AACC ACADEMY

AACC Guidance Document on
Management of Point-of-Care Testing

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INTRODUCTION

The American Association for Clinical Chemistry (AACC) Academy (formerly known as the National Academy of Clinical Biochemistry, NACB) formed a committee of experts on point-of-care testing (POCT) to revise the Laboratory Medicine Practice Guidelines (LMPG) Evidence-Based Practice for Point-of-Care Testing published in 2006 (1, 2). The committee noted several areas of the previous guideline where there have been few additional publications over the past decade, such as transcutaneous bilirubin, intraoperative parathyroid hormone, and pH testing; however, most areas in the previous guidelines have several recent publications including cardiac markers, coagulation, critical care, diabetes, drugs and ethanol, infectious disease, renal function, and reproductive testing. Many of these areas have guidelines that are under revision by other organizations. Tackling all areas needing revision would greatly delay publication of the revised guidelines; hence the committee members felt that the highest priority for revision should address the "management of POCT."

POCT is a now proven approach that can provide faster turnaround (TAT) of laboratory test results. As manufacturers continue to introduce new POCT technologies, POCT is increasing in popularity, breadth of testing, and in the diversity of available clinical applications. POCT is currently routine in all hospitals and has become the standard for patient care in a variety of other health care settings. Therefore, this guideline revision will not focus on the various ways that POCT is utilized to support healthcare, nor focus on proving the value of POCT. Instead this guideline will focus on how clinicians can get the most efficacy and highest quality results from implementing best practices for POCT. A quality assurance program is vital to managing errors and the reliability of POCT results, and the intent of this guideline revision is not to debate the value or need for a quality management program. Instead, this revision will provide an update on the latest peer literature since publication of the previous guideline and focus on several key aspects of POCT process and patient outcomes such as:

- What is the value of an interdisciplinary committee to oversee POCT?
- Does education improve POCT performance?
- What is the optimal staffing model for POCT?
- Do proficiency testing (PT)/external quality assessment (EQA) programs improve POCT performance and patient outcomes?
- Does data management improve POCT outcomes?
- How should staff select POCT devices?
- How does POCT improve process?

Most importantly, this revision will review the current literature and provide guidance to the laboratory, to clinicians, and to operators in how to best adopt POCT in their setting to optimize patient care.

INTERDISCIPLINARY COMMITTEE

Does an interdisciplinary committee improve the quality of POCT?

We consider that an interdisciplinary or multidisciplinary committee is essential for a successful POCT program. POCT operators and clinicians are outside of laboratory medicine and most of them lack medical laboratory training but can contribute expertise and experience in other clinical areas and/or administrative and patient care duties. Committee participation from other disciplines is valuable and should be invited under the leadership of laboratory medicine. We recommend the oversight of an interdisciplinary committee for all aspects of a high quality POCT program.

In its guideline of essential tools for implementation and management of a point-of-care testing program, the Clinical and Laboratory Standards Institute (CLSI) recommends multidisciplinary representation from performing sites to serve on the POCT committee (3). This multidisciplinary approach contributes to continuous quality improvement of POCT in a large health care system (4), and has been recommended by expert opinion (5, 6). The POCT Committee gives consideration to the appropriateness of POCT for specific sites, tests and patients, the selection and evaluation of instruments and procedures, user training, quality assurance, cost/benefit analysis, and risk management. This committee ensures that all local, state/provincial, and national regulatory requirements are met. This committee promotes communication and cooperation between different professional groups involved in the POCT program; reviews and approves protocols of POCT procedures; ensures that POCT policies are available to the users; ensures that relevant policies and procedures are followed; monitors adverse incidents involving POCT devices; and has the authority to withdraw a POCT device if the agreed standards of operation are not met **(Table 1)**. The membership of the interdisciplinary POCT committee should include representation from all the stakeholders, including but may not be limited to the following: director of POCT, POCT manager, POCT coordinator, physicians (typically from emergency medicine, critical care medicine, and/or family medicine), nurses, nurse practitioners, nurse manager, infection prevention/control/public health, supply chain, risk management consultant, information technology, and clinical/biomedical engineering. Consideration should be given to having ad hoc members contribute when there is a need for additional subject matter expertise such as the laboratory; chemistry, coagulation, hematology, or microbiology, depending on the specific test request discussed, as well as clinicians from the site implementing the test. The committee should meet regularly and report to hospital leadership.

The effect of an interdisciplinary committee in POCT performance has been studied over an 18-month period in a children's

hospital in Italy. Prior to implementation of a POCT committee, 800 samples were examined and 64 (8.0%) were identified as preanalytical errors. After POCT committee implementation, only 17 (2.1%) of 800 samples were identified with preanalytical errors (7). There was also significant improvement in external quality assurance/proficiency test for POCT after implementation of an interdisciplinary team; the standard deviation went from greater than 2–3 standard deviation indexes to one standard deviation index for complete blood counts and blood gas/electrolytes/metabolites (7).

TABLE 1. Interdisciplinary POCT committee responsibilities.

- Considers the appropriateness of POCT for specific sites, tests, and patients
- Selects and evaluates instruments and procedures
- Oversees user training
- Ensures quality assurance measures
- Conducts cost/benefit analysis
- Utilizes risk management
- Ensures all local, provincial/state, and national regulatory requirements are met
- Promotes communication and cooperation between different professional groups involved in the POCT program
- Ensures that all POCT policies are available to the users
- Monitors adverse incidents involving POCT devices
- Reviews and approves protocols for all POCT procedures to ensure they include but are not limited to, the following:
  - critical values
  - internal quality control
  - external quality control
  - repeat testing criteria
  - procedures for maintenance and repairs
  - training and competency

Does an interdisciplinary committee improve patient outcomes?

There is limited evidence that an interdisciplinary committee leads to improved patient outcomes. However, the experience and knowledge from other disciplines helps the laboratory implement and manage POCT to meet accreditation requirements and in turn provide better service to its' clients.

An interdisciplinary committee helps laboratory medicine to better understand clinical needs, and this forms the basis of a quality POCT program. For example, a recent survey of 42 family physicians, resident family physicians, and nurse practitioners in the United States identified hemoglobin A1c for diabetes and HIV, and gonococcus/chlamydia for sexually transmitted infections (STIs) as the most desired POCTs (8). Respiratory tract infections (RTIs) are also potential priority areas for POCTs (8). Professionals in laboratory medicine on one hand are well aware of the limitations of current hemoglobin A1c POCT meters compared with the laboratory measurements (9, 10), but on the other hand may not appreciate the POCT needs for STIs, which is important for under-served populations such as LGBT groups, particularly in the inner cities. The difficulty of follow-up laboratory testing in these populations makes POCT vital for diagnosis at the first visit. An interdisciplinary committee provides a good platform for professional dialogue with colleagues in other disciplines. These conversations can coordinate POCT technology reality and future research and development with clinical needs and expectations.

The impact of an interdisciplinary/multidisciplinary team including endocrinologists, intensivists, hospitalists, nurse practitioners, pharmacists, dietitians, and laboratory medicine specialists, has been investigated on inpatient glucose control (11). This committee meets monthly to promote the correct implementation of protocols for management of hyperglycemia and hypoglycemia, educate physicians and nurses, promote clinical decision aids, and input performance measures for quality improvement. While no significant changes occurred in hypoglycemic parameters, hyperglycemic events decreased significantly (11). These data support that an interdisciplinary POCT committee is associated with improved clinical patient outcomes as demonstrated by continued reduction in hyperglycemic events, an independent risk factor of increased inpatient morbidity and mortality.

EDUCATION

Does operator education (training and ongoing competency) improve test performance?

