What's New in Point-of-Care Testing (POCT)?
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Objectives:
1. List the advantages and disadvantages of Point-of-Care Testing.
2. List the most frequently performed bedside testing procedures, the metabolites they test for and factors that may effect these results.
3. Name the various organizations that regulate POCT and the rules they impose with their consequences.
4. Discuss the advantages and disadvantages of the POCC.
5. Explain how connectivity helps benefit POCT.

Point-of-Care Testing
Everyone wants to feel better faster. Increased healthcare costs have reduced inpatient stays with a shift towards recovery in an outpatient or ambulatory environment. These significant changes have placed greater demands on the laboratory for shorter turnaround times (TATs) to facilitate faster diagnosis and treatment. Thus, point-of-care testing (POCT), also known as bedside, ancillary, alternative site and near-patient testing, has become an established part of clinical laboratory practice. Currently, one in four tests is performed at POC and that is expected to rise to 40% of all “laboratory” tests within 5 years. Likewise, the current POCT market estimated at $4.9 billion is expected to double within the next 5-10 years.

POCT more accurately describes a testing delivery option rather than a specific test. Performing lab testing at the patient’s location or bedside is a method of testing widely used in hospital and physician office laboratory, nursing homes, clinics and even in patient’s homes. This often means shorter TATs than standard lab work collected by venipuncture. The result is faster patient treatment and recovery which will lower healthcare costs through faster discharges. Additionally, POCT procedures can be performed at the patient’s convenience, especially important for elderly and homebound patients.

POCT has come a long way since the electronic glucose meters of the late 1970’s and urine dipsticks used in physician offices. A 2001 survey of POCT practices in 584 US hospitals found that 100% were performing glucose testing, 62% offered coagulation tests, 50% blood gas and electrolytes, 36% chemistry assays, 28% hematology, 15% urine chemistry and 4% cardiac markers. POCT is being performed in nontraditional environments such as ambulances, helicopters and jet aircraft where the need for testing critical care patients in transit may arise.

The following describes some of the new technology available:

Urinalysis
This was one of the first areas to involve POCT. In the very beginning, visual inspection of the color and appearance of the urine (and sometimes taste) was the standard for urinalysis. Once chemical methods of analysis were developed, testing moved into the laboratory. But with the advent of strip-based chemical assays, urinalysis was moved back to the patient arena. For many years strips were manually read while manually timing the reaction results. Readers that automate the process and reduce reading variability are now being deployed in many sites, including ERs and clinics. In addition, these devices provide a printed report that reduces time and errors.
Glucose
Whole blood glucose testing is one of the first and most frequently performed bedside testing procedures. Used to monitor blood glucose levels in patients with diabetes mellitus, most POCT glucose testing instruments are small, portable, inexpensive and easy to operate. Since the late 1960s patients have been able to test their glucose at home by applying blood to a color-coded test strip and then visually comparing it to a provided chart to obtain a glucose result. In the late 1970s readers became smaller and provided an automated reading. Since then the glucose monitor has become smaller, lighter, faster and more user friendly. The sample volume required now is 10 microliters or less. This is good news for the approximately 200 million diabetics in the US today.

Arterial Blood Gases
Traditional blood gas measurements require that a blood sample be drawn from the artery into a special heparinized syringe, labeled, then placed in an ice slurry and transported to the lab for analysis. It could take 20 minutes or longer for results. Much of today’s modular POCT instrumentation is designed to fit into the patient’s bedside monitor and has the ability to incorporate arterial blood gas results into the patient’s medical record. These systems do not require blood to be removed from the patient but have single-use, disposable cartridges attached to the patient’s existing arterial line. Arterial blood is drawn into the cartridges’ sensor, where measurement of pH, pCO2 and pO2 are made within 1 minute. Blood then is returned to the patient’s circulation and the arterial line is flushed. Advantages of this type of POCT instrumentation are faster TAT and reduction of blood exposure to both patient and operator. One disadvantage however is cost. This type of POCT analyzer can be quite expensive.

Other types of blood gas analyzers used at the bedside are hand-held devices that use disposable cartridges that hold miniature components integrated with biochemical and silicon chip technology. Abbott Diagnostics has an instrument, the I-STAT analysis which can perform blood gases, electrolytes, general chemistries and hematology. It uses 2 drops of blood and can give results in 2 minutes.

