Implementing point-of-care testing to improve outcomes

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Abstract
Point-of-care testing (POCT) is defined as testing performed outside of the central laboratory at or near the patient’s bedside. A number of devices have been developed that permit a wide menu of tests to be performed at the POC. In most cases the unit cost of POC tests is greater than similar testing performed in the central laboratory. For this reason when implementing POCT it is important to demonstrate an improvement in outcomes to justify the added incremental cost of the testing. Outcomes may be classified as either medical outcomes, financial outcomes or outcomes reflecting an improvement in clinical operations or efficiency. In most cases where outcomes have been demonstrated for POCT the impact has been to improve the efficiency of clinical operations. Less often POCT has been linked to an improvement in medical outcomes. This paper will describe selected case studies available in the literature to demonstrate how improved outcomes can be achieved and documented from POCT in a variety of different settings.

Key words
Point of care testing, Near patient testing, Outcomes, Emergency department

1 Introduction
Interest in efficiency and cost effectiveness in health care has created increasing focus on analyzing outcomes resulting from implementation of new technologies and treatments. Outcomes can be classified into three general categories.

i. Medical outcomes. This category includes such factors as improving cure rates, better management of chronic diseases and improvements in the quality of life.

ii. Financial outcomes. These include reduced overall expenditures and increasing cost effectiveness.

iii. Operational outcomes: This category includes such metrics as reducing length of stay, improving patient throughput, and streamlining complex error prone operations.

Laboratory testing typically accounts for about 4% the typical hospital operating budget [1]. However, because laboratory tests are so central to the diagnostic and treatment process, laboratory testing is believed to influence about two thirds of health care costs [1]. Reducing the cost of laboratory services has been a focus of interest for many years including absolute
reductions to the laboratory budget, reducing the average unit cost of tests and attempts to control unnecessary laboratory utilization. Collectively these efforts have produced significant if inconsistent results. The menu of available laboratory tests has continually increased including the introduction of many new expensive genetic and molecular diagnostic tests. These developments have driven up the overall cost of laboratory services in the majority of hospital laboratories.

2. Discussion

Laboratory testing services can be provided by any one of 4 different methods.

i. Traditional testing performed in a central hospital laboratory.

ii. Reference laboratory testing provided by a central facility outside of the hospital (i.e. sendout referral testing).

iii. Point-of-care testing performed by physicians or nurses at, or near the patient bedside.

iv. Home-based testing performed by the patient or other caregiver.

A large and expanding number of laboratory tests can, in theory, be performed at the point-of-care either in a hospital or outpatient clinic (Table 1). In general technologies for performing point-of-care tests must be small in size, easy to use and fault tolerant particularly in regard to preventing operator errors. In addition a data management system is essential to keep track of test results and to ensure compliance with regulatory guidelines. Manufacturers of point-of-care testing (POCT) devices have progressively improved the hardware and software of their instruments. As a consequence several major trends have emerged over the past decade. Among these is an expansion of the available test menu with improved technologies to provide more accurate results. Manufacturers have also developed consolidated platforms that are able to perform a variety of different tests on a single instrument. Further, robust data management systems are now available allowing electronic transmission of test results and centralized management of POCT programs [2]. Finally, large organizations have improved their ability to manage POCT programs employing nurses and medical technologists specifically trained in the oversight of POCT. As a consequence the utilization of POCT has continued to grow in the hospital and outpatient settings.

<table>
<thead>
<tr>
<th>Table 1. Selected Menu of Currently Available Point-of-care Tests</th>
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<tbody>
<tr>
<td><strong>Chemistry:</strong></td>
</tr>
<tr>
<td>Blood glucose testing,</td>
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<tr>
<td>Blood gases, fetal scalp pH,</td>
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<tr>
<td>Electrolytes, specific gravity</td>
</tr>
<tr>
<td>Basic and Comprehensive metabolic panel</td>
</tr>
<tr>
<td>Cardiac markers: troponin, CK-MB, myoglobin, BNP</td>
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<tr>
<td>Dipstick urinalysis</td>
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<tr>
<td>Pregnancy testing and ovulation assessment</td>
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<tr>
<td>Fecal occult blood and gastric occult blood</td>
</tr>
<tr>
<td>Lipid panel and cholesterol</td>
</tr>
<tr>
<td>Neonatal bilirubin</td>
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<tr>
<td><strong>Hematology:</strong></td>
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<tr>
<td>Coagulation testing: Prothrombin time/INR, D-dimer,activated clotting time and, platelet function</td>
</tr>
<tr>
<td><strong>Microbiology/Serology:</strong></td>
</tr>
<tr>
<td>Physician performed microscopy.</td>
</tr>
<tr>
<td>HIV, Group A streptococcus, H. pylori serology and CLO testing, sexually transmitted diseases</td>
</tr>
</tbody>
</table>

