Study, strategy lift up POC critical value practices

Access interactive product guide

Ann Griswold, PhD

February 2015—Too many point-of-care glucose test results in the critical high and low ranges may be nonreproducible and therefore should be repeated. That was the finding of a study published last year that said POC glucose results in the critical ranges should be considered to have a relatively high probability of signaling a potential preanalytic error.

The retrospective analysis of POC glucose testing in routine patient care settings found that as many as half of all critically high or low test results, when repeated, were not so critical after all (Schifman RB, et al. *Arch Pathol Lab Med.* 2014;138:962–966).

Dr. Schifman

“The lesson we learned is that you need a strategy for confirming, verifying, and reporting critical point-of-care blood glucose values,” says lead author Ron B. Schifman, MD, chief of diagnostics for the Southern Arizona VA Healthcare System, Tucson, and vice chair of the CAP Quality Practices Committee. He hopes such studies will help others become aware that critical values must be addressed in the point-of-care setting just as they are in the laboratory setting.

Over time, Dr. Schifman and colleagues implemented policies, processes, and training that have now nearly eliminated POC glucose critical value test result errors.

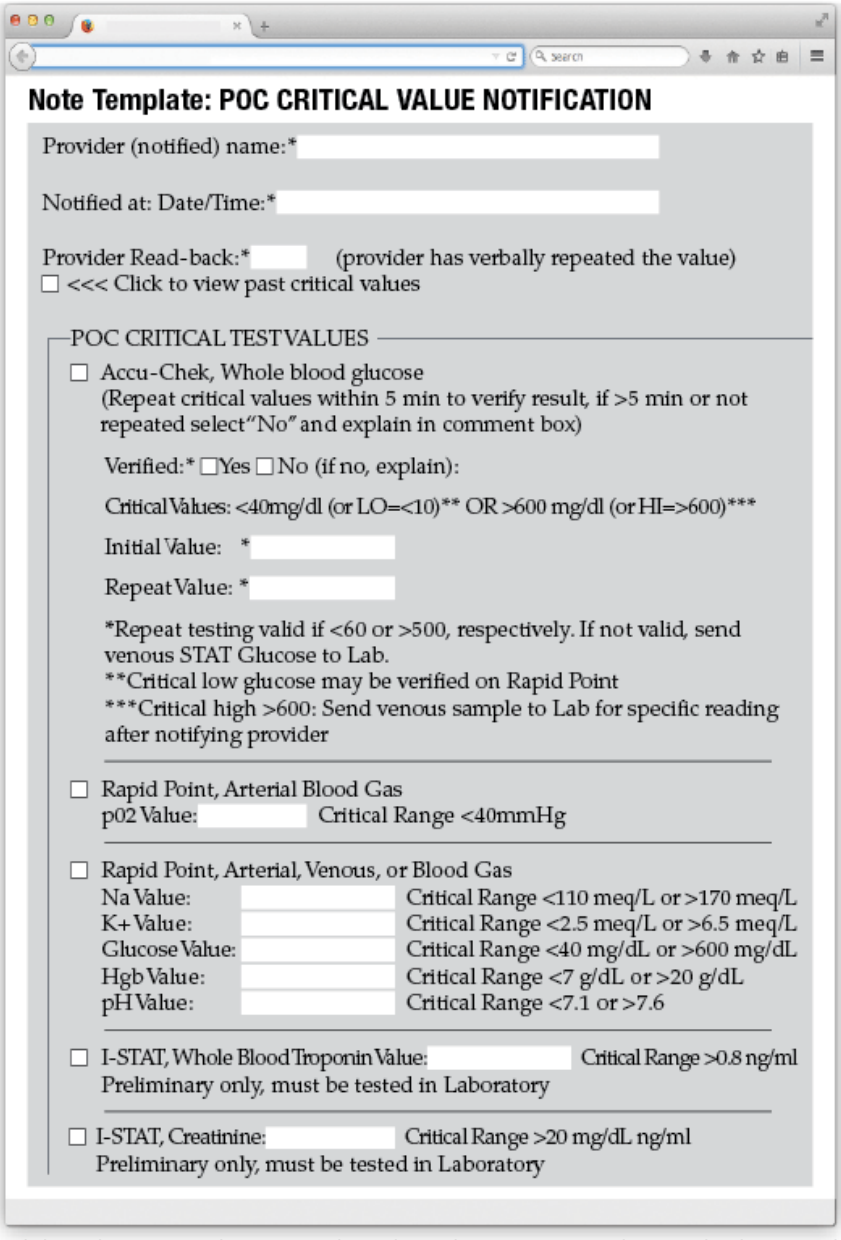
“The study made it clear we needed to develop processes to make the critical value verification, documentation, and reporting easier for our test operators,” he says.

