Best Practices for Effective Management of Point of Care Testing

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Abstract

With the recent COVID-19 pandemic, point-of-care testing has gained tremendous attention, particularly in acute care settings. The point-of-care testing landscape is rapidly expanding and being contemplated for any crucial test with a central laboratory turnaround time >25% of the clinical decision time. A typical point-of-care testing program within a large hospital system encompasses a multitude of operators utilizing a wide range of devices across multiple testing sites. Thus, managing a large point-of-care testing network remains a daunting task with challenges related to staffing, standardization, quality management, training and competency assessment, and data management. This review will focus on understanding the general organization as well as the roles and responsibilities of various point-of-care testing stakeholders in addressing these challenges. More importantly, it will discuss the strategies and best practices for effective point-of-care testing management based on consensus recommendations from professional societies as well as our experience at Texas Childrens Hospital.

1. Introduction

Point-of-care testing (POCT) refers to testing conducted at or near the patient's bedside, providing rapid results to aid in immediate patient care management. A typical POCT formulary for a large network may include glucose, hemoglobin A1c, ketones, occult blood, blood gases, electrolytes, creatinine, urea, drugs of abuse, pH, human chorionic gonadotropin (hCG), coagulation and infectious disease testing for influenza, streptococcus, HIV, and mononucleosis (1). POCT devices are incorporated with biosensors, microfluidics and lateral flow immunoassays and are capable of providing both qualitative (e.g., urine drug screen) and quantitative results (e.g., glucometer) (1). A majority of POCT devices fall under the waived complexity category under the US Clinical and Laboratory Improvement Amendments of 1988 (CLIA), and do not require performance verification before patient testing (2). However, certain POCTs, such as blood gas instruments, are classified as moderately complex and require method verification for precision, accuracy, reference range and analytical measurement range before implementation (2).

POCT is performed outside the central laboratory, in settings like emergency rooms, intensive care units, physician's offices, pharmacies, ambulances, and outpatient clinics, by medical staff with minimal training in laboratory testing. Moreover, medical staff are constantly distracted by other tasks like drug administration, patient monitoring and data recording. Hence, major challenges in POCT are related to quality assurance and regulatory compliance. Despite these limitations, the POCT menu continues to expand, particularly post-pandemic, and it is projected that the global market value will exceed $44.6 billion by 2025, with an estimated annual compound growth rate of 9% (2). Undoubtedly, the advantages of swift traversal within the hospital system and circumventing central laboratory testing far outweigh the limitations posed by POCT in clinical decision-making. Managing the POCT program presents unique challenges, as it involves numerous operators utilizing a wide range of devices across multiple sites within the hospital system. Since operators may lack in-depth knowledge regarding troubleshooting laboratory variations and identifying potential sources of errors during the pre-analytical, analytical, and post-analytical phases of testing, it becomes vital to establish a robust organizational support system spearheaded by laboratory medicine professionals (3). This ensures that expertise and guidance are available to address complex issues and optimize the quality and reliability of POCT results.

2. POCT management:

A large POCT network refers to a system of interconnected testing sites within a healthcare organization managed centrally. For example, in our large pediatric institution, organized POCT services are delivered across multiple units spanning various hospitals and specialty care centers situated in nine geographical locations within the Houston area. With the continuous expansion of the POCT catalog, especially with the introduction of novel molecular assays for infectious diseases, it becomes imperative to continually monitor and evaluate POCT policies and procedures. The following sections will explore the challenges associated with managing a multi-center POCT network. Key considerations in areas such as staffing, standardization, quality management, training and competency assessment, data management, and continuing education will be reviewed (Figure 1).

Figure 1: Pinwheel shows key components related to point-of-care testing management.

2.1. Staffing:

An interdisciplinary team with well-defined roles and responsibilities is the key to successful POCT management, particularly in larger networks (4). The key stakeholders of POCT management include the director, manager, co-ordinators, and POCT committee comprising laboratory, administrative and clinical representatives. These levels are dependent on the volume and complexity of testing and the number of testing sites within the healthcare organization. While the POCT director provides expert advice on the overall operations and implementation, the POCT manager and co-ordinators lead the day-to-day activities. The key duties of POCT co-ordinators (POCC) may include training medical staff, installing and validating POCT assays, troubleshooting spurious results and instrument failures, writing procedures, preparing worksheets and logbooks, maintaining and disseminating reagents and test strips to end-users, and conducting audits and competency reviews (5). Hence, POCCs require a wealth of knowledge on clinical workflows, interfaces, test environments, and regulatory requirements to act as technical consultants for medical staff. There are no mandatory federal requirements for certification or a higher degree other than a high school diploma for performing waived testing. However, if the POCC is acting as a technical consultant for non-waived tests the College of American Pathologists (CAP) requirement is to have a Bachelor of Science (BS) in chemical, physical, biological, clinical laboratory science or medical technology and a 2 years experience with POCT. A survey involving 98 POCCs across the US revealed that ~87% are certified in medical laboratory science (5). Medical laboratory scientists with over 3 years of experience in the central laboratory are ideal for the POCC role. Importantly, the number of POCCs in a program should be proportional to the number of testing centers and menus. This is quite challenging due to ongoing staffing shortages, high staff turnover and contract-based staffing, particularly in post-pandemic era healthcare. A recent study has highlighted several strategies, such as improving visibility, promoting diversity and inclusion, and early recruitment and retention of laboratory medicine professionals to overcome this problem (6). Furthermore, clinical collaboration and communication are critical to efficiently managing POCT at multiple sites with limited staff.

