

POCT HANDBOOK

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Connectivity Aids Compliance

By Alice Travanty, BS, MT(ASCP)



As the number of point-of-care tests (POCTs) expands rapidly, the need to meet more regulatory requirements also increases. Agencies such as the Joint Commission, the Centers for Medicare & Medicaid Services, COLA and the College of American Pathologists have set standards for POCT, including

waived and non-waived testing, to ensure quality results.

Because POCT is often performed by non-laboratory personnel in all areas of the hospital, documentation of compliance can be difficult to achieve. Connectivity—the electronic transmission of data from POC analyzers to laboratory and hospital information systems—aids compliance with regulatory standards.

Operator Competence

With a bidirectional interface, information is sent to meters so only certified operators can perform testing. The system tracks the dates of the operator's original certification and expiration, last good QC and last patient test. Some analyzers allow messages to be sent to operators to warn them when they are getting close to expiration and remind them to perform QC.

Reports can easily document operator competency at initial, six-month, one-year and yearly competency.

QC

Another important regulatory standard is review of QC results. Without connectivity, this review can be difficult, especially at large institutions with hundreds of meters and thousands of operators.

Usually glucose meters are the first analyzer to have connectivity; then, analyzers such as blood gas, coagulation, urinalysis and hemoglobin can be added as resources and budgets permit.

Some systems allow entry of manual results (e.g., occult blood) using the glucose meter. Internal QC can then be documented. Connectivity allows for easy monthly QC review and daily review when out-of-range QC is flagged.

The risk of tests being performed when QC has not been done is eliminated. Outliers can be viewed, reviewed and acknowledged with

necessary corrective action noted. Instruments can be locked out of performing tests if acceptable QC has not been completed in the required time frame.

Some analyzers can be customized to automatically perform QC using the same cartridge doing the testing. These results are documented, viewed and readily available during inspection. QC results from different locations can be managed from one central location.

Patient Identification

Systems are available on some instruments to confirm the patient ID. The patient name will appear after scanning the bar code; a second identifier (e.g., date of birth) confirms the ID. The standard of using two patient identifiers is met and documented. Invalid patient IDs will ▶▶



not pass over to the lab computer system until reviewed, corrected and re-sent, preventing results from going to the wrong patient record.

Critical Values

Reference ranges can be customized with different ranges for adult/infant meters. Action and critical ranges can also be set. Comment codes (e.g., MD notified or RN notified) may be pre-set or entered manually

depending on the meters, documenting notification of critical values. Critical values appear on an alarm screen for review. A check for sample lab analyses can be done if the lab requires confirmation of critical values.

PT Compliance

Proficiency test performance is required for all POCTs. These samples are treated like ordinary patient samples and rotated among operators. With connectivity, this is easily shown by calling up the results, which include operators who performed the tests. Reagent lot numbers can also be shown.

Documenting Results

Regulations dictate documented procedures for entering POC results into the permanent record and reference intervals reported with the results. With connectivity, results are sent directly from the POC analyzers to the lab POC workstation to the lab computer system. The possibility

of clerical error or lost results is eliminated.

Reference ranges can be built into results screens. The more instruments that have connectivity, the greater the number of POCT results documented in the patient medical record.

Reagent Handling

Reagent and control lot numbers and their established values can be entered into the system. New lots of reagents show up on an alarm screen, alerting the POC coordinator that a new lot is in use. If the lot has not been evaluated, action can be immediately taken to remedy this, preventing use of reagents that have not been validated for acceptability.

Bar coding and reagent scanning prevents use of expired reagents by locking them out. This aids in meeting the standard for reagent verification. Results of calibration verification using linearity material with known values can be graphed to document the reportable range of an analyzer.

Quality Improvement

With connectivity comes the ability to organize data and create reports for nurse managers on performance of their unit operators and to track patient results (e.g., glucose) as part of a quality improvement program.

Connectivity is a wonderful aid to help POC coordinators meet regulatory standards. It saves time and can eliminate binders full of paperwork. If during inspection the inspector uses the popular tracer method of following a specimen through the whole testing process, the required information for compliance can easily be documented. ■

Alice Travanty is point-of-care testing coordinator, Wheaton Franciscan Healthcare, Saint Joseph Hospital, Milwaukee.

Glucose Meter Evolution

By Bob Kaplanis



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It's hard to imagine what point-of-care testing (POCT) would be like if the glucose meter had never been invented and all glucose testing was performed in the main laboratory of the hospital. The Ames Reflectance Meter was the first glucose meter used in hospitals in the 1970s¹ and a major reason

why POCT developed into what it is today.

Over the years, the glucose meter has undergone continuous improvements and become vital to the management of critically ill patients, diabetics and recovery after surgery.

Present Day

Interfaces for the glucose meter have made the device's utility increasingly valuable and convenient. They allow results to automatically chart and bill. Now that glucose results are captured by a computer, data manipulation of test results is possible.

Data has given rise to the tight glycemic control protocols that help patients heal faster and avoid infections. Numerous lectures, papers and protocols have been developed around the ability of the glucose meter to send data to a computer.

