Patient Safety and Error Reduction in Surgical Pathology

Raouf E. Nakhleh, MD

Objective.—To review issues relevant to patient safety and error reduction in surgical pathology in the context of continuous quality improvement.

Data Sources.—The literature is reviewed.

Conclusions.—Patient safety goals can and should be addressed within the context of a quality improvement plan.

The Institute of Medicine's report on medical errors first published in late 1999 initiated the patient safety movement. This was followed by the Institute of Medicine's recommendations for dealing with this crisis in health care. Although there was heavy emphasis on medication errors, scrutiny has since been applied to all fields of medicine. Surgical pathology errors have been highlighted in many recent reports of wrong site or wrong patient surgery or therapy because of surgical pathology error. In response, accrediting agencies such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) reevaluated their accreditation standards and effected standards with emphasis on patient safety. In addition, the JCAHO has implemented patient safety goals that must be addressed by all institutions accredited by it. Several of these patient safety goals apply to laboratory services including surgical pathology. These patient safety goals are listed in Table 1.

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DEFINITION

Patient safety is defined as freedom from accidental injury in the delivery of health care. However, the definition that is currently used further imposes that health care institutions ensure that patient safety involves the establishment of operational systems and processes that minimize the likelihood of errors and maximize the likelihood of intercepting them when they occur. This operational definition highlights how patient safety is an essential and inseparable part of a QA plan and how patient safety and QA need to be an integral part of a laboratory's operations.

GENERAL FACTORS THAT LEAD TO ERRORS

To eliminate errors, there must be a good understanding of how and why errors occur. Spath summarizes the literature and describes how errors occur in medicine. Several of these factors (Table 2) apply directly to surgical pathology, including the following: (1) Variable input; a consistent quality product is dependent on consistent input. (2) Complexity; with every step in a process the risk of error increases. It has been estimated that if there is a 1% error rate at each step, with 25 steps the risk of error goes up to 22%. Surgical pathology has numerous steps in receiving, processing, and reporting a specimen. (3) Inconsistency; errors may occur when there is inconsistency in the level of training, in individual performance, in how procedures are used, in the extent of communication by different individuals, and in the use of language or diagnostic taxonomy. (4) Human intervention; humans do poorly at routine repetitive tasks. They are susceptible to boredom or distraction. Machines on the other hand are best for routine repetitive tasks but tend to have problems with unanticipated situations. (5) Time constraints; batch work and deadlines may force individuals to cut corners or at least work in a hurried mode. This may not manifest itself in errors until a system is
stressed with extra work or unexpected reduction in workers. (6) Hand-offs; in medicine this refers to points at which a patient's care is turned over to a new crew either for a shift change or through a transfer and critical information must be accurately delivered. In surgical pathology, hand-offs relate to the specimen. There are 2 critical hand-offs outside of pathology, at the time of specimen delivery and at the time of report delivery. Within surgical pathology there are equally critical hand-offs of the specimen as it is processed and moved from specimen container to cassette to block to slide and then the findings are transcribed to the report. (7) Inflexible hierarchical culture; this type of culture leads to failure because of the inability to adapt and change and the inability to acknowledge the source of errors. An organization must have the ability and the mechanisms for an open exchange of ideas.

### Addressing Patient Safety and Error Reduction Through an Integrated QA Plan

Quality assurance plans are traditionally designed to achieve quality products. In surgical pathology, a quality report is accurate, timely, and complete. Accuracy and completeness are important concepts in patient safety. Therefore, many aspects of a QA plan address patient safety issues and error reduction. Quality assurance plans have a basic structure including preanalytic, analytic, and postanalytic phases of the test cycle as well as turn-around time and customer satisfaction. The latter two do not address patient safety directly and are not addressed in this article. Following is a discussion of problems that occur within each of the test cycle segments in surgical pathology and potential solutions. Many consider only monitors and error reduction is the installment of policies and procedures that ensure quality and force error avoidance behavior or detect errors.

