Management of point-of-care testing

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Point-of-care testing (POCT) is a delivery option for performing laboratory testing closer to the patient. Due to increasing healthcare pressures for faster turnaround of laboratory results and the development of a broader menu of testing devices, POCT is growing in popularity. Devices today are more portable, require less blood, and have computerized information management.

Despite its popularity, point-of-care-testing does not necessarily yield laboratory-comparable results. Delivery of laboratory testing outside the laboratory exposes a device to a variety of environmental, technique and patient factors that can adversely affect the analysis. Quality assurance of POCT requires an appreciation of the technical and operational factors that can influence the testing process.

The potential of point-of-care testing for faster test results does not necessarily guarantee improved patient outcomes. Only through participation of the laboratory on interdisciplinary management teams can the utilization of POCT be optimized for patient benefit. Future expansion of POCT will highlight the importance of the laboratory and develop new, evolving roles for the laboratory consultant in direct patient care.

Point-of-care testing - introduction

Point-of-care testing (POCT) is an alternative to central or core laboratory testing. POCT can be defined as "diagnostic testing conducted close to the site where clinical care is delivered". Other names for POCT include: near-patient, decentralized, ancillary, alternate site, patient-focused, bedside, satellite, and peripheral testing.

These terms describe the considerable variation in which POCT is delivered. POCT devices can be brought directly to the patient's bedside for analysis, or specimens can be collected and carried to stationary POCT equipment

in the patient's bathroom, in a spare utility room on the ward or even on a mobile cart.

Point-of-care testing can meet critical therapeutic needs for selective inpatient populations, like the emergency room, operating rooms, or intensive care units, as well as outpatient clinic, physician's office, and home healthcare nursing. POCT devices are more portable than central laboratory instrumentation and have therefore found application in medical transport vehicles like helicopters, airplanes, and ambulances.

Despite its portability and apparent simplicity, POCT is comparable to other laboratory tests and faces similar preanalytical, analytical, and postanalytical issues [1]. Poor phlebotomy, fingerstick, or collection technique [2-5], lack of patient preparation [6-8], use of anticoagulants, transportation delays, and collection from intravenous lines [9-12] can affect the quality of the specimen.

Inappropriate reagent storage and analysis in hot or humid conditions [13-17], patient hematocrit [18], medications [19-21], and other metabolic conditions [22-25] can affect the accuracy and precision of test results. After analysis, the handling of test results can further create transcription and interpretation errors [26-30]. Overall, as with any laboratory test, considerations for the cost effectiveness and patient benefit impact the utility of POCT [31].

A recent survey of U.S. hospitals illustrates these issues [32]. When asked, "What are the advantages and disadvantages of POCT?" hospitals responded that the greatest advantage is the potential of POCT to impact turnaround time (92 %), patient satisfaction (34 %), and length of stay (21 %). Since POCT provides faster results, there is the potential for more rapid institution of therapy and beneficial patient outcomes.

On the other hand, the disadvantage of POCT is inaccuracy (73 %), difficulty performing/documenting controls and calibrations (58 %), training requirements for multiple staff (58 %), device precision (57 %), and cost (46 %). Although POCT is faster, the technical performance may not be equivalent to traditional laboratory tests conducted in a central laboratory. Yet, despite these potential benefits and concerns, only 2 % of hospitals have actually analyzed the impact of POCT on length of stay or performed cost studies (7 %).

Point-of-care testing, thus, presents the opportunity for improved care, but whether beneficial outcomes are realized depends on the balance of quality and clinical need. The convenience of POCT too often results in poor quality and over-utilization that raise the cost of care. Stringent monitoring is required not only of POCT quality but also of utilization and clinical outcomes.

The number of devices and operators complicates the oversight and practical management of POCT. Institutions can have dozens of devices and hundreds of operators. Testing personnel come from all areas of patient care with various educational levels, from medical technologists to nursing and clinical support staff [26, 29].

Maintaining equivalent levels of device accuracy [11, 33] as well as operator technical competency is a challenge facing those in charge of POCT. Establishment of a POCT quality assurance program requires an appreciation of clinical need, expertise in the technical aspects of POCT devices, and above all an ability to work on an interdisciplinary healthcare team [1, 34-36].