Multiple studies have concluded a single training event is not sufficient, and that ongoing competency, training, and support from the laboratory are needed to maintain improved test performance (12–17). The College of American Pathologists Q-Probes Study on bedside glucose monitoring found that institutions with a policy for scheduled performance reviews of operator or repeat/ongoing training had performed better than their counterparts (12, 13). We therefore recommend that POCT programs maintain on-going training and support for the clinical staff in conjunction with consistent monitoring of test performance.

One of the challenges of POCT is both ensuring and maintaining test accuracy and reproducibility (i.e., performance), given the sizeable number of operators and instruments (18–20). Intuitively, it makes sense that an understanding of (i) how to operate the POCT device, (ii) troubleshooting instrument errors, and (iii) understanding the importance of using QC material and (iv) proper handling and storage of quality control material and pa-

tient samples, would lead to improved test performance. Despite the growing role of POCT, there have been only a few studies that have been able to assess the impact of operator training and ongoing competency on test performance (12, 21–23); however, there are several studies that assess POCT test performance via multiple simultaneous interventions, of which operator education and training is one component (14, 16, 17, 24).

A recent study by Huang et al. examined the effects of user competency on the analytical performance of glucose meters in a hospital setting (21). In this study, user competency was evaluated by the number of QC tests performed by each operator, and the imprecision associated with the measurements was a surrogate marker of analytical performance. Approximately 59,000 QC points were collected at each level over 20 glucose meters, and operators performed between 1 and 242 tests (21). They observed that users who performed fewer QC tests generated results with greater imprecision, subsequently concluding that user competency was a significant factor affecting analytical performance (21).

Another study investigated the analytical bias between 4 neonatal POCT glucose measurements obtained in a neonatal intensive care unit (NICU) compared to measurements obtained in the central laboratory on the same type of glucose meter (0.28 mmol/L) (22). Four operators performed testing in the NICU: operator A performed nearly half the testing with a mean difference of 0.11 mmol/L; whereas the other three operators (B, C, D) had a mean difference of 0.52 mmol/L. This study demonstrated that the observed bias observed in the NICU could be attributed to operator error (22).

A systemic review with the aim of describing the impact of training nurses in POCT concluded that training improved nurses' competence (15). In one study, most clinical nurses reported that they felt the training they received improved the quality of glucose measurements and their understanding of the significance of QC. Precision of glucose measurements run by the two nursing units (2.4% and 3.7%) and laboratory (2.9%) were equivalent and improved throughout the follow-up period (unit, 2.4%–2.8%, laboratory, 2.6%) (16). The same group performed a follow-up study comparing trained and untrained nurses using the same type of instrument and same lot of glucose strips. The results demonstrated that trained nurses had lower CV% (4.5%) than nurses who had not gone through the training (6.0%). One caveat is that the trained and untrained nurses were located at different hospital sites (23).

The Quality Assurance of Aboriginal Medical Services (QAAMS) was designed to initially support POCT of HbA1C in 45 sites across Australia (14). Several years later, QAAMS expanded to support urine albumin-creatinine ratio (UACR) and HbA1C testing to 100 sites (24). This included comprehensive programs in education, training, quality assurance, and ongoing management support. Every 6 months, 12 quality assurance specimens were analyzed for precision and accuracy to identify analytical issues; support and resources were provided to rectify analytical problems. This resulted in performance that equaled the central laboratory at the 2-year mark; however, there was no statistical difference between the two since the program began. For both HbA1C and UACR the median CV% of testing at the QAAMS POCT sites steadily improved (14, 24).

A comparison of glucose meter performance before and after an educational intervention found that the average total error decreased (17). Before the intervention, some meters had a bias of >20%, with the majority of instruments showing a bias of >10% for both the low and high controls compared to the reference method. After the intervention, the average total error for all meters fell to 6.3% (range 5.5%–7.6%) for the low control and 4.8% (4.1%–6.5%) for the high control (17). The intervention included a 2-hour seminar, in-person training by the laboratory point-of-care (POC) manager, and ongoing communication between clinical services and the POC manager. One caveat to this study is that before the educational intervention the meters used were different brands, different ages, and had no quality management. The educational intervention coincided with the installation of new POCT glucose meters that appear to be by the same manufacturer and establishment of a quality control program (17).

STAFF

What is the optimal staffing for POCT?

Staffing for a POCT program can be broadly divided into administrative/managerial staffing, i.e., those individuals responsible for providing the regulatory, technical, quality, and clinical oversight of a POC program and those individuals responsible for performing the POC test, typically referred to as "operators." Publications are lacking that explicitly describe the ideal amount of administrative staffing and operator staffing needed for a POCT program.

A 2014 survey conducted by the Canadian Society of Clinical Chemistry POCT interest group indicated more than half of respondents cited a lack of staff to support their POC program as their number one problem (25). Questions remain regarding the optimal number of individuals needed to manage a POCT program with respect to quality results and patient outcomes. An assessment of the current state of POC staffing is needed to establish a baseline. Future studies are required to identify the ideal number of POC management personnel needed relative to the scope of the POCT program (POC test menu, number of devices, number of operators).

What types of personnel are needed for a quality POCT program?

Ideally oversight of a POCT program should be provided by individuals with experience in clinical laboratory sci-

ences and quality management. Numerous publications describe staffing approaches in the establishment of a POCT or program (3, 5, 26–31). Collectively these publications highlight the relative roles and responsibilities of three different groups: POCT directors, POC coordinators, and POC operators.

See **Table 2** for the typical responsibilities associated with oversight of a POCT program.

TABLE 2. Responsibilities of POC administration.

- Quality management (e.g., identification and monitoring of quality metrics)
- Compliance with regulatory and accreditation standards
- Technical troubleshooting
- Analytical method evaluations
- Operator training and competency assessment
- Evaluation of request for new POCT
- Review and approval of policies and procedures related to POCT

POCT directors

Ultimate oversight of a POC program rests with the "Director of POCT." Directors of POCT must meet the CLIA requirements for Technical and/or Clinical Consultant. In some instances, the Director of POC is the same individual who holds the CLIA license required to perform POCT. Based on a review of AACC membership, directors of POCT typically possess a doctorate (PhD) in the biological or physical sciences or an MD/DO and are certified by an appropriate board such as the American Board of Clinical Chemistry or the American Board of Pathology.

POC coordinator

Essential to the successful execution of a POCT program is the identification of one or more POC coordinators (depending on volume and scope of the POCT program). These individuals should have a background in clinical laboratory science and experience in POCT. In addition, strong interpersonal skills are required as POCCs serve as the primary interface between the central lab and the clinical testing personnel (i.e., operators). The responsibilities of the POCC are listed in **Table 3** (5, 30).

POC operators

Operators responsible for generating results from POCT devices are usually non-laboratory trained personnel with backgrounds in various disciplines, such as but not limited to nursing, pharmacy, medical assistants, and emergency medicine services (e.g., Emergency Medical Technicians). The ideal number of operators needed to ensure consistent quality results at the POC is unknown as this has not been formally studied. However, it is the recommendation of this expert panel that the number of operators needed should be proportional to the volume of POC performed to ensure that each operator maintains competency via experience with the device.

TABLE 3. Responsibilities of the POC coordinator.

- Supervision and management of the POCT program
- Quality management (e.g., identification and monitoring of quality metrics)
- Compliance with regulatory and accreditation standards
- Ensuring compliance with the policies and procedures
- Operator training and competency assessment
- Surveillance of the entire testing process
- Quality control and quality assurance procedures
- Enrollment and participation in approved proficiency testing
- Technical consultant responsibilities
- Resolving technical problems—technical troubleshooting

What benchmarks of quality should be monitored to judge the ongoing success/failure of a program after implementation of POCT?

