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# The Lifecycle of an Evidence-Based Laboratory Practice Guideline: Origin, Update, Affirmation, and Impact!

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# The Lifecycle of an Evidence-Based Laboratory Practice Guideline

## Origin, Update, Affirmation, and Impact!

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The College of American Pathologists (CAP) made a strategic decision 10 years ago to develop and publish evidence-based laboratory practice guidelines (LPGs). As the CAP had worked previously with the American Society of Clinical Oncology (ASCO) to develop the HER2 breast cancer guideline, the CAP Pathology and Laboratory Quality Center (the Center) was officially launched in 2010 with the publication of the estrogen and progesterone testing guideline. Since then, the Center has published 14 LPGs, with 9 more in progress at various stages of development in partnership or collaboration with 20 different medical societies.<sup>1</sup>

Evidence-based LPGs are created with the expectation that they will be adopted by laboratories. Ultimately, improved patient care is the primary reason for developing guidelines. We believe that we are succeeding in this mission to improve laboratory practices, advance medicine, and promote patient wellness and safety. A secondary benefit has been to raise the profile of pathology and laboratory medicine as leaders in advancing evidence-based

patient care. This article will describe the process the Center uses to develop and maintain LPGs.

### HOW ARE TOPICS SELECTED?

The Center is deliberate in soliciting topics from a wide range of pathologists representing various subspecialties and practice situations. Our focus has been in areas where laboratories need guidance to assure appropriate testing. Topics are carefully vetted and vigorously debated to ensure that a proposed evidence-based guideline is practical, timely, and desirable. Patient safety and a demonstration of a practice gap in a particular area are among the primary factors used for selection. Another factor that influences our decision is the ability to focus a clinical question by using the PI/TCO format (population, intervention/test, comparator, and outcome)<sup>2,3</sup> so that rational recommendations can be articulated and easily adopted.

### HOW IS A GUIDELINE DEVELOPED?

The Center follows rigorous procedures for guideline development using standards outlined in the National Academy of Medicine's (formerly Institute of Medicine) "Clinical Practice Guidelines We Can Trust."<sup>4</sup> There are 7 basic principles that have been defined for trustworthy guidelines: (1) establish transparency, (2) manage conflicts of interest, (3) establish multidisciplinary panel, (4) perform systematic review, (5) rate the strength of recommendations, (6) articulate recommendations, and (7) include external review. Similar to laboratory standard operating procedures, the Center has written procedures that addresses each one of these standards and updates accordingly. The CAP is an organizational member of the Guidelines International Network (G-I-N) and strives to maintain current best practices in guideline development.

### WHAT HAPPENS TO A GUIDELINE ONCE IT'S PUBLISHED?

The initiation of every new guideline project comes with the recognition that the work of the project expert panel does not end with publication. Important elements in every guideline are the dissemination of the guideline, education at national meetings, the creation of educational tools for expected users, and some manner for monitoring its

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The following authors are current or past members of the College of American Pathologists Center Committee: Drs Nakhleh (chair), Fitzgibbons (vice chair), Nowak, Najarian, Keren, and Colgan. Ms Fatheree is the director of the CAP Pathology and Laboratory Quality Center.

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adoption and effectiveness. Guidelines are living documents that have to keep up with changes in patient populations, laboratory methods, and available knowledge. We are committed to doing the research to understand how a guideline affects practice and understanding the barriers and facilitators to adoption. This is nicely demonstrated by work investigating the adoption of recommendations for immunohistochemical (IHC) assay validation; these recommendations initially focused on HER2, but later expanded with a more general guideline to include all predictive and non-predictive markers.<sup>5,6</sup> Soon after the initial release of the ASCO-CAP HER2 Testing in Breast Cancer guideline,<sup>6</sup> we conducted a survey of laboratories to determine the guideline's impact on laboratory practices.<sup>7,8</sup> At the same time, others set out to prove that some recommendations could be modified to make practice easier.<sup>9</sup> One example is the demonstration that fixation of tissue for greater than 48 hours was not detrimental to measurements of HER2 expression.<sup>9</sup> All of this added knowledge was used to update the guideline in 2013.<sup>10</sup> This is the framework for how guidelines are created and updated. The Center does not have a direct role in setting accreditation or proficiency testing requirements; however, the knowledge gathered by the Center is shared openly with all CAP divisions. The Laboratory Accreditation Program, independent of the Center, may choose to create or change a checklist standard if they believe it improves patient care.

In 2010 laboratories were surveyed regarding their practices in validating predictive and nonpredictive IHC markers other than HER2.<sup>11</sup> This survey demonstrated a significant gap in practice indicating the need for a generalized guideline for initial analytic validation of IHC assays. After publishing this LPG,<sup>5</sup> another survey was conducted to determine its effectiveness as well as to identify possible barriers and facilitators to acceptance.<sup>12</sup> This was valuable in gaining further knowledge that will be used in future guideline updates. This work has been supported by a 5-year cooperative grant from the Centers for Disease Control and Prevention under award number 1U47OE000057.

### HOW LONG DOES A GUIDELINE LAST?

The National Guideline Clearinghouse (NGC) criteria for posting an LPG on their Web site state that the guideline must have been developed, reviewed, or revised within the past 5 years.<sup>13</sup> At the Center, defined procedures have been established to reassess each guideline every 4 years or earlier if new evidence indicates an update is warranted. Using the same methodology as the original guideline, and in agreement with any partners/collaborators, the literature is searched for new knowledge. To date, we have updated guidelines for HER2 testing in breast cancer and molecular testing for lung cancer patients (both soon to be published). (Note added in proof: the updated molecular testing for lung cancer patients guideline was published as an Early Online Release on January 22, 2018.) We will soon update the validation of whole slide imaging given the recent US Food and Drug Administration approval of digital pathology systems as a primary diagnostic modality.

### WHAT HAPPENS TO A GUIDELINE IF THERE IS NO NEW KNOWLEDGE?

Recently, the "Consensus Statement Effective Communication of Urgent Diagnoses and Significant, Unexpected

Diagnoses in Surgical Pathology and Cytopathology" published with the Association of Directors of Anatomic and Surgical Pathology was examined for new research or concepts that would lead to a change of the recommendations.<sup>14</sup> We followed our defined procedure for this assessment and finding no new evidence, we chose to reaffirm this LPG. The documentation of this process was then submitted to NGC and is posted as a reaffirmation.<sup>15</sup>

### WHAT IS THE IMPACT OF THE CAP'S GUIDELINES?

The primary purpose of the guidelines is to promote uniform, quality pathology and laboratory services based on the best evidence available. The ultimate goal is to ensure optimal patient care. There are secondary benefits to having guidelines as well. The establishment of best practices for pathologists allows for ready documentation of quality for those agencies charged with such oversight, often linking quality behaviors with reimbursement. The availability of evidence-based guidelines has been immensely useful to payers in acknowledging the importance and necessity for certain services. That is of benefit not only to pathologists and the institutions they work for, but for the patients who need those services. Guideline collaboration is an example of how the CAP as a whole is working together with other organizations to solve problems for the benefit of patients. Because of success with LPGs, other organizations look to us to join forces on other patient care improvement projects. Since their introduction, CAP guideline PDFs have been downloaded more than 184,000 times and they have been cited in the literature 8052 times in journals from 115 countries, demonstrating wide acceptance and interest, and hopefully, overall adoption. We believe their main impact has been in better testing processes and improved patient care.

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