Perspectives on Cost and Outcomes for Point-of-Care Testing

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KEYWORDS

• Point-of-care testing • Cost • Outcomes

PERSPECTIVES ON COST

It is generally perceived that point-of-care testing (POCT) is more expensive on a unit-cost basis than testing performed in a centralized laboratory.[1–7] This concept reflects the fact that the cost of consumables for POCT is typically greater than it is for tests performed using automated laboratory instruments and the fact that point-of-care tests are performed one at a time and, therefore, cannot achieve the economy of scale afforded by high-volume automated testing. Various studies have compared the cost of POCT to that of central laboratory tests, as summarized by Foster and colleagues (**Table 1**).[2] Although most studies indicate that POCT is more expensive than central laboratory testing, that is not always the case. Some studies have shown that POCT is not invariably more expensive, depending on the test volume, testing technology, program management, and other factors.[3] In one study, Bailey and colleagues[8] reported an institutional savings of $392,336, with a reduction in unit cost from $15.33 per panel to $8.03, following institution-wide implementation of POCT for blood gases and electrolytes.

Despite a significant volume of literature on this subject, calculating the actual cost of POCT compared with that of the central laboratory remains an enigma. Unit cost reflects only one part of the overall equation. Other factors must also be considered, as summarized in article by Lewandrowski.[9] These include the impact of reduced turnaround time on the time to diagnosis and treatment, impact of testing on the overall cost of care, issues of workflow on clinical units, impact on test use, length of patient stay, and potential improvements to clinical outcomes. Lacking a clear consensus in the literature, the decision of whether to implement POCT or use a central laboratory

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Table 1
Selected cost comparisons between POCT and central laboratory testing (in US dollars)

Tests	POCT Cost	Central Laboratory Testing Cost	Reference
Glucose	$11.50	$3.19	3
	$6.62	$3.30	4
	$7.12	$6.85	5
Blood gases/electrolyes	$45.00	$9.50	5
Chemistry and hematocrit	$14.37–16.67	$20.62	6
Mixed emergency department menu	$19.20	$2.94	7

Data from Foster K, Despotis G, Scott M. Point-of-care testing. Cost issues and impact on hospital operations. In: Lewandrowski K, guest editor. Point of care testing. Clinics in Laboratory Medicine, vol. 21, no. 2. Clin Lad Med 2001;21:269–84.

will depend on a number of factors beyond unit cost. Many of these factors are unique to the individual hospital or care unit.

One of the issues related to unit-cost analysis for POCT concerns the conceptual model for determining labor costs. In contrast, the cost of consumables is usually straightforward. In calculating labor costs for central laboratory testing, one must include in-laboratory labor costs and preanalytic labor costs for services such as phlebotomy and nursing (**Table 2**). To obtain a central laboratory test, phlebotomy supplies must first be gathered, a requisition (or order entry) test request must be completed, tubes must be labeled, and the sample specimen must be collected. The specimen must then be packaged and sent to the laboratory, either by pneumatic tube or by human courier. After the sample is in the laboratory, the test request must be accessioned (or, in the case of order entry, receipt acknowledged), the specimen must then be processed, and the testing performed. In contrast, using POCT, supplies must be gathered, the specimen collected, and the test performed. In this model, POCT eliminates many of the preanalytic steps, all of which involve labor cost. Calculating the actual labor cost requires a detailed time-and-motion study and must take

Table 2
Hypothetical labor steps involved in central laboratory testing versus POCT

Steps	Central LaboratoryTesting	POCT
Order test	X	X
Acknowledge order	X	X
Label tubes or other consumables	X	X
Collect specimen	X	X
Package specimen	X	—
Transport specimen	X	—
Receive and acknowledge receipt (or accession)	X	—
Process specimen	X	—
Perform test	X	X
Release result	X	—
Receive result	X	X

into consideration differential hourly rates for phlebotomists, nurses, and medical technologists. Conceptually, the POCT labor model can be significantly less expensive than the cost for all of the labor-consuming steps that are involved in the central laboratory model. However, each test is different and each clinical situation unique. It is therefore not possible to make generalizations about the labor-cost model for POCT compared with the central laboratory model.