A large percentage of hospitals have policies for repeat testing of POC critical value results, but Dr. Schifman worries that many of those institutions have not yet implemented useful criteria for interpreting repeat test results.

“Ultimately, there are no guidelines out there to help us,” he says. “Every lab director or program director is pretty much on their own in terms of how they want to design or develop their guidelines for repeat tests, and how to interpret them.”

How quickly should a POC glucose test result in the critical range be repeated? Should it be repeated with capillary blood using a handheld meter or with venous blood specimens on a chemistry analyzer in the core lab?

“These questions have been left unanswered,” Dr. Schifman says. “No experts have reviewed the literature and developed best practices associated with critical values in the point-of-care setting.”



Note Template: POC CRITICAL VALUE NOTIFICATION

Provider (notified) name:*

Notified at: Date/Time:*

Provider Read-back:* (provider has verbally repeated the value)

☐ <<< Click to view past critical values

POC CRITICAL TEST VALUES

☐ Accu-Chek, Whole blood glucose
(Repeat critical values within 5 min to verify result, if >5 min or not repeated select "No" and explain in comment box)

Verified:* ☐Yes ☐No (if no, explain):

Critical Values: <40mg/dl (or LO=<10)** OR >600 mg/dl (or HI=>600)***

Initial Value: *

Repeat Value: *

*Repeat testing valid if <60 or >500, respectively. If not valid, send venous STAT Glucose to Lab.
**Critical low glucose may be verified on Rapid Point
***Critical high >600: Send venous sample to Lab for specific reading after notifying provider

☐ Rapid Point, Arterial Blood Gas
p02 Value: Critical Range <40mmHg

☐ Rapid Point, Arterial, Venous, or Blood Gas

Na Value:		Critical Range <110 meq/L or >170 meq/L
K+ Value:		Critical Range <2.5 meq/L or >6.5 meq/L
Glucose Value:		Critical Range <40 mg/dL or >600 mg/dL
Hgb Value:		Critical Range <7 g/dL or >20 g/dL
pH Value:		Critical Range <7.1 or >7.6

☐ I-STAT, Whole Blood Troponin Value: Critical Range >0.8 ng/ml
Preliminary only, must be tested in Laboratory

☐ I-STAT, Creatinine: Critical Range >20 mg/dL ng/ml
Preliminary only, must be tested in Laboratory

Note template used by point-of-care operators in the Southern Arizona VA Healthcare System to document critical values and notification of responsible health care providers in the EMR. All POC testing operators must report critical results to the provider within 30 minutes of the time the test is completed and the result is verified.

For the study published last year, he and his coauthors analyzed one year's worth of POC glucose test results from routine patient care settings.

Gathering the data proved to be relatively straightforward, thanks to electronic interfaces that connect the Southern Arizona VA Healthcare System's glucose meters, and its RapidPoint and Vitros analyzers, to the laboratory information system. The institution routinely collects information about critical values as part of the laboratory's quality assurance plan, providing further data for the study.

At the time of the study, medical technologists, nurses, and other personnel at the Southern Arizona VA Healthcare System relied on first-generation Roche Accu-Chek Inform glucose meters and Comfort Curve test strips to measure blood glucose levels in outpatients, critical care patients, and emergency department patients.

