Implementation of Point-of-Care Testing in an Ambulatory Practice of an Academic Medical Center

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ABSTRACT

Objectives: *Point-of-care laboratory testing (POCT) offers reduced turnaround time and may promote improved operational efficiency. Few studies have been reported that document improvements from implementing POCT in primary care.*

Methods: *We measured metrics of practice efficiency in a primary care practice before and after implementation of POCT, including the total number of tests ordered, letters and phone calls to patients, and revisits due to abnormal test results. We performed a cost and revenue analysis.*

Results: *Following implementation of POCT, there was a 21% decrease in tests ordered per patient (*$P < .0001$*); a decrease in follow-up phone calls and letters by 89% and 85%, respectively (*$P < .0001$ *and* $P < .0001$*); and a 61% decrease in patient revisits (*$P = .0002$*). Estimated testing revenues exceeded expenses by $6.62 per patient, and potential cost savings from improved efficiency were $24.64 per patient.*

Conclusions: *POCT can significantly improve clinical operations with cost reductions through improved practice efficiency.*

Point-of-care laboratory testing (POCT) offers reduced test turnaround time and, therefore, more timely medical decision making, which can improve clinical operations.[1] Testing for routine chemistries, lipid panels, and hemoglobin A_{1c} (HbA_{1c}) are commonly required in the primary care setting. Laboratory results for these and other tests may be obtained by one of three approaches[2]:

1. Sending the patient to a central laboratory after the office visit: This approach is inconvenient for the patient and prevents test results from being reviewed with the patient at the time of the visit. Subsequent letters and phone calls to the patient and follow-up office visits may be required.
2. Sending the patient to a central laboratory several days before the office visit: This approach assumes that the required tests can be anticipated in advance but has the advantage of allowing test results to be reviewed with the patient during the office visit. From the patient's perspective, this approach requires an extra trip to the laboratory, which may be inconvenient and may incur costs, including travel, parking, and potentially lost wages.
3. Testing in the physician's office concurrent with the patient's visit using rapid POCT devices: This approach does not require anticipation of necessary tests, and the results can be reviewed directly with the patient before the end of the visit. Follow-up communications, including letters and phone calls, may be reduced and revisits for abnormal test results potentially eliminated.

A number of studies have reported improved outcomes following the implementation of POCT in a variety of inpatient and outpatient settings.[1] Outcomes can be classified

into three general groups: (1) medical outcomes (eg, improved survival or control of disease), (2) operational outcomes (eg, improved patient throughput or decreased length of stay), and (3) financial outcomes (eg, reduced cost or improved cost-effectiveness).[1] Published literature commonly cites operational outcomes improvements, particularly when POCT affects patient flow through a queue in a clinical operation. Examples include rapid POCT for cardiac markers, drugs of abuse, and D-dimer in the emergency department and creatinine testing in radiology.[3-6] In reported studies, POCT improved medical outcomes by enhancing more timely medical decision making, resulting in more rapid diagnosis or enhanced compliance with accepted clinical guidelines.[7,8]

There are no published studies relating to improved outcomes from POCT in the primary care setting other than POCT for HbA_{1c}, which may improve glycemic control in patients with diabetes.[7] We previously reported an outcomes study evaluating the impact of primary care POCT on patient satisfaction in which POCT was associated with a high level of patient satisfaction (score 3.96 on a scale of 1-4; 1 = poor, 4 = excellent).[2] Free-text comments by patients indicated that satisfaction resulted from improved testing convenience and from the ability to review results with their provider at the time of the office visit. In our current study, we hypothesized that POCT would reduce the number of tests ordered at the time of the visit, the number of follow-up letters and phone calls, and the need for additional appointments due to abnormal laboratory tests. We also hypothesized that POCT would be financially advantageous for the primary care practice.

Materials and Methods

Study Context

With institutional review board approval (Partners Healthcare Institutional Review Board), we performed a study on metrics of practice efficiency before and after implementation of POCT in the Ambulatory Practice of the Future at the Massachusetts General Hospital (MGH) in Boston. Informed consent from patients was not required by the institutional review board because the study was based only on review of medical records. The Ambulatory Practice of the Future is an adult primary care practice providing care to employees of the MGH and their spouses/domestic partners. The practice was launched in 2010, in part as an innovative collaborative research site to develop new models for providing team-based primary care. The Ambulatory Practice of the Future is presently staffed with three part-time (1.5 full-time equivalent) internal medicine staff physicians, two internal medicine residents, two part-time (1.5 full-time equivalent) nurse practitioners, three medical assistants, and other support staff.