Point-of-care testing - quality concerns

Although POCT devices are widely marketed and even available to the general public for personal testing purposes, the devices are not necessarily innocuous. Glucose meters are involved in the largest number of complaints filed with the U.S. Food and Drug Administration for any medical device [37]. As of 1993, over 3,200 incidents have been recorded from patient self-management, including at least 16 deaths.

Poorly maintained blood gas analyzers [38] and urinometers [39-40] on inpatient medical units can act as an infectious reservoir for antibiotic-resistant organisms. Even desktop cholesterol analyzers can

generate misleading results [41]. In a survey of British outpatient clinics, 21 % of proficiency survey samples were >1 mmol/L (39 mg/dL) from the target mean, leading to a misclassification of as many as 16 % of patients [41].

POCT devices as a remote extension of the laboratory generate medical information that leads to clinical action. When the device is used inappropriately and incorrect results are produced, further diagnostic intervention can result in increased healthcare costs and risk to the patient.

Point-of-care testing devices are deceptively simple to operate, but simplicity does not guarantee quality. The particular application of the POCT must consider the peculiarities of the patient population (**Fig. 1**). In home use for patient self-monitoring, POCT devices are utilized by a single operator to serially monitor one patient.

POCT in the home employs capillary samples on ambulant, generally well patients. In contrast, hospital use of POCT devices are utilized by many operators on multiple acutely ill patients. Since many of these patients already have intravenous lines, samples other than fingerstick capillary blood are possible [1].

Point-of-care glucose testing comparability

Home use	Hospital use
• single operator • single patient, self-management • serial measurement • on one patient • ambulant, well patients • capillary use only	• multiple operators • multiple patients • glucose meter • interspersed with lab values • recumbent, ill patients • other specimens • possible(line, arterial, etc.)

FIG. 1: Comparison of clinical applications for point-of-care glucose testing. Home testing presents different demands on the testing device than hospital testing.

Precision is more important in home use, while accuracy is paramount to inpatient use. For home use, a device may be biased from truth, but the device is functional provided that the patients know how to trend and treat themselves off the results generated on that particular device.

The absolute accuracy of that device versus a laboratory reference is not as important as the precision and day-to-day consistency. In a hospital, however, patients may enter through the emergency room, have surgery in an operating room, spend time in an intensive care unit and a general medical unit, and, after discharge, have home nursing or outpatient visits where POCT results are intermixed with laboratory values.

POCT results in a health system must correlate to the laboratory value or else the clinician must mentally correct the value to the laboratory reference for treatment. Standardization of POCT is particularly difficult given the lack of stable, whole-blood-based international standards and the inability of many POCT devices to accept samples other than whole blood. POCT, therefore, must indirectly standardize to other analyzers that can be made traceable to the International System of units.

Comparability is the goal of POCT quality assurance and the motivation behind regulations that govern laboratory testing in the United States. Federal regulations from the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) [42-45] and private laboratory accrediting agencies like the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) [46-47], College of American Pathologists (CAP) [48], and Commission on Office Laboratory Accreditation (COLA) [49] regulate the performance standards of laboratory testing not only in central laboratories but also at the point of care.

Specifically, these agencies ensure that written procedures for POCT exist, appropriate quality control is performed, operators have specific training on the devices, ongoing operator competency is documented, and a result trail can be reconstructed linking the test result to the operator (and their training) and the device (and quality control performed on that device).

Additional guidelines for more complex POCT require on-site laboratory supervision, validation of devices and reagents, daily sign-off of patient results, and incorporation into institutional policies for performance improvement, leadership, human resources, management of information, and infection control.

Overall, point-of-care testing is treated the same as other laboratory tests by ensuring that proper controls have been instituted over variables that can affect test performance.

Management of point-of-care testing

Managing the quality of POCT requires an interdisciplinary team approach. Since the testing is performed on the medical unit by clinical staff with immediate interpretation, the laboratory must ensure test quality through the clinicians. Many institutions have formed interdisciplinary committees to set policies and direct performance improvement of POCT.

