A Pathologist's Take on POCT
By Richard A. McPherson, MD, MS

Point-of-care testing (POCT) devices have largely been designed to provide tests for critically ill inpatients on intravenous therapy who need close monitoring of their electrolyte and fluid balance. The medical necessity for POCT in elderly patients being seen in their own homes or assisted living facilities takes on a different form, as the testing technologies are often used in combination with history and physical examination to determine whether patients require higher level care or can remain in their present locations.

The most medically informative tests for this application include potassium and creatinine to assess renal function and possible need for dialysis; potassium can also be depleted by diuretic use. Also of value are hemoglobin, for which adequate POCT is available, and white blood cell count (WBC), for which no good POCT exists. The WBC in the context of physical findings and fever would be extremely useful for management decisions about escalating level of care (e.g., in suspected pneumonia) and could be a very successful POCT for the out-of-hospital arena.

A report on U.S. hospitalizations between 2007 and 2009 of adults 65 years of age or older after ED visits for adverse drug events identified four drugs responsible for 67% of events: warfarin, insulins, oral antiplatelet agents and oral hypoglycemic drugs.

Warfarin is an oral anticoagulant drug that takes several days or longer to achieve a plateau effect because it blocks the action of vitamin K in synthesis of coagulation factors in the liver. Many other drugs and even a patient's diet can severely alter its action, so patients require periodic monitoring of the prothrombin time (PT) to adjust dosage. For sheer convenience of immediate results, many physicians and even pharmacists have turned to POCT for the PT in their patients. While quality of fingerstick blood specimens could be improved, so too could more frequent testing in distant locations to avoid adverse complications from excess...
Testing platelet inhibition by these drugs needs to be done soon after collection and without artifact from rough transportation.

Testing is only one of many factors to consider when adjusting dosage in a broader based algorithm, including genetic information.

Self-monitoring of blood glucose by POCT has wide acceptance for diabetes care; it is disappointing that insulins and oral hypoglycemic agents should cause so many adverse events. Perhaps too much emphasis on tight glycemic control has led to hypoglycemic episodes from overly aggressive insulin dosing. One important factor has been the hematocrit effect in which below-normal hematocrits allow more plasma to enter the analytic pad of a glucose measuring strip, thereby reporting a falsely high glucose concentration. Based on those erroneous results, too much insulin could be given, leading to hypoglycemia. The next generation of glucose meters promises to compensate for variation in hematocrit.

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Reference
workups. Rapid detection of Lyme antibodies also allows immediate treatment.

Current POC methods for direct detection of infections such as influenza and group A Streptococcus are, however, inferior to laboratory-based methods such as culture and molecular amplification. Emerging technologies in molecular diagnostics are beginning to generate POC infectious disease tests that perform as well as laboratory-based methods and that will have a significant impact on individual patients and public health.

**Competency Assessment**

To ensure your hospital’s POC program is operating optimally and able to implement additional POC assays as they become available, staff must be competent and assessed accordingly. The words “competency assessment” can send shivers down the spine of even the most seasoned point-of-care coordinator (POCC); with so many regulations with which to comply, operators to observe and skills to assess, where should a POCC begin?

Competency assessment is actually several steps into the quality management system process and must be preceded by well-written, functional policies and procedures that define the laboratory’s POCT program. Essential contents of these documents include:

- the names of the tests that will be performed;
- the manner in which specimens will be collected, labeled and processed;
- detailed step-by-step directions for test performance;
- explanation of control procedures and corrective action steps;
- limitations and reference intervals; and
- instructions for entering results in the patient record.

An excellent reference for use in the development of procedures is CLSI document GP02, Laboratory Documents: Development and Control.1

This document provides guidance on development, review, approval, management and use of policy, process and procedure documents. Once the policies and procedures are drafted and finalized, the POCC should implement any necessary training to ensure staff members have the knowledge to perform the indicated tests.

Adequate training is essential and must be completed before the operator can be held accountable for proper test performance. Important questions to consider when planning such training include:

- Who will be the trainer(s)?
- How will the information be presented?
- What steps are prone to error and will need focused attention?

Also, the POCC should decide how to document comprehension of the training. This step can be accomplished through the use of questions on a post-training test, the testing of blind samples or direct observation of skill performance by the trainer.