Personnel certified to perform POC glucose testing were instructed to retest glucose levels within 10 minutes of

critically low or high results at less than 40 mg/dL or greater than 600 mg/dL. Those instances are relatively rare; the study found that only a quarter of POC glucose test operators encountered a critical value during the one-year study period. But for the most part, operators followed through: 85 percent of critical value results were retested within four minutes, and more than 90 percent were retested within the hour. Before adding that requirement to the training program, Dr. Schifman says, the repeat rate for critical values had been about 65 percent.

According to the laboratory's guidelines, repeat testing can be performed on another capillary sample using the glucose meter, or on a venous specimen using the Siemens RapidPoint 405 system. Alternatively, samples can be sent to the core laboratory for testing on an Ortho-Clinical Diagnostics Vitros chemistry analyzer. The laboratory automatically performs testing of venous blood specimens when repeat critical high POC glucose results fall below 500 mg/dL or repeat critical low values are above 60 mg/dL.

Of the 105,928 POC glucose tests performed at the Southern Arizona VA during the study period, the authors identified 256 critical value measurements. Results in the critical high range were twice as common as critical low values and five times more common in patients from the emergency department than in other units.

An analysis of the 204 critical value measurements that were repeated within 10 minutes produced surprising results: Almost half of the test results were inaccurate, meaning critical low values differed from repeat measurements by at least 15 mg/dL, and high values differed by more than 20 percent. (ISO 15197:2003 was used as the criteria for the accuracy of critical values.) No QC problems were found with the Accu-Chek method, the study says.

A different glucose meter was used to repeat the testing in nearly 30 percent of the cases; a different operator repeated the test in about 40 percent of the cases. These divergences were found to occur more often in the critical care and inpatient units than in other units.

"Critical values were less likely to be confirmed when retested by a different meter or operator," Dr. Schifman notes. "This suggests that there may have been a concern about the initial test result, perhaps in some cases based on inconsistent patient signs and symptoms that caused the operator to seek assistance from another operator or use another measuring device."

Extremely low values (<10 mg/dL) were relatively rare and often erroneous, the study found. High critical values were more common and also more likely to be confirmed, despite the potential for sample site contamination to falsely elevate POC glucose results.

Point-of-care glucose results in the critical range, the authors concluded, "should be considered to have a relatively high probability of signifying a potential preanalytic measurement error that may be due to difficulties with collection, sampling, or processing of capillary blood specimens."

A 2006 study in *Archives of Pathology & Laboratory Medicine* evaluated the performance of Accu-Chek and similar glucose meters in hospitalized patients with diabetes and other serious underlying conditions. Those authors found that 45 percent of critical-range hypoglycemic and 22 percent of hyperglycemic POC glucose test results differed significantly from subsequent test results, consistent with the Southern Arizona VA study.

That 2006 paper proposed that providers send a serum or plasma sample to the central laboratory whenever a hypo- or hyperglycemic result is observed.

More recently, a 2013 CAP Q-Probes study that Dr. Schifman coauthored found a 50 percent error rate in critical value test results reported by 50 laboratories. That study found that 76 percent of all POC glucose critical values were retested within 10 minutes, and that health care providers were notified about confirmed critical values about half the time.

For years, the Southern Arizona VA Healthcare System has been implementing gradual changes to lower POC glucose testing error rates and improve reporting.

“Several years ago, we were developing a policy for critical values and it dawned on us that we didn’t have a solid critical value policy for point of care. We had it for the core lab, but we wanted to create a level playing field for blood glucose measured by the point-of-care method and by the core laboratory,” Dr. Schifman says.

Core laboratory testing is sufficiently accurate that critical value measurements usually need not be confirmed with further testing. “The time it would take to retest the sample before reporting it probably poses a higher risk to the patient than just reporting the critical value from the core laboratory,” Dr. Schifman notes.

But the same is not true of point-of-care testing, he says. “We found that, unlike in our core laboratory, critical value results do need to be verified through repeat testing before they are reported.”