2.2. Standardization:

Currently, many POCT platforms are available for any given analyte of interest. For instance, there are 137 FDA-waived POCT assays specifically designed for pregnancy testing using urinary hCG, as reported by the CLIA test complexity database. Each of these assays comes with manufacturer-specific instructions regarding quality control and specimen handling procedures. Consequently, it becomes essential to standardize POCT by utilizing the same assays and instrumentation across all testing sites within a hospital system. The advantages of POCT standardization are manifold (4). First, it simplifies the management process by allowing a single policy to be shared among operators for training and competency purposes. Additionally, it facilitates quick troubleshooting via running parallels for instrument comparisons across different sites. Moreover, it enables monetary savings by cutting down on the vendor fees associated with instrument maintenance and reagent expenses due to increased test volume. Standardization also allows POCCs to maintain loaner devices to be deployed across the hospital system as needed. POCT system selection is another major consideration that requires the evaluation of operational and economic parameters. As per the Association for Diagnostics and Laboratory Medicine guidance document, the key characteristics for review should include device footprint, connectivity, electrical, waste, training and maintenance requirements, implementation and operational cost comparison (4).

2.3. Quality management:

For a large POCT network, having a homogenous quality management system (QMS) is desired. Waived tests are performed according to the manufacturer's instructions provided in the package insert. Moderately complex tests require two levels of quality control each day before patient testing or developing an individualized quality control plan (IQCP) after conducting a risk analysis, particularly for infectious disease and coagulation testing (4). A QMS plan should provide guidelines to conduct: 1. monthly site audits, 2. reporting questionable test results, 3. corrective/preventive actions, 5. proficiency testing, and 6. POCT operator training and competency (7). While conducting monthly site audits, POCCs should assess the internal quality control and patient testing logs, instrument maintenance logs, temperature and humidity logs, proper storage and expiry of the regents and test strips, and the testing area. Deficiencies from the site audit should be documented and communicated to the testing unit leadership for corrective or preventive measures, which may include retraining, direct observation, and removal of testing privileges (7). Moreover, it is crucial to review risk management strategies such as error reporting systems, root cause analysis, and corrective actions in a center or location-specific manner, considering the distinctive challenges associated with each particular center. Well-established tools such as Ishikawa diagrams and failure modes and effect analysis (FMEA) can be adapted in this context (8). Quality Indicators (QI) are a set of benchmarks that form an integral part of QMS for continuous quality improvement. Currently, 57 QIs to evaluate the key processes within pre-analytical, analytical and post-analytical phases are recommended for central laboratory testing by the International Federation of Clinical Chemistry and Laboratory Medicine (9). High variability in the testing environment is a major barrier to developing POCT-specific QIs. Based on a national survey of quality practices across 12 large POCT networks within 8 Canadian provinces, the following QIs were evaluated: patient identification, instrument lockouts, sample collection errors, failed quality control, transcription errors, result amendment, turnaround times, training and competency

documentation, and instrument errors (10). POCT center-specific performance assessment of these QIs is necessary for a large POCT network. Such an approach is exemplified by a recent study that performed a process mapping and risk assessment to establish QIs for point-of-care glucose testing (11). Proficiency testing (PT) facilitates quality assessment of the total testing process, including pre-analytical, analytical, and post-analytical phases, hence serving as a surrogate marker for POCT performance. Although federal guidelines (CLIA) do not require PT for waived tests, POCT centers accreditated by CAP should enroll in Health and Human Services (HHS)-approved external PT programs or PT verification programs for regulated analytes (4). Alternatively, PT assessment by split sample testing should be considered at least semi-annually. PT samples should be processed in the same manner as patient samples by a blind operator, and documentation should be retained for a period of 2 years. All acceptable PT results should be reviewed for bias and trends, whereas unacceptable PT results (score <80%) requires investigation to identify sources of error for corrective actions (12). A POCT site-specific manager or educator serves as a liaison and delegates the activities like scheduling and submitting PT results. Furthermore, it is recommended to distribute PT, and quality cross-checks to engage staff from all shifts and departments performing POCT.