CLSI document GP21, Training and Competence Assessment, presents a four-stage process for establishing a training program, the components of which are:

1. training needs identified,
2. training guides developed,
3. training implemented and
4. training outcomes evaluated.2

**Assessment Methods**

To be competent is to be capable, proficient and skilled. The Joint Commission lists several options for competency assessment methods, which include performance of a test on a blind specimen, periodic observation of routine work, monitoring quality control (QC) performance and the use of a written test.3 The College of American Pathologists (CAP) phrases its elements of competency assessment as: direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

- monitoring the recording and reporting of test results;
- review of intermediate test results or worksheets,
- QC records, proficiency testing results and preventive maintenance records;
A NEED FOR SPEED

By Valerie Neff Newitt

Point-of-care testing (POCT) is rooted in an urgent need for speed, particularly where infectious diseases and public health intersect. Sheldon Campbell, MD, PhD, FCAP, Department of Laboratory Medicine, Yale University School of Medicine, says a POCT “explosion” has had a radical effect in rapid identification and treatment of people with HIV.

“It used to be when people went to a confidential HIV testing facility, they would give a blood sample then call back in a couple of days to get results,” explains Campbell. That might have been OK where follow-up is a failsafe, but not in the world of HIV up to a third of people infected in the U.S. do not know it.

“Only 70 percent who go to confidential testing sites return for the results,” says Campbell. “Think about it. People have to work up courage to get the test, then they have to work up courage to get the results. It may be something they don’t want to face. They could be in denial, fear.” And they might never go back.

Rapid Test Means Rapid Treatment, Prevention

With rapid HIV POCT, negative or provisional positive results are immediate. Those tested are referred for treatment, or counseled about prevention. “The most critical components of the encounter happen immediately, all at once,” says Campbell.

Other healthcare scenarios also have been impacted by rapid HIV POCTs. “They are being used in EDs,” explains Campbell. “Not everybody who needs to be tested for HIV makes the effort. Now we often do ‘opt-out testing’; people who encounter the healthcare system are testable unless they specifically tell us not to.”

He says the imperative in public health is to test anyone 13 years of age and older for HIV. “Now it’s a manageable disease,” says Campbell. “Everybody should be tested so we don’t miss anyone whose life can be extended with therapy; and treatment will also decrease transmission.”

POCTs have been “somewhat revolutionary” in preventing transmission of HIV to newborns, as well. The rate of transmission from an infected mother to her infant is 30 percent without prophylactic anti-retroviral therapy prior to delivery. “But that number drops to one percent if a woman receives therapy, even at labor onset,” says Campbell. “When an untested woman starts labor, you can’t wait two days to get an HIV result. You end up treating a lot of people unnecessarily, and you don’t want to do that with newborns. Providing that result immediately is an essential part of labor and delivery care.”

Certainly laboratories have personal reason to applaud the availability of HIV POCT in needlessticks and other exposures. “Instead of putting everyone on prophylaxis for days, we can test the source patient immediately and give prophylaxis in a more thoughtful and risk-based manner,” says Campbell.

POCTs in Development

Yet the strengthening of POCTs is not all about HIV; there is a new rapid test for Hepatitis C that Campbell calls “highly significant.”

Traditionally, rapid influenza testing has been markedly inferior to laboratory-based testing. “It’s a challenge to get good specimens,” explains Campbell. “We get specimens with hundreds instead of thousands-ofMV viral particles. To detect with a rapid antigen test we need thousands of particles. So the rapid flu test, compared to viral culture or the gold standard-molecular amplification-is only 50-70 percent effective, sometimes less.”

Campbell says within the next few years “instead of doing inferior antigen tests for flu, strep or respiratory syncytial virus at point-of-care, we’ll do really good POCTs for infections using molecular diagnostics.”

The tests will employ polymerase chain reaction (PCR) or some other molecular method. “There are a lot in development. A couple of instruments are simple enough to allow for rapid flu testing in a small hospital lab, a hospital ED or a physician’s office laboratory and to get back a sensitive, specific result in a clinically useful time frame.”

In fact, in late December, Quidel Corp. received FDA clearance for the sale of its molecular Influenza A+B assay, which, according to Quidel, provides for simple transport, storage and a short time to result.

When tools are in place for POCT molecular diagnostics, “it also will be a real game-changer in sexually-transmitted disease testing,” says Campbell. “Right now tests for gonorrhea and chlamydia take two days. Those infected are often from transient populations, and may have social issues that make it hard for them to return for results. If we could test for those things in a single visit we could improve control of those diseases.”

