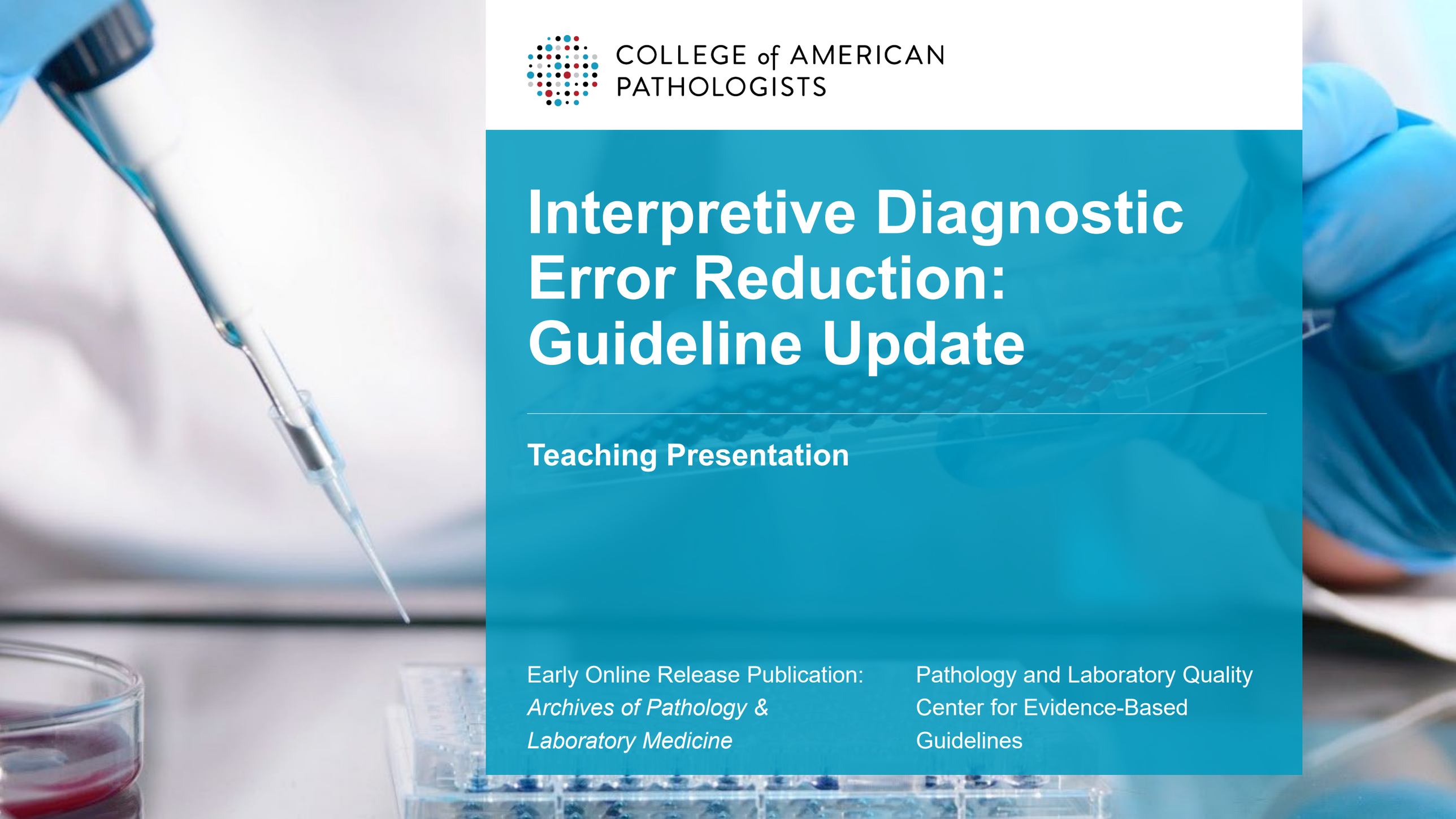

COLLEGE of AMERICAN PATHOLOGISTS

Interpretive Diagnostic Error Reduction: Guideline Update

Teaching Presentation

Early Online Release Publication:
Archives of Pathology & Laboratory Medicine

Pathology and Laboratory Quality Center for Evidence-Based Guidelines

Outline

- Introduction
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- Key Questions and Results
- Guideline Recommendations and Good Practice Statements
- Guideline Development Process
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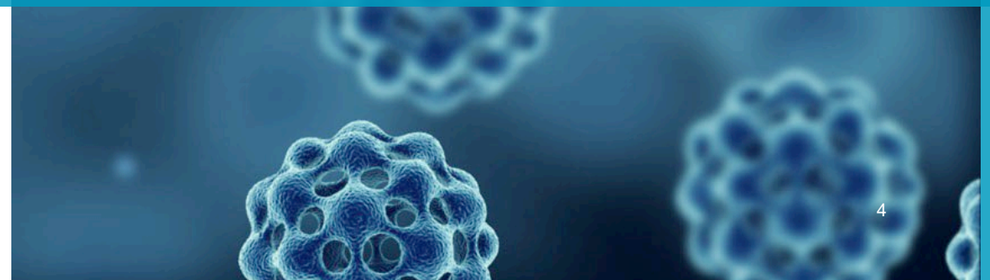
Introduction

- In 2026, a multidisciplinary panel of experts developed evidence-based guidelines to reduce diagnostic errors in anatomic pathology.
- With advancements in digital technologies and new evidence, the original guidelines were reviewed and updated, reaffirming and introducing new recommendations for pathologists.

Objective

To assess evidence published since the release of the original guideline and update evidence-based recommendations for reduction of diagnostic errors.



Key Questions and Results

Key Questions (KQs)

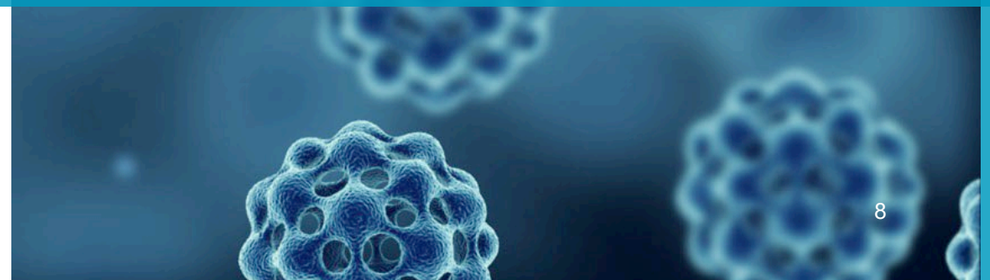
1. Does targeted review (done at either the analytic or the post-analytic phase) of surgical pathology or cytology cases (slides and/or reports) reduce the error frequency (often measured as amended reports) or increase the rate of error detection compared with no review, random review, or usual review procedures?
2. What methods of selecting cases for review have been shown to increase/decrease the rate of error detection compared with no review, random review, or usual review procedures?
    a. Does the use of artificial intelligence increase or decrease the rate of error reduction?
    b. Does the use of ancillary studies in specific clinical situations reduce diagnostic error?

Guideline Recommendations and Good Practice Statements

Recommendation Statement 1

Anatomic pathologists should develop procedures for review of pathology cases to detect disagreements and potential interpretive errors, and to improve patient care.

- Strong Recommendation. The certainty of evidence was *moderate.*



Rationale/Discussion

- Establishing standardized procedures for pathologists ensures consistent, reliable methods for secondary diagnostic review.
- Standardized protocols can be designed, validated, and implemented as a secondary-review framework to uncover initial diagnostic errors.
- Procedures may help to enhance diagnostic accuracy and precision.
- Error rates ranged from 0.1% to 10.0% depending on the method of review and type of cases.