Each program should track specific POCT indicators that can identify areas for improvement. Negative performance trends can provide documentation to discontinue POCT in clinical areas, while positive trends can demonstrate program improvement over time.

POCT programs should define key performance indicators that are important aspects of quality for the institution. Ongoing monitoring of quality indicators can be used to identify opportunities for improvement, need for staff intervention, and evidence for removal of POCT, as well as documentation of program success and benefits to patient care. Data from performance trends can be reported to laboratory administration and hospital quality department to document the effectiveness of the POCT program. Compliance indicators such as resulting manual tests to the patient medical record, troubleshooting QC failures, and re-dating open expiration of tests and controls are some benchmarks that can be monitored (4, 32, 33). Indicators of staff training/competency such as correct patient identification, documenting QC, selecting the appropriate level of QC, and reporting critical values are also popular monitors, as well as device failures requiring repairs or replacement (34, 35). Common sources of error make good indicators to monitor like clerical errors, incorrect interpretation of results, sample mix-ups, and failure to document temperatures (36). POCT programs may also want to monitor program effectiveness and operations such as result turnaround time, test volume, costs, specimen rejection rates (result error flags), and

clinician/patient satisfaction (37). The specific indicators that a program chooses to monitor will depend on the institutional focus and may change over time as new goals and directions are developed for both POCT and the institution. **Table 4** lists some common performance indicators that are monitored by POCT programs.

TABLE 4. POCT program performance indicators.
This is a partial list of some common performance indicators or benchmarks of quality that can be monitored by POCT programs.

COMMON POCT PERFORMANCE INDICATORS
Preanalytic
• Correct patient identification
• Hemolysis rates
• Temperature monitoring
• Redating open expiration dates of kits and controls
• Device maintenance and cleaning/disinfection
Analytic
• Correct test interpretation
• Error flags with result
• Troubleshooting QC failures
• Selecting appropriate level of QC
• Staff ratio of patient to QC test volume
• Successful proficiency testing
Postanalytic
• Documenting results in medical record
• Reporting critical values
• Clerical error—result transposition/transcription error
• Documenting QC
• Test turnaround time
• Test volume
• Cost
• Physician/patient satisfaction

PT/EQA PROGRAMS

Does participation in proficiency testing (PT)/external quality assessment (EQA) improve the quality of POCT performance?

Multiple studies document improved performance and quality of POCT when laboratories participate in PT/EQA programs, incorporate the PT results into a total quality improvement program, and act on the trends to identify and correct their mistakes. We recommend that all laboratories performing POCT participate in a PT/EQA program for each test that they perform.

Proficiency testing (PT)/external quality assessment (EQA) programs challenge a laboratory with a set of samples mailed periodically throughout the year. Laboratories analyze the samples, as they would patient samples, and return test results for grading and comparison to peer laboratories performing the same test and methodologies. PT/EQA documents that a laboratory can get similar results as their peers in the hands of their own operators. This validation is especially important for POCT sites where multiple operators with varying levels of education and experience are performing POCT analysis. Beyond operator technique, PT/EQA also verifies that the test kits have been stored appropriately, reagents are viable for testing, POCT devices are functioning, and staff are appropriately timing and interpreting test results. The advantages of PT/EQA are not insignificant considering the thousands of operators, hundreds of devices, and multiple locations involved in POCT within a healthcare institution.

PT/EQA is a surrogate marker for POCT performance. Successful PT results assume that patient test results will be successful, although the technique for analyzing PT is often different than collecting and analyzing a patient sample. Proficiency samples are frequently packaged in vials or glass ampules. Some are lyophilized and require reconstitution and accurate dilution before analysis, while others require thawing and calibration to room temperature. Respiratory and rapid streptococci A sample proficiency may contain swabs that require manipulation prior to testing. PT/EQA samples are preserved for stability due to the need to store and send samples to multiple sites. This preservation creates matrix effects that contribute to method biases between different POCT devices or methodologies, and this challenges manufacturers to create samples that are stable under variable shipping conditions for reasonable periods of time. This matrix effect forces manufacturers to create different PT samples for different POCT devices (38). Due to potential issues with commutability, PT cannot be used to compare differences in test performance on different devices, however PT/EQA for POCT is still useful for judging agreement between laboratories using the same manufacturer and device.

Many studies have documented improvements in POCT performance over time when laboratories participate in PT/EQA programs. In a Norwegian study of C-reactive protein (CRP), glucose, and hemoglobin, the results from 19 surveys between 2006 and 2015 showed the percentage of participants exhibiting good performance increased from 73% to 90% for CRP (as judged by +/- 3SD from CRP median), 69% to 83% for glucose (+/- 2 mg/dL or 5% from glucose target), and 88% to 94% for hemoglobin (+/- 0.1 g/dL or 3% for hemoglobin) (39). Interlaboratory EQA samples for hemoglobin show good precision (variation ranging from 0.6%–4.1%), close agreement between sites, and no difference in precision or bias between hemoglobin measurement on blood gas instrumentation located inside or outside the central laboratory (40). For prothrombin time/international normal-

ized ratio (PT/INR) over a series of 4 surveys at up to 20 sites, 54% of sites had every result within consensus (<15% from peer median), 38% had only a single PT/INR >15% from median, two sites had 3 of 4 surveys with >15% outliers, and no sites had all 4 surveys with result discrepancies, suggesting that those sites that had discrepant results were able to correct the problem and were subsequently able to obtain PT/INRs which were similar to the other sites (41). For urine albumin, continuous participation in an EQA program improved the performance of quantitative urinalysis at general practitioner offices. The number of years that the physician office participated in EQA was inversely related to the percentage of poor results for quantitative instruments, and after 2003, the percentage with assessments of very good or good results increased then stabilized at 75%–90% (42). Physician office laboratories and small hospitals improved performance in the CAP Excel Surveys for chemistry, hematology, immunology, and blood bank from 1987 to 1993 (43). Error rates with the CAP Excel program continued to decline over time, suggesting that the improvement was more than simply learning tasks specific to performing PT (such as performing dilutions, reading forms, and mastering data entry) (43). When frequent hemoglobin A1C (HbA1c) EQA schemes were organized, an overall improvement was observed in the precision for all manufacturer devices (44). In the Australian Aboriginal Community Controlled Health Services study, the performance of HbA1c improved over 3.5 years to laboratory equivalence with a median imprecision (CV%) of 3.8% over the last 5 cycles of the study (14, 45). Accuracy of HbA1c has also improved over the past 20 years due to efforts to standardize the measurements by manufacturers in relation to their device performance on PT/EQA programs (46). Performance on PT/EQA surveys have also led a manufacturer to make device changes that improved the performance of their product for total cholesterol, HDL cholesterol and triglycerides (47). PT/EQA programs have also been proposed to improve the quality of patient self-testing. The percentage of poor results among diabetic patients (>10% from target) decreased significantly from 11.2% to 1.9% over 3 years of patients participating in an EQA program (48), and EQA has been proposed as a means of documenting patient self-testing PT/INR result agreement with those results obtained by professionals (49). Participating in a PT/EQA program can thus improve the quality of a variety of POCT methods by increasing precision, enhancing accuracy, decreasing the number of errors or unsuccessful challenges, and documenting result agreement with peers.