These committees represent every discipline that has a stake in the testing process with members from the laboratory, nursing, physicians, purchasing, infection control, and administration. Each discipline brings its expertise to the table to discuss and resolve issues. These committees function best when the members look beyond the personal goals of their discipline (multidisciplinary teams) towards the common goal of premier patient care (interdisciplinary teams).

A major function of an interdisciplinary committee is the selection of appropriate POCT technologies to match the needs of various patient populations. While use of a single device may be the easiest means of managing POCT, technical limitations do not always allow equivalent application to all patients. Home-use devices are frequently calibrated to function in the range of normal hematocrits, but hospitalized patients do not have normal hematocrits.

Trauma, postsurgical, and oncology patients frequently have hematocrits of 25-35 %. Neonates and polycythemic patients, on the other hand, may have hematocrits of 50 % and higher. POCT devices, like glucose meters, can be adversely affected by extremes in hematocrit [2, 18]. Consideration of patient effects should also include patient medications [19-21], lipemia [8], and other metabolic conditions like uremia [18].

Oxygen tension can affect device performance such that the difference between arterial, capillary and venous blood may be unacceptable [9-10, 24-25]. Collection of inpatient specimens from lines and the effect of those specimens on POCT should be analyzed.

The environment may also preclude use of some devices. Extremes of temperature, light, and humidity can degrade POCT reagents [13-14, 16-17]. Use of POCT in home health-care nursing practices where the devices may be exposed to freezing temperatures in the winter and hot temperatures in the summer may require the staff to store the devices in their home rather than the trunk of a car.

Vibrations as experienced in a moving vehicle can also affect POCT results. Further, consider the effects of altitude when measuring blood gases in a helicopter or pressurized airplane [16, 50]. A quality assurance program for POCT must therefore consider factors that can affect the testing process [51] that may not be an issue for plasma/serum analysis in the well-controlled conditions of a central, non-mobile laboratory (**Fig. 2**).

Since point-of-care testing is meant for rapid analysis, most POCT devices utilize whole blood or other types of specimens that do not require extensive processing. The use of whole blood for POCT creates technical biases when compared to the central laboratory. Whole blood to plasma/serum correlations are offset depending on the patient's hematocrit.

For glucose in a patient with a hematocrit of 45 %, the whole blood value is approximately 11 % lower than in plasma/serum due to the lower concentration of water inside erythrocytes [1] (**Fig. 3**). Consensus recommendations for POCT glucose to laboratory result differences should be less than 15 % and POCT device precision should be less than 5 % of the coefficient of variation,

Factors affecting point-of-care testing results

Physiological

- hematocrit
- lipemia
- oxygen tension
- metabolites (uremia)
- fasting state
- drugs

Analytical/Reagent storage

- light
- temperature
- humidity
- altitude
- air exposure

Technique

- volume of sample
- reaction timing
- sample type (venous, arterial, capillary, urine, etc.)
- sampling artifacts (clearing lines)
- poor sample collection (capillary)
- sample additives

FIG. 2: Factors affecting point-of-care testing results. A host of preanalytical, analytical, and postanalytical variables can impact the quality of a point-of-care result.

which yield a total, medically acceptable tolerance of 20-25 % for comparison of POCT and central laboratory results [52-56].

This leaves little room for a whole blood to plasma bias. Glucose meter manufacturers have therefore created "plasma" calibrated devices and mathematical offsets to improve laboratory correlation. By calibrating to a plasma "reference" method, POCT glucose results can better match the central laboratory that predominantly analyzes plasma or serum samples.

Whole blood to plasma conversion

If:

Plasma water content = 93 %
Erythrocyte (RBC) water content = 73 %
Hematocrit = 45 %
Whole-blood water content is:

= [RBC contribution] + [Plasma contribution]
= [Hct x RBC water content] + [(1-Hct) x plasma water content]
= (0.45) x (73 %) + (0.55) x (93 %)
= 84 %
= 84 mL of water per 100 mL of whole blood
Because glucose is equally distributed in blood water:

(Plasma water content)/(Whole blood water content)
= 93 % / 84 % = 1.107

Plasma glucose is approximately 10.7 or 11 % higher than whole-blood at 45 % hematocrit.