The central concept underlying the justification for POCT is turnaround time. The presumption is that faster turnaround time is necessarily better for patient care and for hospital operations. However, in many situations this is not the case. More to the point, test results must be made available in a clinically relevant time frame. For example, the use of whole-blood cardiac-marker POCT testing in the emergency department permits physicians to make rapid decisions concerning triage, diagnosis, and disposition for patients who have acute coronary syndromes. This may facilitate the making of treatment decisions and allow for efficient disposition of the patient to the appropriate hospital setting (eg, observation unit, catheterization laboratory, cardiac intensive care unit). As an alternate example, prostate-specific antigen (PSA) testing is commonly used in outpatient settings to screen for prostate cancer. Usually this test is co-ordered with other screening tests such as cholesterol and fasting plasma glucose as part of the routine health assessment. Implementing a point-of-care test for PSA in a primary care setting would be costly and would not appreciably alter clinical care or physician practice efficiency unless all of the screening tests were made available at the time of the office visit. On the other hand, implementing POCT for hemoglobin A1c in a diabetes clinic setting could potentially allow for immediate adjustments to the patient's diabetic care during the office visit, regardless of what other tests may have been ordered.

There are some tests that, regardless of cost, must be performed at the point of care. An example is the activated clotting-time test. This test (described further in the article by Van Cott in this issue) is used to monitor high-dose heparin therapy in patients who are undergoing cardiac surgery, interventional radiological procedures, extracorporeal membrane oxygenation, and other procedures. After the sample is collected, the blood immediately begins to clot. There is no time for transport to a central laboratory. Another common example is provider-performed microscopy that involves potassium hydroxide preparations in outpatient settings that are removed from a central laboratory. As one final example, rapid influenza testing can be used to identify patients who may benefit from antiviral therapy. These antibiotics must be administered very early in the course of infection to reduce the patient's symptomatic interval. Few central laboratories offer around-the-clock influenza testing. In many outpatient clinics, the time required for transport to a central laboratory is impractical to allow for timely decisions concerning antiviral therapy.

When compared with the cost of many heath care services, laboratory testing is inexpensive. It is generally recognized that laboratory testing comprises only about 4% of the average hospital budget. Yet laboratory testing directly impacts nearly two thirds of hospital activities and the cost associated with this care. Viewed in this perspective, laboratory testing should be seen as an enabling technology that can improve (or impair) the efficiency and quality of patient care. When considering whether to implement POCT, it is important to consider unit cost compared with unit value. An expensive test such as a rapid cardiac troponin test that can influence medical decision making or improve the efficiency of clinical operations may be highly cost effective.[7] Conversely, an inexpensive test for troponin that is too slow may negatively impact care and result in inefficient use of expensive hospital capacity. The rapid troponin test has a high unit value, whereas the slow but inexpensive test is essentially

worthless. As one final example, POCT for creatinine is being increasingly used in radiology departments to evaluate renal function in patients before administering contrast agents for CT scans. Patients who have impaired renal function, as reflected by an abnormal estimated glomerular filtration rate, are at increased risk for contrast-induced acute kidney injury. Screening patients at the point of care permits rapid decisions to be made concerning which patients need appropriate preventive measures and promotes more efficient use of highly expensive CT scanners. If the same test were sent to the clinical laboratory, CT scans might be significantly delayed. The CT scanner would stand idle, resulting in inefficient use of expensive CT capacity.

PERSPECTIVES ON OUTCOMES

Because POCT is generally more expensive than central laboratory testing and may be difficult to manage from a regulatory perspective, it is important when considering implementation of POCT to document that some positive impact has been achieved. In other words, you need to show that the testing actually accomplishes something useful to justify the increased incremental cost. The term generally used for this is ''outcomes.'' Outcomes may take several forms, as shown in **Table 3**. In the authors' experience, there are different types of outcomes. First, there are medical outcomes. These outcomes are reflected in data on morbidity and mortality. The patient lives longer, has fewer complications, or shows other improvements in his or her medical condition. In the authors' experience, these types of outcomes can be very difficult to document. Often, studies on medical outcomes require large numbers of patients and long follow-up. As an example of this problem, consider that with all of the research that has been performed on PSA screening and mammography, there is, as yet, only inconclusive evidence that the screenings actually improve long-term survival. In some cases, performing controlled outcomes studies would be ethically questionable because patients could be denied laboratory testing that is part of the established standard of care.

