

## Q&A column

### Editor: Frederick L. Kiechle, MD, PhD

Submit your pathology-related question for reply by appropriate medical consultants. CAP TODAY will make every effort to answer all relevant questions. However, those questions that are not of general interest may not receive a reply. For your question to be considered, you must include your name and address; this information will be omitted if your question is published in CAP TODAY.

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**Q. Every month our anatomic pathology laboratory amends patient reports. Does the CAP have a benchmark for amended reports, such as how many are acceptable per month?**

A. August 2022—CAP anatomic pathology checklist item ANP.12185 does not provide a benchmark for amended reports.<sup>1</sup> Amendment rates vary significantly based on practice setting; complexity of case mix; method of error detection (active versus passive); practice structure (mandated double-review before signout or not); preferences of pathologists, clinicians, and institutions regarding the taxonomy of errors and types of errors requiring amendment; and the structural capabilities of laboratory and hospital information systems.<sup>2-4</sup>

Amendment rates range from 0.1 to 10 percent.<sup>2-4</sup> Therefore, the CAP accreditation requirement focuses on ensuring that the laboratory has a process to minimize patient harm from significant changes to reports instead of setting a numeric benchmark for amendments.

Checklist item ANP.12185 states, “The laboratory issues an amended report and promptly notifies the responsible clinician(s) when there are changes to reports that significantly affect patient care.” The report must include the reason for the amendment, who made the change, who was notified of the revision, and the date. Notably, the responsible clinician may not be the clinician who had ordered the tests if the amendment is issued after a significant time lag between the original and the corrected report.<sup>5</sup> Furthermore, there is disagreement as to whether communication to a surrogate in a physician office is acceptable for a significant and unexpected change to a diagnosis.<sup>6</sup>

That said, quality improvement plans in anatomic pathology should monitor fractional amendment rates (for example, errors due to misinterpretation and misinformation) and have rate- and rule-based triggers to detect failures in the system as soon as possible. Rate-based triggers are useful for monitoring process flows and identifying system-based breakdowns, which in some cases may be upstream of the pathology department. For example, implementing computerized order-entry systems in operating rooms may increase misinformation amendment rates due to autopopulation errors from entering ICD-10 code-based history or from workflow changes, such as transferring order entry from physicians to operating room nurses.<sup>7</sup> In these instances, the corrective action plan requires an institutional-level intervention.

Rule-based triggers are more effective for monitoring and preventing harm from high-severity or unusual failures. Institutions should define rule-based triggers based on their case mix and practice parameters. A common rule-based trigger is mandated review of cases with primary level misinterpretation errors where a diagnosis is changed from negative to positive or vice versa. While such discrepancies often have a ready explanation (for example, variable diagnostic cut-offs among experts), these can signal cognitive or proficiency deterioration in a previously high-performing pathologist.

We do not recommend using the term “diagnostic error” for a misinterpretation error. The CAP uses the term “interpretive error.”<sup>4</sup> This is because the seminal report by the National Academies of Sciences, Engineering, and Medicine titled *Improving Diagnosis in Health Care* defines diagnostic error as any error that leads to a diagnosis

not being accurate or communicated to the patient in a timely manner.<sup>8</sup> Therefore, virtually all pathology errors are diagnostic errors. Even a misinformation error in which data are entered incorrectly, leading to a delay in the patient receiving a diagnosis, is a diagnostic error.

In summary, the goal of amendments is to correct inaccuracies in patient reports. The CAP does not provide numeric benchmarks for amendments.

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2. Zarbo RJ, Meier FA, Raab SS. Error detection in anatomic pathology. *Arch Pathol Lab Med*. 2005;129(10):1237-1245.
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4. Meier FA, Zarbo RJ, Varney RC, et al. Amended reports: development and validation of a taxonomy of defects. *Am J Clin Pathol*. 2008;130(2):238-246.
5. Parkash V, Domfeh A, Cohen P, et al. Are amended surgical pathology reports getting to the correct responsible care provider? *Am J Clin Pathol*. 2014;142(1):58-63.
6. Staats PN, Parkash V, Otis CN, Sharma P, Ioffe O, Bracamonte ER. The current state of communication of urgent and significant, unexpected diagnoses in anatomic pathology. *Arch Pathol Lab Med*. 2020;144(9):1067-1074.
7. Wilkerson ML, Henricks WH, Castellani WJ, Whitsitt MS, Sinard JH. Management of laboratory data and information exchange in the electronic health record. *Arch Pathol Lab Med*. 2015;139(3):319-327.
8. Committee on Diagnostic Error in Health Care; Board on Health Care Services; Institute of Medicine; National Academies of Sciences, Engineering, and Medicine. Balogh EP, Miller BT, Ball JR, eds. *Improving Diagnosis in Health Care*. National Academies Press; 2015.

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(The views expressed by Dr. Auerbach are his and do not reflect the official policy of the Department of Army/Navy/Air Force, Department of Defense, or U.S. government.)

**Q. What is the best practice for performing a urine specific gravity test? Which method is preferred—a refractometer or an automated dipstick? Should we correct for elevated glucose and protein or report high specific gravity? Should we correct for x-ray dyes or add a comment and list possible interfering substances?**

A. A refractometer is the preferred method for measuring urine specific gravity.

CLIA regulations specify that it is the laboratory director's responsibility to ensure test methods can provide the quality of results required for patient care. Consequently, the medical practice committees or laboratory directors at some institutions have determined that the performance characteristics of automated and visual dipsticks do not meet patient care requirements. Our institution uses refractometry to perform all urine specific gravity measurements.

There is no need to correct for glucose, protein, or contrast dyes since they contribute to urine specific gravity and the assessment of hydration status. Glucose, protein, and contrast dyes are not interfering substances.

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Standard: Laboratory director responsibilities. 42 CFR §493.1445(e)(3i). <https://bit.ly/493-1445-e3i>

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