Point of Care Testing Toolkit

Introduction

Worldwide, one of the fastest growing aspects of clinical laboratory testing is point of care testing (POCT), estimated to be increasing at least 10-12% per year overall and upwards to 30% per year in some testing areas. In contrast, central laboratory testing has grown approximately 6-7% annually.

When first widely introduced, POCT was largely for home use or physician office laboratory (POL) testing. In hospitals, it was considered as supplementary to central laboratory testing. It was not generally regarded as a primary responsibility of centralized pathology services and was often treated by central hospital laboratories with indifference, benign neglect, or frank hostility, and considered as substandard or second tier testing that was unmanageable. Some laboratorians considered POCT to be a potentially disruptive competitor to their services. POCT was also an added responsibility that many laboratories or nursing services found difficult to assume. The attitude of POCT as an inferior stepchild or orphan testing has changed with government regulations, the growth of the technology, an expanding perspective and spectrum of healthcare services, and different expectations from healthcare providers and consumers. Decentralized patient care and access to testing in under-served areas are key elements in the evolving expansion of POCT.

POCT continues to mature both as a technology and in the eyes of healthcare providers, laboratorians, regulators, administrators, and vendors. While the technology has become more varied and robust and performance has improved, the various groups associated with POCT have grown more realistic and demanding about its potential. No longer does the Everest theory prevail — just because it exists does not mean POCT should be used in all situations. The need for comparability with central laboratory testing, efficacy, operational device and kit fail-safes, management and oversight requirements, operator performance standards, economic indicators, and patient outcome data are all now considerations when deciding whether to employ POCT in specific situations.

POCT is increasingly being seen as a testing modality with performance expectations similar to traditional laboratory testing and requiring the same high standards. Rather than inferior testing or a nuisance, it is increasingly seen as a complementary or alternate type of testing that meets specific care needs and is an integrated part of clinical laboratory services, either; under the formal direction of the central laboratory or with consultation or guidance by laboratory services. POCT should be considered as a part of the continuum of the clinical laboratory's contribution to healthcare and a fundamental responsibility of laboratory services. It needs to be regarded with the same expectations of quality involving the total testing process, covering the pre-, intra-, and post-analytic phases of testing. As healthcare reform changes the perspective from fee for service to the optimization of over all patient care, POCT can be a critical factor in streamlining and improving laboratory services.

The Laboratory Director is a mandated and fundamental position required for any clinical laboratory to function. As POCT is now frequently a component of laboratory services, it is essential that pathologist Laboratory Directors see it as their responsibility to be actively involved in all aspects of POCT.

Definition of POCT

To fully understand and appreciate POCT, it is necessary to understand its breadth, encompassing varied sites, uses and technical options.

a. POCT is referred to by many different terms. Each may specify an aspect of the more general POCT term. Alternate terms for POCT include:
    1. Bedside testing
    2. Near-patient testing
    3. Ancillary testing
    4. Satellite testing
    5. Remote testing
    6. Physician's office laboratory (POL) testing
    7. Patient self-management
    8. Decentralized testing

b. POCT has several definitions based on geographical, functional, technological, or operational context:
    1. Geographical context– where the test is conducted (outside of the main or core laboratory)
        a. Hospitals (ED, OR, ICU, neonatal care, etc.)
        b. Ambulatory care settings (clinics, physician office laboratories, rural clinics, student health clinics)
        c. Health fairs
        d. Pharmacies
        e. Prisons
        f. Military operations
        g. Visiting nurses
        h. Nursing homes
        i. Patient self-management
        j. Disaster and medical relief
        k. Remote clinics, under developed sites or countries
        l. Transport vehicles (ambulances, helicopters, trains, cruise ships, airliners)
        m. Mobile health vans – blood mobiles, clinics, public events
        n. Corporate healthcare operations
        o. Definitions based on location include:
            i. The analysis of clinical specimens as close as possible to the patient, including bedside, patient care unit or stat response labs that service specified areas- e.g. the "ER or ICU".
            ii. Laboratory and other services provided to patients at the bedside. POCT is defined as tests designed to be used at or near the site where the patient is located, that do not require permanent dedicated space, and that are performed outside the physical facilities of the clinical laboratories. Examples include kits and instruments that are hand carried or otherwise transported to the vicinity of the patient for immediate testing at that site (e.g., capillary blood glucose) or analytic instruments that are temporarily brought to a patient care location (e.g., operating room, intensive care unit). POCT does NOT include limited service satellite laboratories with fixed dedicated testing space.
    2. Functional context– rapid or fast turnaround of test results which are readily accessible for patient care;
        a. POCT is defined as diagnostic testing at or near the site of patient care.[4] The driving notion behind POCT is to bring the test conveniently and immediately to the patient. This increases the likelihood that the patient will receive the results in a timely manner
        b. Near patient testing is defined as any investigation carried out in a clinical setting or the patient's home for which the result is available without reference to a laboratory and perhaps rapidly enough to affect immediate patient management.
        c. Rapid test turnaround times (TATs) and access to results are assumed to improve patient care and healthcare delivery. Sometimes the central laboratory may assume a POC function and produce very rapid turnaround times but more frequently testing at the point of care produces an overall shorter TAT.
    3. Technologic context– testing is usually, but not always, conducted with small, portable devices or manual kits. POCT is accomplished through the use of transportable, portable, and handheld instruments (e.g., blood glucose meter,) and test kits (e.g., HIV salivary assay). Cheaper, smaller, faster, and smarter POCT devices have increased the use of POCT approaches by making it cost-effective for many diseases, such as diabetes and acute coronary syndrome
        a. POCT may be performed on platforms that are also found in central laboratories. These are usually small to midsized instruments amenable to be transported to the patient's location
        b. Conversely, the central laboratory may use small POCT devices when these make sense for the volume or type of testing a laboratory provides.