Then there are financial outcomes. In theory, these should be easy to document if one applies a robust cost accounting system. In practice, however, the task is not so easy. Medical care involves a complex interaction of a large number of variables, each of which influence the others in sometimes poorly understood ways. In isolation, one can add up the cost of testing reagents and labor and assign a value for overhead to determine which test, point-of-care or central laboratory, is more expensive. However, such analysis does not take into consideration the possible impact of

Table 3
Classification of clinical outcomes

Types of Outcome	Examples/Comments
Medical outcomes	Decreased morbidity or mortality, improved functional status. May be difficult to document. May require long-term follow-up of large numbers of patients.
Financial outcomes	Decreased cost or cost avoidance. May appear to be straightforward to document, but in practice most financial outcomes rely on highly artificial cost accounting models.
Operational outcomes	Decreased hospital length of stay, improved capacity use. Usually not difficult to document. Many operational parameters are already routinely monitored by hospitals.

a more rapid test result on medical decisions, patient outcomes, hospital operations, differential reimbursement rates, and other factors. As a consequence, most cost analyses that the authors have observed concerning laboratory testing, including those that they have published, are highly artificial and are, for practical purposes, essentially worthless.

Finally there are operational outcomes. These include metrics such as length of stay, throughput, and other measures of efficiency. These are usually not too difficult to measure, and in fact, most hospitals perform these measurements routinely as part of clinical operations dashboards. In the case of POCT, it is not difficult to measure, for example, emergency department length of stay before and after implementation of a new test.[1,7,10] Indeed, there is only modest and selective evidence in the literature that POCT as opposed to central laboratory testing improves clinical outcomes. However, there is abundant evidence that POCT can improve efficiency and hospital operations.

An important consideration when evaluating the impact of POCT on outcomes is to evaluate whether the outcome simply resulted from the availability of a new test or whether it resulted specifically from implementation of POCT. For example, Mueller and colleagues[11] reported on a prospective, randomized, controlled study of 452 patients who presented to the emergency department with dyspnea. Patients were assigned to a diagnostic strategy using a point-of-care B-type natriuretic peptide assay or to standard care without natriuretic peptide testing. The time to discharge and the total cost of treatment were evaluated. The study demonstrated that the patients who received POCT natriuretic peptide testing had a decreased hospital length of stay (8 days versus 11 days) and a decreased total cost of care ($5,410 versus $7,264). Presumably, these outcomes resulted from the ability of the POCT test to provide a rapid diagnosis and allow for earlier commencement of appropriate treatment for patients in that group compared with the patients that did not receive natriuretic peptide testing. In a separate study, Green and colleagues[12] evaluated hospital length of stay, postdischarge mortality, and rates of rehospitalization following implementation of N-terminal prohormone brain nutriuretic peptide (NT-proBNP) testing in the central laboratory. They documented a decrease in hospital length of stay of 1.86 days, a decrease in postdischarge 60-day mortality, and a decrease in the rate of rehospitalization. The question then remains, were the outcomes the result of POCT or were the outcomes the result of making natriuretic testing available, either in the central laboratory or at the point of care. Another example of this dilemma concerns the use of fecal occult blood testing (FOBT) to screen for colorectal carcinoma. There is clear evidence that the appropriate use of FOBT can reduce mortality from colorectal cancer (see the article on FOBT by Sanford & McPherson in this issue). FOBT can be performed in the home, the physician's office, or a central laboratory. There is no clinical or operational need for rapid testing. Rather, it is important that the test is performed, that the results are followed up, and that the test be done properly according to established guidelines. Although FOBT is often considered a point-of-care test, the performance of this test at the point of care offers no real advantage.