In the framework of the test cycles, specimen identification accounted for about one third, defective specimens accounted for 4% to 10%, analytic misinterpretation accounted for about one fourth, and defective reports were about one third to two fifths of the errors. Therefore, studying and addressing errors in surgical pathology required examination of the total test cycle.

### Preanalytic

In the preanalytic phase of the test cycle in surgical pathology, the most significant problems relate to specimen identification and the availability of reliable clinical information. Although some would consider the availability of reliable clinical information more of an analytic problem, both of these issues relate to clinical input given to pathology.

Specimen identification problems must be addressed in a comprehensive manner. A quick or short-term solution is unlikely to result in a sustained reduction in identification errors. The declaration by the JCAHO and the CAP that patient and specimen identification are primary patient safety goals gives pathology the legitimacy and the muscle to strictly enforce prescribed labeling standards. Improperly labeled specimens should not be accepted. This also gives the pathologist the needed support to upgrade outdated systems. The best course of action to address specimen identification errors should include a sustained awareness campaign that involves all potential participants, particularly those not trained by the laboratory. This must be accompanied by education that is periodi-

### Table 1. Patient Safety Goals*

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### Table 2. Factor Contribution to Errors in Surgical Pathology

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* JCAHO indicates Joint Commission on Accreditation of Healthcare Organizations; CAP, College of American Pathologists.
cally reinforced and the necessary materials to easily comply with labeling standards.

In a study of 1 million surgical specimens in 417 laboratories, 6% of cases were defective at accessioning with respect to required elements (median, 3.4%). Seventy-seven percent of these problems were related to lack of some aspect of required information needed for specimen processing. Defective specimen identification was the second largest category at 9.6%. In another study focused on clinical information in surgical pathology, approximately three fourths of a million specimens were examined in 341 laboratories. No clinical history was given in 2.4% of cases. When pathologists were asked to identify cases that required additional information regardless of the information provided, 5594 cases were identified (0.73%). This delayed the diagnosis in about one third of cases and led to a change in diagnosis in 6.1% of cases. Clinical information has also been implicated in a study of amended reports in which 10% of amended reports were the result of additional clinical information and 20% of amended reports were because of the clinician requesting review of a case presumably because of clinicopathologic discrepancy. In a study of malpractice claims, 20% of cases were because the pathologist failed to obtain all relevant information.

Improving clinical information in surgical pathology is likely to come from improvement in information technology. One of the principal advances that many institutions have already adapted is the introduction of the electronic medical record. Although variable in its use, this has tremendous potential. At some point in the future, one may envision a day when the ordering physician’s note would automatically be attached to the biopsy or resection specimen’s requisition thus relaying the physician’s thought process in leading to the biopsy or resection. In the meantime, when an electronic medical record is available, the pathologists can access physicians’ notes, as well as laboratory results and radiographic or endoscopic findings, leading to improved clinicopathologic correlation and hopefully better diagnoses with fewer errors.

Rather than stepping into an unknown situation, before an intraoperative consultation the pathologist can access the electronic medical record and become familiar with the cases scheduled for that day and therefore can more directly deal with the question at hand. A pathologist may also access the medical record at the time of intraoperative consultation without significant delay if a workstation is available. Remote order entry could also be used to enhance obtaining clinical history, but this must be made secure particularly if it is expanded for use on the Internet from remote clinics and physicians’ offices.

Analytic

The analytic phase of the test cycle encompasses gross specimen examination, dissection and sectioning, histologic processing and staining, and microscopic evaluation. Although there is ample opportunity for error in all of these areas, this discussion is limited to diagnostic accuracy.

Peer review is the current single most widely used method to determine diagnostic accuracy. Although peer review has inherent biases, no other acceptable method has emerged. A recent study has shown that in review of more than 5000 cases in 71 laboratories, 6.8% of cases were found to have discrepancies, but a specific error rate was not given. Forty-eight percent of these discrepancies were within the same category (eg, benign to benign and malignant to malignant), 21% were categorical (eg, benign to malignant or malignant to benign), 18% represented typographical errors, 9% had errors related to patient information, and 4% had discrepant margins. Another study of nearly 9000 specimens undergoing blind review at a single institution also found a disagreement rate of 6.9% and an error rate of 0.8%. They categorized error types in a slightly different way: 33% were false-negative and 6% were false-positive. These errors may equate to categorical discrepancies. Twenty-nine percent were related to type; these may be similar to discrepancies within the same category. Twenty-nine percent were listed as threshold, 2% margins, 2% grading, and 1% clerical.