Unlike testing in a central laboratory where fixed costs can be distributed across a large volume of tests to achieve economy of scale, POCT tests are performed at low volume one at a time. Consequently the unit cost of POCT is almost
invariably higher than testing in the central laboratory. Further, when testing is performed by non-laboratory personnel, most organizations have experienced significant difficulties with regulatory compliance. In large organizations, management of a multi-site distributed network of testing locations can be particularly challenging. For these reasons, when considering implementation of POCT, it is important to demonstrate some improvement in outcomes medical, financial or operational.

The underlying concept behind POCT is that when testing is performed at the bedside, the results are immediately available for medical decision making. This contrasts with testing performed in a central laboratory where results for commonly ordered tests may take hours or, in the case of an outside reference laboratory, a day or more. Presumably, when test results are immediately available, an improvement in outcomes may occur, including more rapid diagnosis and treatment or an improvement in operational efficiency. These improvements should offset the added incremental cost of POCT. Although this concept appears simple, in practice there are relatively few peer reviewed publications to document improved outcomes resulting from POCT. This article will describe selected case studies from the literature supporting the concept that POCT can improve outcomes in a variety of settings. For this purpose we will highlight specific settings in which the value of POCT has been well established rather than attempt an exhaustive review of the entire subject. Articles cited in this manuscript were selected as examples of where POCT has been shown to improve outcomes in a variety of settings including the emergency department, in-patient and outpatient clinical sites, ancillary services (radiology) and testing performed in the patients home. Not all published studies on POCT have described an improved outcome. Indeed, some studies have shown no improvement in outcomes despite increased incremental cost. The studies described in this paper were not selected in any systematic way but rather were chosen to illustrate examples of improved outcomes across the spectrum of care.

2.1 Point-of-care testing in the emergency department

The main goals of patient care in the emergency department (ED) are initial triage, establishing a diagnosis, providing any necessary immediate treatment followed by a decision on disposition either home, admission to the hospital or transfer to another facility. Each of these steps involves a number of decisions and queues which require information to be gathered before the patient can move to the next step in the ED operation. Diagnosis and initial treatment are dependent, in part, on the availability of laboratory test results. Logically it follows that if the test results are provided more quickly than the ED length of stay (LOS) for the patient will be decreased and in some cases medical outcomes will be improved.

A number of studies have looked at the impact of rapid POCT on ED LOS. In two early studies Kendall et al and Parvin et al studied the impact of providing blood gas and electrolyte testing at the POC in the ED. Parvin evaluated the impact of a POCT electrolyte panel and found no impact on ED-LOS. Kendall et al studied the impact of a POCT device for electrolytes, blood gases and hematocrit and reported that some medical decisions were made an average of 74 minutes faster but there was no impact on ED-LOS. One issue with these studies concerns the test menu. First, only a small minority of ED patients receive testing for arterial blood gases. Second, the great majority of ED patients who are tested for electrolytes also have other common tests ordered simultaneously including tests for renal function and a complete blood count. Unless the POCT menu includes most of the routine tests ordered on the patient, there will be no impact on LOS because clinicians must wait for the results of the remaining tests to arrive from the central laboratory.

Cumulative experience with ED POCT has shown that specific tests that determine a key medical decision point or allow the patient to move through a queue are the ones most likely to impact ED-LOS. Examples include cardiac markers for acute coronary syndromes and heart failure, D-dimer for venous thromboembolic disease, rapid strep A and drugs of abuse. For example, an algorithm for the use of D-dimer testing is shown in figure 1. In a patient suspected of having a deep venous thrombosis (DVT) the first step is to perform a risk assessment. Moderate to high risk patients are sent for a venous ultrasound examination. However, the majorities of patients are low risk and are first tested for D-dimer. If the
D-dimer is negative (the majority of patients) then a DVT can be effectively ruled out without the need for an ultrasound examination. Therefore the turn around time for the D-dimer test is the key step in determining the patients ED-LOS once the physician has made the initial assessment. One published study documented a decrease in both the mean and median LOS following implementation of a point-of-care D-dimer test [6].

