Critical Values in Anatomic Pathology?

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In the May 2006 ARCHIVES, the companion articles “Critical Values in Anatomic Pathology” by Drs Silverman and Pereira, and “Communicating Critical Values in Anatomic Pathology” by Drs LiVolsi and Leung, set forth for examination and discussion by the pathologist community, with the prospect of adoption and endorsement of the College of American Pathologists, a set of guidelines to inform clinicians of surgical pathologic and cytopathologic diagnoses that, because of their life-threatening nature, may require the clinician’s immediate attention. Several reports on the progression of such guidelines are evident. Silverman and Pereira, Pereira et al, and the Association of Directors of Anatomic and Surgical Pathology have recently proposed possible critical value situations in surgical pathology and cytology; LiVolsi and LiVolsi and Leung have examined methods for effective communication of the values. The authors’ proposal is consistent with the general trend toward the use of guidelines in health care. The College of American Pathologists has endorsed guidelines for anatomic pathology practice; for example, its recent joint publication with the American Society of Clinical Oncology of recommendations for HER2 testing in breast cancer patients. But the use of guidelines is a recent phenomenon in anatomic pathology; as such, the use of guidelines should be carefully considered, and proposed guidelines should be crafted as well as possible in order to avoid unintended consequences of their acceptance and use. The authors’ proposal is a good opportunity to evaluate some issues that may arise, including some medical-legal issues.

CRITICAL VALUES

The proposed critical values for anatomic pathology have been suggested as an extension of the well-established use of critical values in the clinical laboratory, the development and evolution of which has occurred during the last 3 decades. The original definition of a critical value situation, still applied to clinical pathology critical values today, was advanced by Lundberg and is appropriate for determining potential critical values in a surgical pathology context. Lundberg described a critical value situation as one that is “life threatening unless something is done promptly and for which some corrective action could be undertaken.” The concept of developing critical values in anatomic pathology is supported by the continuing success of the use of critical values in clinical pathology. Although similarities exist, clinical laboratory critical values and proposed anatomic pathology critical values are not completely analogous. The decision to communicate a chemistry or hematology critical value is quantitative: although the exact cutoff point to render a test result a critical value may vary between laboratories, no individual qualitative judgment needs to be made by a laboratory technologist with each test result to deem it a critical value. Although microbiology critical values (eg, for blood cultures and cerebrospinal fluid cultures) require an individual laboratory technologist’s qualitative judgment to determine whether an organism is present in the specimen, once the organism is identified, the microbiology technologist exercises no independent judgment whether to notify the clinician about that result as a critical value. Potential surgical pathology critical values—requiring the independent judgment of the pathologist in determining whether or not a specific surgical pathology finding meets the definition of a proposed surgical pathology critical value—are more analogous to clinical practice guidelines than to clinical laboratory critical values, and are best considered in that context.

CLINICAL PRACTICE GUIDELINES

During the past several years, the growing focus on evidence-based medicine has resulted in the proliferation of clinical practice guidelines—more than 1000 are presently posted on medical Web sites according to one author—that serve as tools for communicating to clinicians aspects of emerging therapies and expectations regarding standards of care. Professional societies and specialty societies play a unique role in guideline implementation when they endorse guidelines and promote their widespread use. Because of the presumption of credibility given to these societies, their endorsement of guidelines may help to fully promote guideline use. Ideally, guideline use should improve health care outcomes and reduce potential medical liability. To be effective, clinical practice guidelines must be clear and reproducible. But clarity and reproducibility conflict with another necessary guideline attribute, that they be drafted in general terms to try to accommodate the case-specific nature of the practice of medicine, along with variables including physicians’ education and experience, and patient-specific factors. Among other things, guidelines should allow for variation and recognized individual patient differences and variability of health care resources in different geographic areas, and should provide clinical,
scientific, and economic data needed to make decisions.22 Because clinical practice guidelines are not meant to supplant a physician’s professional judgment, a guideline requiring mindless devotion to evidence would be impractical.23 Indeed, valuable clinical practice guidelines are not rigid regulations but rather are readily usable, comprehensible information and are most useful in situations in which medical uncertainty exists.24,25 By their nature, if the evidence is clear, guidelines add no value compared to a review article or a textbook.24

Ease of use is another important attribute of valuable clinical practice guidelines, and many manifest themselves as evidence-based algorithms with treatment-specific information found on the front of the patient’s chart.26 Because clinical practice guidelines present recommendations aimed at influencing or altering clinicians’ behavior, it is important for potential users to critically appraise the validity of these recommendations.27 Similarly, pathologists must independently appraise the validity of the proposed critical values in anatomic pathology.

