittsburgh, Pennsylvania

Purpose: Patient identification errors in surgical pathology often involve switches of prostate or breast needle core biopsy specimens among patients. We assessed strategies for decreasing the occurrence of these uncommon and yet potentially catastrophic events.

Materials and Methods: Root cause analyses were performed following 3 cases of patient identification error involving prostate needle core biopsy specimens.

Results: Patient identification errors in surgical pathology result from slips and lapses of automatic human action that may occur at numerous steps during pre-laboratory, laboratory and post-laboratory work flow processes.

Conclusions: Patient identification errors among prostate needle biopsies may be difficult to entirely prevent through the optimization of work flow processes. A DNA time-out, whereby DNA polymorphic microsatellite analysis is used to confirm patient identification before radiation therapy or radical surgery, may eliminate patient identification errors among needle biopsies.

Another advocate of so-called DNA fingerprinting is Mary P. Bronner, M.D of the Cleveland Clinic⁹. Her suggested procedure is outlined below.

⁸ Eric J. Suba,* John D. Pfeifer and Stephen S. Raab *Patient Identification Error Among Prostate Needle Core Biopsy Specimens—Are We Ready for a DNA Time-Out?* Journal of Urology Vol. 178, 1245-1248, October 2007



RESULTS REPORTING

The results of DNA fingerprinting are reported as the number of non-identical alleles between the known and unknown samples. An interpretation as to the identity of the unknown specimen is provided if the suspected source tissue is also included.

SPECIMEN REQUIREMENTS

Requirements for DNA fingerprinting on known and unknown specimens vary and are detailed here. Known specimen: The formalin-fixed paraffin block containing representative tissue or 5 to 10 unstained 5 µm formalin-fixed, paraffin-embedded tissue sections of a “known” tissue sample certain to derive from the patient are required. When sections are submitted in lieu of a block, they should be placed onto charged, unbaked glass slides. A corresponding H&E slide should be marked by the submitting pathologist to indicate the tissue of interest for testing. To reduce the risk of contamination in the event that micro dissection is required, a separate, known-identity block from the block with the unknown tissue is requested. Alternatively, overnight shipment of 4 mL of EDTA anti-coagulated whole blood (at room/ambient temperature and not refrigerated) may also be submitted for analysis. Unknown specimen: Either the formalin-fixed paraffin block with the tissue of questionable identity is required or 5-10 charged slides with unstained 5 µm unbaked sections containing the tissue of unknown identity. A corresponding H&E also is required, marked by the submitting pathologist to indicate the tissue for identity testing. If deeper slide levels have exhausted the tissue of interest from the block and the only sample remaining for testing is tissue on the original stained slides, removal of the cover slip to use the stained tissues for DNA testing can be attempted. This has been accomplished successfully on many occasions. Analysis can be attempted from any fragment size, but success rates are lower for samples smaller than 2 mm in size. Methodology DNA is extracted from a sample of known identity and from the unknown sample. The suspected source of a possible contaminant may comprise a third specimen. Micro dissection is performed as needed, in which a pathologist microscopically assesses the tissues on the slides and marks the slides with a permanent marker under microscopic guidance. A technologist uses the markings to dissect the indicated tissues, also under microscopic guidance. PCR amplification of 16 highly polymorphic short tandem repeat loci [D3S1358, THO1, D21S11, PentaE, D5S818, D13S317, D7S820, D16S539, CSF1PO, PentaD, vWA, D8S1179, TPOX, D18S51, FG, and a sex chromosome specific locus amelogenin] is performed (1). Fluorescently labeled PCR products are detected, analyzed, and quantified by capillary gel electrophoresis. Positive and negative external controls are included with every assay.

⁹ DNA Fingerprinting Analysis for Specimen Identification
<http://referencelab.clevelandclinic.org/DBSearch/TestDetail.asp?ID=2676>



VI. METHOD TO REDUCE/PREVENT ADVERSE PATIENT OUTCOMES

As identified in this paper, DNA “fingerprinting” has been advocated to catch those errors which are undetected by existing quality systems, even those systems which adopt precise error reduction programs (e.g. RFID or bar-coding).