4. Operational context– usually performed by non-laboratory personnel who may include:
    a. Nurses, Nursing Assistants and Technicians
    b. Physicians, Residents, Physician Assistants
    c. Emergency Medical Technicians
    d. Medical Office Assistants
    e. Pharmacists
    f. Medics
    g. Respiratory Therapists, Perfusionists
    h. Patients (self-testing)
    i. Definition of POCT based on testing personnel:
        i. Clinical laboratory testing conducted close to the site of patient care, typically by clinical personnel whose primary training is not in the clinical laboratory sciences or by patients (self-testing).
        ii. POCT may be performed by laboratory staff who work in POLs, small decentralized laboratories, clinics, or other non-central laboratory sites.
5. POCT is a dynamic discipline. With the evolution of technology and changing medical needs, sites, and operators, the definition and spectrum of POCT is expected to change over time.

Advantages and Disadvantages

POCT has a variety of advantages and disadvantages that should be weighed when considering POCT as an option.

1. **Advantages**
    a. Rapid test results with the potential to expedite medical decision-making
    b. Small sample volume – patient convenience (capillary fingerstick vs. venous phlebotomy), pediatric benefit, and less blood loss and anemia for patients requiring frequent testing (e.g., "ICU")
    c. Portable devices with wide menu of analytes – allow testing to be performed in a variety of locations, with flexibility to meet the diversity of medical needs
    d. Unprocessed specimen – whole blood analysis not requiring time for clotting, centrifugation or aliquoting
    e. Lean process – testing on-site requires fewer steps than transporting a specimen to a core laboratory, processing, aliquoting, testing, and communicating results back to clinical staff
    f. Clinical staff efficiency – works within the clinical management setting. As the physician examines the patient and determines the need for testing, POCT is conducted and medical care is promptly implemented, avoiding the need for physicians to refamiliarize themselves with a case after test results are returned from a central laboratory
    g. Potential to improve patient outcome or workflow by having results immediately available, especially when POCT results can be linked to patient management in order to move individual patients through the system faster or handle more patients at a time
    h. Ability to provide laboratory testing in a wider variety of sites or circumstances, such as underserved populations, rural areas, and locations with limited infrastructure or personnel (e.g., disaster, accident or military sites)
    i. Reduced potential for sample deterioration – most POC tests are initiated and performed rapidly once the sample is obtained. This reduces the potential changes that may occur to samples sent to the central laboratory due to continued cellular metabolism, cooling, analyte instability, exposure to the environment, etc.
2. **Disadvantages**
    a. Reliability of POCT results
        i. Questionable quality can occur, given the variety of educational and experience levels and turnover of staff that perform the tests
        ii. Greater inter-individual variability in results (compared to central laboratory testing) is common
        iii. Waived category does not guarantee reliability. Simplicity is deceptive and there are many ways that staff can inadvertently generate a wrong result with waived or "simple" tests if they are not focused on what they are doing or skipping steps.