The POCT device has become as integral a part of ►►

What we have is what most have asked for—cheaper, faster and smaller sample size.

patient care as the intravenous pump or vacutainers for blood drawing.

Uncertainty

So what is ahead for this marvel of science? Faster results, smaller size and more software features. The FDA is taking a serious look at the glucose meter and will surely influence the future of this along with the suggestions of other organizations and manufacturers.

In March 2010, the FDA held a two-day public meeting in Gaithersburg, MD, so experts and interested parties could offer comments on the direction of the glucose meter. Transcripts of the meeting are available on the FDA's website at: <http://www.fda.gov/medicaldevices/newsevents/workshopsconferences/ucm187406.htm>.

Participants put forth several recommendations for the glucose meter of the future. More than one person stated they wanted faster, more accurate results using a smaller sample size and meter; they also wanted a less expensive device with fewer interferences. In various discussions I have had with peers and manufacturers +/- 10% of the main laboratory value is the target to strive for. I am part of the Clinical and Laboratory Standards Institute review team for a few POCT documents. Recommendations for glucose meters in acute care hospitals are also part of the discussions within this group.

The group asked glucose manufacturers for input. Several manufacturers commented that their customers have asked them for the same enhancements listed above. So

why hasn't this been achieved yet?

Part of the reason is technology has not progressed to the point that all of the desirable features can be incorporated into one device. One manufacturer said it could make the device more accurate, but size, speed and cost may be sacrificed. If the meter is made to perform faster with a smaller sample size, accuracy may suffer.

Also in conversations with manufacturers, I have been told that customers drive the manufacturing process. What we have is what most have asked for—cheaper, faster and smaller sample size. This design has been at the expense of accuracy. A more accurate meter may mean a longer time for a result and be more expensive.

With all the variables and uncertainty about the market, it is not surprising that LifeScan Inc. has decided to withdraw from the hospital market by March 31, 2013.

Tight Glycemic Control

Trying to monitor a patient's glucose level with meters on the market and keep patient results within a specified range is difficult. Some hospitals have been more successful than others.

It is interesting that the FDA has stated that current glucose meters are not approved for tight glycemic control but prohibiting them for this use would do more harm to patient care than good. So while meters are not as advanced as we would like, they are better than the alternatives in terms of expense and turnaround time.

Pre-analytical

Variability introduced by user technique also is an important consideration in the glucose meter discussion when comparing results to the main lab. Surely the future of glucose testing will involve continuous glucose monitoring with an associated insulin delivery system. Companies are working on such a solution. Systems would monitor glucose levels real time and deliver the correct dose of insulin, keeping the glucose level within a desired acceptable range. ■

Bob Kaplanis is system technical specialist, POCT, Banner Hospitals, Laboratory Sciences of Arizona/Sonora Quest Laboratories.

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Growth of POCT

By Carlos Prieto-Granada, MD, and
James H. Nichols, PhD, DABCC, FACB



As an emerging, rapidly evolving and ever expanding specialty in laboratory medicine, point-of-care testing (POCT) has been generating a whole new set of issues since its popularization in the late 1980s. The concept of POCT, also known as bedside, near-patient testing and ►►

› **Table**
6 Elements of Competency Assessment

1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing.

2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results.

3. Review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records.

4. Direct observation of performance of instrument maintenance and function checks.

5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

6. Evaluation of problem-solving skills.

* Source: College of American Pathologists. Laboratory General Checklist, Statement GEN.55500 and Point of Care Checklist POC.06900. Northfield, IL. 06/17/2010

decentralized testing, relates to tests that are conducted by clinical operators at the site of patient care where immediate medical action is taken on the results.¹

The fact that POCT represents a departure from

conventional laboratory medicine has created new challenges, especially regarding standardization and regulation. These topics, including new regulatory changes, glucose meter performance criteria and increasing reliance on transcutaneous POCT methods, are addressed.

Changes in CMS Competencies

The Centers for Medicare and Medicaid Services (CMS) is enforcing more stringent regulations for operator competency of moderate and high-complexity POCT. Previously, CMS provided six elements for demonstration of competency, allowing sites to be flexible at selecting which of the six elements were relevant to their staff depending on the test (Table). Now, CMS is requiring all six elements of competency for each operator. The CAP and Joint Commission have modified their inspection checklists to comply, and sites performing coagulation, blood gas and other moderate-complexity POCT will start to be inspected against these new regulations in 2011.

Many of the competency elements represent principles already addressed in the training/competency programs by most laboratories (result reporting, quality control, maintenance and problem solving). However, direct observation of test performance by each POCT operator is a resource-intensive and time-consuming task, especially for institutions that may have hundreds of operators to document competency each year.

Another element requiring documentation of test performance using previously analyzed specimens, internal blind samples, external proficiency or other samples with known results is also quite challenging and expensive for institutions. Some tests, like blood gas and activated clotting time, cannot physically be repeated because of the instability of the analyte. With hundreds of operators, not

every staff member may have the opportunity to perform proficiency testing each year. Staff also have fewer opportunities to perform quality control, given that many POCT devices have built-in controls within each test cartridge and POCT manufacturers have decreased their QC frequency recommendations from daily to receipt of new shipments of reagents/controls and periodically (weekly to monthly) during storage.