Recommendation Statement 2

Anatomic pathologists should perform case reviews in a timely manner to have a positive impact on patient care.

- Strong Recommendation. The certainty of evidence was *moderate.*

Rationale/Discussion

- **“Timeliness” is not specific and can be broadly defined as the absence of meaningful delay. In pathology, the timeliness of secondary review is context-dependent and must be assessed relative to the clinical situation. A review is considered timely if it has been completed (and the diagnosis modified, if necessary) before management has been initiated.**
- **The ideal secondary review should be performed by an independent reviewer, with at least equal, if not greater, expertise and experience, and in a psychologically safe environment.**

Rationale/Discussion *continued*

- **Secondary reviews should be conducted prospectively and before finalization of the diagnosis to:**
  - **prevent delayed or inappropriate treatment**
  - **reduce the risk for confusion and error propagation in the electronic medical chart by ensuring that only the correct diagnosis is displayed**
  - **ensure that the current and responsible physician receives the diagnosis; the patient may have been handed off to a physician other than the listed surgeon (eg, the medical oncologist)**
  - **minimize the potential of patient distress, especially in the post-21st-century Cures Act era, where patients not-infrequently see their results before the clinician**
  - **reduce the need for rework and amendments**
  - **build trust and confidence in the laboratory system**

Good Practice Statement 3

Anatomic pathologists should have documented case review procedures that are relevant to their practice setting.

Rationale/Discussion

- The expert panel proposes that laboratories have documented processes for secondary case reviews aligned to their specific practice setting as an integral component of their overall quality management (QM) plan.
- To determine which review procedures are the best fit and have the highest impact for the practice setting, the following factors should be considered:
  - skill level of laboratory personnel and pathologists
  - case type, volume, and complexity
- Literature review yielded scenarios that a practice may consider when developing case review procedures:
  - secondary review for low-volume organ systems or diagnoses
  - analysis of error rates and types to identify areas that may warrant secondary review processes

Good Practice Statement 4

Anatomic pathologists should periodically monitor and document the results of case review.

Rationale/Discussion

- **The expert panel acknowledges that implementing continuous quality improvement (CQI) initiatives will require careful consideration of the unique cultural, technical, and structural features of the practice. The targets for quality improvement should be reviewed and modified as practice volume, personnel, and systems change.**
  - **Possible targets for assessment include:**
    - **evaluation of practice variability within their network (standardize processes)**
    - **identification of case types in which diagnostic agreement may be improved by internal or external consultation (develop group consensus)**
    - **recognition of pathologists who may benefit from additional skill development (develop group norms)**

Rationale/Discussion

- To monitor and document review processes, laboratories should develop written policies and procedures for intradepartmental quality review.
- Methods used to document interpretative diagnostic error improvement include:
  - recording percentage (rate) of secondary case review
  - designating mandatory review of specific case types
  - tracking of amended or addended reports
    - These reports can help provide information about types of errors, monitor laboratory processes, and guide quality improvements
  - frozen section-paraffin correlation and cytology-follow-up tissue biopsy correlation
- Practices should periodically monitor the reviews to ensure the proper functioning of and compliance with the process

Good Practice Statement 5

If pathology case reviews show poor agreement within a defined area, anatomic pathologists should take steps to improve agreement.

Rationale/Discussion

- Poor interobserver agreement in anatomic pathology is a well-recognized issue, particularly in the interpretation of borderline or complex cases such as dysplasia, tumor grading, or margin assessment.
- Several strategies can help reduce diagnostic variation:
  - intra-departmental consensus conferences
  - use of standardized criteria
  - calibration slide sets
  - open discussion of challenging or ambiguous cases
  - reinforcement of agreed-upon diagnostic criteria and terminology
- The most effective methods in improving agreement may vary depending on practice setting or disease process. However, shared approaches and diagnostic calibration have repeatedly shown benefit in improving agreement.