Several factors impact laboratory performance on PT/EQA surveys. A systematic review of the literature between 1945 and January 2017 concluded that adoption of quality management, including performance of internal quality controls and participation in an EQA program, with support of laboratory medicine professionals, improves the quality of results produced (45). EQA does not itself improve quality; however, EQA is an excellent system to monitor quality and to identify areas of operation that need closer attention (i.e., steps in the process that need to be improved) (50). Unacceptable results by a PT provider is an unexpected outcome for a laboratory. In response, the laboratory should investigate the causes of the unsuccessful PT challenge and correct the procedure that led to PT failures to reduce or eliminate the possibility of recurrence (51). Most PT failures for chemistry and blood gas analysis were found to be related to technical, equipment failure, or methodological errors in the laboratory, and were not caused by performance or manipulation of the PT sample itself (51). Another study with hematology and microbiology testing found the top three reasons for PT failure were morphologic identification errors (microscopic recognition of cellular forms), specimen problems, and laboratory technical problems (52). Individual analyte PT failure is a common event in clinical chemistry and blood gas laboratories, but failures in successive or alternate events tend to be rare and point to areas of the laboratory in need of attention (53). In a CAP Q-Probes Study, the most frequent reasons for PT failure were laboratory methodologic, technical or clerical. Analysis of common failures suggest that investigation of the pathway for testing could reduce unexplained failures and correct sources for the failure (53).

Does the number of tests performed by an operator improve performance on PT/EQA?

While no studies have examined the number of tests performed by an operator as a factor for successful POCT PT performance, there are publications that indicate laboratories performing more than 10 tests a week, or greater than 100 tests per month, perform better on PT surveys and have fewer failures. We recommend that sites performing at least 10 tests a week or greater than 100 tests per month enroll in PT/EQA programs to monitor their performance and those performing POCT less frequently reconsider the clinical need for POCT at that location.

EQA is an important part of a quality improvement system and is used to monitor the participant performance and to assess the methods used (39). Independent factors associated with good performance include the type of instrument, the number of times the laboratory has analyzed EQA, performing internal QC weekly, performing 10 or more tests weekly, and having laboratory-qualified personnel perform the tests (39). Choice of glucose meter was found to be the most important variable required for good EQA performance (54). Success rates were higher for glucose EQA in the central laboratory compared to POCT. On average, 1%–2% of participants failed in the central lab, compared to 9%–10% for POCT EQA, and the central 95% of all glucose measurements in a central lab deviated less than 10% from the assigned target, whereas POCT central 95% of results exceeded 15% deviation from the target value (54). For physician office laboratories us-

ing a bench-top chemistry analyzer, those laboratories performing fewer than 100 tests per month appear to be at higher risk of failing PT requirements (55). Instrument-specific training by the manufacturer stresses quality control and quality assurance protocols and was the most effective predictor of acceptable PT performance for a benchtop chemistry analyzer, even more than professional background (55).

Other studies have shown that laboratory personnel perform better than nursing staff with POCT group A streptococcal antigen testing (56). Hospitals and independent laboratories have fewer PT failures than all other testing sites (57). This may be related to laboratory staff having more experience with PT/EQA compared to clinical staff, due to the CLIA requirements for enrollment of all CLIA moderate and high complexity test analytes in a PT/EQA program, as well as clinical personnel realizing the benefits of PT/EQA, since most physician offices perform only CLIA waived testing that does not require PT/EQA enrollment. Indeed, laboratories with more experience participating in PT have fewer failures (43), and laboratories that participate in multiple surveys, such as the CAP linearity (LN) survey, perform better on PT surveys (58). Failures noted on the linearity survey forewarn of linear range and calibration problems before they are experienced with PT failures, allowing time to make appropriate corrections before the next PT challenge (58). The intent of PT/EQA programs is to function as a component of total quality control, as a vehicle for self-improvement, as a mechanism for continuing education, and as fulfillment of regulatory requirements (59). When laboratories take note of their PT failures to determine root causes and take appropriate corrective actions, the performance of the laboratory can improve; however, some PT/EQA programs have noted laboratories that fail to improve over time (60). The CAP EXCEL Throat Culture Module designed for small hospitals, clinics, and physician office laboratories provides feedback on performance relative to peers and an educational discussion analyzing performance, suggesting best practices to the participants with each cycle of testing. Despite this consistent feedback, there was no significant change in participant performance throughout the study period in 1996–2001 (60). This suggests that current utilization of PT results in laboratory improvement programs is suboptimal for throat culture in these small laboratories and physician offices (60). In summary, many factors contribute to successful PT performance; the device, the operator and their experience and training, quality management of POCT (performance of at least weekly quality control), and incorporating PT/EQA into a total laboratory quality assurance program to learn from PT failures and act to change policies that reduce the possibility of errors in the future.

Does participation in a PT/EQA program improve patient outcomes?

There is only indirect evidence that participation in PT/EQA can lead to improved patient outcomes. However, the experience gained by participation in PT/EQA programs enhances staff proficiency with the same techniques that are used for patient testing using POCT devices. Participation in PT/EQA is therefore recommended for all tests and locations where POCT is conducted, even for CLIA waived tests.

The improvement in performance of PT scores over time indicates that staff are becoming more proficient at the techniques required to analyze PT samples, such as sample handling, sample application, operation of the device, timing, interpretation, and recording of the POCT results. Other than the unique patient preparation and handling requirements, the same techniques are required to analyze patient samples with POCT. So, indirectly, more experience with POCT and PT sample handling may enhance the performance of patient testing. Evaluation of PT deficiencies offers the opportunity to enhance overall POCT quality by examining and correcting POCT practices. The added benefit of successful PT/EQA indicates that sites can obtain results comparable to others performing the same test and provides reassurance to the quality of patient testing performed at that location. The minimal expense and benefits obtained from PT/EQA outweigh the resources required to analyze PT samples, even for CLIA waived tests where PT/EQA is not mandated by regulations. Participation in PT/EQA is therefore recommended for all tests and locations where POCT is conducted.

DATA MANAGEMENT

Does data management improve the quality and management of POCT results?

Interfacing, connectivity, and data management are essential components of quality assurance for POCT. Data management ensures the capture and documentation of all patient and control results, with fewer manual transcription errors. It also automates billing. Less staff resources are needed to review results compared to manual logs. Data management and computerization are recommended for all POCT devices.

A volume of data is generated by POCT devices. Patient results must be recorded in the medical record and associated with a physician order for billing and insurance compliance. Operators must be trained and have regular competency checks. Instrument performance must be verified before use in patient care. Ongoing device maintenance and cleanings must be documented. Controls should be performed as recommended by the manufacturer and linked to the specific device, data, and time for regulatory compliance. Management of data is thus an integral part of the delivery of POCT.

Many POCT devices are visually interpreted test kits that still

require manual documentation. Institutions can have dozens of sites with hundreds of devices and thousands of operators to manage (33, 61). To review quality control records from hundreds of devices manually is a formidable task, let alone generating control means and standard deviations by hand to look for trends. Ensuring that control failures are investigated and corrected prior to patient testing is also challenging with an entirely manual system. For POCT, there are generally insufficient staff to review the volume of data generated by POCT devices adequately and to ensure that thousands of patient results are correctly recorded in the patient's medical record (33, 61). Manual POCT results may not get documented, as this is an added step, which presents a risk that clinical staff may act based on a result that is never recorded in the patient's chart. Manual results also pose a risk for transcription errors and duplicate charting.