FIG. 3: Whole blood to plasma conversion of glucose levels. RBC = Red blood cell, erythrocyte, Hct = hematocrit.

The use of whole blood by POCT also creates difficulty with the evaluation and control of POCT devices. While plasma/serum is more homogeneous, whole blood has cells that tend to settle, creating sample discontinuities. Analytes like glucose are stable once separated from erythrocytes in plasma/serum, but glycolysis continues in whole blood, decreasing glucose levels over time. Hemolysis can also occur in whole-blood and result in analytical interferences and increases in intracellular analytes like potassium.

Whole blood controls are manufactured with cell stabilizers that can further create biases with some devices. Use of these artificial specimens can affect results as evidenced on whole-blood proficiency surveys [57-58]. Devices like the HemoCue hemoglobin analyzer that requires cell lysis for hemoglobin to contact reagents during analysis, may show continuously increasing values over time as the cells slowly lyse. Use of stabilized whole-blood products with such devices require longer

incubation periods than fresh patient specimens. These factors must be built into quality control procedures.

Point-of-care training and continuing education

Quality assurance of POCT must not only consider analytical effects on the device, but must also ensure that operators interact with the devices in a consistent manner. Since POCT is widely marketed, both patients and clinical operators must demonstrate acceptable levels of competency.

Initial training should be standardized so that the same information is delivered in an identical fashion. This can be accomplished through the use of training check lists, written procedures, demonstrations, and even videotapes.

Nothing, however, compares to a validation of the actual performance of the operator both before initial use and at frequent ongoing intervals to ensure the same level of performance over time. In a recent survey by the College of American Pathologists, standardized training and frequent measurement of ongoing operator competency were aspects of glucose programs that demonstrated the most significant levels of performance improvement [34].

For POCT, operator performance is dependent on motivation, technical competency, and the complexity of the testing device (**Fig. 4**). On a busy medical inpatient unit, performance of quality control and maintenance/ cleaning of POCT devices frequently take a secondary place to direct patient care. This can lead to more frequent problems with POCT on intensive care units.

Use of POCT by patients or clinical staff who do not appreciate the technical factors affecting POCT analysis may further result in inaccuracies solely because the operator unknowingly introduced biases. Simpler devices with internal checks that prevent result reporting when controls fail are thus easier to manage at the point of care than more complex devices that require elaborate maintenance.

While an advanced degree with a laboratory training background is more important for such complex devices, studies have shown that for simpler devices the performance of operators is independent of their educational level, provided that the operators complete a standardized training program [27-29].

Patients and clinical staff who appreciate the necessity of POCT in disease management are more likely to take better care of the devices and show an interest in performance improvement. The interdisciplinary committee is often a good place to resolve issues of staff motivation and quality assurance compliance, since its members represent a variety of both laboratory and clinically focused opinions.

This committee must consider motivational factors and weigh clinical necessity when deciding whether to utilize POCT at a particular site and how operators should be trained.

Point-of-care management comparability

Central laboratory testing	**Point-of-care testing**
• few analyzers • limited operators • laboratory trained • dedicated to testing • traditionally • control • analyzer	• multiple devices • numerous operators • clinically trained • patient care focused • both device and operator are factors

FIG. 4: Point-of-care management comparability. The number of devices and patient-focused operators complicates the practical management of the testing process outside a central laboratory.

Information management

The addition of information management capabilities to devices assists the practical management of point-of-care testing. Instruments that require operator and patient identification, reagent lots and date/time in order to perform a test enhance compliance and the

ability to track and trend data automatically through a computer. Compliance with manual documentation is one of the flaws of POCT.

Even with the best quality assurance program, there are tests that are conducted whose results do not get recorded. Unfortunately, these tests are difficult to trace, and only counts of reagent utilization can offer clues to missing tests and lost billing opportunities. Where and when those tests were conducted is virtually impossible to trace. Currently, over half of POCT is manually or visually interpreted.