Good Practice Statement 6

When there is poor agreement in grading, anatomic pathologists should use established clinically relevant (published) morphologic grading criteria that often have fewer tiers, but focus on clinically relevant cut points.

Rationale/Discussion

- Grading systems in pathology offer structured ways to evaluate the degree of differentiation or disease process (eg, activity, aggressiveness). These systems help stratify risk, predict prognosis, and guide treatment decisions. However, grading systems are frequently reported to have poor agreement.
- A study within the systematic review indicated that using fewer categories in a grading scheme improved diagnostic agreement.

Guideline Development Process

Panel Composition

Expert Panel (EP)

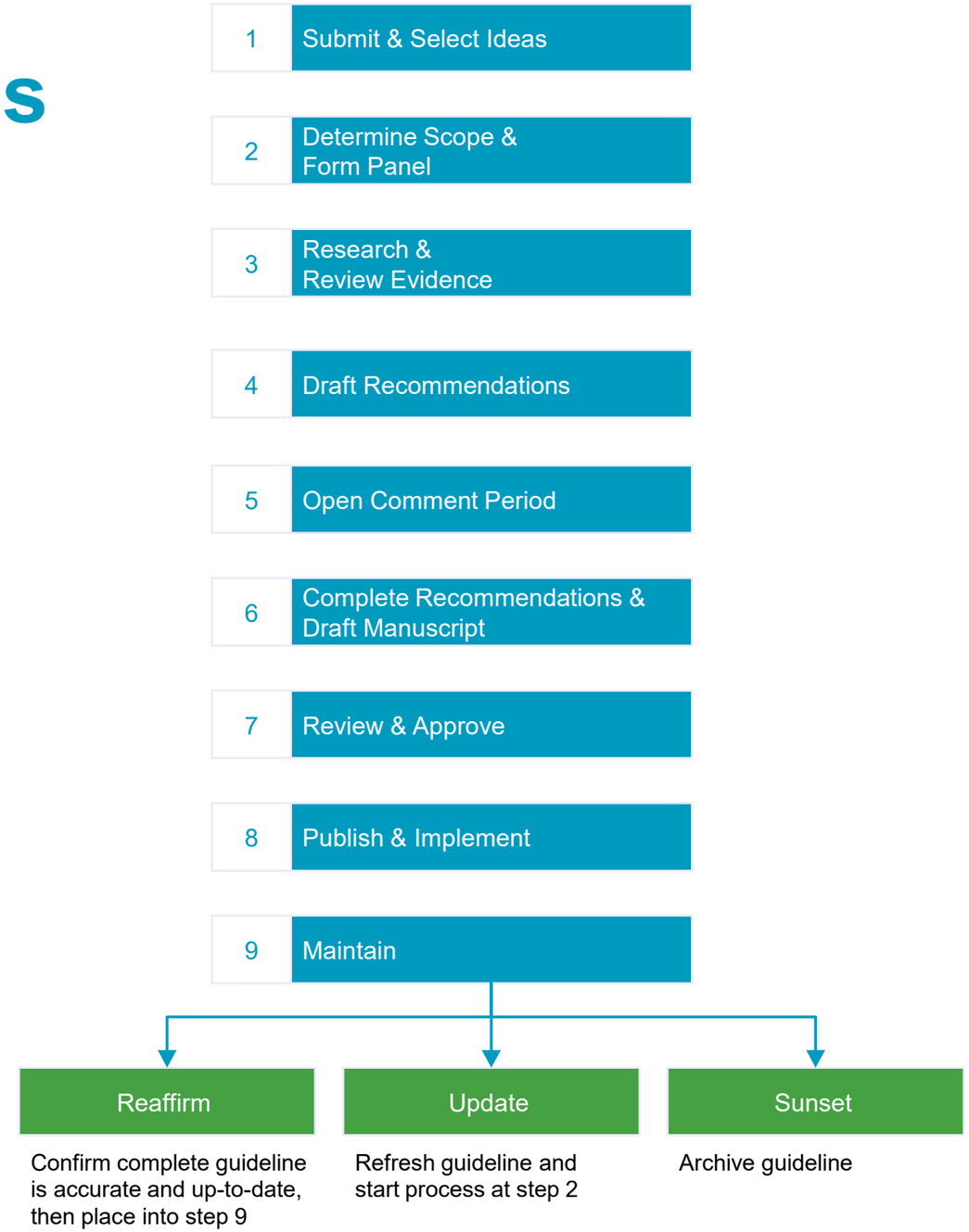
- Suzanne M. Dintzis, MD, PhD, FCAP, Co-Chair
- Stephen S. Raab, MD, FCAP, Co-Chair
- Juanita J. Evans, MD, FCAP
- Marisol Hernandez, MLS, MA
- Tanja Kalicanin, MLS(ASCP)^{cm}
- Christina Lacchetti, MHSc
- Raouf E. Nakhleh, MD, FCAP
- Christopher N. Otis, MD
- Liron Pantanowitz, MD, PhD, MHA, FCAP
- Vinita Parkash, MBBS, MPH, FCAP