Coagulation
Present coagulation POCT analysis available include prothrombin time (PT) and international normalization ratio (INR), partial thromboplastin time (PTT) and activated partial thromboplastin time (APTT), activated clotting time (ACT), and heparin management test (HMT). Because approximately 1% of the US population (2 million people) receives oral anticoagulant therapy, management of prothrombin time is critical. Oral anticoagulants (e.g. warfarin) present a difficult dosage regimen because patient PT values must be kept within a narrow range. This is often complicated by certain foods and drugs which affect test values. These patients require frequent assessment of PT to ensure adequate warfarin dosage. Patients taking warfarin who are not monitored are at risk of complications ranging from bleeding to thromboembolism (blocking of a blood vessel by a particle that has broken away from a blood clot at its site of formation).

Traditional PT testing involves performing PT/INR tests by venipuncture sampling in a clinic or laboratory setting and waiting an hour or more for the results. With POCT, coagulation tests may be performed at a clinic or physician’s office. A single drop of blood is placed on a test strip treated with thromboplastin reagent. Sample movement is monitored by the instrument as it reacts with the reagent and eventually forms a clot. Generally, the applied sample is detected by peristaltic movement, optical detection of capillary blood flow or detection of oscillation of iron oxide particles. Sample types vary by machine and can be capillary, venous blood or citrated plasma.

Activated clotting time is an analysis of intrinsic coagulant factor activity and is used to monitor heparin therapy. Heparin is given to patients with disorders of clotting, a tendency for abnormal
bleeding or as a post surgical precaution. One POCT coagulation analyzer, the Hemochron Jr. Signature (International Technidyne Corp), automatically mixes and times the sample, and can perform coagulation tests that monitor low dose heparin for anticoagulation therapy, monitor low to moderate levels of heparin used in dialysis and cath lab procedures, and monitor moderate to high levels of heparin used in cardiac bypass procedures.

**Cardiac Markers**
Several markers have been identified as useful in the evaluation of patients with suspected cardiac problems, including:
- myoglobin
- troponin T and troponin I
- B-natriuretic peptide (BNP)
- Pro-BNP

Manufacturers have developed POC systems that provide single or multiple marker testing necessary to effectively triage the patients. These tests are to be done near the patient or in the lab provided the time delay is minimal. Some institutions may have them available at the bedside in ER, cardiac or pulmonary clinic. Others will prefer that testing stay in the lab providing there is acceptable transport, testing, and TAT.

**POCT Regulation**
Point of Care Testing is used in many areas. Near-patient testing can provide much faster test results by using whole blood samples and eliminating the need for sample transport and processing. Healthcare professionals at varying levels perform POCT including physicians, anesthesiologists, perfusionists (heart/lung machine technicians), registered nurses, respiratory therapists, phlebotomists and patient care assistants. But during laboratory surveys performed in the late 1980s, JCAHO (Joint Commission of Accreditation of Healthcare Organizations) noticed that hospitals were increasingly relying on testing performed outside the clinical laboratory. And that many individuals performing these tests had little knowledge of the principles of quality control or the parameters of testing methodologies for the instrument they used. Under the Clinical Laboratory Improvement Amendment (CLIA) of 1988, the Department of Health and Human Services (HHS) regulated the settings in which POCT can be used. HHS also regulates the specific tests for which POCT technology can be applied, based on the level of expertise of the use and the availability of quality controls to ensure the equipment is functioning properly. If these criteria are satisfactorily met, CLIA offers waivers for which facilities can apply if they wish to implement the program.

In 1990, JCAHO issued a set of guidelines on decentralized testing standards. The intent of these guidelines is that whichever department within an organization is responsible to oversee POCT, it must ensure that testing is performed in a reliable and appropriate manner. The standards also state that because POCT data are to be used for the diagnosis, management and treatment of a patient, then the organization, in addition to the specific controlling department, is also responsible for ensuring that testing is performed correctly. The central laboratory does not want loosely controlled or independent POCT sites and personnel to jeopardize its CLIA certificate due to non-compliance issues. CLIA regulates all clinical laboratory testing regardless of where it is performed. POCT usually uses either waived or moderately complex methodologies. The only quality requirements for waived testing, the least complex of all test classifications, is to follow manufacturers’ protocols.