In response, manufacturers have developed POCT devices with data storage and computerized functionality. These instrumented devices can capture a result at the time of testing and link that result to the device serial number, date, time, operator, and the quality control analyzed on that device. This ensures that all results, including failed as well as successful QC and repeated patient tests, are documented. The control and patient results can be transferred automatically to a data management system and ultimately the patient's records in a laboratory or hospital information system (33, 61). Prior to the development of computerized POCT devices, less than 10% of POCT was managed by the central laboratory computers, hence critically important results were not found in the patient's electronic medical record (62). Proprietary data management systems have since been developed by many manufacturers that contain extensive data storage, maintenance logs, online training, operational manuals, multiparameter report generators, and remote access capabilities (63). The data management systems allow test results to be ordered, billed, and documented, training updated, instrument status monitored, and software upgrades installed remotely and automatically through radio frequency and wireless data transmission networks (64). The biggest obstacle encountered with POCT over the years was the need for a system that allowed users complete freedom to analyze any sample for any combination of tests available on the analyzer while ensuring that such tests would be properly ordered, billed, and documented in an information system (65).

A limitation of a data management system is its functionality and ability to link to multiple POCT devices from different manufacturers. Connectivity standards have created uniform interfaces to interconnect computerized POCT devices with data management systems (66), and several data management system vendors currently offer connections to dozens of different devices and manufacturers. A recent systematic review of the literature on barriers to the adoption of POCT cited device performance and data management issues in 51% of publications (67). Data management issues often stem from a lack of adequate connectivity capabilities. Nine articles assessed in this review highlighted the generally poor connectivity of POCT devices. The Connectivity Industry Consortium was convened in 1999 to create connectivity standards for POCT devices; still, 15 years later, POCT devices are often found not to be compliant with these standards, either due to a lack of updating original submissions or the manufacturer's unwillingness to embrace the fundamental requirements of the Connectivity Industry Consortium (68).

Connectivity is at the core of POCT growing pains. The effects of a lack of adequate connectivity are most readily seen in large institutions or within multi-site systems where a dispersed set of devices can create data management issues. POCT results are presented in a simplistic manner, which often must be manually recorded by the operator due to the lack of adequate connectivity (67). Issues can occur with the transposition of the test results. Two clinics in South Africa using POCT noted a 1% transcription error (incorrect manually reported results) when conducting a statistical review of the data (69). Another study implementing a POCT management system in rural Australian clinics noted low reconciliation rates (match between POCT device data at the time of testing to patient demographics acquired from the hospital patient administration system during result verification). A lack of electronic record systems in rural clinics was cited as one of the main reasons for the low reconciliation rates. Other issues included incorrect entry of patient identifications into POCT devices, the lack of resources to ensure that medical record numbers are available for new patients, and that the patient visit is updated in the hospital administration system at the time of POCT (70). Reconciliation rates increased from 20.2% in the second month post implementation of a POCT management system to 48.6% by the 13th month post POCT implementation (70). The use of barcoded patient information and positive patient identification within the POCT device (requires confirmation of a second patient identifier—birthdate or name confirmation after scanning or entering the patient information) significantly improves data reconciliation rates and decreases patient identification errors with POCT devices and data management systems (71, 72).

Does data management improve regulatory compliance of POCT?

Data management systems automate the ordering and billing of results, generation of control statistics and patient reports, trending of instrument error codes, and documentation of operator training/competency that assist POCT programs in ensuring regulatory compliance. Operator and control lock-out assures that QC is analyzed as required and only trained and competent operators use the devices. The use of data management is recommended to ensure regulatory compliance of POCT.

Data generated through POCT devices should be handled in a manner consistent with the standards of the central hospital laboratory and regulatory requirements (63). The Clinical Laboratory Improvement Amendments of 1988 (CLIA), the College of American Pathologists (CAP), the Joint Commission and COLA, Inc. all stress the need for laboratory oversight and review of POCT quality control and patient results (33). The current POCT data management paradigm focuses on interfacing stationary or portable POCT devices to a stand-alone data management system. This data management system collects POCT device, operator, QC, and result data to generate basic reports. The dispersion of POCT devices throughout the hospital and critical care environment creates unique challenges for data management. POCT operators may not recognize device malfunctions, QC problems, or whether laboratory results are technically correct, clinically relevant, or deviate excessively from past trends. To address these issues, data management systems would require "smart" software programmed with artificial intelligence and algorithms that are designed to identify and expediently communicate device and data deviations to the operator, the data management system manager, or preferentially to centrally based laboratory technicians assigned to oversee the POCT program (73). In a separate Dutch study, an iterative process of healthcare actors and value transactions designed an optimized care model for the dynamic integration of POCT into the general practitioner's network of care delivery. This study noted that centralized laboratories (diagnostic centers) need connectivity between the POCT product and the LIS to decrease the number of actions related to POCT usage and eliminate the manual reporting action by the general practitioner's assistant. By connection to the LIS, the central laboratory can check the quality and reliability of the POC technology. The laboratory cannot assure quality without knowledge of the occurrence of human or technological errors (74).

Oversight of instrumented tests can be facilitated by electronic data management systems and requires less on-site assessment of compliance (75). Auditing of quality control and quality assurance activities is more difficult for manual POCT than for instrumented tests because of the necessity of maintaining manual records. For hemoglobin, one institution found that total compliance with manual documentation of quality control and resolution of control failures was difficult to achieve (33). Numerous failures were repeatedly noted in logs without concurrent resolution. Manually, there was no way to verify documentation of all control testing, and patients were being treated on results from analyzers with documented control failures. Hemoglobin data management provided the ability to capture patient data and correlate POCT results with central laboratory results from the same patient by generating exception reports of data outside allowable tolerance limits. Exception reports were useful when determining preanalytic operator errors. Evidence of better accuracy and quality of results was available after implementation of data management through collection of quantitative data for performance improvement. Through a more critical review of POCT data, operational errors of nursing staff emerged, indicating the need to enhance the awareness of POCT operators to preanalytic variables (33). Data management was also required to detect trends and errors in glucose meter testing sufficiently in a continuous manner. Computerized algorithms were needed to automate the QC review process and generate summary reports of the data (33). A CAP Q-Probes study of 544 institutions quality control practices demonstrated a performance advantage by those using the data storage capabilities of glucose instruments (12). While this might reflect a higher level of interest and attention to the program, it may also be related to more frequent and thorough monitoring of the program as a consequence of the ease and accuracy of data collection and analysis. The CAP Q-Probes study recommended that the data storage capabilities of blood glucose monitoring instruments be used, whenever practical, as a means of increasing compliance with "good" laboratory practices (12).

POCT data management offers many features that improve regulatory compliance. First generation glucose meters had no data management capability, necessitating manual record keeping (76). Manual quality control and patient records are notoriously unreliable and difficult to manage, presenting major challenges in meeting regulatory requirements. Second-generation glucose systems introduced rudimentary data management software, which permitted manual downloading of quality control results to a personal computer. The downloaded data permitted basic QC reports to be obtained, which enhanced oversight of the POCT program. These early data management systems were cumbersome to use and required that the meter and a personal computer be physically brought together for downloading data. Third generation glucose meters, currently in use, eliminate manual downloading, since the instruments are networked via an intranet to a data management computer. In addition to archiving patient and quality control results, a variety of quality control reports are created. Third generation glucose meters are configured to utilize barcoded operator and patient identification systems, an auto-competency protocol (saving large amounts of time on annual operator competency), and lockout of users that have not been approved to use the system. Collectively, these innovations have significantly improved the ability of physicians and nurses to monitor diabetic patients in the hospital setting with reduced cost, greater accuracy, and enhanced regulatory compliance (76).

