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Review and update of the guidelines for review of gynecologic cytology in the course of litigation

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The guidelines for review of gynecologic cytology in the course of litigation were initially written by the American Society of Cytopathology in 2000 and have been reviewed and reapproved several times since then. This communication seeks to summarize the background for these guidelines and details the issues that were addressed in the most recent review.
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Context

The guidelines for review of gynecologic cytology in the course of litigation grew out of a perception that some statements made during expert testimony in this setting were difficult to verify. These issues were extensively discussed at the College of American Pathologists Conference XXX on quality and liability issues with the Papanicolaou (Pap) smear.[1,2] The guidelines were initially developed and written by the American Society of Cytopathology (ASC) Ethics Committee in 2000, approved and adopted by the ASC Executive Board on November 10, 2000, subsequently reviewed by the ASC Ethics and Conduct Committee on June 30, 2011, and approved by the ASC Executive Board on July 27, 2011. Several other organizations have also approved similar guidelines based on those approved by the ASC (see Table 1).

In 2013, the ASC developed a formal process for reviewing the organization's guidelines, which included an opportunity for members to express their concerns about any guidelines of the society. Previous reviews of the ASC position statements and guidelines were done on an ad hoc basis, without a formal written protocol, and without an open comment period. Other organizations, including the Institute of Medicine[3] and the American Cancer Society[4] have developed formal methods to review their clinical practice guidelines. These guidelines address specific issues

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Table 1 Organizations that have approved the "Guidelines for Review of Gynecologic Cytology in the Course of Litigation."

National Organizations
College of American Pathologists (1998)
American Society of Cytopathology
American Society for Clinical Pathology
American Society for Cytotechnology
State Pathology Organizations
Alabama (2001), endorsed CAP guidelines
Arizona
California (1996), own guidelines
Colorado
Florida
Georgia
Illinois (2005)
Kansas
Kentucky
Maine, accepted Vermont's
Massachusetts
Michigan (1998)
Minnesota (2001)
Nevada
New Hampshire
North Carolina
Ohio
Oregon (1998), accepted CAP version
Pennsylvania
Rhode Island, accepted California's
Vermont, own guidelines
Virginia (1999)
Wisconsin, accepted CAP version
South Carolina (1994)
Texas, accepted modified CAP version
Wyoming
State Cytology Organizations
Alabama Society of Cytology
Arkansas Society of Cytology
Florida Society of Cytology
Kansas Cytology Association
Minnesota Cytology Society
South Carolina Society of Cytology (1994)
Southern Association of Cytotechnology
Texas Cytology Society
State Medical Societies
Kentucky
Pennsylvania
Wisconsin

Abbreviation: CAP, College of American Pathologists.

including but not limited to transparency, resolution of conflict of interest, evaluation of the strength of the evidence for any recommendations, and an opportunity for feedback from the community and stakeholders that the organization represents. The ASC's review process was modeled on these processes, and an open comment period for the guidelines under review was held from December 2012 through February 2013.

Recommendations of the ASC Guidelines Review Committee

Six comments from 9 members were received concerning the litigation guidelines. After careful consideration of these comments, it was the unanimous opinion of the ASC Guidelines Review Committee* that the current guidelines on the whole are clearly written, relevant, up-to-date, appropriately general in scope, and supported by published scientific evidence. Although, no large-scale changes were deemed necessary, 4 minor revisions were proposed. These proposed revisions took into account both the comments received from ASC members and changes in Pap testing technologies that have become more prevalent over the past decade since these guidelines were initially drafted. The current revisions are highlighted here and included in Table 2.

In the introductory paragraphs, mention of an "irreproducible false negative rate of about 5%" has been brought up as quantitatively inaccurate and not necessarily backed by existing published data. The perceived intention of this line is to convey the notion that the Pap test, which as a screening test is not 100% sensitive and is associated with a small but unavoidable error rate intrinsic to the test. This laboratory error rate is multifactorial in nature, influenced by specimen collection and screening methods, as well as by differences in what defines a false negative test. Although this figure "of about 5%" does not currently appear to be a point of contention in the setting of litigation, it is felt that any potential confusion over this number can be avoided while preserving the true intention of the statement by simply eliminating the clause "of about 5%" and having the rest of the paragraph read as is.

In guideline point 2, the terminology used for equivocal squamous and glandular abnormalities has been updated to be consistent with the terminology used in the second edition of *The Bethesda System for Reporting Cervical Cytology*. Atypical squamous cells (ASCUS) has been changed to atypical squamous cells (ASC) to include ASC-US and ASC-H and "atypical glandular cells of undetermined significance (AGUS)" has been updated to "atypical glandular cells (AGC)."

Guideline point 3 concerns the use of unbiased blinded rescreening. Some of the comments received addressed perceived difficulties in this process. It was the conclusion of the committee and the executive board that blinded rescreening is still the most objective mechanism to reduce the bias associated with the rescreening process in the background of litigation. In addition, since the initial drafting of these guidelines in 2000, the marked increase in the use of liquid-based preparation methods has been

*ASC Guidelines Review Committee 2012-2013 members: Paul VanderLaan, MD, PhD, Chair; Guliz Barkan, MD; Barbara Benstein, PhD, SCT(ASCP)CM; Brian Collins, MD; Michael Henry, MD; Michele Smith, SCT(ASCP).

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