For moderately complex testing, CLIA sets minimum testing standards for quality control (QC), personnel, proficiency testing (PT), quality assurance and inspection. The minimum CLIA QC requirements include following the manufacturers’ instructions for test performance; having a procedure manual; performing or verifying calibration at least once every six months; assaying, for
most tests, at least two levels of control material each day of testing and keeping records; performing and documenting remedial actions and maintaining records of all QC activities for two years.

The Centers for Medicare and Medicaid Services inspects moderately complex laboratories every two years for regulatory compliance. Deficiencies in compliance can result in required plans of corrections, fines, sanctions and even suspension of testing. POCT sites accredited by the JCAHO or the Laboratory Accreditation Program of the College of American Pathologists (CAP) must follow the more stringent quality requirements specified by these organizations’ standards.

More immediate test results are definitely advantageous in the pursuit of better patient outcomes, but inaccurate or incorrect results can affect situations that can lead to devastating outcomes. With so many POCT devices becoming available for both professional and at-home use, factors such as training on instrument operation, operator competency, and regulatory issues (QA/QC) must be monitored continually.

Training
POCT personnel should be trained in patient preparation and identification, sample requirements, collection and handling, universal precautions and disposal of biohazardous materials. Reagent handling procedures should include proper storage and checking for outdates. CLIA regulations outline that all personnel performing waived tests have the ability to read, understand and follow the instrument manufacturer’s directions, and that personnel performing moderate complexity testing be qualified and competent through documented education, training and experience.

All POCT training must include a clear and concise quality control protocol, as well as detailed procedures for instrument maintenance, troubleshooting and backup. Today, many of the POCT devices require little or no maintenance or troubleshooting. Additionally, personnel performing moderate complexity testing must have a competency assessment performed twice during the first year of testing and once annually thereafter. They must adhere to policies and follow procedures for the entire testing process, from specimen handling and processing, to reporting and maintaining laboratory POCT records of patient test results.

Training the POCT operators can be provided by instrument vendors, POCT coordinators or designated personnel within the healthcare organization, and/or training modules. Vendors often provide trainers to ensure customer satisfaction through the correct use of products. In-house studies have shown that formal, instructor-provided training facilitates better learning and that learning was more effective in a group setting.

While institutional instructors from the laboratory, nursing or POCT committee all can provide highly customized training, involving laboratory personnel in POCT training is an invaluable aid in helping to maintain an organization’s accreditation. But that does not mean that the traditional laboratory approach to testing is right for nonlaboratory personnel. For example, nurses may respond to a nurse trainer who can focus on POCT as a means to improve patient care, and respiratory therapists to a trainer that emphasizes testing as an adjunct to patient respiratory treatment.

Training a diverse non-laboratorian staff (including MDs, RNs and RTs) across multiple shifts, instruments, methods and then monitoring their competence on time is a formidable task which increases with each test added and with department size. The testing site director has the ultimate responsibility to ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical and postanalytical phases of testing. The testing site director ensures their competency and maintenance of competency to process specimens, perform test procedures and report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education.
Competency
General competency assessment in laboratory testing performance can be a formidable goal, and POCT is no exception. The following table suggests procedures to evaluate competence from the CLIA regulations (493.1413(8) (i-vi); however, the applicability of the approach is dependent upon the specific test.

Suggested Procedures to Evaluate POCT Operator Competence
- Direct observation of test performance, including patient preparation where applicable
- Monitoring the recording and reporting of results
- Review of quality control and proficiency testing records
- Direct observation of instrument maintenance and function checks
- Retesting previously tested samples
- Assessment of problem-solving skills through written tests, direct observation or both

Regulatory
Regulatory affairs are a complex and evolving aspect of POCT. Understanding and remaining current on regulatory requirements requires ongoing review and reassessment. The most frequent deficiency found in CLIA inspections of test sites performing only nonwaived testing (article is from March 2002) is failure to follow manufacturers’ directions. Much of POCT is classified as waived testing, and CLIA’s only requirement of this classification is to follow manufacturer’s direction. While the government does not inspect waived testing for compliance the Centers for Medicare and Medicaid Services (CMS), recently conducted a pilot study of waived testing in Colorado and Ohio. This study was undertaken because of the increasing number of waived tests, the large number of POCT sites with essentially no oversight, and serious noncompliance findings in complaint investigations.

