An Analysis of Pathology Closed Claims

By Carolyn Akland, MBA, RN, CPHQ, LNCC

A review of SVMIC pathology claims from 2007 – 2016, where a monetary loss was paid on behalf of an insured, reveals the top two diagnoses involved to be: Cervical Cancer and Hodgkin's Lymphoma.

The vast majority of the claims involved a misread, which resulted in cancer advancement and emotional/financial injury. In 38% of the claims, there were systems issues that coincided with the misread specimens, which contributed to the indefensibility of the claims. These "systems" issues occurred primarily in the pre-analytic phase but also in the analytic phase and most certainly complicated the defensibility of the medical malpractice lawsuit.

The types of Systems Issues are illustrated in the chart below:

Specimen Loss/Mix-ups accounted for 78% of the systems issues and included the collection and handling practices of the submitting physician by his/her staff; the processes within the lab to transport and receive the specimen; accessioning and slide identification. Mislabeling, misidentification, sorting, routing and pour-off (decanting) errors were involved in these steps, all of which can have profound consequences on patient safety.

Specimen contamination (floaters, carry-over artifacts and cross-contamination) accounted for 22% of the systems errors.

Often the dispute between who caused the mix-up (the surgeon's office, the hospital frozen section suite personnel, the couriers or the pathology lab) goes unresolved. It can seem like the only "fault" of the pathologist is that he/she was next on the sign out schedule when a "systems" mistake occurred. Having well-documented and consistently used processes for accessioning, handling specimens and identifying slides in the process of being read is essential to accurate and timely diagnosis as well as to the defense of a claim.

The following are some examples of the types of claims seen by SVMIC where the defense was complicated by systems issues:

Pre-analytical phase mix-ups:

Case #1: A 48-year-old with an elevated PSA underwent a prostate biopsy in his urologist's office. His father likewise underwent the same procedure that afternoon. The specimens were switched either in the urologist's office or in the lab, resulting in the son undergoing a radical prostatectomy with a normal pathology report to follow and the father being given a normal pathology report when, in reality, he was the one with the prostate cancer who needed the surgery. His diagnosis and treatment were delayed while his son had unnecessary surgery that left him impotent. The pathologists reading the specimens were sued along with the urology practice.

The lab examined the written procedures pertaining to specimen receipt and found that these procedures were followed to the letter. They discovered that the two specimens were handled by two different technicians, which meant that for a mix-up to occur both techs would have had to make simultaneous errors, which is virtually impossible to do. The lab was also able to present evidence of past deficiencies by the urology group including mixed up specimens, empty containers, male specimens labeled female and vice-versa. Furthermore, it was argued that this was the only group of surgeons that refused to use the biopsy containers provided by the lab. In the end, negligence was undisputed, and the allocation of liability was disputed between the urology group and the pathology group. However, because of the scrupulous and standardized procedures in place at the lab, SVMIC paid the majority of the loss on behalf of the urology group rather than the pathologists.

Case #2: A 60-year-old with a history of hematuria and proteinuria, underwent a kidney biopsy complicated by hemorrhage and hypertension. One week later it was discovered that the biopsy specimen was missing. The biopsy had to be repeated. In retrospective review; it was discovered the specimen was reviewed in the frozen section lab, determined to be adequate and given to the transporters. The specimen was recorded in two logs and the specimen and paperwork placed in a biohazard bag for transport. The transporter took the specimen to the lab and left it on the counter. The specimen was never accessioned. A thorough search took place in the frozen section suite and in the waste, as well as the transporter's car and in the lab waste. Further investigation of chain of custody, log-in and transport processes also took place. The employees handling the specimens were long term and well experienced with a track record of no specimen having been lost at that lab in years. Once again, negligence was undisputed. The claim was settled for an amount that would cover costs to pay for the repeat biopsy and other medical costs.

Following this incident, changes were made by the lab for future transfers. Rather than use a courier to transport the specimens from the frozen section suite to the lab, it was decided that Fed Ex would be used and the transport bag would be stapled shut. Furthermore, the specimen transport log was to be faxed to the lab to verify the delivery of specimens as they arrived. Any specimen delivered to the lab was to be entered into the log book. A weekly check was initiated for any specimens not signed into the log.