Given the previous discussion and the nuances described when evaluating outcomes, it is useful to consider cases in which there is good evidence to indicate that improved outcomes resulted from the implementation of POCT (**Table 4**). Selected examples are described in this article, and some of them are discussed further in other articles by Sanford & McPherson, Lewandrowski, Alter & Deines and Campbell in this issue. Previous publications regarding POCT and outcomes provide augmentation of this discussion.[13–15] Of particular note, the reader is referred to article

Table 4
Selected examples of improved outcomes resulting from POCT

Tests	Outcomes/Comments
1. Patient home capillary-glucose monitoring test	Permits tight glycemic control with associated improved outcomes.
2. Tight glycemic control in intensive care settings	Improved outcomes in intensive care settings (see article in this issue by **[first author's name]** on tight glycemic control).
3. Patient home self-monitoring of anticoagulation	Documented improvements to maintaining appropriate level of long-term anticoagulation.
4. POCT cardiac markers in the emergency department	Multiple studies show reduced emergency department length of stay.
5. POCT D-dimer test in the emergency department	Decreased emergency department length of stay and increased rate of discharges to home.
6. POCT rapid urine drugs-of-abuse test	Decreased emergency department length of stay.
7. Rapid influenza test	Facilitates early antiviral therapy.
8. Rapid HIV test in emergency departments and outpatient clinics	Facilitates identification of HIV infection and improves rate of appropriate follow-up.
9. Intraoperative parathyroid hormone test	Improved success of parathyroid surgery.

by Nichols and colleagues.[13] which includes a comprehensive evidence-based discussion of a number of point-of-care technologies.

Home Self-Testing of Capillary Glucose in Patients who have Diabetes Mellitus

Capillary blood glucose tests originally gained popularity as a means for patients who have diabetes to self-monitor their own glucose levels. These technologies revolutionized diabetes care, permitting patients to maintain tight glycemic control. They have been clearly linked to improved outcomes in terms of retinopathy, nephropathy, and certain vascular complications.

Tight Glycemic Control in Intensive Care Settings

This topic is covered in detail in the article by Alter & Deines in this issue.

Patient Home Self-Monitoring of Anticoagulation

Patient self-testing to monitor Coumadin therapy was, for a number of years, highly controversial. Laboratory professionals were concerned that self-testing for prothrombin time was potentially dangerous and that the devices were unreliable compared with tests performed in the central laboratory. Subsequent studies have shown that with proper training and more reliable devices, patients can achieve better anticoagulation management using self-testing as opposed to being monitored exclusively in the physician's office. This topic is discussed further in the article Van Cott in this issue.

POCT for Cardiac Markers in the Emergency Department

Several studies have documented that the performance of rapid, whole-blood, cardiac-marker testing (eg, for troponin, creatine kinase-MB, myoglobin) may result in a decrease in either emergency department or hospital length of stay (**Table 5**).[16–18] This topic was recently reviewed by Storrow.[18] Virtually all studies have shown significant reductions in test turnaround time, which is, itself, an outcome. However, reduced turnaround time is only helpful if it is associated with improved patient care, financial improvements, or improved efficiency of clinical operations (such as decreased emergency department length of stay). One result of these studies is that an increasing number of hospitals are implementing rapid, whole-blood, cardiac-marker testing in the emergency department. However, it is noteworthy that no published studies to date have documented cases of patients who had acute coronary syndromes for whom improved clinical outcomes resulted from the implementation of rapid cardiac marker testing at the point of care. The clinical justification for rapid cardiac-marker testing is discussed further in the article on cardiac markers by Lewandrowski in this issue.

POCT for B-type natriuretic peptides has also been shown to reduce hospital length of stay, but as with a previous discussion in this article, it is not clear that this outcome resulted from simply making the new test available, regardless of whether it was performed in a central laboratory or at the point of care.

POCT for D-Dimer to rule out Deep-Venous Thrombosis and Pulmonary Embolism

D-dimer is a protein product of fibrinolysis that can be measured in the blood. When a blood clot forms, the fibrinolysis system is activated to begin removal of the clot. One component of this system is the enzyme plasmin, which digests fibrin in the clot, producing fibrin fragments in the blood. One of these fragments is D-dimer. An elevated level of D-dimer indicates that fibrinolysis is occurring and, by inference, that a clot is present. In patients who have deep-venous thrombosis (DVT) or pulmonary embolism (PE), the D-dimer level is typically elevated. The D-dimer test is not specific for DVT or PE, however, because there are other causes for an elevated D-dimer level such as disseminated intravascular coagulation and liver disease. One of the cornerstones in the approach to a patient who has a possible DVT is the concept of risk stratification to determine the pretest probability of a DVT (see **Fig. 1**). The most commonly used system is the Well's Score. This system assigns points for various risk factors for DVT, such as cancer, immobilization, and edema of a single leg. The points are added to assign the patient into a low-, moderate-, or high-risk category. In low-risk patients, the appropriate first step is to test for the presence of D-dimer. If