To confirm the findings of the initial study, CMS expanded it to include eight additional states. It was found that within these 10 states, 32% of the waived test sites failed to have current manufacturer’s instruction, 32% did not perform quality control (QC) as required, 16% failed to follow current manufacturer’s instruction, and 7% did not perform calibration as required by the manufacturer.

Barbara Goldsmith, Director of POCT Programs at Alliance Laboratory Services (Cincinnati, Ohio), surveyed five POCT sites in her CAP-accredited facility and identified several specific causes of POCT errors. Failure to follow procedures topped her list. She recommends that after selecting a POCT device, the first step in ensuring high-quality POCT is to develop written procedures in a language that is understandable and easy to follow by nonlaboratory personnel. It is also important to note that the written procedure should reflect both the recommendation of the manufacturer and those of the individual site or institution.

Having a procedure manual that all personnel who administer the test can follow, is key to quality POCT. While the CLIA has no specific procedure manual requirement for waived testing, test sites performing waived tests must follow manufacturer’s directions. It should also be noted that if POCT sites are not following the manufacturer’s directions the waived tests are automatically classified as highly complex and all CLIA requirements for that category of testing must be followed.

Costs of POCT
POCT costs are another concern. Does POCT increase or decrease the cost of care? There is no doubt that POC tests, done one at a time, are more expensive to produce than those provided in a central laboratory. While individual POCT instruments are usually less expensive, the organization usually has more of them. In addition, moving some testing out of the central laboratory typically does not reduce its staffing costs – the most expensive component of the service.
Computing labor costs related to POCT may be the most controversial part of any cost assessment. With POCT, the professional staff, usually nurses, acquires additional responsibilities and demands on their time. It is obvious that if nurses perform the testing, their patients can benefit from the “instant” information. However, the nurses also acquire additional responsibilities such as entering the data into patient records, performing quality control, etc. None of their responsibilities for taking care of the patients are reduced. The labor costs in POCT are often overlooked in the cost assessment process.

On the other hand, the claimed benefits, including decreased costs per episode of illness; decreased length of hospital stay; better and more rapid diagnosis; faster treatment and rapid recovery are difficult to document.

**Problems with POCT**

**Connectivity**

The appropriate documentation of test results and related information (such as patient and operator identifiers and quality control data) has been an issue since the inception of POCT. Depending on the POCT device, results may appear on a screen with temporary printouts available. Those results may get mishandled or misplaced and never find their way into the patient’s permanent medical record. This lack of documentation may also have an affect on potential reimbursement issues.

Connectivity is the ability to electronically and automatically transfer information pertaining to the test (result, identifiers) and the testing process (material calibration, QC information, etc.). Where appropriate, it would be good to have this flow bidirectional.

The evolution of docking systems (or other similar access points) now permits remote control of information transfer from the device to a central repository, sometimes called a data manager (DM). From this location, the necessary information is passed to the Laboratory Information System (LIS) or Hospital Information System (HIS), thus appearing in the patient record. It is also available for accounting and other purposes.

Result validity, traceability and verification or transfer to the correct medical record, are critical issues. This data transfer requires two interfaces: one between the device and DM and the other between the DM and LIS/HIS. Early interfaces were proprietary, either scripted or electronic data interfaces. This issue of connectivity and the push for the development and implementation of a connectivity standard is one of the most important advances in POCT.

The Clinical and Laboratory Standards Institute is updating its current guideline, the POCT1-A connectivity Standard, which seeks to establish a universal, open-architecture standard with plug-and-play capability. In addition, guides for both service providers and manufacturers are in preparation. The objective is to facilitate the implementation and widespread use of connectivity solutions to improve the POCT process and efficient use and management of POCT data. On a related point, early POCT devices, especially glucose meters, lacked the software capacity to force QC and block the use of the instrument if QC was either not done or did not pass. They also lacked effective noncertified operator blocking capacity.

