

Topic: Validating Whole Slide Imaging Systems for Diagnostic Purposes in Pathology: 2021 Guideline Update

Date: May 18, 2021

Why was this guideline updated?

The CAP is committed to updating its guidelines to ensure they are informed by the most current data. The 2021 guideline update¹ evaluated literature published since the 2013 original guideline release.

What's the main difference between the original guideline and this update?

While the recommendations themselves are largely similar, the process used to develop the guidelines differed. The 2021 guideline update had panel representatives from two collaborating societies: the Association for Pathology Informatics (API) and American Society for Clinical Pathology (ASCP). Additionally, the GRADE approach was used in the development of the update. As a result, the recommendations are classified as either strong or conditional. Other statements with little to no data are categorized as good practice statements.

What are “good practice statements” and why aren’t these recommendations?

Good practice statements are defined as statements having a “high level of certainty that the recommendation will do more good than harm (or the reverse), but where there is little direct evidence.”^{2,3} Unlike recommendations, they are not evidence-based. The expert consensus opinions found in the 2013 guideline are now categorized as good practice statements in the update.

How did you determine that 60 cases should be used in the validation process?

This recommendation is re-affirmed from the 2013 guideline. Studies in our systematic review showed that going beyond 60 cases did not improve mean concordance. Refer to the guideline manuscript to review the evidence table for Recommendation 1.

The 2021 update includes a recommendation that concordance between light microscopy and WSI be greater than 95%. Shouldn't there be 100% concordance?

Ideally, 100% concordance is desired, however, this does not reflect the subjective nature of pathology as practiced with glass slides where inter- and intraobserver variability is an established reality. The weighted mean percent concordance across the 33 studies in our systematic review was 95.2% and this formed the basis for Recommendation 2.

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

As with any clinical evidence-based guideline, following the recommendations is not mandatory. Laboratories should follow regulatory and/or their accrediting agency. It is only highly encouraged that laboratories adopt these recommendations.

REFERENCES

1. Evans A, Brown RW, Bui MM, et al. Validating whole slide imaging systems for diagnostic purposes in pathology: guideline update from the College of American Pathologists in Collaboration with the American Society for Clinical Pathology and the Association for Pathology Informatics. *Arch Pathol Lab Med.* 2021;146(4):440-450. doi: 10.5858/arpa.2020-0723-CP
2. Guyatt GH, Alonso-Coello P, Schunemann HJ, et al. Guideline panels should seldom make good practice statements: guidance from the GRADE Working Group. *J Clin Epidemiol.* 2016;80:3-7
3. Tugwell P, Knottnerus JA. When does a good practice statement not justify an Evidence Based Guideline? *J Clin Epidemiol.* 2015;68(5):477-479.