b. Cost – per test costs for POCT are often significantly higher than the cost of central laboratory testing. However, the overall cost of care may be lower when POCT is employed, especially if patients may be treated or moved through the system more quickly and care outcomes are improved
c. Number of testing personnel– the number of operators to manage is much larger in magnitude than centralized laboratory staff.
d. Management of POCT is challenging – there can be dozens of sites, hundreds of POCT devices/kits, and thousands of operators to manage to assure quality of testing.
e. Personnel performing POCT may inappropriately use a test kit or device outside of its intended use or the written procedure (e.g. performing Hemoccult testing on gastric contents instead of feces, performing glucose testing on IV solutions instead of blood).
f. POCT results are not necessarily comparable to central laboratory results – Standard methods may not be used in POCT and thus it may not be possible to compare results across sites (e.g. when patients travel and are tested at different sites). Differences in specimen types, (e.g. serum, plasma, or whole blood,) may also affect results between traditional central laboratory methods and POCT. Thus, clinical protocols based on central laboratory results may need to be revised when utilizing POCT results.
g. Not all methods are appropriate for diagnosis or monitoring treatment. Some POCT may only be adequate for screening with follow up testing required for definitive results (i.e. diabetes can not be diagnosed based on a single glucose test).
h. POCT kits and devices may not be FDA approved for all uses that a similar test in the central laboratory can be used for (e.g. waived PT/INR approved for monitoring Coumadin Warfarin therapy but not for diagnosis or assessment of bleeding diathesis).
i. POCT does not necessarily mean improved patient outcome – POCT only provides faster test results. The entire clinical pathway must be optimized to expedite clinical management based on a faster test result in order to achieve improved outcomes.
j. The required documentation of test results, normal range values, units, operator ID, internal control results, etc. may be haphazard and difficult to standardize.
k. Reagent storage is decentralized and widespread, making management of supplies and monitoring of storage conditions problematic.
l. The significance of an error is not uniform. Producing a false test result at home or in a POL may have less potential for adverse outcome than in an acute care facility where a patient may have a procedure or treatment based on that result (e.g., a false negative pregnancy test followed by a radiology test or a falsely high glucose followed by insulin injection).
m. Interfacing results to the electronic patient record may be more difficult.

History

A. The Past, Present, and Future of POCT

1. In the beginning, all testing was performed near the patient.
    a. As early as 1500 BC urine was noted in relation to diabetic symptoms in Egypt since ants were attracted to the sweetness of urine from diabetics. One of the earliest diagnostic practices was uroscopy, in which urine was visually examined and assessed for sweetness by tasting.
2. Testing moved to central laboratories as hospitals were built (1800-1900's) and testing technologies were developed.
    a. The development of hospitals and specialized care fostered the creation of laboratories, which required the transport of specimens from the patient to a central testing site. The introduction of advanced and automated technologies also encouraged centralization of laboratory testing. Economies of scale, regulations, and specialized technical staff were further incentives to consolidate testing.

3. Shifts from the central laboratory to POCT and steady growth in the type and number of POC tests performed (late 1900's to date) have been stimulated by:
    a. Technological advancements:
        1. Method and operation simplification
        2. Lockouts and failsafe mechanisms
        3. Electronic quality control
        4. Interconnectivity with laboratory and hospital information systems
        5. Portability
    b. Demand for faster turnaround times and testing platforms to facilitate patient care (e.g. ICUs, POLs)
    c. Waived testing designation under CLIA88. See below.
    d. Creation of specialty clinics
    e. Desire for self-testing and patient control
    f. Mergers and reorganizations of healthcare systems, resulting in decreased numbers of central laboratories in the US
    g. Need for simple, robust testing tools in developing countries and other sites, e.g. military or disaster, underserved populations. See previous "Definition of POCT" with the multiple sites using POCT
    h. CLIA88 provided a tremendous impetus for growth in POCT. The history of that important legislation is summarized below