Table 5
Studies documenting improved outcomes resulting from POCT for cardiac markers in the emergency department

Studies (Year)	Outcomes
Apple (2006)[16]	Decreased hospital length of stay of 4 hours
Lee-Lewandrowski (2001)[7]	Decreased emergency department length of stay of 47 minutes. Increased rate of discharge of patients who had chest pain.
Singer (2005)[17]	Decreased emergency department length of stay of 1.9 hours.

Data from Storrow A. A systematic review of emergency department point-of-care cardiac markers and ED efficiency measures. Point of Care, in press.

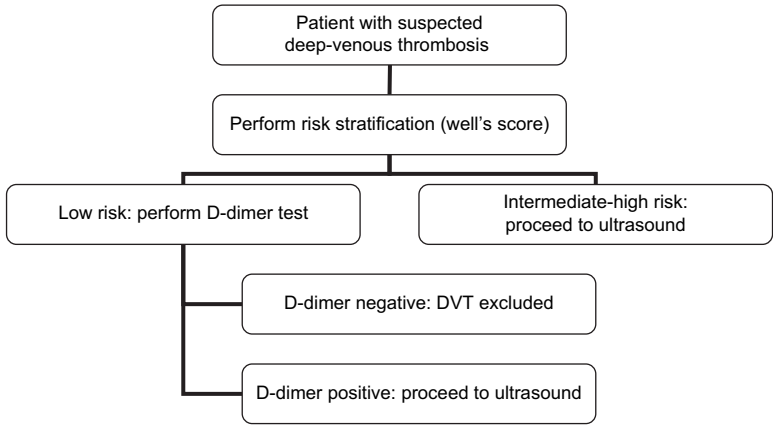

Fig. 1. Approach to the patient who has suspected deep-venous thrombosis (DVT).

the D-dimer test is negative, that finding will essentially exclude the diagnosis of DVT. If the test is positive, then an ultrasound is required to confirm the diagnosis. Moderate- and high-risk patients require an ultrasound regardless of the D-dimer value. For these patients, D-dimer testing is unnecessary before ultrasound procedures are performed. The approach for the patient who has a suspected PE is very similar. The first step is to perform a risk stratification to determine the pretest probability of a PE. Patients are divided in low-, moderate- and high-risk categories. Low-risk patients should be tested for the presence of D-dimer. If the D-dimer test is negative, then the diagnosis of PE can be essentially excluded. If the test is positive, then a CT scan or other study should be performed to confirm the diagnosis. Moderate- to high-risk patients should receive a CT scan regardless of the D-dimer value. Therefore, in the evaluation of possible DVT or PE, D-dimer testing is primarily useful for the exclusion of a diagnosis of DVT or PE in low-risk patients. Positive results must be confirmed using the appropriate radiologic study. The D-dimer test is of little value in moderate- to high-risk patients, who always require radiologic scans. Conceptually, the D-dimer test should help to reduce the use of unnecessary and expensive ultrasound and CT scans. Used appropriately, the test is highly cost effective.

One recent study reported on the implementation of a rapid, whole-blood, D-dimer test in the emergency department.[1] After implementation, the mean and median length of stay in the emergency department was significantly reduced for patients who received the rapid, D-dimer, point-of-care test. Another outcome that was demonstrated was a change in patient disposition. With the rapid test, fewer patients were admitted and a higher percentage was discharged home from the emergency department. There was also an increase in patients who were admitted to a short-stay observation unit, presumably at the expense of regular hospital admissions. Interestingly, there was no significant change in the use of radiologic testing after implementation of the test.