The group did an evaluation and found, at their institution, that repeat tests of critical values often gave conflicting results and critical values were not reliably reported to providers. To remedy the problem, they established a set of institutional guidelines and placed it in the most obvious location possible.

“We posted information about critical values—what a critical value is, how to confirm it, and how to interpret a repeat result—on each meter to provide a visual guide to the operators,” Dr. Schifman says.

Their blood glucose meters automatically lock for testing if more than 24 hours has elapsed between sets of quality control checks. Medical technologists calibrate each new lot of test strips and check linearity for each new lot or meter. Certified glucose meter operators, usually nurses, perform daily QC and proficiency testing three times a year using the CAP’s whole blood glucose Survey. Personnel who perform POC glucose testing are trained and certified under the supervision of clinical laboratory technologists and tested twice a year, then annually thereafter.

“The problem is, you’ve got so many different operators—hundreds of operators—who may go through years of testing before they encounter their first critical value. It’s hard to get compliance with a policy when there’s so little experience. So that’s why training and visual aids are important,” he says. “It’s not enough to have a policy in place. There are so many other things you need to do to get compliance with the policy.”

The Southern Arizona VA upgraded to the Accu-Chek Inform II meter last June. Dr. Schifman’s group set two goals during the transition: operators were retrained to repeat the test for point-of-care glucose and notify providers of critical range results.

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“In order to switch, every operator had to go through training with the new meter and take a new test to prove they were competent,” says Susan T. Page, MT(ASCP), a coauthor of the Archives study and chief medical technologist at the Southern Arizona VA Healthcare System.

“It all tied in so well,” Page recalls. “People were very happy to get the new meters because they are much more user-friendly, with the smaller sample size requirement. Also, the spot on the test strip where you apply the blood was moved in the newer version, making it much easier for every operator to use. And the new meters actually tell you if there’s too much sample, or too little.”

The transition afforded the opportunity to make other changes as well. New visual aids were placed on all meters. Most important, Dr. Schifman says, the team took advantage of the timing to unveil a new template for POC glucose critical value reporting. The template (see page 50), designed by the former QA and POC coordinators, fits

into the patient's electronic medical record and has helped ease the process of checking and documenting critical results.

"This template actually states our policy for point-of-care glucose testing," says quality assurance manager and lead laboratory technician Teresa Cox, who helped update and implement the template. "So not only does it help by providing documentation that there was notification to the provider, but it also gives operators a review of which test results should be repeated, what the critical ranges are, and so forth."

Cox

"As soon as we put the Accu-Chek Inform II in place," Cox adds, "we saw a huge reduction in the number of critical values that showed up on our reports."

Since April 2014, the institution has halved the number of critical POC glucose values and vastly lowered the error rates. More than 95 percent of critical values are retested within 10 minutes. And almost half of all confirmed critical measurements are documented in letters to providers.

The laboratory saw a marked improvement in accuracy with glucose testing when it switched from the Accu-Chek Inform I to the Inform II. Between April and November 2014, Dr. Schifman says, 100 percent of all critical low and 81 percent of all critical high measurements were confirmed as accurate.

"The Accu-Chek I requires 4 µL of capillary blood, but the Accu-Chek Inform II requires only 0.6 µL. So the risk of undersampling, which would cause an erroneous low result, has in our experience been eliminated. Technology has really solved that problem," Dr. Schifman says.

Erroneous high glucose measurements, on the other hand, likely stem from the disinfectants used to clean patients' skin before collecting a capillary blood sample. "If that disinfectant doesn't dry, it can interfere with the measurement and give a falsely elevated glucose test. So that aspect of it relies on training and an adequate collection technique to make sure you don't collect the sample through a wet field. We have had success with that, but not full success," he says.

In the meantime, his team continues to work to bring everyone on-board.

Says Cox: "We talk about this initiative in our monthly patient safety meetings and in nurse manager meetings, so we can get other people engaged in our goals and objectives for high-quality point-of-care testing. It's not just about the laboratory. Everyone needs to get involved."
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Ann Griswold is a writer in San Francisco.