B. The Clinical Laboratory Improvement Amendments of 1988 (CLIA88)

1. Soon after Medicare and Medicaid went into effect in 1965, the United States government became aware of the programs' vulnerability to fraud and abuse. To assure that money was not being siphoned off through overcharging for services and that the quality of services financed with tax dollars was adequate, the federal government established minimum quality requirements for those clinical laboratories that wished to participate in Medicare.
2. Beginning in 1987, a series of newspaper and magazine articles were published on the quality of laboratory testing. Simultaneously, television programs were aired concerning the number of laboratories that were not subject to either federal or state regulations. Congress held hearings in 1988 and heard testimony from "victims" of faulty laboratory testing. Specific concerns were raised about the validity of cholesterol screening and the accuracy of Pap smear results.
3. On October 31, 1988, in response to the congressional hearings, Congress enacted Public Law 100-578, the Clinical Laboratory Improvement Amendments of 1988 or CLIA88, which greatly revised the authority for the regulation of laboratories. It was enacted as a means for the Secretary of Health and Human Services to develop comprehensive quality standards for all laboratory testing. Based on the concept of "site neutrality", CLIA88 was to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. CLIA88 defines a laboratory as <u>any facility that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention and treatment of disease, or for assessment of health</u>. Facilities that do not accept Medicare or Medicaid or accept only cash must also be certified under CLIA88. <u>It is the act of performing a laboratory test that defines the requirement of certification</u> and not if or how the test is paid for. The definition of "laboratory" was also expanded to <u>include any site where clinical laboratory testing occurs.</u> Therefore, sites performing POCT, such as the patient's bedside, a POL, or clinic, also assumed "laboratory" designation, a concept that was not fully appreciated by some clinical providers.
4. CLIA88 also introduced the complexity model for test methods. Three categories of tests were established: waived, moderate complexity (including the subcategory of provider-performed microscopy), and high complexity. The more complicated the test, the more stringent the requirements. While CLIA88 specifies quality standards for personnel, patient test management, proficiency testing (PT), quality control, and quality assurance for moderate and high complexity tests, <u>waived testing requirements are minimal</u>.
    a. **Waived Testing**
        1. Waived tests were defined under CLIA as "…simple laboratory examinations and procedures that are cleared by the Food and Drug Administration (FDA) for home use; employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or pose no reasonable risk of harm to the patient if the test is performed incorrectly."

2. According to CLIA88, to perform waived tests, a laboratory must simply:
    i. Enroll in the CLIA program
    ii. Pay applicable certificate fees biennially
    iii. Follow manufacturers' test instructions for tests that are FDA-approved for waived testing
    iv. Be inspected if complaints or issues arise
3. The original list of waived tests was limited to:
    i. Urine dipstick or tablet testing (bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrites, protein, pH, specific gravity)
    ii. Fecal occult blood testing
    iii. Ovulation tests for luteinizing hormone (LH)
    iv. Urine pregnancy testing
    v. Erythrocyte sedimentation sate (ESR), non automated
    vi. Hemoglobin by copper sulfate
    vii. Blood glucose testing by meters
    viii. Microhematocrit, spun
    ix. (Hemoglobin by a single test device was soon added)
4. The concept of waived testing caused a great deal of controversy…..It was felt that the waived testing category created a dual standard for testing, with some laboratories having higher standards than others. Conceptually, many believed it was not really possible for a procedure to be so simple that the chance for error is negligible, or for a clinically useful test to have a negligible possibility of causing harm. For that reason, accrediting agencies other than the US government, such as the CAP and some states, have imposed stricter requirements on waived testing than are mandated by CLIA88.
5. The numerous comments received about the waived testing category generated concerns both that the criteria were too subjective or too strict. In September 1995 proposed clarification criteria were issued by HHS through the Healthcare Financing Administration (HCFA) and Public Health Services (PHS). These were formally adopted in 1997. Any test already approved by the FDA for home use was considered to be simple and have insignificant risk of error and therefore granted waived status. Tests that were substantially similar to already waived tests were given an expedited review process. New applications for waiver status needed to show performance characteristics that demonstrated the test was simple, easy to perform, and essentially error free. Standard protocols for test evaluation were used to remove the subjectivity in deciding that a test met waived criteria. These new criteria included:
    i. Specimens must be direct, not processed or manipulated
    ii. Quantitative tests must be fully automated
    iii. Qualitative tests are limited to single reagent impregnated devices giving positive or negative results
    iv. Failsafe mechanisms must allow no results outside of the reportable range or when the system malfunctions
    v. No invasive trouble-shooting can be necessary. Electronic or mechanical maintenance must not be required.
    vi. Instructions must be written at a 7th grade level, clearly defining all steps of the process and actions to be taken if quality control or calibrators were out of range
    vii. Operators must follow manufacturers' instructions; if they do not, the system immediately is classified as highly complex with all the strict requirements governing high complexity tests.

6. These new clarified criteria were also meant to ensure that the operator skills required to perform and interpret waived tests were minimized so that non-laboratory personnel could not disrupt the procedure or introduce error. Since waived testing had no personnel requirements, HHS wanted to ensure that POC tests have minimal chance of producing an erroneous result.
7. Because the requirements for waived testing are significantly less stringent than those for non-waived testing (moderate and high complexity testing), implementation of waived tests became attractive to many facilities. Facilities did not need to comply with the detailed CLIA88 requirements that include sections on accreditation, proficiency testing, administration, facilities, quality systems

(covering all phases of testing and encompassing test verification, competency assessment, result reporting, etc), personnel standards, inspections, and enforcement.