The experience with rapid POCT for cardiac markers and D-dimer illustrates an important concept concerning outcomes and POCT. Not all forms of POCT in the emergency department have been shown to improve patient care or emergency department operations. For example, two studies evaluated POCT for common, routine analytes (eg, electrolytes, blood gases, hematocrit) in the emergency department.[19,20] In both studies, laboratory test turnaround time was significantly reduced,

but there was no demonstrable impact on emergency department length of stay. The important difference between the menu of tests used in those studies as opposed to tests for cardiac markers and D-dimer is that the latter two tests directly impact a key point in decision making concerning triage, diagnosis, or disposition, as shown in **Fig. 1**. In contrast, performing a small number of routine chemistry tests is ineffective because those tests do not directly affect key decision steps in the evaluation of emergency room patients. Furthermore, in regard to tests of blood gases and electrolytes, in most cases, other routine tests such as a complete blood count or liver function are co-ordered with those tests. Accomplishing a rapid turnaround time for some, but not all, of those tests would usually have minimal impact on emergency department length of stay.

POCT for Urine Drugs of Abuse in the Emergency Department

A recent study evaluated the impact of implementation of rapid urine drugs-of-abuse testing in the emergency department.[10] In that study, a decrease in the mean and median length of stay in the emergency department was documented. One unique feature of the study site was that the emergency department included a large acute psychiatric service. Drugs-of-abuse testing was performed as one component of the protocol to medically clear patients before admission or discharge to an outpatient care setting.

POCT for Influenza A and B

This topic was discussed previously in this article and is discussed in the article by Lewandrowski in this issue.

Rapid POCT for HIV Infection

Several manufacturers have marketed rapid point-of-care HIV tests that use either blood or salivary samples. This topic is discussed in more detail in the article by Campbell in this issue. There are three settings in which these tests have been employed:

A. Employee needle-stick (sharp) injuries: Hospital employees may be put at risk for occupational HIV infection resulting from needle-stick injuries from infected patients. A key component of managing these cases is to decide whether to administer prophylactic antiretroviral drug therapy to the employee. This decision may be guided by testing the patient for HIV antibodies. Most hospital laboratories are not equipped to offer timely HIV testing on a 24-hour basis. In such a situation, rapid HIV tests may be employed.
B. Rapid point-of-care HIV testing in outpatient clinics and emergency departments: A significant number of patients who are infected with HIV are unaware of their infection. Some of these patients lack heath insurance, are indigent, or are otherwise at risk for being lost to medical follow-up after HIV testing. When testing is performed in a central clinical laboratory, the test results typically are not available until after the patient has left the clinic or emergency department. Implementation of POCT for HIV permits results to be made available before the patient has left the clinical facility. Presumably this allows patients to be set up with outpatient HIV treatment resources before they are lost to follow-up.
C. Rapid HIV testing in pregnant patients presenting in labor but without prenatal care: In patients presenting in labor who have had no prenatal care, there is potential risk for maternal–fetal HIV transmission during delivery. In an HIV-infected mother, the risk for transmission can be significantly reduced by administration

of antiretroviral prophylaxis. The decision to administer these drugs can be guided by using rapid HIV testing.

POCT to Monitor Hemostasis in Surgical Patients

The potential utility of POCT for intraoperative hemostasis monitoring of patients during cardiopulmonary bypass was reviewed by Despotis and colleagues.[21] Such patients are at increased risk for excessive perioperative blood loss that may necessitate the transfusion of blood products. POCT can facilitate patient-specific adjustment of heparin and protamine dosing, resulting in reduced blood loss and need for transfusions.

SUMMARY

POCT is usually more expensive on a unit-cost basis than testing performed in a central laboratory. POCT is also notoriously difficult to manage, and it is challenging to maintain regulatory compliance for POCT, especially in large institutions. For these reasons, it is important to demonstrate that POCT can improve patient outcomes or clinical operational efficiency before testing is implemented. Although the literature on POCT and its relationship to improved outcomes is not extensive, some POCT technologies have been shown to improve patient outcomes (eg, patient self-glucose monitoring in the home, tight glycemic control in intensive care settings) or to improve hospital or emergency department operations (eg, whole-blood cardiac-marker testing and D-dimer testing in the emergency department). In some cases, these outcomes result simply by making a new test available rather than by being a direct consequence of performing testing at the point of care. However, in most cases, the rapid turnaround time provided by POCT is the main factor that is ultimately responsible for the improvement in outcomes.

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