Beyond glucose meters, most POCT instruments today have the ability to "lock-out" testing personnel when quality control fails or when quality control frequency has not been met. This prevents testing personnel from reporting results until quality control has been performed or the failure has been corrected (61). A built-in barcode reader is used to identify the test strips, for quality control, and to record the identification of the patient and operator. The device will not operate unless quality control

has been performed, and outdated test strips are rejected; moreover, the device will lock out operators who have not been properly trained (77). Laboratorians appreciate the value of electronic gathering of information as an essential asset for doing business, especially when it comes to quality control/quality assurance, billing/compliance, and regulatory requirements. POCT requires that the laboratory maintain control of critical care testing by (i) insuring that all POCT meets all regulatory requirements, (ii) that appropriate and documented training of all POCT personnel has taken place, (iii) timely review of calibration and QC data, (iv) verification of all POCT results prior to reporting, (v) that the information management mechanisms are in place for acquisition, storage, and reporting of POCT results, and (vi) that the laboratory has a means for automatic charge capture, coding and billing for POCT that is in compliance with all Healthcare Finance Administration rules for reimbursement (62). Private use of a POCT device by healthcare personnel is not allowed, as a physician's order is required. It is not acceptable to scan a patient's armband for personal use, run samples under a different mode on the analyzer or create identification numbers, and use the device for personal use. With data management, this kind of abuse will be caught during chart and database audits (68).

Does POCT data management improve patient outcomes?

Data management facilitates the ability to trend patient data over time, compare populations of patients for quality measures (average HbA1c for clinics or PT/INR in-range results), and monitor hospital treatment goals (glucose averages for intensive insulin protocols). While data management does not directly improve patient outcomes, data management provides the tool to collect information that allows clinicians to better manage their patients, and this subsequently helps to improve patient care. Data management is recommended to document patient trends and document improvements in patient outcome over time.

Through the capture of patient results, POCT data management provides the opportunity to generate reports that are utilized for data trending, documentation of clinical quality measures, and evidence of patient outcomes. Use of a coagulation device with data management documented the ability to not only create quality control charts and reports by lot number, instrument, test and level of control, but also patient reports and charts that could be used to monitor for test trends (77). Use of POCT in an Emergency Department triage documented a reduction in turnaround time for test results (26.5 min for POCT compared to 83 min for laboratory cardiac marker testing) that allowed a faster rule-in/rule-out strategy for patients with suspected acute myocardial infarction and negative electrocardiogram (78). This POCT system had connectivity and data management to the laboratory information system to allow remote control of the POCT device from the core laboratory, in particular the validation and storage of the results concerning maintenance, patients, and quality control results and the possibility to reject an analytical result on the basis of control data (78). Non-ST segment elevation patients followed in an ambulance fitted with experimental software able to receive data from a POCT device and transmit to a protected server demonstrated a faster turnaround of results (12 min for POCT compared to hospital turnaround time of 40 min for troponin) and ability to remotely manage the patient in transit (79). Interfacing POCT devices to a clinical electronic order communications system reduced patient wait times in a British Emergency Department. Test orders entered into an integrated clinical environment system produced a bar code label read by the individual POCT analyzers. Once the required tests were assayed, the results were transmitted back to the integrated clinical environment system, where they could be viewed by users across the hospital. The time interval between requesting a test and receiving results for POCT was 23 min compared to 60 min for laboratory tests, which led to a decrease in patient wait times of 31 min (time of discharge compared to time of arrival was 167 min for POCT compared to 208 min for the clinical laboratory) (80). The study noted POCT had many advantages with respect to quality and safety of data management including reliable identification of the requesting clinician and patient and assurance that the right result is allocated to the right patient. The study also found that POCT devices used as stand-alone (stationary) analyzers are fairly promiscuous about data, accepting XXX instead of unique patient identifiers and ### or shared passwords in place of preregistered and trained users. Patient data may be printed out on paper strips and results manually transcribed in case notes (with a 6% error rate). The improvement in patient outcome (a reduction in patient waiting time) was only observed when patients received POCT exclusively (80). POCT data management in these studies was key to documenting results, compliance with quality regulations, and the patient outcomes achieved.

Many home use devices include software capabilities enabling patients to share important health information with health care providers using a computer. Patients have been able to record and transmit their blood glucose levels to providers since the advent of hand-held blood glucose meters equipped with computer software. Newer technologies include home weight management and electrolyte measurements in the setting of congestive heart failure, and even blood glucose monitoring systems connecting to a smart phone as an interface. Australia introduced home-based acute care services enabling patients to be treated by an acute hospital-based team at home. Patients were given therapeutic interventions such as leg ulcer dressings while being monitored for PT/INR and electrolytes coordinated with a lab information system. Home POCT can be implemented to streamline healthcare services to patients with acute and chronic diseases limiting hos-

pital admissions, readmissions, and delays in care, and can ultimately lead to better outcomes as well as cost savings for patients and providers (80). POCT data management systems further allow the generation of reports that can document quality measures for outpatient clinics, such as the percentage of patients in-range with PT/INR results for a coumadin clinic or the average hemoglobin A1c for diabetic patients in an endocrine practice. Use of intensive insulin management protocols can monitor the achievement of targets (percentage of patients at target or percentage of those undertreated above target glucose or overtreated hypoglycemic) by calculating average glucose values over time for ICU patients on insulin management protocols through the use of glucose meter POCT data management systems. There are numerous ways that POCT data can be utilized once captured by a data management system to facilitate patient treatment and improve patient outcomes. While data management does not directly improve patient outcomes, data management provides the tool to collect information that allows clinicians to better manage their patients, and this indirectly improves patient care. Data management is recommended to improve the quality, regulatory compliance, and provide the information to allow physicians to better manage their patients using POCT.

SELECTING POCT

What information is needed prior to selection of POC testing system?

An operational and clinical needs assessment should be performed, as well as a review of facilities and material management requirements to identify the test use characteristics required in the potential POCT devices. When assessing clinical needs, the following should be addressed:

1. How will the POC result be used (i.e., what is the impact of POCT on patient management and resource utilization)?
2. What is the true improvement in availability of test results (i.e., TAT, relative to laboratory-based testing)?
3. How will the POCT be integrated into practice guidelines, order sets, medical directives, and critical pathways?

The use of POCT will depend on the need for and the ability to achieve a rapid TAT for clinical decision making. POCT for cardiac markers has a definite place in management when a very short TAT is required such as in the Emergency Department. When the laboratory TAT exceeds 25% of the decision time, then POCT should be considered. When rapid therapeutic decisions are needed, only POCT may be able to fulfill the TAT requirement (81).

POCT can prevent evacuation and transport of patients from remote clinic locations to an acute hospital by assisting in triage and therapy onsite. In Australia, POCT prevented 60 unnecessary medical retrievals from remote health centers to a hospital emergency department. A total of 200 patient cases met selection criteria in this study (48/147 chest pain, 10/28 missed dialysis, and 2/25 acute diarrhea). The associated cost savings were AUD $4674, $8034, and $786 per patient translating to Northern Territory-wide savings of AUD $13.72 million, $6.45 million, and $1.57 million per annum (AUD $21.75 million in total) for chest pain, missed dialysis, and acute diarrhea presentations, respectively. This study demonstrated that POCT, when used to aid decision making for acutely ill patients, delivered significant cost savings for the Northern Territory health care system by preventing unnecessary emergency medical retrievals (82).

Rapid molecular testing for infectious diseases has benefits in reducing unnecessary antibiotic and antiviral administration, reduced mean waiting time in the ED, decreased isolation time, and led to fewer tests being ordered (83–85). In a study attempting to show the benefits of rapid influenza testing on physician decisions, 418 patients were enrolled and 391 completed the study. In this group, 202 individuals tested positive for influenza. In 96 cases, the physician was made aware of the result, and in 106 cases, the physician did not get the result that the patient tested positive. When the doctor was aware that the patient was positive while still in the ED, it led to significant reductions in ED length-of-stay, the number of additional tests ordered, and reduction in unnecessary antibiotic prescriptions (86).