8. While POCT is not synonymous with waived testing, in practice most POCT is waived testing. Therefore, the growth of waived testing has resulted in the expansion and development of POCT, in ways not fully anticipated by HHS.
9. Initially, most POCT/waived tests were simple ones that had been performed in the central laboratory or in home or self testing (e.g., urine dipsticks, fingerstick glucose monitoring, pregnancy testing) and were then redeployed as POCT. Soon, however, manufacturers responded to the growing demand for waived tests by developing new test methods, many designed specifically to be used outside of the traditional laboratory setting by non-laboratory personnel (e.g., hemoglobin A1c in diabetes clinics, prothrombin time and INR in coagulation clinics). As the technical expertise needed to perform some of these new test methods decreased, physicians in specialty areas (e.g., coagulation clinics, HIV clinics, dialysis centers) became interested in assuming responsibility (and revenue) for such tests, rather than sending them to a central laboratory. Similarly, simple POCT devices (e.g., INR) allowed patients who desired more responsibility for managing their health to perform self-testing.
10. All these factors have contributed to the steady growth in the type and number of POCT tests performed. In 2010, it was estimated that one billion POCT tests would be performed in US hospitals, and that volume of testing would grow by 12.5% per annum.

Drivers of POCT

1. For the foreseeable future, it is anticipated that the trends described above will continue, driving robust growth in POCT. Specific drivers for adoption of POCT will include changes in the testing itself, and in the clinical, regulatory, and commercial environments.
    a. Changes in POCT methodology
        1. Technical advances will make POCT testing more attractive by making it:
            i. More accurate
            ii. More robust
            iii. Cheaper
            iv. Easier
            v. Better interfaced to computerized patient records
            vi. More inclusive of quality assurance and documentation features
    b. Changes in the clinical environment
        1. Demand for POCT will increase due to:
            i. Economic needs of hospitals for shorter stays and rapid patient turnaround. Test results are needed rapidly not only for reasons of clinical urgency but to ease patient backlog in the emergency department, post anesthesia care unit, or other areas.
            ii. Innovative therapies requiring rapid laboratory feedback
            iii. The critical shortage of qualified medical technologists, which is likely to worsen
            iv. Increasing demand for medical support at diverse sites (e.g., sporting events such as marathons, resorts, cruise ships, schools, camps)
            v. Increasing demand for rapid testing in outpatient settings (e.g., cancer centers for outpatient chemotherapy)
            vi. Increasing demand for self testing in patients' homes
            vii. Underserved populations and underdeveloped regions without the infrastructure power for central laboratory testing
    c. Military applications
        1. The US military system is comprehensively organized into echelons of care, ranging from Echelon 1, the most basic care on the battlefield, to Echelon 5, representing tertiary care at an Army hospital. The system is intended to provide

access to the highest quality care to soldiers, in return for their service, but also to maximize combat effectiveness.

POCT Coordinator Development and Role

1. In order to support or lead an effective POCT program, a pathologist Laboratory Director needs to use all his/her skills as a leader, communicator, and educator. Essential to that function is recruiting, mentoring, and supporting a POCT Coordinator. Below, in the words of an experienced POCT Coordinator and educator, is a discussion of that role.
2. The role of a **POCT Coordinator** is a unique one. Many diverse skills are required for the POCT Coordinator to be successful in his/her role. In selecting and mentoring a POCT Coordinator, the pathologist Laboratory Director should be aware of the variety of additional skills that will be required. The following are some characteristics to look for when selecting such an individual and provide a framework for mentoring emerging laboratory leaders for the challenging role of POCT Coordinator.
    a. The individual should have a history of a strong patient-centered focus and good customer service experience and skills. Since the coordinator acts as a liaison between the central laboratory and the POCT site(s), the individual should be able to collaborate well with non-laboratory personnel to ensure effective testing operations and promote patient-focused care.
    b. A candidate for POCT Coordinator should have exemplary written and oral communication skills. This individual may be called upon to draft policies and procedures, design training and competency modules, communicate with a variety of healthcare professionals regarding POCT regulatory compliance issues and give presentations to POCT personal. This individual should be comfortable in communicating with all levels of healthcare personnel including patient caregivers, administrators, medical directors and other senior leaders.
    c. The POCT Coordinator should be able to work in partnership with the Laboratory Director, respecting the director's responsibilities, keeping the director apprised of developments, but being independent enough to carry out routine functions and also advise the director.
    d. The POCT Coordinator should also be successful in working in and leading teams. Advanced training in process improvement/LEAN/Six Sigma can provide the individual with added tools in facilitating a quality POCT program.
    e. The POCT Coordinator should exhibit creative problem solving and strong facilitation and negotiation skills.

REFERENCES

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