Case #3: A 45-year-old female underwent a gastric biopsy as an inpatient. The biopsy was sent to the pathology services lab and read as atypical but benign. Slides from the biopsy material later read by another lab showed a diagnosis of malignant lymphoma. Subsequent testing showed no cancer but rather contamination of the original biopsy material. Since male colon tissue was mixed in with this female's gastric biopsy on every paraffin block, the slides were contaminated either by the GI clinic or in the pathology lab. The GI clinic was suspected of affixing the labels to containers prior to the procedure, which could have led to the wrong container being selected for the specimen. However, this was never confirmed. The case was settled, in part due to the significant risks of the finger pointing between the defendants.

Analytical phase mix-ups:

Case #1: An 82-year-old man with a history of stomach cancer had several biopsies taken by his surgeon, including one from the umbilicus and one from the chest wall. The chest specimen was reported as adenocarcinoma when the cancer was actually in the umbilicus. The patient underwent an unnecessary wide excision of the chest wall. The pathologist accepted the blame by acknowledging that he mixed up the two specimens. It was suspected that he had more than one case file open at a time so that the accidental entry of data into the wrong file was possible. The patient sought recovery for medical bills, pain and suffering.

Case #2: A 36-year-old male was referred by his primary care physician to a head and neck surgeon with complaints of a lump in his throat. He underwent a fine needle aspirate of the submandibular lump. The pathology report was negative for malignancy. A month later, the patient had a lymphadenectomy done. The specimen pathology was reported as "no immunophenotypic evidence of non-Hodgkin lymphoma". The patient continued with swelling and knots in his throat. He was referred by his head and neck surgeon for consult where he underwent another biopsy. This biopsy returned positive for Classic Hodgkin's Lymphoma. The initial slides were requested for review and were also read as positive for Classic Hodgkin's Lymphoma. The patient underwent a lengthy treatment process of chemotherapy and radiation therapy.

A lawsuit was filed alleging delay in diagnosis, which, in turn, required a more aggressive treatment. The defendant admitted liability for missing a diagnosis that was obvious. He believed he likely picked up the wrong tray of slides (it was his practice to have the slides and paperwork of two patients on one tray) and failed to validate the name and the identification number on the paperwork with the name and number on the slides.

LESSONS LEARNED:

Better defenses can be asserted by doing the following:

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.
11. Minimize distractions when reading studies.
12. Perception and interpretation can improve by availing yourself of all readily accessible clinical information.
13. Proofread your voice dictation or transcribed reports for errors (example: mucinous cystadenoma vs. mucinous cystadenocarcinoma), deleted words, and confusing or conflicting statements before signing. Inaccuracies can look sloppy to a jury and communicate indifference and a lack of care or concern for the patient.
14. Document all non-routine communications including the time and method of communication and, specifically, the name of the person to whom the communication was delivered. Such documentation is best placed in the pathology report, but may be entered in a department log. Examples of these situations follow;
    1. Communication with the referring physician regarding a discrepancy between the preliminary and final diagnosis.
    2. Communication with the referring physician regarding urgent or unexpected findings including the critical values defined by lab policy.
    3. Communication with the referring physician in situations where a small sample size or poor quality of tissue fixation may limit interpretation of a specimen.
    4. Communication with a patient about the risks/alternatives of the procedure (i.e. when performing a bone marrow biopsy or fine needle aspiration). The pathologist performing the procedure should obtain the patient's consent. This conversation should be documented in the procedure note along with indications for the procedure and potential complications. The hospital consent form is typically a generic form, which is not sufficient to describe the conversation that took place with the patient.
15. Document instances where a comparison is made with prior pathology case material and/or reports.
16. Use a corrected, amended or addendum report to make any changes to a verified pathology report and to document errors.
17. Implement a system to communicate the results of amended reports. Use a corrected report and if significant, speak with the referring physician and document

having done so.

18. Implement a system to communicate abnormal findings when the patient has been discharged prior to receiving results. If significant, personally communicate findings to the referring physician. Document all efforts to communicate with the treating physician, along with the information that was relayed in the “Comments” section of the report.

Be aware that the person signing the report may bear all or partial responsibility for the content of the report, even when signing on behalf of a colleague. The signer of the report should look at the slide(s) to seek agreement with the findings. Resolve any disagreements before reporting the results.
