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**Topic:** Interpretive Diagnostic Error Reduction in Surgical Pathology and Cytology

**Date:** May 13, 2015

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**Was the guideline created because of recent pathology or laboratory error disclosures?**

No. The guideline was created in recognition of the substantial body of literature documenting disagreements in a percentage of cases that are reviewed more than once and as part of a comprehensive effort of the College to improve the specialty. The purpose of the guideline is to help pathologists improve diagnostic accuracy, to reduce the likelihood of clerical and interpretive errors and improve patient safety. The guideline also provides guidance about how and when a second review may be most useful. The guideline is part of the College-wide initiative to continuously improve pathology and laboratory medicine.

**Can you clarify what “selected” pathology cases mean? Does this mean targeted selection or randomized selection of cases?**

There are different methods used to select cases for review; selection of cases may be done randomly or selected based on specific criteria (eg, all malignancies, all initial breast biopsies, etc). A combination of methods may also be used. There is evidence that targeted review (review of a specific type of case) is more efficient at finding important diagnostic discrepancies or errors than randomly selecting cases for review.

**Is there a guideline for pathologists to determine how many diagnostic errors are considered substandard? What should be the threshold of the number of interpretive errors a pathologist should make that would require a corrective action?**

Not all disagreements are errors or mistakes. There are no guidelines or convincing evidence to determine how many errors are substandard.

**How do you define “significant error”?**

Most of the literature reviewed defined significant error in one of three ways: 1. an error resulting in a clinically significant change in the diagnosis (eg, benign versus malignant), 2. an error resulting in a real or potential change in the patient's treatment, and 3. an error resulting in a real or potential change in the patient's outcome.

**Do you recommend secondary (prospective) reviews of all malignant cases?**

This guideline does not recommend secondary (prospective) review for any specific case type or situation because the evidence was not consistent for these criteria. Because every pathology department is different in the types of cases they diagnose and the expertise and experience of their pathologists, the panel believes it is up to individual practices to determine what case type(s) should be reviewed and provide an expert consensus opinion. While there are situations where review of a new malignancy is appropriate, in most laboratories, the review of all malignancies may not be the most effective way to use limited resources available for second reviews.

**These internal reviews only increase the workload and paper work of the pathologist. Wouldn't you agree that the correct diagnosis is dependent on the knowledge and experience, and not necessarily the secondary screening?**

All disagreements are not errors, and the second diagnosis is not always correct. Current studies have shown that some pathology departments already review up to 10% of cases when all types of reviews (directed reviews, tumor boards, etc) are measured. Second review is just one tool in the pathologists' arsenal to improve the accuracy of their diagnoses. An accurate diagnosis is dependent on the pathologist's knowledge and experience, as well as clinical correlation and the prudent use of ancillary studies when available. Internal reviews are a good way for pathologist to have an opportunity to discuss a case with a colleague and possibly to learn from someone more knowledgeable or experienced in a particular disease.



**Is there a standard way of reviewing pathology cases (eg diagnostic criteria)?**

No. Case review may be done in numerous ways. Prospective reviews are usually done within a department before sign-out to confirm a finding or lack of a finding. Some departments review cases shortly after they are signed out (immediate retrospective review). A combination of these may be appropriate. On many occasions, a pathologist may seek expert consultation (review) on a unique or rare disease from a pathologist at another institution. Frequently, cases are reviewed in the process of preparing for attendance at a tumor board or clinical-radiographic-pathologic review conference as well as other conferences. Finally, patients often have specimens generated at one location and the final treatment and/or follow-up is done at another institution. This typically involves review of the original material by pathologists at the second institution.

**A second opinion is not always a better opinion. Can the experts comment on this?**

Ideally, second opinions are requested from a more experienced pathologist while others occur because the patient is seen at another institution where the reviewing pathologist may not be a subject matter expert. Even when the second opinion does not change the diagnosis, it may add value in highlighting subtle findings and in addressing the need for additional information to manage the patient. There are documented instances where a second opinion is subsequently shown to be wrong. So a pathologist should critically evaluate the reviewing pathologist's interpretation, particularly when that opinion is substantially different or unexpected. In some cases, a third opinion from an independent pathologist may be of value. In addition to tailoring their review processes to local needs and situations, individual practices can and should discuss strategies for deliberating and resolving significant differences of opinion.

**What percentage of cases should be reviewed?**

There was no consistent evidence that defined the extent of reviews. Based on the literature and certain CLIA regulations, up to 10% of cases are reviewed in some departments and that should be determined by the laboratory director in their practice setting.

**What constitutes a "timely" review of cases?**

"Timely" review of cases may be prospective or retrospective but must occur before the patient undergoes definitive treatment. Informing the treating physician whenever there may be a delay before a second review is planned is the best way to avoid harming a patient.

The "[CAP-ADASP Consensus Statement on Effective Communication of Urgent Diagnoses and Significant, Unexpected Diagnoses in Surgical Pathology and Cytopathology](#)" recommends that pathologists should communicate urgent diagnoses as soon as possible to because it may directly affect patient care.<sup>1</sup>

**The best practice of secondary reviews may be feasible in large academic institutions, but can be burdensome for many solo or small practice pathologists. What do you suggest for these situations?**

A pathologist in solo practice should document when cases are sent to another institution and cases discussed at conferences/tumor boards at the very least. In addition, with digital imaging and telepathology becoming more common, timely reviews by additional pathologists may be more feasible and accommodating.

**How do we document secondary case reviews?**

Secondary case reviews may be documented in the report when they are done prospectively, but could also be documented in a separate intra-department consultation file or consensus conference case log.

**Are there specific cases that should have a standing recommendation for targeted or secondary reviews?**

In general, targeted review should include high risk lesions or clinical history, but departments should periodically assess and determine which types of specimens should be reviewed. The type



of specimens is likely to change over time as knowledge and comfort with the diagnosis of different diseases and organs changes, and as new problematic or difficult diagnostic areas are identified.

**How will the guideline be enforced? What happens if a laboratory doesn't follow the guideline?**

As with any clinical evidence-based guideline they are not mandatory. These recommendations *may* be added to future versions of the CAP Laboratory Accreditation Program (LAP) Checklist; however, they are not currently required by LAP or any regulatory accrediting agency unless as previously defined in CLIA. It is encouraged that laboratories adopt these high-level evidence-based recommendations.

**REFERENCES**

1. Nakhleh RE, Myers JL, Allen TC, et al. Consensus statement on effective communication of urgent diagnoses and significant unexpected diagnoses in surgical pathology and cytopathology from the College of American Pathologists and Association of Directors of Anatomic and Surgical Pathology. *Arch Pathol Lab Med.* 2012;136(1):56-60.
2. Nakhleh RE, Nosé V, Colasacco C, et al. Interpretive diagnostic error reduction in surgical pathology and cytology: guideline from the College of American Pathologists Pathology and Laboratory Quality Center and the Association of Directors of Anatomic and Surgical Pathology. *Arch Pathol Lab Med.* 2016;140(1): 29-40.