Table 2. Examples of Implementation of Point-of-Care Testing (POCT) and Outcomes

<table>
<thead>
<tr>
<th>Test(s)/Reference</th>
<th>Setting</th>
<th>Sample size</th>
<th>Significant Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Cardiac markers (21)</td>
<td>ED</td>
<td>369</td>
<td>Decreased ED-LOS</td>
</tr>
<tr>
<td>2. HbA1c (16)</td>
<td>OP</td>
<td>201</td>
<td>Improved 6 month and 1 year glycemic control</td>
</tr>
<tr>
<td>3. Creatinine (18)</td>
<td>Radiology</td>
<td>441</td>
<td>Avoidance of cancelled CT/MRI scans</td>
</tr>
<tr>
<td>4. Influenza (11)</td>
<td>ED-P</td>
<td>391</td>
<td>Decreased ED-LOS, antibiotics and tests ordered</td>
</tr>
<tr>
<td>5. PT-INR (20)</td>
<td>OP</td>
<td>102</td>
<td>Increased percentage of patients in INR control range</td>
</tr>
<tr>
<td>6. CMP (12)</td>
<td>ED</td>
<td>2,323</td>
<td>Reduced ED door to decision time</td>
</tr>
<tr>
<td>7. BNP (10)</td>
<td>ED</td>
<td>225</td>
<td>Decreased hospital LOS</td>
</tr>
<tr>
<td>8. Drugs of abuse (9)</td>
<td>ED</td>
<td>197</td>
<td>Decreased ED LOS</td>
</tr>
<tr>
<td>9. D-dimer (6)</td>
<td>ED</td>
<td>462</td>
<td>Decreased ED LOS, no decrease in radiologic studies</td>
</tr>
</tbody>
</table>

Notes:
1. Observational study comparing ED-LOS in patients presenting with signs and symptoms of acute coronary syndrome before and after implementation of rapid cardiac markers.
2. Randomized controlled trial in an outpatient adult diabetes specialty practice evaluating glycemic control with or without POCT for HbA1c.
3. Observational study in a radiology department evaluating the impact on CT/MRI scans after implementation of on-site creatinine testing in patients presenting without a recent creatinine/estimated glomerular filtration rate.
4. Observational study in a pediatric emergency department using POCT influenza testing. Compared influenza positive cases where physicians were either aware or unaware of the POCT result.
5. Observational before/after study in a family practice setting. Evaluated the percentage of patients within the INR control range using POCT with a warfarin management protocol versus central laboratory testing.
6. Randomized controlled trial in an emergency department comparing patients who received POCT to those whose testing was sent to a central laboratory.
7. Randomized controlled trial in a hospital emergency room comparing LOS in patients who received POCT testing for BNP to those who did not.
8. Observational study comparing ED-LOS in patients receiving toxicology testing before and after implementation of POCT drugs of abuse testing.
9. Observational study comparing ED-LOS in patients with signs and symptoms suggesting venous thromboembolism before and after implementation of POCT d-dimer testing.

A number of studies (but not all) have shown that POCT for cardiac markers can decrease ED-LOS as recently reviewed by Storrow et al [7] and Hart et al [8]. Most patients (90%) who present with symptoms suggesting an acute coronary syndrome ultimately are found not to have had an acute myocardial infarction (AMI). The results of the electrocardiogram and blood cardiac markers including troponin I or T are key pieces of diagnostic information that are necessary to rule out or rule an AMI. Consequently the turnaround time for cardiac marker results would be expected to influence ED-LOS. Indeed this has been shown to be the case in a number of studies [7].

In another study, implementation of rapid POCT urine drugs of abuse test in the ED was shown to decrease mean and median length of stay [9]. In many of the patients this test was a key part of the physician’s assessment to medically clear patients with psychiatric or substance abuse disorders for transfer to another facility.