Among the methods of peer review, no single method has proven itself superior to others in detecting errors. Most laboratories use multiple strategies to detect errors such as review of cases for conferences, review of cases prior to send-out, review of specific types of cases (eg, all breast cancers), or review of a selected percent of cases. The most common method used to prevent diagnostic errors is second review prior to case sign-out. A study published in 2002 indicates that in 0.5% (range, 0%–2%) of all cases expert consultation is obtained. An unpublished survey from the performance improvement program in surgical pathology of the CAP indicates that 42% and 43% of breast and prostate needle biopsy diagnoses, respectively, are routinely reviewed by a second pathologist. The survey also found that 58% of melanoma cases and 34% of gastrointestinal malignancies are also reviewed by a second pathologist. The figures are much lower for benign disease in needle biopsies (6% breast, 18% prostate). A recent study of all cases at a single institution indicates that approximately 13% of all cases are reviewed by a second pathologist prior to sign-out. The practice of second pathologist review of selected cases seems to be gaining momentum as many laboratories are adopting policies of second review for selected types of cases. Two separate studies have shown that amended reports are decreased with second pathologist review.

Only one study has addressed what correlates with an error rate. Factors that correlated with errors included the pathologist, the specimen type, the diagnosis, dermatopathology, and the number of pathologists on the report. Factors that did not correlate with error included the amount of workload, the years of experience, and the use of special stains. These data are unconfirmed and are difficult to validate because few institutions are using blind review as a method to detect errors.

There are many studies with varied result that demonstrate discrepancies in up to 40% of cases. However, when focused on significant error rates, the range is 0.26% to 1.7%. Most authors believe that the error rate in surgical pathology is likely less than 1%. In determining whether this is acceptable we need to consider other standards. The established six sigma standard for manufacturing is 3.4 defects per million. A 1% error rate equates to 10 000 errors per million. A 0.1% error rate equates to 1000 errors per million. By this analogy one may conclude that pathology is likely less than 1%. In determining whether this is acceptable we need to consider other standards. The established six sigma standard for manufacturing is 3.4 defects per million. A 1% error rate equates to 10 000 errors per million. A 0.1% error rate equates to 1000 errors per million. By this analogy one may conclude that pathology is likely less than 1%. In determining whether this is acceptable we need to consider other standards. The established six sigma standard for manufacturing is 3.4 defects per million. A 1% error rate equates to 10 000 errors per million. A 0.1% error rate equates to 1000 errors per million. By this analogy one may conclude that pathology is likely less than 1%.
There are a number of issues that may be addressed within the analytic phase of the test cycle concerning specimen handling and processing within the gross room and histology, but this is beyond the scope of this article. In brief, a number of main points can be made to prevent errors: (1) Standardize all procedures including tissue dissection and sectioning. (2) Remove distraction from work areas such as frequent phone calls. It is best that the job of answering the phone or another function that interrupts work be segregated from jobs that require focus such as accessioning, tissue sectioning, histologic cutting, and microscopic evaluation. (3) Introduce automation for routine tasks whenever possible; this reduces the chance for errors because of distraction or boredom and inconsistencies in individual performance. (4) Take away inconsistent tools such as handwriting; use printers, barcode scanners, or computers whenever possible.