**Errors**

At the POC, considering that testing is performed and reported by non-laboratory personnel and many screening, if not diagnostic, decisions are made at the bedside based on POCT results, much room is left for error. Errors can arise in the areas of patient identification, specimen collection, and result reporting. This possibility can be lessened by the use of a single individual to process the test. To enhance patient safety, the same standards in use in the laboratory should be strictly adhered to. These standards include operator competence, procedure adherence, quality control, and results integrity. POCT education programs should include operator training, program supervision, competence assessment, and proficiency demonstration.
POCT coordinators
POCT coordinators (POCCs) act more like managers, and some laboratorians are in charge of POCT work in addition to their own responsibilities without any additional compensation. Unlike the section supervisors that deal only with the lab and medical director, the POCC must interact with all persons involved in POCT either directly or indirectly, including medical, nursing and administrative staff. One of the biggest complaints of POCT professionals is salary. Many admit that when they agreed to take on the role, they were unaware of the challenges that the job would hold in the future. Because POCT titles and roles vary so widely from facility to facility, no standard for compensation really exists. Some hospitals and facilities may not be able to devote an entire full-time equivalent to the position of POCC, based on costs. One POCC in a Cleveland hospital said the biggest challenge to POCCs is “keeping all the balls in the air - staying current with the standards, proficiency survey, quality control (QC) use, competency of all staff, and making sure that communication is maintained both up and down.” One POCC from upstate NY said she is responsible for quality assessment, quality improvement, compliance, central services, in-house specimen collection and physician offices, in addition to being the only person from the lab responsible for the oversight, development and implementation of the POCT program at her facility.

Some suggest the POCC needs to be a full-time position. Others suggest a credentialing agency specialty exam for POCCs might help the situation. Perhaps that level of recognition would bring the position to a higher level of compensation.

Advantages of POCT
POCT can offer several benefits, most importantly the instant implementation of treatment decision rather than waiting, sometimes for several hours, for the results from a more traditional central laboratory-based analyzer. By the time those results become available, the condition of the patient may have changed. In the case of POCT, immediate results mean immediate care. Specimen transport time is minimized as no staff have to leave the OR or bedside to carry a sample to the lab. In some cases, there may even be a reduction in pneumatic tube traffic. POCT also reduces the risk of preanalytical errors that may accompany traditional laboratory testing, such as the handling, labeling, and transport of samples.

Another advantage of POCT is a decrease in phlebotomy-related blood loss. Some analyzers used in central laboratories have menus that require a minimum sample size, whereas POCT devices use smaller samples. For patients requiring transfusion, erythropoietin therapy, or treatment for iron or other nutritional deficiencies, the volume of blood withdrawn for testing may be a significant cost factor. Replacement costs for blood by transfusion are about $0.50/mL and there is a substantial cost for erythropoietin, iron therapy, and other nutritional supplements. This is a particularly significant issue for infants and or patients requiring frequent testing where the cumulative blood loss from phlebotomy becomes substantial.

Changes, Improvements (2006)
Formerly, JCAHO waived testing standards were non-specific and open to institutional interpretation. However, to improve safety, JCAHO recently made changes to a few of its five waived testing standards, specifically those regarding reporting of results, competency and QC. New in the yearly requirement of competency assessment using two of the specified methods in JCAHO’s Elements of Performance (EP) is a set of specific guidelines affected by JCAHO for the purpose of more objective compliance assessment.

Also new is a requirement that applies to instrument-based testing. Once only applicable to glucose meters, JCAHO requires QC once a day for instrument-based testing. For noninstrument-based tests, the former frequency requirement of following manufacturer recommendations is still in effect; however, JCAHO lists specific criteria in its EP.
Unlike the JCAHO, the CAP POCT checklist has undergone few changes to govern quality of POCT, whether waived or moderate. Although CAP has not yet published specific evaluation or validation criteria, vendors often provide guidelines to accomplish such tasks.

Regardless of what guidelines are used for validation purposes, the first step is to determine what QC is available (e.g., onboard, internal, electron, liquid) for a given test system or device, then establish what phases of testing are assessed. Vendors often are able to provide such information as well.

