Q&A column, 3/16

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.

Submit a Question

Q. I have a question regarding auto-verification delta checks, not for a single patient but between all patients tested during a given period. Are there labs that use postanalytic comparisons of clinical lab results during the testing interval between quality assurance checks to ascertain if the autoverified results being released are reasonable?

We recently had an occurrence in which the released lab results were all somewhat elevated, but not significantly so, during an eight-hour period. The health care workers who received the lab results noticed that for their patient population only about 30 percent could be expected to have abnormal values and yet the autoverification process was releasing borderline elevated results on all patients.

A. Delta checks, which identify larger than expected differences between previously tested and current results from the same patient, are used to detect individual testing problems such as mislabeled specimens, interference (e.g. hemolysis), or random analytical errors. On the other hand, detecting systemic errors, such as the problem you described, is best done by using moving average techniques that evaluate successive patient test results in between testing quality control samples.

Your question about delta checks for quality control is interesting and timely because a recent article by Jones1 described a novel method termed "average of deltas," which uses moving averages of results on sequential delta values, rather than individual patient results, to monitor assay performance. This innovative twist on the typical moving average method has the theoretical advantage of reducing inter-individual biological variation that can mask significant drifts or systematic errors in analytical performance. The results were promising in simulated studies, but the method's application as an adjunct to quality control in laboratory practice awaits further evaluation. Furthermore, this technique would be applicable only to laboratories that receive a high proportion of specimens in which there is a large number of repeated tests on the same patient, i.e. inpatients.

In contrast, moving average quality control procedures have been studied and used for more than 30 years.2 Various systems for analyzing sequential patient specimens are available on instruments and laboratory information systems as well as middleware applications. Moving averages work well in hematology but have not been nearly as successful for monitoring performance of chemistry assays, especially if a high proportion of specimens are from inpatients. However, Fleming and Katayev3 in 2015 described a promising real-time monitoring algorithm using sequential outpatient test results in a large commercial laboratory that, in their setting, has overcome the limitations inherent in using moving averages for chemistry testing.

If your laboratory processes a large proportion of outpatient specimens, you may wish to evaluate various middleware (Data Innovations, for example) or other moving average systems for monitoring performance of chemistry tests in between running liquid quality control samples. In the meantime, we will need to await further studies that evaluate Jones' clever and promising idea for using a combination of both delta values and moving averages to answer your question with certainty.

1. Jones GR. Average of delta: a new quality control tool for clinical laboratories. Ann Clin Biochem. 2016;53(1):133-140. Published online

ahead of print March 23, 2015.

- Cembrowski GS, Chandler EP, Westgard JO. Assessment of "Average of Normals" quality control procedures and guidelines for implementation. Am J Clin Pathol. 1984;81(4):492–499.
- 3. Fleming JK, Katayev A. Changing the paradigm of laboratory quality control through implementation of real-time test results monitoring: for patients by patients. Clin Biochem. 2015;48(7-8):508-513.

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Q. Do slide identifications for urine or sputum eosinophils need to be in the IQCP?

A. The Individualized Quality Control Plan, or IQCP, does not apply to manual microscopic observations.

For nonwaived testing, the CAP has defined eligibility requirements for the IQCP. (See the eligibility determination flow chart at <u>http://j.mp/IQCP_flowchart</u>.) Eligibility is limited to tests that meet *both* of the following criteria:

- The testing is performed in a discipline other than anatomic pathology or cytopathology. (Exceptions are tests in anatomic pathology or cytopathology that can be assigned to another discipline.)
- The test system has an internal control process (electronic, procedural, or built-in). (Exceptions exist in microbiology for media, identification systems, and susceptibility testing, which qualify for the IQCP even though there is no internal quality control.)

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Dr. Kiechle is medical director of clinical pathology, Memorial Healthcare, Hollywood, Fla. Use the reader service card to submit your inquiries, or address them to Sherrie Rice, CAP TODAY, 325 Waukegan Road, Northfield, IL 60093; srice@cap.org. Those questions that are of general interest will be answered.