The competency elements of direct observation and testing a specimen of known concentration are difficult for POCT to implement, so labs will struggle in 2011 to comply with this requirement. Staff also have fewer opportunities to perform quality control, given that many POCT devices have built-in controls within each test cartridge and POCT manufacturers have decreased their QC frequency recommendations from daily to receipt of new shipments of reagents/controls and periodically (weekly to monthly) during storage. The competency elements of direct observation and testing a specimen of known concentration are difficult for POCT to implement, so labs will struggle in 2011 to comply with this requirement.

Reducing Errors

Non-instrumented POCT devices include the simplest form of laboratory testing such as urine dipsticks, fecal occult blood test cards and rapid flu tests that are assessed without the aid of an instrument. The majority represent waived tests, i.e., no CLIA-specific requirements other than follow the manufacturer's instructions. However, "good laboratory practice" should be observed to minimize the possibility of pre- and post-analytical errors and to ensure quality performance of these tests. A new Clinical and Laboratory Standards Institute (CLSI) guideline, POCT08-A, was released in December of 2010. This document ►►

provides users of non-instrumented POCT devices with a useful framework which, if carefully followed, would help reduce the chance of pre- and post-analytical errors.

Glucose Meter Performance

Glucose meters have been around for more than three decades as a useful tool to manage Diabetes Mellitus both at home and in the hospital. Newer meters have become faster, smaller and more accurate. Nevertheless, thousands of medical device reports (MDRs) have been filed citing a number of adverse events and even deaths attributed to glucose meters. These problems relate to the analytical performance (accuracy/precision) of the meters and the potential for shared POCT devices to transmit nosocomial infections. Glucose meters have been linked to the transmission of hepatitis B in several nursing homes. They also can be affected by a number of interferences that may not be recognized by the operator, including high or low hematocrit, drugs, lipids, maltose, Vitamin C and environmental effects such as temperature or altitude.

Glucose meters, originally developed for home use, have found wider application in the acute care hospital setting, particularly for management of intensive insulin protocols in recent years. Performance criteria for use in outpatient self-management of insulin did not account for the increased need for tighter technical performance of inpatient insulin management.

For this reason, the FDA held a number of meetings in 2010 to consider tighter performance criteria for hospital meters. These tighter regulations are based on internal FDA data and changes proposed to the ISO 15197 guideline and the CLSI guidelines under development. These tighter performance criteria for meter accuracy and precision must further be achieved in light of the variety of potential interferences posed by critical care populations.

Manufacturers will be struggling through 2011 and into the future to better meet the tighter performance standards when introducing new hospital meters to the market.

As well, the CDC recently issued recommendations to reduce the risk of transmitting infections from glucose meters and other POCT devices. Meters should be cleaned with a hospital-approved disinfectant between each patient use or hospitals should assign a meter to a single patient for the duration of their inpatient stay.

The added expense of assigning a meter to every patient will not be practical for most hospitals. But, hospitals will also face challenges implementing these recommendations with the current number of meters, given that most hospital cleaners must dry on the surface of the meter to be effective. These cleaners can take 5–10 minutes to thoroughly dry. So, disinfection of meters between each patient will prolong testing prior to meals, or hospitals will have to provide extra meters for staff efficiency, allowing use of one meter while another meter dries.

These cleaning recommendations also apply to other POCT devices shared between patients, like blood gas analyzers and coagulation devices. Thus, hospitals will need to comply with these patient safety recommendations in 2011.

Non-invasive POCT

The possibility of making non-invasive transcutaneous POCT analysis is extremely attractive, particularly in neonatology and critical care settings. The use of percutaneous bilirubin meters in neonates has become more popular in recent years. However, studies from Mayo Clinic² suggest that these devices can overestimate serum bilirubin levels when compared to laboratory determinations using the Doumas reference method. In addition, these devices have only been approved for use in limited populations.

Performance in other ethnicities with different skin tones has not been well-characterized.

Pulse oximeters, breathalyzers and continuous glucose meters are also being utilized at the point of care, both in home self-monitoring and inpatient, acute care settings. As transcutaneous POCT devices are not subject to CLIA regulations (no sample is withdrawn from the body), there is ongoing debate over quality assurance of these devices and what needs to be done to validate the initial and ongoing performance. This will continue to be debated in 2011 as additional non-invasive POCT devices hit the market.

The emergence of POCT as a valid clinical tool represents a paradigm shift from traditional laboratory practice. POCT originated as a response to the need for rapid decision-making in evolving clinical settings that require faster, more accessible and simpler tests. The development of newer technologies and overall improvement of POCT quality has led to an exponential growth in the POCT field. Nevertheless, careful evidence-based validation of these new methods and devices as well as more defined regulatory criteria are required to ensure that POCT performs at the expected level and quality to provide clinicians with reliable and consistent test results. ■

Drs. Prieto-Granada and Nichols are with Baystate Health, Department of Pathology, Springfield, MA. Dr. Nichols also is professor of Pathology, Tufts University School of Medicine.

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