These include occult blood, urine dipsticks, pregnancy tests, pH, drugs of abuse, urine microscopy, and infectious disease. However, for instrumentation-based POCT like blood gases, coagulation, glucose, electrolytes and hemoglobin, the acquisition of pertinent information at the time the test is conducted assists documentation.

POCT information management involves three components: data capture, connectivity, and data management. Each device collects information during testing. Data from many devices are then transmitted via connection to a common, remote database or collection site where it can be reduced and managed. Currently, there are a variety of ways to transmit data; internet, radio, infrared, and direct serial connections.

The immediacy of POCT, however, presents a dilemma for information management. Since treatment optimally occurs at the time the test is conducted, data collected by a POCT device for later transmission are irrelevant to clinical treatment. POCT results are generally recorded manually to the patient's medical record along with clinical action at the time the test is conducted. If the POCT device only intermittently transfers data, then one record of the test exists in manual, written form and another in electronic format, increasing the chance for transcription errors and duplicating the documentation effort.

This "immediacy" dilemma is a challenging aspect of POCT information management. Direct connection devices are currently the most widely marketed means of reliably connecting POCT devices to laboratory information systems and hospital information systems. However, by attaching a cable, the POCT device is no longer portable and loses its functional advantages.

On the other hand, portable devices only transmit data intermittently, whenever they are brought into connectivity or docking stations. In order to get around this problem, some manufacturers have incorporated battery rechargers into the docking stations, requiring the device to eventually get back to its station in order to continue working. Still others lock out further testing until the device is connected after each test.

Once collected in a central database, by whichever connectivity means, the information can be utilized to document regulatory compliance, monitor trends for performance improvement, and determine clinical outcomes. In troubleshooting discrepancies between POCT and the laboratory, data linking the operator and individual device to the test result are fundamental to determining the nature of the problem.

The electronic database provides this documentation by containing records of quality control performed on the device as well as operator competency. These records also serve to document routine performance of quality control as required by regulatory agencies.

In our institution, we have set up a custom database (**Fig. 5**) that contains five components. The first documents initial performance of the device and reagent/control lots for later reference in troubleshooting. The second utilizes operator quality control to document operator competency.

Each month, the means and standard deviation for each control are calculated for the entire hospital and compared to the mean and standard deviation for each operator (**Table I**). Those operators having a mean outside two group standard deviations from the group mean are targeted for reeducation.

The Johns Hopkins Medical Institutions' Quality Assurance Program

Device validation data

- document initial device performance
- document control/reagent performance for troubleshooting

Quality control

- document ongoing operator competency
- document compliance with daily quality control regulatory requirements

Correlation samples

- proves accuracy of results across different devices, sites, and methods
- routinely verifies the performance at high, mid, and low ranges

Program compliance

- monitors operator compliance with quality assurance policies at each site

Medical history review

- determines appropriate test utilization (turn around time of results)
- documents clinical necessity and patient outcomes

FIG. 5: The Johns Hopkins Medical Institutions' Quality Assurance Program. Five databases in our program monitor aspects of quality assurance and offer quantitative parameters for continuous performance improvement.

By utilizing quality control conducted during routine use, we avoid having to visually inspect operators on a regular basis and prevent the additional testing (and cost) involved in those inspections. The objective, quantitative measures of quality control replace the subjectivity of visually monitoring operator performance and set a standard performance goal for operators to achieve.

These algorithms are automatically performed by the computerized database and allow only problem reports to be generated. Only reports that actually require technologist or nursing intervention are printed. This reduces paperwork and the task of manual review, saving labor and cost while maintaining quality.

A third component of our database stores proficiency and patient correlation results, allowing us to continuously verify the accuracy of individual devices against the laboratory. A fourth component trends performance monitors on the medical unit. Deficiencies in policy compliance and problems occurring on the units can be targeted for continuing education.

The effect of those education efforts can also be quantitatively determined. A final component is patient outcome. Since the POCT database interacts with the electronic patient medical record and the laboratory information system, the effects of POCT can be determined on selective patient populations.