The operational assessment for the implementation of POCT should include:

1. Staffing needs, both for actual test performance as well as labor needed for management and oversight.
2. Material management assessment: What are the storage requirements, for example, space requirements (size of the consumable packaging), shelf life (expiration dating), and temperature (room temp vs refrigerated)? This will then help define the storage requirement needs for the POCT system and determine the ability to accommodate them. It will also determine the amount of material that can be ordered at one time and thus minimize the amount of testing required for acceptance of new lot/shipments.
3. Information technology assessment: What will be the mechanism for the capture of patient testing and Quality Control data and how will it be recorded in laboratory records and the medical record?
4. Cost: Financial justification for POCT needs to be assessed against laboratory test. The financial responsibility for devices/meters, strips/cartridges, and QCs usually belong to the clinical units.

What specifications should be compared when selecting a POCT system?

When selecting a POCT system the following characteristics of the system should be reviewed/evaluated.

1. Testing complexity: Is the test system classified as waived or

moderate? This will define the level of education/training needed for the testing personnel, as well as the quality control/quality assurance requirements for the testing system.
2. QC testing
   a. QC material storage: package size (space requirements), storage temperature (shelf, refrigerator or freezer.)
   b. QC testing frequency: Waived tests follow manufacturer's instructions as defined in the package insert. Moderately complex tests must perform two levels of QC testing on each day of patient testing or develop an IQCP (Individualized Quality Control Plan) after performing a risk analysis.
3. Device
   a. Footprint
   b. Electrical requirements: None, battery, or line power
   c. Waste
   d. Maintenance requirements
4. Operator management: Does the system maintain a list of competent operators and lock-out non-authorized operators? Does it have QC lockout, preventing test performance if QC has not been successfully performed within the prescribed time frame?
5. Connectivity: Does the system interface with the LIS/EMR, either directly or through a data manager, or do results have to be manually entered?
6. Specimen: Urine, fingerstick, venipuncture, arterial stick, anticoagulants required, sample size.
7. Training: The extent of training depends upon the complexity of the system. What are the anticipated number of operators? Is training done directly by laboratory personnel or via a train-the-trainer program. For testing that involves many devices and operators, is vendor assistance available for training at start-up?

A detailed specification should be prepared to include the number of samples to be processed, sample preparation requirements, the footprint of the instrument, maintenance requirement, consumables storage, power supply, and network ports (87).

How should an evaluation be performed to identify preferred POCT system?

A framework for introducing a new technology to a healthcare system includes a few steps: analytical and clinical accuracy assessment, clinical validity/utility determination, and economic evaluation (88).

After the potential systems are identified, a preliminary cost assessment and performance evaluation should be performed. Cost includes both start-up/implementation costs as well as ongoing operational costs and total cost. A preliminary evaluation should include assessing within and between day imprecision, a method comparison using patient samples, and an assessment of measuring interval (89). Clinical utility studies require data on the influence of POCT on outcomes. There are few studies on clinical utility, but more data exist on clinical validity and analytical performance. A value proposition may be another method to evaluate the benefits of POCT to all the stakeholders and services affected by the test (90).

Equipment selected should have received a successful independent performance evaluation. If an independent evaluation has not been performed, the purchaser should assess the device according to the protocol in this document. POCT devices should generate results that are comparable to those of the local laboratory (87).

The following is an outline of what should be addressed in an evaluation of a POCT system. It is up to the site to determine the analytical performance requirements needed to assure that a system is fit for purpose. Sufficient concordance between POCT results and results obtained in a comparative laboratory (the hospital or central laboratory) must be guaranteed within acceptable tolerance limits when POCT is implemented. The specifics of these requirements will be dependent on the clinical use, such as screening, diagnosis or monitoring, of the POCT results, as well as to whether other systems are available for the performance of the analysis.

1. Analytical performance assessment
   a. Lab directed vs. vendor directed vs. third party independent assessments
   b. Accuracy relative to lab reference method
      i. Patient comparisons
      ii. Clinically acceptable bias/Total allowable error (TEa)
   c. Precision: Within run and between run
   d. Linearity/AMR
   e. Analytical specificity/interferences
2. Cost assessment
   a. Start-up/implementation costs
   b. Operational costs
3. End user acceptability
   a. Focus groups

A survey of laboratorians showed that, when developing new POC devices for disasters, high clinical sensitivity (>90%), high clinical specificity (>90%), rapid processing speed, and the ability to operate on battery power were all predictive of device selection by survey respondents. A high value attribute of POCT is the ability for flexibility and adaptability; therefore, POCT should be easy to use and function in austere low resource environments (91).

PROCESSES AND OUTCOMES

Does faster turnaround time (secondary to POCT) lead to improved processes and outcomes?

Unarguably, POCT generates faster test result TAT when compared to central lab (CL) testing secondary to mark-

edly reduced collect to in-lab and in-lab to result time segments. In turn, end-user clinical providers (especially those in time sensitive/critical care such as the Emergency Department (ED) and Intensive Care Unit (ICU) clinical areas) believe that faster TAT necessarily translates into improved patient care because there is the opportunity for quicker clinical responses leading to better patient outcomes or quicker patient care processes; hence, their desires to continually expand POCT menus.

The intent of this discussion was to review existing literature to determine what available evidence, if any, exists to support the hypotheses that faster TATs secondary to POCT; improve outcomes (decreased morbidity and mortality) or patient care processes (decreased admissions or shortened length of stay (LOS).

This review did not include studies assessing POCT vs. CL methods in terms of method characteristics (accuracy, linearity, and precision) nor were speculative studies about the ability of specific POCT to improve outcomes/processes included. In addition, outcomes evidence associated with POCT self-monitoring was not reviewed for this discussion.

PUBMED free text literature searches were performed using the following terms: POC, POCT, point of care, point of care test, or point of care testing combined with emergency, length of stay, LOS, throughput and outcome, hemoglobin A1c or HbA1c. Strict cost analysis comparing POCT to CL were also not included In addition, PUBMED "related articles" searches were performed on key references initially identified, as well as for identified as use/utility review articles.

References were reviewed (and selected if identified) by title, abstract, and body (if necessary) to see if either of these two topics were discussed:

- Did POCT improve patient care processes (e.g., length of stay or decreased admissions).
- Was the impact of POCT compared against comparable central lab processes with respect to specific patient populations and disease states to see if patient care improved in terms of, outcome, prognosis, morbidity or mortality.

As several "meta-analytic" reviews on this topic (67, 92–96) have already been done, they were cited instead of their cited references with uncited or prominent references cited individually. Of note (92), provided the general structure used in this discussion to breakdown POCT by scenario. This reference was the most complete summary of POCT related evidence; however, it was not solely used without identification of additional references.
With respect to this study, there is a hazy boundary between improved process and improved outcome with overlap between the two. Studies were classified as either "process" or "outcome" based on which appeared to be more prominent in the discussion.

PROCESS

Analyte

Creatinine (92, 97–99): Creatinine testing prior to contrast radiology studies speaks for itself with respect to how it improves patient process. Glomerular filtration rate (GFR) based on blood creatinine levels is used to assess for underlying chronic kidney disease; a risk factor for contrast induced nephropathy (CIN), and an individual's subsequent risk for CIN. Provision of creatinine near/prior to such radiology studies allows for a rapid assessment of renal function without waiting for a CL assayed result. POCT in this process should theoretically improve radiology throughput; however, no studies were identified in the literature confirming faster throughput.