Likewise, there’s an urgent need for speed in less-developed, TB-endemic parts of the world, where patients travel hours or days to reach a clinic, and may not be reachable after they return home. “There’s a relatively new system, the GeneXpert, which detects TB and rifampin-resistance in TB using PCR, it’s still quite expensive,” says Campbell. “It’s simple to use, but it’s still complex as far as durability and maintenance go, so there are barriers to widespread use.”

Noting there is a tremendous need for POCT diagnostics for diseases like malaria, dengue, and other diseases of less-developed areas, Campbell hopes continuing developments will forge a fast track to worldwide impact.

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2. clean the site with alcohol and allow to dry?
3. wipe away the first drop of blood?

In this way, important elements of specimen collection are listed separately, allowing the observer to evaluate each criterion independently and specifically identify deviations from proper procedure. An operator who follows all steps as defined in the procedure demonstrates an understanding of the procedure manual content during his competency assessment direct observation.

The POCT setting is more susceptible to variables in the pre-examination phase of testing than the typical laboratory setting. CLSI document POCT07, Quality Management: Approaches to Reducing Errors at the Point of Care, includes tables addressing the most common pre-examination variables considered potential sources of errors. Potential errors include:
- nutritional status and diet of the patient;
- pharmaceuticals or food supplements taken by the patient;
- contamination or dilution of the specimen;
- hemolyzed, lipemic or icteric specimens;
- missing or incorrect patient or test personnel identification.5

Performing the direct observation of a routine patient test in the setting typical for that operator (as opposed to at a skills fair) may provide a more representative indicator of the operator’s usual test techniques and a better opportunity to identify the presence of these preexamination errors.

**Monitoring Recording, Reporting of Test Results**

Interfaced instruments have allowed for efficient and accessible monitoring of result reporting. Most data management software allows for the creation of reports and/or the use of filters to selectively review critical values and values outside the analytical measurement range (AMR). When manual POCT is ordered and resulted through the use of an electronic medical record (EMR), the POCC can monitor compliance with result reporting procedures by quickly generating a list of all patients in the hospital information system or laboratory information system for which particular tests have been ordered. By using the EMR to review those patients’ records, the POCC will gain a clear picture of the operators who are incorrectly reporting results. Frequent reporting errors may also identify a process problem and lead to opportunities for improvement by changing the format of the electronic reporting system or limiting the available reporting options. For example, restricting allowed results to only those values within the AMR will prevent the error of charting values outside the AMR. This approach can invoke immediate compliance when even the best education attempts have failed.

**QC, Preventive Maintenance Records**

While lock-out features available on many POCT instruments make in-range QC required before patient testing, QC review should be a part of the POCT quality management plan. It is easily accomplished through the use of interfaced instruments and meets two requirements at once. Review of these records not only reveals instrument and reagent issues, but also identifies operators who repeatedly require corrective action steps, pointing out errors with sample application, instrument setup or testing techniques. Following the corrective action steps as defined in the procedure will demonstrate an operator’s knowledge of the procedure manual content.

Operators who experience difficulty with control testing should be supervised closely to detect whether the same issues are also occurring with patient tests. Determine an acceptable control success rate (e.g., 90 percent within range) and use operator statistics reports, which are available within most data management software, to monitor an operator’s performance.

In the POCT checklist, CAP states, “Proficiency testing records can be an important part of the competency and continuing education in the personnel files of those individuals performing testing.” The checklist also advises that “proficiency testing samples should be periodically rotated among all personnel who routinely test patient specimens.” For glucose testing, most proficiency test providers allow the submission of 20 results so the opportunity exists to satisfy proficiency simultaneously. Some providers of proficiency samples also allow the purchase of extra sample sets for internal use and, because these additional results are not reported or graded, the cost is reduced.

**Previously Analyzed Specimens and Blind Testing Samples**

While use of proficiency samples can prove efficient for small groups, it may also leave hundreds of operators without the opportunity to participate. Again, the POCC should consider using events already occurring to compensate for this disproportion.

