Diagnostic Error in Anatomic Pathology

To the Editor.—Diagnostic error has only recently received significant attention. The seminal Institute of Medicine report, To Err Is Human (2000), made only a couple of mentions of error. Since then, there has been a tangible focus on this issue, including, for example, the establishment of the Society to Improve Diagnosis in Medicine. Although pathology is a diagnostic specialty, most diagnoses are made in the context of direct patient interactions; ~60% of diagnostic errors are made in the outpatient setting. Although pathology accounts for a relatively small portion of diagnoses, anatomic pathology focuses on diseases in which the implications of error can be profound. Hence, the release of the combined College of American Pathologists—Association of Directors of Anatomic and Surgical Pathology guideline is potentially important. Interestingly, no professional organization specifically focused on cytopathology was included.

The report, which took a couple of years to develop, is, in the final analysis, based only on expert opinion. The “Methods” section describes an extensive (“systematic”) literature review, but a detailed and thoughtful statistical analysis of that literature was not reported. For example, there was no quantification of the magnitude of the problem or meta-analysis of the literature. The 5 recommendations (table 4) are meritorious. However, on the whole, the report is somewhat disappointing. The recommendations lack novelty, and each is likely to have been developed without an analysis of the literature. Second, each of the recommendations has the key word “should” embedded in it and, thus, lacks the impact one might have hoped for to help change the practice of surgical pathology and cytopathology. Hopefully, these recommendations will be incorporated into the laboratory checklist. Lastly, there is little information about how to operationalize the recommendations into individual laboratories.

The topic of diagnostic error will continue to be an important area to help improve the quality of health care delivery in this and other countries. Such a focus “should” be facilitated by the upcoming report from the Institute of Medicine on diagnostic error, which is expected to be released in the early fall of 2015. The hope is that this “white paper” will lead to improvements that will reduce harm and that this publication is just one of a series of pathology-focused initiatives.

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The authors have no relevant financial interest in the products or companies described in this article.

doi: 10.5858/arpa.2015-0229-LE

In Reply.—First, we thank the authors for their letter to further put the spotlight on diagnostic error. We appreciate that our recommendations are “meritorious.” We also thank the authors in pointing out our omission in the “Panel Composition.” It should have stated that we “…convened an expert panel consisting of practicing pathologists with expertise and experience in surgical pathology and cytopathology” because 2 authors were recruited for their expertise in cytopathology quality (Stephen Raab, MD, and Andrew Renshaw, MD). In addition, we included the American Society of Cytopathology (Wilmington, Delaware) and the Papanicolaou Society of Cytopathology (San Francisco, California) in our peer review of draft recommendations.

We wholeheartedly agree that more should be done to address diagnostic errors. Anatomic pathology diagnoses are multifactorial. As previously described, an accurate diagnosis requires the pathologist’s knowledge and experience, clinical correlation, possible ancillary studies, a standardized diagnostic language, and case reviews. There are also numerous factors that lead to preanalytic and postanalytic error. We chose to limit the scope of the guideline and address an area that had the potential of being actionable, focusing our key questions on secondary review of cases. Our analysis of those data demonstrated a positive impact whereby review of cases leads to improved diagnoses.

We drafted and finalized the recommendations during a considered judgment process based on the totality of the quality, quantity, and consistency of the evidence in conjunction with expert opinion and the applicability and generalizability within the pathology community. The quality of evidence for pathology literature addressing diagnostic error is low. Essentially, all the studies considering errors in pathology are case-cohort studies. Further, those studies present the potential impact of errors, not the direct or real effect on patients. Given the important differences not only in how error was defined but also in how a case was defined in those studies, we did not feel it was statistically appropriate to perform further quantitative and meta-analyses on those data at this time.

In review of the literature, we realized that the types of error vary from laboratory to laboratory; therefore, the best strategies to operationalize methods to improve quality also likely vary from laboratory to laboratory, depending on resources (personnel, etc) and case mix. In the absence of strong evidence, we wanted to leave room for the pathologists in each laboratory to tailor the process to their needs because we feel that the individual pathologist within a laboratory likely has the best information on where the problems lie and what might be the best solutions. In addition, because most of the resources to pursue quality assessment activities are unreimbursed for pathologists, it is in everyone’s interest to ensure that pathologists are allowed to choose the best and most-efficient programs available for their own particular practices. We sought to ensure that all such programs incorporate particular features so the quality and effectiveness of these programs in a pathologist’s particular practice setting can be measured, and pathologists are not forced to pursue quality assessment activities that may sound good or may be effective in other settings but do not achieve that standard in their own laboratory.