Drug of abuse screening (92, 100): Only one study was clearly identified; it showed a decreased LOS in the ED with testing. Hypothetically, the lack of outcomes related studies is due to analytic limitations of POCT drug of abuse testing (i.e., possibility of false negatives or false positives). For example, in the presumed drug intoxicated individual, a negative test requires CL confirmation; whereas, in term of compliance monitoring, a positive test would require CL confirmation. For the former situation, presence or absence of a rapid result should not hinder or limit urgent, as needed, clinical care.

Human chorionic gonadotropin (hCG) (92): With respect to hCG testing, there is the dilemma of POCT qualitative result vs. CL quantitative result complicated by the dilemma of the "indeterminate" POCT result. Per the review, there is a difference of opinion between radiologists and non-radiologists on which test is preferred. In one study, no reduction in LOS was seen with the use of POCT.

D-Dimer (92): One study noted that emergency department D-Dimer testing (negative result) use was able to decrease admission by 14% and increased discharges by 21% in cases of suspected pulmonary embolism.

Condition

Influenza (101–105): There were numerous references supporting ED use of POCT influenza diagnosis. They all reported decreased antibiotic use, reduced testing, and decreased admissions for the "positive" testing patients. There was inclusive evidence that ED LOS was reduced.

Location

Emergency Department (ED)/Urgent care (92, 106–121): Mixed results on whether POCT could shorten LOS or admissions with the majority showing some decreases in LOS. One study noted that implementation of POCT resulted in a 20% reduction in treatment time compared to a non-POCT track. Electrolytes were shown to decrease LOS. ED POCT troponin testing is included in the troponin discussion.

OUTCOME

Analyte

Glucose (92, 122): Multiple studies have conclusively demonstrated that improved glycemic control in the inpatient population decreases morbidity and improves outcome, provided that the glycemic threshold is not too low (140–180 mg/dL); however, the data in those studies are CL based. In spite of multiple search strategies, no studies were identified reviewing the impact of POCT glucose on inpatient processes or outcomes. The absence of studies is probably associated with the fact that there are analytic concerns regarding inpatient specimen quality secondary to underlying illness and acuity, as well as medication-related interferences. These findings apply to intra- and peri- operative testing as well.

HbA1c (92, 122–125): Multiple studies have confirmed that POCT HbA1c testing not only is a physician/patient satisfier (an immediate result to confirm/deny glycemic status with subsequent one-on-one discussion) but also showed improved HbA1c level and changes in treatment as needed, as well as improved costs by decreased testing, fewer clinic visits, and less hospital admissions. One study indicated that ED use was useful in detecting additional cases of diabetes independent of blood glucose levels.

Blood gases/electrolytes (Intraoperative) (92): No outcome studies for POCT intra- or peri- operatively were identified.

Blood gases/electrolytes (ICU/ED) (92): Multiple studies identified that showed quicker result turnaround time with varying responses as to whether they impacted LOS or prognosis. One study showed that clinical decision time increased; however, without any changes in LOS, mortality or rate of hospital admission due to other inherent hospital barriers (availability of physician or bed space). Interestingly, one study showed that ICU clinicians prefer CL over POCT results because of the former's better accuracy.

Troponin (92, 96, 125, 126): In spite of numerous references discussing POCT troponin, there are few outcomes-related studies. Improved outcomes were noted in remote/rural settings. POCT was able to improve outcome by stratifying patients requiring, and not requiring, transfer for sophisticated cardiac care. In the DISPOACS (US), use of POCT was associated a significant reduction in time to discharge and in the RATPAC (UK) study, there was increased rate of successful discharge and a reduced LOS.

Brain natriuretic peptide (BNP and NT-ProBNP) (127–131): Circulating concentrations of the hormone brain natriuretic peptide (BNP) and its precursor molecule, NT-proBNP, are increased in those with heart failure. Normal levels of these hormones have established the role of these biomarkers in ruling-out the diagnosis of congestive heart failure. Results of POCT of natriuretic peptides have demonstrated earlier rule-out of heart failure and lower healthcare costs compared to clinical diagnosis based on history and clinical symptoms and hospital laboratory analysis. A recent meta-analysis also indicates that BNP/NT-ProBNP may have clinical application for excluding a diagnosis of ischemic stroke, specifically cardioembolic stroke. Incorporation of rapid POCT BNP in early stroke management guidelines has been suggested to improve stroke risk stratification and accelerate the start of secondary preventive measures, further diagnostic examinations, and rehabilitation interventions; however, the demonstration of improved patient outcomes from this strategy has yet to be published.

Hemoglobin (92): One study was identified that showed multi parameter POCT in the NICU reduced blood transfusions in the very low birthweight infant.

Platelets: No studies were identified.

Activated clotting time (ACT): No studies were identified; however, this test was designed to be a near patient test for real time assessments of clotting status, especially for those patients on heparin during vascular related procedures.

Thromboelastography (TEG): No studies were identified. However, this test was designed to be a near patient test for real time assessments of intra-operative and trauma related clotting status.

Condition

Sepsis (Lactate) (92): Lactate was found to reduce ICU admission rates and mortality in one study, as well as to increase time to administer IV fluids but not antibiotics. Another study identified a lack of evidence for the use of lactate in community settings.

Location

Remote rural communities (92): Multiple studies were identified that focused on regions (Australia and New Zealand) where centralized medical facilities were markedly distant from remote hospitals. In all of these studies, POCT reduced transfers and increased diagnostic certainty at the remote locations, allowing for overall cost savings. In one study, use of POCT cardiac markers as part of remote risk stratification reduced 30-day mortality by better determination of which patients should be transferred to tertiary care centers for invasive treatment. Similar improvements in morbidity were also noted with POCT lipid testing, significantly reducing total cholesterol in the patients tested locally instead of specimens sent to a CL. Mention is made of the use of HbA1c and albumin/creatinine ratio (ACR) in remote communities to assist with diagnosis, glycemic control, and monitor for renal complications, but no mention is made of its impact. Lastly, the Canadian Agency for Drugs and Technology (CADTH) sponsored a Health Technology Assessment project with respect to the use of POCT troponin (Tn) in remote/rural locations. It concluded that in locations without laboratory testing, POCT Tn testing reduced transfer to central locations.

Primary care practice (92): Limited data on whether POCT affected outcomes in primary care practices. The few studies

available were confounded by the cost/benefit of POCT vs. central laboratory (CL) testing. POCT was more expensive than CL but clinically effective in ACR but not HbA1c testing (see specific section on HbA1c).

Community pharmacy (92): Utilization in this area is widely available but it has not been studied as to whether it improves patient outcomes.

Nonstandard Abbreviations

AACC, American Association for Clinical Chemistry; NACB, National Academy of Clinical Biochemistry; POCT, point-of-care testing; LMPG, Laboratory Medicine Practice Guidelines; TAT, turnaround; PT, proficiency testing; EQA, external quality assessment; CLSI, Clinical and Laboratory Standards Institute; NICU, neonatal intensive care unit; QAAMS, Quality Assurance of Aboriginal Medical Services; INR, international normalized ratio; HbA1c, hemoglobin A1C; CAP, College of American Pathologists; ED; Emergency Department; ICU, Intensive Care Unit; LOS, length of stay.

Author Contributions

All authors confirmed they have contributed to the intellectual content of this paper and have met the following 4 requirements: (a) significant contributions to the conception and design, acquisition of data, or analysis and interpretation of data; (b) drafting or revising the article for intellectual content; (c) final approval of the published article; and (d) agreement to be accountable for all aspects of the article thus ensuring that questions related to the accuracy or integrity of any part of the article are appropriately investigated and resolved.

Authors' Disclosures or Potential Conflicts of Interest

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