**MEDICAL-LEGAL RAMIFICATIONS**

Factors influencing the physician adherence to clinical practice guidelines include awareness, familiarity, agreement, self-efficacy (belief that one can actually perform a behavior), outcome expectancy, ability to overcome inertia of previous practice, and external barriers to performing the guidelines.28 Pathologists must consider these factors in analyzing the proposed critical values for anatomic pathology.

Each of these factors bears examination with regard to the proposed critical values for anatomic pathology, but one potential external barrier will undoubtedly require severe scrutiny: the issue of the medical-legal ramifications of adopting the proposed anatomic pathology critical values. In this regard, it is instructive to examine the literature regarding medical-legal ramifications as they relate to the adoption and use during the last several years of clinical practice guidelines. Some authors believe that malpractice litigation is poised to remain a growth industry in the future,29 and the pathology community must be aware of the legal implications when formulating guidelines to avoid introducing unanticipated legal consequences, which would, at the very least, encourage unwarranted defensive medical practice.30 Even though there is evidence that physician adherence to guidelines lowers liability risk, many physicians fear guideline use will promote litigation.30,31 And more routinely, attorneys and medical administrators investigating medical-legal and discipline concerns have been using clinical practice guidelines to measure physician performance and enforce punitive actions.13 However, parameters within a guideline may not apply to the specific facts at issue in litigation and they should be cautiously applied to the highly specific fact patterns of malpractice cases.32

There is a concern that any perceived deviation from a guideline may be considered as a possible fault by the physician and used as evidence in a medical malpractice action, reducing the chances of success in a lawsuit.25,33,34 An additional concern is that guidelines, once endorsed by a society, will be considered the leading rules in that subspecialty and theoretically legally binding to some degree so that, even without the explicit status of a legal rule, they will have a significant influence on testifying medical experts.25,34 Attorneys may attempt to have physicians designate guidelines as authoritative references in medical malpractice depositions.35 The evidentiary weight of various courts place on adherence of clinical practice guidelines varies, and in some cases is significant.29,31

The main issue in medical malpractice lawsuits is usually whether a breach of the standard of care occurred, and some courts have allowed the introduction of guidelines as evidence of the relevant standard of care rather than considering the validity of a guideline as an issue of admissibility of scientific evidence, with the various theoretical and actual assurances of scientific legitimacy that are associated with such admissibility.36,37 Professional societies sponsoring clinical practice guidelines often issue disclaimers stating that guidelines may not represent the standard of care, but clinical practice guidelines are nonetheless employed in evaluating standards of care in medical-legal settings.32,38 A major concern is that a guideline’s use in court may shift the burden of proof—if a physician has not complied with a guideline, the physician may be required to prove that the harm to the patient was not caused by the physician’s noncompliance39; that is, guidelines may shift the default rule from the normal one, in which a plaintiff must prove negligence, to a rule of per se negligence requiring that the physician overcome the burden of proof that assumes the physician’s actions in question were negligent.

Medical-legal issues similar to those arising in the context of clinical practice guidelines, as well as other issues specific to pathology, may arise if the proposed anatomic pathology critical values are adopted by pathologists on a national basis; the pathology community should fully address such concerns and determine the guidelines’ feasibility before there is nationwide acceptance and society endorsement. Pathologists must strive to avoid, by adoption of any anatomic pathology guidelines, the assumption of a new duty of care under the law, in which pathologists themselves change the default rule now in place—that pathologists use their judgment guided by their training and experience—and replace it with a new default rule in which pathologists assume a duty of care to always follow a guideline. Although it is the responsibility of the court to determine whether a party has a duty of care, courts have shown their willingness to let parties in a lawsuit, by their actions or words, voluntarily assume a duty of care.40

**CONCLUSION**

Problems in communication are not new. For many years educators in pathology have stressed the critical nature of pathologist-clinician communication.41–47 Silverberg47 stated more than 2 decades ago that “the importance of communication between the clinician and the pathologist is often underestimated by both.” In 2003 the Association of Directors of Anatomic and Surgical Pathology41 noted that a basic learning objective of a residency in anatomic pathology is to “effectively communicate pathologic findings to colleagues and provide consultative information regarding patient manage-
ment.” This proposal to institute anatomic pathology critical values also serves as a clarion call for increasing cooperation and integration between pathology programs and clinical medicine programs in order to train residents to communicate effectively and to facilitate communication.

The responsibility for fully addressing the feasibility and potential repercussions of these proposed guidelines rests solely with pathologists. Physicians, as stated by Brennan, “are the stewards of quality. They must aggressively develop an agenda for improvement.” Such is the case here.

References
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