For example, the laboratory’s competency assessment program can be designed to include a report that matches all laboratory and POC tests for the same analyte performed on the same patient within 10 minutes of one another. Not only can such a report compare the operator’s POCT result to its comparable laboratory value and meet the previously analyzed or blind sample criteria, but it can also be used to monitor the operator’s problem-solving skills when a discrepancy in values is noted. In addition, it can serve as a means to document the correlation of
the POCT instrument to the laboratory method. Use competency assessment as a learning opportunity and remind trainers and observers to approach the assessment steps not as a means for disciplinary action, but as an educational process. Following such a process can provide an opportunity to refine the information the operator retained during initial training, correct any misunderstandings and pinpoint areas that need improvement in the training program or testing procedure. Laboratorians share the comprehensive goal of better patient care; a well-planned competency assessment program proves that POCCs and POCT operators are intent on achieving it. 

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References
existing conditions on admission and discharge of the patient. This complete documentation will improve patient care and decrease unnecessary readmissions with positive impact on the clinical effectiveness and financial returns for the institution per the payment scales used in the VBP system.

**Accuracy and Reliability**

The comparability of POCT to central laboratory in terms of test result accuracy and reliability continues to be raised when the concept of POCT is introduced. Diagnostics companies have responded to the test result quality concerns by improving the analytical performance of assays offered. Many tests now offer higher accuracy and precision, with capabilities for detecting interfering substances.

**Migration of Moderate Complexity Tests to POCT**

As POCT continues to expand, several analytes that required rigorous quality control are now assayed on devices available for POCT. current regulations for managing waived testing may be inadequate for ensuring accuracy and reliability of the newer tests for POCT. Elements of good laboratory practice, however, require that some form of quality assurance be employed for all testing performed for patient care. This will vary from running quality control specimens as required by the manufacturer’s procedure to enrolling in a proficiency testing program and full compliance with CLIA ‘88. In the near future, we foresee that regulations concerning POCT in terms of quality assurance will be as stringent as required for moderate complexity tests, including enrollment in a proficiency program to ensure quality of results.

**Test Results Management**

Managing the post-analytical aspects of POCT remains a nagging concern. Recent technology enhancements for data capture and development of data management systems (DMS) has eased the post-testing documentation in POCT, especially in the hospital environment. However, these DMS have been mainly deployed for use in management of POCT blood glucose testing, which has one of the highest test volumes in POCT. In recent years, newer versions of DMS have the capability of capturing data from other test devices that include urinalysis, coagulation testing and more. It is anticipated that with economy of scales, these DMS will gradually become affordable for use in the physician office laboratories, nursing homes, health fairs, etc.

**Cost per Reportable**

In spite of these improvements, POCT continues to be a challenge. The unit cost per test is still high when compared with that of the same test if performed by the clinical laboratory. This will have to be weighed against the advantages of a rapid result that may improve outcome for the patient.

Cost recovery is another consideration in POCT. Where there is no record of the POCT carried out in the patient’s electronic records, recovery of cost becomes impossible. This is often the case in many centers where DMS are non-existent and other means of documenting testing are not explored. Furthermore, reimbursement by insurance companies requires the establishment of medical necessity as well as adherence to a stipulated testing frequency. POCT often will exceed this testing frequency and therefore may not be reimbursed. Amongst in-patients where reimbursement is usually based on disease related groups, POCT may exceed the reimbursement received. These are challenges that need to be addressed to prevent POCT expenses from becoming prohibitive.

The justification for implementing POCT after the test result accuracy and reliability have been validated requires an unbiased analysis of the clinical versus the financial implications within the total health system. Questions to be addressed should include how the implementation will enhance the quality and outcome of patient care. For example, in the request for cardiac markers (Troponin or CKMB), the requesting physician should indicate if the test result is required for therapeutic intervention (e.g., ST versus non-ST myocardial infarction) or if it is used for confirmation. Financial questions to be addressed will include impact of the improved turnaround time on overall length of stay and/or discharge decisions. The development of the right questions and appropriate evaluation of the situation can significantly elaborate the returns on investment (clinical and financial) from use of POCT in the VBP system. POCT will continue to expand, especially as it presents an opportunity for improved reimbursement in the VBP system if it is appropriately evaluated for contributions to improved patient care.

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2.  [Clinical Laboratory Improvement Amendments of 1988, 42 U.S.L. 263a PL100-578, 1988](https://healthit.gov/sites/default/files/collections/2016/Medical-Interoperability-Point-of-Care_ez.pdf)