Information management thus has unlimited potential not just for POCT but also for other laboratory tests, since the cost and labor-saving computer algorithms developed to ensure the quality of POCT can be applied to other modes of more traditional testing.

The advantage of our custom database allows us to connect and manage information from any device in the same manner. With almost 1 million tests conducted yearly at the point of care, we would not be able to manage the data in a cost-effective way without automatic computer algorithms. We chose to create a custom database because of limitations with currently marketed POCT software.

The primary limitation of current POCT is its exclusivity to a single device. For institutions with different types of device, a separate computer database must be maintained, with different software and reports. Current software also does not allow institutions to customize reports or data reductions. Since our database resides in a common format, standard queries can be constructed by our point-of-care testing coordinators as our needs change.

Operator summary statistics report for POCT glucose (ward A)							
				OPERATOR			
Name	Report Interval	Control Type	Data Points	Z-score	Mean	SD	CV
John Doe	July 1994	Control	8	-0.20	85.5	1.85	2.2
		High	8	0.13	310.3	8.97	2.9
		Low	8	0.27	49.8	2.66	5.3
Jane Doe	July 1994						
Jean Nurse	July 1994	Control	1	-0.37	85.0		
		High	1	3.44*	360.0		
		Low	1	-0.91	47.0		
Ann Public	July 1994	Control	17	-0.33	85.1	2.15	2.5
		High	16	-0.25	304.4	17.04	5.6
		Low	14	-0.14	48.8	1.67	3.4
* Failure outside 2SD limits from Johns Hopkins Group.							

TABLE Ia

Operator summary statistics report for POCT glucose (ward A)						
			GROUP			
Name	Report Interval	Control Type	Data Points	Mean	SD	CV
John Doe	July 1994	Control	494	86.1	2.83	3.3
		High	454	308.2	15.04	4.9
		Low	418	49.1	2.32	4.7
Jane Doe	July 1994					
Jean Nurse	July 1994	Control	494	86.1	2.83	3.3
		High	454	308.2	15.04	4.9
		Low	418	49.1	2.32	4.7
Ann Public	July 1994	Control	494	86.1	2.83	3.3
		High	454	308.2	15.04	4.9
		Low	418	49.1	2.32	4.7
* Failure outside 2SD limits from Johns Hopkins Group.						

TABLE Ib

TABLE Ia and b: Johns Hopkins Medical Institutions' POCT data management report summarizing operator statistics for glucose. This report allows quantitative comparisons of operator performance and can indicate operators whose performance differs from other operators, Jean Nurse high control, or who are not compliant with quality control testing, like Jane Doe. Control = optical check or electronic control, SD = standard deviation, CV = coefficient of variation, Group = entire institution.

$$\text{z-score} = \frac{\text{Mean(operator)} - \text{Mean(group)}}{\text{SD(group)}}$$

Finally, current software does not generate management reports. While individual operator or meter statistics can be calculated, no comparative statistics are utilized. These current limitations prevent the small institution from realizing the potentials that can be gained from POCT data in an electronic format.

Thus, manufacturers of POCT devices need to coordinate and standardize the industry to a common electronic format in order to allow future advancements in the area of POCT data management. Collection and manipulation of manual POCT will also be an area for future development.

Clinical outcomes

Turnaround time is frequently the driving force for point-of-care testing. However, in a recent survey of British physicians who utilized blood glucose and urine dipstick testing, 85 % of the clinicians trusted central laboratory results, 38 % did not trust bedside results, and 35 % would not accept responsibility for results obtained at the bedside [30].

Quality is thus a major concern, and there is a considerable effort expended in ensuring the quality of POCT. Managing technical interferences, assuring operator competency, and management of POCT data cost an institution in labor, oversight, and reagents. Without documentation of patient benefit, there is little reason to choose POCT over central laboratory testing.

The cost of POCT is often misleading due to the interdisciplinary nature of the testing process and the hidden costs of supervising the test quality. In general, POCT is characterized by low to moderate device cost and high individual test cost when compared to centralized laboratory instruments that can cost hundreds of thousands of dollars but pennies per test in reagents [31].