Advisory Panel (AP)

- Richard Brown, MD, FCAP
- Kumarasen Cooper, MD, PhD, IFCAP
- Yael Heher, MD, MPH
- Angela Lapus, MD, MPH, FCAP
- Sine Phelan, MD, MBChB, MBBCh

Guideline Development Process

- The Center follows the standards endorsed by the National Academy of Medicine for developing Clinical Practice Guidelines.
- The Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach was used in updating the guideline.
- A detailed description of the guideline development process can be found online: Evidence-Based Guidelines Development Methodology Manual



Literature Search

- Search was conducted in Ovid MEDLINE, Embase, Cochrane Library.
- Initial literature search ran on June 6, 2022.
  - 3,469 studies from January 1, 2015, to June 6, 2022
- Literature refresh ran on October 24, 2024.
  - 1,195 studies from June 6, 2022, to October 24, 2024

Systematic Review of the Literature

Each level of systematic review (title-abstract screening, full-text review, and data extraction) was performed in duplicate by two members of the expert panel.

Quality Assessment

- Systematic Reviews (SRs) and meta-analyses questions were assessed as per the Assessing the Methodological Quality of SRs (AMSTAR) tool
- Non-randomized studies were assessed using the Risk of Bias in Non-Randomized Studies–of Intervention (ROBINS-I) tool.
- Diagnostic studies were assessed using the Quality Assessment of Diagnostic Accuracy Studies (QUADAS) tool.

Open Comment Period

Open Comment Period held from October 23 to November 20, 2024

Review and Approval

- The AP reviewed and provided feedback on the draft recommendations and manuscript.
- The EP approved the final recommendations and good practice statements with a formal vote.
- The independent review panel (IRP) representing the Council on Scientific Affairs reviewed and approved the guideline for the CAP.
  - IRP members were masked to the expert panel and vetted through the conflicts of interest (COI) process

Conclusion

Conclusion

- Evidence-based, consistent terminology and standardized second review processes significantly help in reducing unnecessary variation.
- The two guideline recommendations and four good practice statements are intended to help pathology practices of all sizes and settings in developing meaningful ways to assess and improve diagnostic agreement.

References

Dintzis SM, Evans JJ, Hernandez M, Kalicanin T, Lacchetti C, Nakhleh RE, Otis CN, Pantanowitz L, Parkash V, Raab SS. Interpretive Diagnostic Error Reduction: Guideline Update from the College of American Pathologists in Collaboration with the Association of Directors of Anatomic and Subspecialty Pathology. *Arch Pathol Lab Med*. 2026 Apr. doi:10.5858/arpa.2026-0016-CP. Epub 2026 April 28.

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