**Conclusions**

Does POCT improve the quality of care as measured by patient outcomes? Multiple studies have and are addressing these issues and more are needed. While the jury is still out on the final answer, POCT, viewed in the context of decreased turnaround time alone, does not equal an improved patient outcome. By incorporating comprehensive education, training, and competency guidelines and policies for both laboratory and nonlaboratory POCT personnel, healthcare facilities can ensure the quality and cost effectiveness of testing results in the POCT environment.

**The following are comments from personnel from the Science Advisory Board concerning their perceptions of Point-of-Care Testing. These are people on the “front lines”. Each paragraph comes from a separate individual:**

“The problem in our institution is compliance with JCAHO requirements for POCT testing. I believe that there is potential for decreased cost to the patient if the POCT eliminates them from having a more invasive test done. There are some cons to testing though, sometimes there is a large variation in the POCT vs. actual lab values, poor compliance with QA/AC testing, and currently we document all results manually.”

“We are equally worried about turning the bedside into a very busy place. Need to balance need for information with the added burden of more people and unfamiliar equipment and procedures for the patient to assimilate.”

“I find the POCT technology has far exceeded the ability and willingness of the personnel utilizing it on a daily basis, e.g. clinical staff. We are asking nurses and ward clerks to think and operate as MTs. It’s not fair to them and it’s dangerous to patients. If the lab had the time and staffing to correctly train clinical staff, POCT would be a critical element in reducing in house patient days. But as it is now, it is merely controlled chaos.”

“Another issue of concern relates to interpretation of test results. In the central lab, there is always someone senior present to interpret test results in the context of clinical information and other test results. When the POCT tests are run by nurses for junior physicians, this may not always be the case.”

“Our POCT has increased efficiency, decreased patient wait times and procedure cancellations. I would LOVE HIS/LIS integration!”

“POCT is vital for home birth midwifery care.”

“I only have experience with bedside pulmonary function testing and glucose monitoring. Abg’s (Arterial blood gases) are still run elsewhere. It seems that POCT works mainly because patients who are very ill do not need to leave their hospital room to have certain testing done.”

“I think that POCT is here to stay and I guess that is a good thing since I am so involved in it at my hospital! I have found the technology to be sound. But getting nurses to think like Med Techs has
been a definite challenge! Sometimes results must be challenged because of patient condition, prior history, etc. It has been my experience that this is not always the case at the unit level.”

“With our Emergency Services becoming responsible for chem. 7 testing on the Nova we have actually had several nurses (charge nurses) refuse to perform testing. These same RNs also wanted to send every urine pregnancy test to the lab for result verification. We have had to really push them to perform the tests and to fully perform the necessary steps – QC, data entry, result review. They don’t like the time necessary to carefully/fully perform testing and they certainly do not like the responsibility.”

“As a laboratory professional, the greatest misgiving I have about POCT is the apathy about QC/QA on the part of some who would use the devices. For example, nurses who are suddenly required to perform STAT BUN’s and creatinines are more likely to be concerned with the patient result than verifying QC values. I also question the accuracy of such devices. I work in a CLIA-approved facility and frequently check patient glucometers against our own analyzer. The results are often shockingly dissimilar (e.g., a patient result of 120 compared to an assayed value of 180). The patient and physician are left not knowing what to believe. I hope you will understand that these observations are valid concerns for me and many of my colleagues, and not just the knee-jerk response of someone fearing the loss of his/her job. I do believe that POCT will be an asset to patient care if the bugs are worked out. I further believe that lab personnel will continue to be important contributors to the practice of medicine.”

“Speaking with the patients and explaining to them what tests we do and maybe showing them the results is in my opinion very useful. The patients feel more important and more taken care of.”

“The key to POCT is improving patient outcomes. The cost/test or cost/device is minor compared to overall cost savings associated with better patient outcome. In many situations, faster turn around time alone may improve patient outcome by allowing more timely therapy or adjustment in therapy (e.g., anticoagulation, blood sugar, cardiac enzymes). In some situations, better record keeping may result in better care and better outcome. To do this, of course, POCT must be as accurate and reliable as central lab testing.”
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