Ways to minimize the cost of POCT include increasing the testing volume on each device, decreasing non-patient quality control testing, minimizing the number of trained operators, utilizing lower paid operators, and limiting POCT to medically necessary populations [11, 59-62]. POCT too often tends to be an additional service in an institution rather than a replacement for central laboratory testing.

While there are numerous cost comparisons published, there are few well-controlled studies of POCT patient outcome. In one study, the use of coagulation testing was examined in cardiac surgery patients diagnosed with microvascular bleeding (N=66) [63]. The control group received standard aPTT and PT testing from the central laboratory (N=36), while the experimental group had access to POCT and utilized a simple treatment algorithm (N=30).

Those patients with access to coagulation POCT had fewer transfusions (fresh frozen plasma, platelets, and packed cells), decreased operative times, fewer reoperative admissions for bleeding, and less mediastinal chest tube drainage. The overall savings was estimated at USD 1,200 per patient or USD 215,000 annually.

Although coagulation POCT has the potential for patient benefit, the manner in which the POCT device is integrated into treatment and diagnosis will determine the utility of POCT. When utilizing POCT-activated partial thromboplastin for femoral sheath removal, over 93 % of bedside values agree with central laboratory result based on a single decision point [64].

However, agreement of only 53–78 % with the central laboratory was found for the same device when utilized for more complex therapies (heparin dosage adjustment or heparinization after thrombolysis) based on two to five decision points. Clinicians must therefore understand the limitations of the POCT device as a diagnostic tool and rely on the laboratory for more complex therapeutic interpretations.

POCT is too often over-utilized with little patient benefit. In an Australian study, a retrospective chart review was conducted on 2,294 hospitalized patients [65]. The hospital had a policy of obtaining a bedside dipstick urinalysis on admission. The charts indicated that no result was recorded in 12 % of patients, a normal result

in 75 %, an expected abnormal result in 9 %, and an unexpected abnormal result in 4 %.

Physicians were questioned in the 101 cases where an unexpected abnormal result was recorded. Of these, the physician was aware of the abnormality only a third of the time (N=30), ordered additional investigations in only half of those cases (N=15), and altered treatment in none of the cases. Thus, the expense of conducting routine admission urine dipsticks did not lead to any change in treatment or beneficial outcome. One has to ask why this test was conducted in the first place.

In the urine dipstick POCT study, physician acknowledgment of the POCT result was an issue. If POCT is meant to improve laboratory turnaround time then acknowledgment of the result and therapeutic action should take place concurrently. Delays in physician acknowledgment and therapeutic action from POCT have been examined at the University of Southern California Medical Center, Los Angeles [66].

The components of laboratory turnaround time were examined to justify the construction of a satellite laboratory in the emergency room. While minor improvements could be made to those steps of the testing process under laboratory control; namely transportation, processing, analysis, and result reporting, a delay of 45 minutes was noted before clinicians became aware of test results and instituted therapy.

Due to this delay, the construction of a satellite laboratory was not justified. Thus, laboratory testing, whether conducted at the point of care or in a central laboratory is only one component of patient therapeutic management. In order to optimize patient benefit, all steps of the patient's pathway must be examined and optimized.

Summary

Point-of-care testing offers the potential for immediate test results and therapeutic action. However, merely offering POCT on a medical unit does not guarantee beneficial patient outcome. Delays in physician acknowledgment, overutilization of POCT, and inconsistencies in quality can actually increase healthcare costs and risk to the patient.

POCT is a remote extension of the laboratory and has the same preanalytical, analytical, and postanalytical concerns that face central, core laboratory testing. The portable nature of POCT adds environmental, patient, and operator factors that are unique to its application outside of the well-controlled environment of a formal laboratory.

As inpatient populations become more acute, the demands for a wider menu of tests, with faster results, on smaller volume specimens will only increase the pressure for POCT and find new applications for POCT in the future.

As POCT expands, the traditional laboratorian's role will need to change as they take on a more direct, active participation on the patient care team. In this role, the laboratorian will bring expertise in laboratory analysis into the manufacturing realm, improving the design of POCT devices, and onto the medical unit, improving the quality and laboratory comparability of POCT results.

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