2.4 Training and competency assessment:

POCT operators originate from diverse educational backgrounds depending on the testing site, such as nursing, pharmacy, emergency medical technicians and medical assistants. Hence, all qualified POCT users must complete comprehensive training, orientation and competency assessment of each test method prior to patient testing. Online training modules should cover theoretical aspects of test methods, instrument maintenance, calibration, performing internal quality control, patient safety, sample interferences and results reporting. These operators should also undergo in-unit training and competency assessment once every year (12). Since involving every operator in this process is cumbersome, it is crucial to designate one superuser for every ten operators in the testing unit who is knowledgeable about quality control, quality assurance and safety regulations. Additionally, these superusers serve as the primary contact for communication between medical staff and POCT leadership.

POCT competency assessment essentially involves 6 elements as per the CAP checklist: 1. direct observation of the routine patient testing, including patient identification and preparation, and specimen collection, handling, processing and testing, 2. recording and reporting of test results, including critical results, 3. review of quality control records, proficiency testing results, and preventive maintenance records, 4. direct observation of the performance of instrument maintenance and function checks, 5. assessment of test performance through testing previously analyzed specimens like internal blind testing samples or external proficiency testing samples, and 6. evaluation of problem-solving skills (12). For a large POCT network, an online-based learning management system (LMS) may be utilized for the electronic recording of training and competency for each operator.

2.5. Data management:

Poor connectivity is a major barrier to POCT adoption, particularly in remote subspecialty care centers within a large hospital system. Currently, not all POCT devices are interfaced with patient electronic medical records, requiring manual entry of the results by the medical staff. This triggers errors, delays and duplicate testing, further increasing the costs. It is crucial for POCT manufacturers to follow guidelines from the Clinical and Laboratory Standards Institute (POCT01) that enable easy information exchange between POCT devices, electronic medical records, and laboratory information systems (13). Nowadays, POCT middleware providers such as TELCOR are widely used among large hospital systems due to the convenience of data integration, data validation, result routing, and rules or alert set-up. Data management functionalities offered by these middlewares improve quality by preventing untrained operators from accessing the device. This is achieved by mandating the entry of a valid operator identification number before initiating any testing. Additionally, data management lockouts ensure that regular quality control is conducted and prohibit patient testing if quality control measures have not been performed or if the controls exceed an acceptable target range. By implementing these POCT data management strategies, the likelihood of incorrect results reporting from common operational mistakes is significantly reduced (14).

2.6. Continuing education:

A plethora of educational opportunities exist to stay abreast of the evolving technological and regulatory landscape of POCT. POCCs are encouraged to enroll in the point-of-care specialist certification program offered by the Critical and POCT (CPOCT) division of the Association for Diagnostics and Laboratory Medicine. The online course comprises eight learning modules that encompass a range of topics such as instrument selection and validation, quality management, regulations, policies and procedures, connectivity and information technology, education and training, administration, and communication (15). Individuals successfully finishing this program are credentialed as Certified Point-of-Care Testing Professionals (CPPs). More than 1733 laboratory professionals currently hold this certification. However, this involves an enrollment fee. There are several free resources for continuing education credits in POCT. Some of the examples include a one-hour on-demand course offered by the Centers for Disease Control and Prevention (CDC) on CLIA-waived testing requirements, a youtube channel hosted by POCT Center for Teaching and Research at the University of California Davis and the webinars offered by the Whitehat Communications (16). POCT leaders should strive to incorporate these materials and host case conferences as a part of medical staff training and continuing education.

3. Conclusions

In a nutshell, managing a large POCT network requires a multidimensional approach that addresses challenges related to staffing, standardization, quality management, training and competency assessment, data management, and continuing education. As reviewed by our group previously (17), by adhering to evidence-based guidelines and recommendations put forth by professional societies such as the Association for Diagnostics and Laboratory Medicine and the International Federation of Clinical Chemistry and Laboratory Medicine, healthcare organizations can navigate these challenges successfully. Delineation of POCT responsibilities among various stakeholders, such as POCT leadership (director, manager, and test site leaders), POCCs and POCT operators, is key to a successful POCT program. By establishing a robust organizational support system and implementing effective strategies, hospitals can optimize the quality, reliability, and efficiency of their POCT programs, ultimately benefiting patient care and outcomes.

Declarations of interest

None.

CRediT author statement

Anil K Chokkalla: Conceptualization, Investigation, Writing - Original Draft. Brandy Reico: Conceptualization, Investigation, Writing – Review & Editing. Sridevi Devaraj: Conceptualization, Investigation, Writing – Review & Editing, Supervision.

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