In another study, Mueller et al [10] studied the impact on hospital LOS in a randomized controlled trial of ED POCT for B-type natriuretic peptide testing in patients with heart failure. In patients who received the POC test the hospital LOS decreased from 11 to 8 days. Presumably the immediate availability of the POC test permitted more rapid diagnosis and implementation of appropriate therapy much sooner than in patients who did not receive the POC test.

In a study in a pediatric ED, Bonner et al [11] evaluated the impact of a rapid influenza test in a pediatric ED. Patients who received the rapid test showed a significant decrease in the total number of laboratory tests ordered (complete blood count, blood cultures, etc.), a decrease in the number of antibiotic prescriptions and a decrease in ED LOS.
One recent multicenter study evaluated the impact of implementing a routine POCT chemistry analyzer for basic and comprehensive metabolic panel testing in the emergency department[12]. The authors documented a significant decrease in test turnaround time and a decrease in “door to clinical decision time”. No data was provided concerning ED-LOS.

2.2 Point-of-care testing for glucose and hemoglobin A1c in patients with diabetes

Measurement of the capillary blood glucose level may be performed in a variety of settings including patient self-testing, testing in outpatient clinics, bedside glucose testing in the management of diabetic patients in the hospital and testing to support intensive glycemic control protocols in acute care settings. Prior to the introduction of hand-held glucose meters, diabetic patients could only monitor their blood glucose using crude semi-quantitative measurements such as visually read urine and blood glucose test strips. The availability of simple, easy to use, quantitative home-use capillary blood glucose meters revolutionized the ability of diabetics to perform self-monitoring to maintain tight glycemic control. Both the Diabetic Control and Complications Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS) demonstrated improved outcomes from intensive glycemic control in both type 1 and type 2 diabetes including retinopathy, microalbuminuria and neuropathy (DCCT) and microvascular complications (UKPDS)[13, 14].

In the hospital setting bedside glucose testing is utilized to monitor diabetic patients during their hospital stay. There are no controlled studies to document improved medical outcomes from the use of bedside glucose testing. However, performing glucose measurements three or more times a day using a central laboratory would be very inefficient in terms of nursing labor and workflow. For this reason POCT for the management of diabetic inpatients is the only practical solution. Further, performing multiple blood draws per day to manage diabetic patients using a central laboratory would contribute to therapeutic anemia which has been consistently associated with adverse outcomes.

Many institutions have implemented protocols for tight glycemic control to prevent hyperglycemia in critically ill patients. Although some aspects of tight glycemic control are controversial (and beyond the scope of this review) [15], such protocols would be impossible to manage without bedside glucose testing meters. There remains, however, some controversy whether point-of-care glucose meters are sufficiently accurate and precise to reliably support these protocols.

A number of POCT devices have been developed to measure hemoglobin A1c (HbA1c) in outpatient settings. Some, but not all, of these devices have been shown to have acceptable analytical performance. The appeal for testing HbA1c at the point-of-care is that diabetic patients can obtain test results at the time of their office visit as opposed to being sent to a laboratory after seeing their primary care provider. Presumably having the result immediately available permits the physician to educate the patient during the time of the office visit and make adjustments to therapy as indicated. At least one study has shown that immediate feedback to patients concerning their HbA1c results at the time of the office visit improved glycemic control compared to utilization of a central laboratory [16]. However, this improvement in outcomes was not shown in a second study [17].

2.3 Point-of-care testing for creatinine in radiology

Measurement of the blood creatinine level (with an estimated glomerular filtration rate (eGFR)) is essential in patients who are to receive contrast agents for computed tomographic scans (CT) or gadolinium-based contrast agents for magnetic resonance imaging (MRI) to prevent contrast induced acute kidney injury and nephrogenic systemic sclerosis [18]. However, it is relatively common for patients to present for CT or MRI scans without a recent creatinine value. In many cases this necessitates either cancellation of the scan or performance of the study without contrast, both of which are suboptimal outcomes. Aside from the inconvenience to the patient and the resulting treatment delays, cancelling or modifying scans disrupts workflow in the radiology department and creates significant inefficiency in the use of high cost radiologic facilities. One study evaluated the operational impact of implementing rapid whole blood creatinine testing in the radiology department of an academic medical center [18]. Overall 5.3% of patients presenting for scans (441 per month)
did not have a recent creatinine value. Testing was then performed at the POC. Of these, 74% had normal creatinine-eGFR values permitting the scan to be performed without further consideration. In this case, POCT for creatinine resulted in a significant improvement in radiology operations at a minimal incremental cost for laboratory testing.