A method to assure that biopsy identity switches, undetected by current systems, are detected before a patient suffers an adverse outcome (i.e. undertreatment/overtreatment) is to positively confirm that the specimen belongs to the patient through the utilization of DNA **PRIOR TO INITIATING TREATMENT**. Only by developing a DNA profile from a reference sample from a patient and matching it to the DNA profile from a tissue sample from the patient can one be certain that the tissue is that of the patient. And only by performing confirmatory DNA matching prior to the initialization of treatment can patient safety be assured and the quality of care improved. Performing such a test post-treatment does not increase patient safety.

THE KNOW ERROR® SYSTEM

One system that incorporates both an error reduction system AND DNA fingerprinting is the **know error®** system developed by Diagnostic ID, LLC. The **know error®** system employs both bar-coding AND forensic DNA confirmation in a **prospective** process which, when adopted by pathology labs and their referring physicians, can reduce switching errors and assure that no adverse patient outcomes will occur from, otherwise, undetected misidentifications.

HOW THE KNOW ERROR® SYSTEM WORKS

Tagging: **know error®** biopsy kits employ patient specific ID codes or “tags” in the form of two-dimensional bar-codes. Each kit is assigned a unique bar-code number (both human and computer readable), and every individual component of the kit is tagged with the matching code the benefit of which is a reduction in switching errors.

DNA identity testing: Included in the **know error®** kits are cotton swabs (“buccal swabs”) used to obtain a DNA reference sample from the patient by swabbing the inside of his or her cheek. This is the very first step in the **know error®** biopsy protocol, and establishes the initial link between the patient and the assigned kit’s unique number – at both an administrative and molecular level. The buccal swabs are sent directly to a forensic DNA lab where they are accessioned and stored. Once a comparison with pathology tissue is

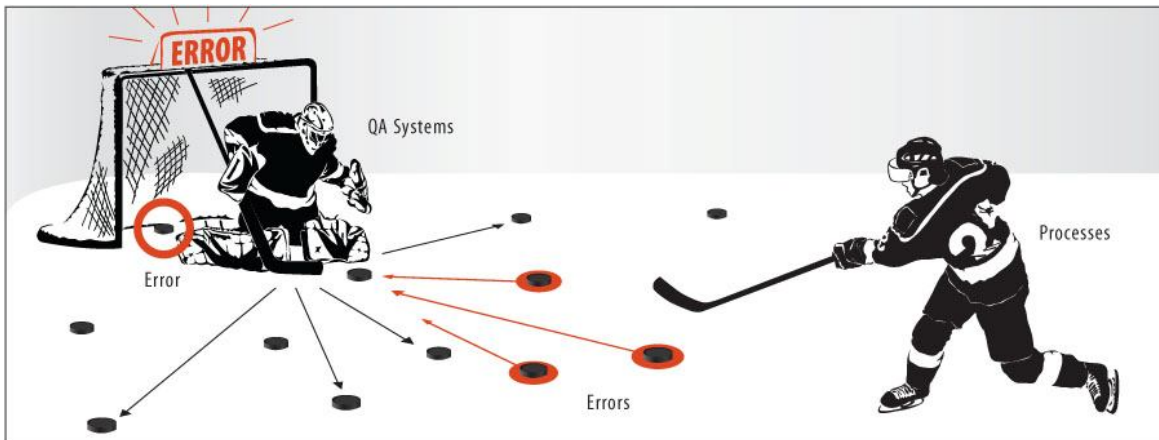


ordered by the physician, the biopsy tissue used by the pathologist for diagnosis is sent to the forensic DNA lab whereby DNA is extracted and then compared with DNA extracted from the buccal swab having the identical bar-code tag. A report is issued within 5 business days of receipt of the tissue indicating whether there is a match or a no-match.