Postanalytic

There are 2 important issues in the postanalytic phase of the test cycle that must be addressed for the sake of patient safety: complete reports and critical values. Complete reporting has always been an issue in pathology but has come into focus recently because of the progress toward evidence-based medicine. This has been particularly important in oncology in which the Commission on Cancer of the American College of Surgeons added a standard for cancer center designation that requires that 90% of cancer pathology reports have required elements based on the CAP's publication Reporting on Cancer Specimens.26,27 Most institutions have adopted computerized synoptic reporting, which seems to be an effective tool. Branstorn et al28 in 2002 published a randomized controlled trial of computer form–based reporting and concluded that there was a 28.4% increase in complete reporting. They commented that pathologists found them acceptable and clinicians preferred them. In noncancer specimens, criteria for complete reporting are not as well defined for all specimens. Frequently, the extent of complete reporting is dependent on the clinical information available at the time of evaluation and the pathologist's level of experience with a particular specimen.

Critical diagnoses also known as critical values are becoming more important. The JCAHO and the CAP have put emphasis on communication of critical results in their patient safety goals. The Association of Directors of Anatomic and Surgical Pathology recently published their proposal for a guideline for critical diagnosis.29 They suggest that, although there may be common critical values, critical values should be customized for each institution.

**FACTORS NEEDED FOR SYSTEMS IMPROVEMENT AND ERROR REDUCTION**

A number of factors need to be in place for optimal patient safety and error reduction. The best possible results will happen when patient safety, QA, and error reduction schemes are integrated into daily activities. These factors include issues related to the workforce, continuous education and training, the use of technology, standardized tasks and language, and the ability to change.

First and foremost, the workforce of a laboratory must be flexible, well trained, and knowledgeable. These ideas should apply to all levels. People should be qualified for their positions, but more importantly they need to be suited for their jobs. Putting an individual who is qualified in a situation for which he or she is not prepared is a sure recipe for problems. As an example, although pathologists are broadly trained, a particular pathologist may practice for years without seeing a bone tumor or an unusual pediatric tumor. In these situations, realizing one's limitations and deferring is the best option. The same can be said for placing the technical staff in situations for which they have not been fully trained. Examples include asking a technologist to accession cases on a new computer system without training or asking a pathologist's assistant to dissect a type of specimen he or she has never handled. Because of these issues the workforce must have sufficient redundancy in their skills so that in the absence of an individual the work does not come to a stop and is not done by individuals who are unfamiliar with the process.

Having a knowledgeable well-trained staff is dependent on continuous education and training. Through multiple channels, a laboratory must continuously seek new knowledge. This knowledge must then be discussed and collectively adopted or rejected. It is imperative that all involved be on the same page. New knowledge must also be integrated into new hire training and ongoing education. Continuous education must address patient and employee safety issues, QA, and updates on particular job changes.

Comprehensive computer systems offer the best opportunities to reduce errors. Few comprehensive systems exist today. As time goes on, the opportunity to tightly integrate the entire test cycle in surgical pathology will offer significant advantages. Although no one can predict what future systems will look like, a comprehensive computer system could offer many features that integrate the whole process. A comprehensive computer system could track specimens from their source of origin (doctor's office, endoscopy suite, operating room, etc) and then automatically include the physician's note relevant to that procedure. At the same time the system could generate materials (blocks, slides, labels, etc) necessary for processing that specimen in the laboratory. Case logs would also be generated to check cases off as they arrive in the laboratory. Once the case is in the laboratory it could be tracked using a barcode or other type of label that would eliminate input errors. As technology evolves, a number of checks can be built into a system to avoid errors and to ensure that cases are accurately reported. Real-time QA reports could be generated with alerts for incomplete, delayed, or nonsensical reports.

Standardization of tasks and language is needed to address consistency and simplicity. There should only be one procedure for each task; this simplifies a situation by removing conflicting procedures. It also simplifies training, because only one procedure needs to be taught. More important is the need to standardize language and diagnostic criteria. It has been shown that when pathologists are taught to use specific criteria in the diagnosis of a disease, higher diagnostic agreement is achieved. When there are competing diagnostic systems, only one should be used and the decision should include the clinicians involved because they will ultimately use that information.

An organization must have the ability to adapt and change. The basics of light microscopy have not changed in a long time, yet there has been significant development in addressing specific disease entities. Pathologists must have the ability to change as new developments occur.
References