2.4 Point-of-care testing for anticoagulation

Patients receiving anticoagulation with warfarin require regular monitoring of their prothrombin time/international normalized ratio (PT-INR). Point-of-care devices for measuring the PT-INR using a fingerstick sample have been developed for use in the home and in outpatient clinics. These technologies permit patient self-monitoring in the home or testing performed directly in the clinic at the time of the office visit. Presumably the latter would permit immediate adjustments to dosing and an opportunity to educate the patient in a direct face to face encounter. Anticoagulation may be either inadequate, raising the risk of thrombosis, or excessive, raising the risk of hemorrhage. For this reason the patient’s PT-INR must be maintained within a narrow therapeutic range. Initial fears that operator errors and the inherent inaccuracy of these POC devices would result in an increase in adverse events have subsequently been disproved in large clinical studies. Patient self-monitoring has been shown to result in a decrease in thrombotic/hemorrhagic events and an increase in the number of patients with PT-INR values within the therapeutic range compared to usual care in the general internist office (but not compared to care in a specialized anticoagulation clinic)\(^\text{[19]}\). POCT for PT-INR in the outpatient clinic setting has also been shown to be safe\(^\text{[20]}\) and, when combined with a Coumadin dosing protocol, effective in terms of increasing the percentage of patients within the therapeutic range.

3 Conclusions

POCT is typically more expensive on a unit cost basis than testing performed in a central laboratory. For this reason it is important to document an improvement in outcomes resulting from the implementation of POCT. In most cases where a specific outcome has been demonstrated the major improvement has been to clinical operations such as a reduction in length-of-stay or greater operational efficiency. Typically tests that improve clinical operations are ones that impact a branch point in clinical decision making or reduce a queue in patient flow. In this paper we have described selected studies on POCT where an improvement in outcomes was demonstrated. Not all studies on POCT have shown improves outcomes despite an added incremental cost.

The menu of available POC tests continues to expand along with improvements in device design, analytical quality and information management. For these reasons the opportunities provided by POCT to improve patient care will likely increase into the future.

Once POCT has been implemented in a particular clinical setting and some outcome has been documented (e.g. decrease in emergency department length-of-stay) the issue often arises whether the POCT is cost effective. Determining the unit cost of a laboratory test is relatively straightforward. The cost of specimen acquisition, processing, analysis (including labor and consumables) and of reporting the results are easily determined by a time-in-motion study or through other cost accounting methods. As previously described the POCT test is typically more expensive than the central laboratory. However, determining the economic value derived from the impact of a more rapid test on the overall episode of care can be extremely challenging and often highly contrived) as illustrated by the following example. We recently implemented POCT creatinine testing in our radiology service as described above. As paraphrased from the original article, “the unit cost for the POCT whole blood creatinine was estimated to be $10.06 per test. With a test volume of 441 tests per month the total annual cost was approximately $53,238. The cost for a creatinine in the central laboratory including phlebotomy was $5.32. Therefore the added incremental cost for POCT versus the central laboratory is $4.74 per test and $28,154 per year. Each of the POC test permitted a scan to be performed with contrast or avoided cancellation of the scan. If a scan was cancelled, the patient would have been referred to a laboratory phlebotomy site for testing and the scan rescheduled. This process incurs many costs including phlebotomy, testing and personnel time in radiology to reschedule the scan. The CT or
MRI would idle time when scans were cancelled resulting in lost revenue. The amount of lost revenue is difficult to calculate because it depends on variable reimbursement rates based on the payor. While it is impossible to accurately calculate these costs and potential lost revenue it seems reasonable that they greatly exceed the $4.74 incremental cost of the point-of-care test\(^1\). As shown by this example, calculating the cost effectiveness for POCT is extremely difficult because the rapid test result has a pervasive impact on the overall episode of care including complex aspects of clinical operations and revenue. In the final analysis evaluating the cost effectiveness of POCT often comes down to a common sense assessment which relies more on judgment than a rigorous actuarial analysis.

References