DNA profiling is performed via PCR (polymerase chain reaction) and electrophoresis techniques developed for the forensic identification of biological materials¹⁰. Unlike visual inspection of hand-written patient records, tissue slide labels, and pathology reports, forensic DNA matching provides an absolute and unambiguous confirmation of identity. The benefit of DNA matching is catching previously undetected switching errors and, thus, helping to prevent adverse patient outcomes.

HOCKEY ANALOGY

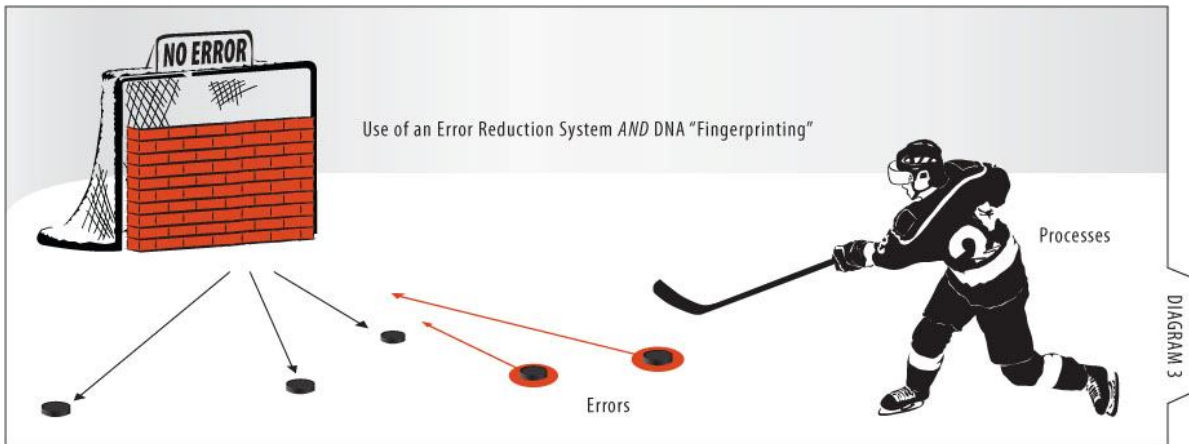
Assume that a hockey player shooting pucks towards a goal represents the normal processes at a hospital, physician office, or pathology lab (Diagram 2). Each puck represents an error that is inadvertently created by these normal processes. Most pucks (errors) are deflected by the goalie (the SOP's and quality assurance systems in-place) whose objective is to prevent the other team (human error) from scoring a goal (an adverse patient outcome). Unfortunately, no goalie (or QA system) is perfect, and inevitably pucks (errors) will get past the goalie and into the net.



¹⁰ The protocol examines the same 16 genetic loci as those commonly used for forensic identification by the FBI and other international authorities. These loci and techniques represent the international gold-standard for human identification in the forensic community



Implementing an “error reduction program” (e.g. inking or bar-coding) reduces the number of “shots on goal” (errors) and thus reduces the burden on the goalie (QA System) to some degree, but does not eliminate the possibility of a puck (error) getting past the goalie. However, by utilizing a prospective DNA “fingerprinting” system such as the **know error®** system, the goal is effectively blocked such that virtually no goals (adverse outcomes) are possible (Diagram 3).



VII. SUMMARY

Numerous studies have indicated that specimen identity issues are a source of error that continues to plague surgical pathology. Biopsy switching and misidentification errors do occur, some of which have adverse consequences to patients. What is expected by society and the legal community, however, is zero errors.

DETECTION

To determine the frequency of switching errors that are not detected by quality assurance systems, a study must be commissioned that performs a prospective, multi-institutional trial to define the specimen identification error rate in the routine practice of surgical pathology using DNA-based identity determination. Only by using DNA, can an accurate estimate of errors be made.

CONCLUSION

Only by using a quality system which both reduces errors and prevents patient biopsy misidentification such as the **know error**[®] system can the medical community protect the patient from the adverse consequences of specimen identity switching.