Study Design, Participants, and Outcome Measures

In 2012, we implemented on-site POCT for HbA_{1c} using the Siemens DCA Vantage Analyzer (Siemens Healthcare, Norwood, MA) and a lipid panel and comprehensive metabolic panel using the Abaxis Piccolo Xpress Analyzer (Abaxis, Union City, CA). The Siemens DCA Vantage Analyzer performs and provides results for HbA_{1c} from a fingerstick blood sample in 6 minutes. The Abaxis Piccolo Xpress Analyzer performs and provides results for a comprehensive metabolic chemistry or lipid panel from phlebotomized blood in 12 minutes. The instruments were validated for accuracy, imprecision, reportable range (linearity), and reference range in the central laboratory by crossover to existing laboratory instruments according to standard criteria of The Joint Commission. The practice assistants were trained in sample acquisition, quality control, and testing by the central laboratory. Ongoing oversight of the testing for regulatory compliance was also overseen by the clinical laboratory. Quality control for the testing was performed daily according to requirements of the Clinical Laboratory Improvement Amendments (CLIA) and manufacturers' guidelines. All patients who required HbA_{1c}, fasting lipid, or comprehensive metabolic panel testing for either screening or disease monitoring, as deemed appropriate by their provider, were eligible to receive POCT if they could stay for discussion of their results. Because this was a clinical trial study, some of the test results were manually entered into the electronic medical record (as opposed to using an electronic interface).

The medical records of 149 sequential patients who received POCT and 137 historical control patients were reviewed. For each patient, we recorded the type of office visit (new patient visit, annual examination, follow-up or sick visit). We then recorded the number of tests performed, the number of follow-up phone calls and letters generated, and the number of follow-up visits resulting from an abnormal test result. For the purpose of counting laboratory tests, the HbA_{1c}, lipid panel, and comprehensive metabolic panel were each counted as one test, respectively.

We also performed a basic cost analysis to determine the economic impact of POCT on our practice. The cost of performing the testing was calculated using the cost of the reagents and other consumables (including phlebotomy or fingerstick sampling) and the labor required (using activity-based costing) for clinical staff to perform the testing and follow-up. Potential revenues were estimated using Medicare fee schedules, including a phlebotomy charge of $3.00.

Data Acquisition

Data concerning patient characteristics and practice metrics (patient demographics, phone calls, letters, and revisits) were obtained from an electronic medical record (Oncall). Oncall is an MGH locally developed web-based

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Table 1
Breakdown of Patients Included in the Study

Characteristic and Visit Type	Control Patients	POCT Patients	*P* Value[a]
Total patients, No.			
New patient	66	54	
Annual	32	42	
Follow-up	39	53	
Total	137	149	
Mean age, y			
New patient	46	40	.01
Annual	53	58	.10
Follow-up	55	52	.36
Total	50	50	.67
Sex, % male/% female			
New patient	59/41	61/39	.85
Annual	59/41	57/43	1.0
Follow-up	64/36	49/51	.2
Total	61/39	56/44	.47
Percent with diabetes mellitus			
New patient	23	24	1.0
Annual	44	45	1.0
Follow-up	54	58	.68
Total	36	42	.33
Percent with dyslipidemia			
New patient	48	37	.27
Annual	47	55	.64
Follow-up	46	47	1.0
Total	47	46	.81
Percent with hypertension			
New patient	26	15	.18
Annual	34	45	.47
Follow-up	54	45	.53
Total	36	34	.80

POCT, point-of-care testing.
[a] All *P* values have been rounded.

framework that supports all MGH institutional medical records (inpatient and outpatient) to provide portability, shareability, and aggregation of clinical data for clinical and epidemiologic needs. It has been certified for meaningful use (per definitions outlined in the Affordable Care Act) since 2011. Oncall captures all relevant patient-related data, including notes, letters, phone calls, laboratory results, referrals, specialists' notes, operations, pathology reports, radiology, cardiology, endoscopy, neurophysiology, and other data.

Data Analysis

Statistical analyses were performed using the R statistical scripting language (http://www.r-project.org/). Confidence intervals for outcome metrics (tests, calls, letters, and additional visits per patient) were calculated using a bootstrap procedure. This procedure, as described by Carpenter and Bithell,[9] uses resampling to provide empiric, nonparametric confidence intervals. In particular, we used the "basic" bootstrap method (eg, non-Studentized pivotal method) as implemented in the R package boot.[10] Zero was substituted as the lower bound on calculated confidence intervals extending below 0, since negative values were nonsensical for all outcome metrics. Ten thousand bootstrap replicates were used for each confidence interval. *P* values comparing patient age and the number of tests, calls, letters, and additional visits per patient between the POCT and control groups were calculated using a two-tailed permutation test as described by Ludbrook.[11] Permutation tests provide a distribution-free estimate for the likelihood of obtaining results as or more skewed than observed under the null hypothesis. In particular, for each metric, we simulated the null hypothesis that the POCT and control groups had the same mean on the metric by randomly reshuffling the point labels (POCT vs control) 10,000 times. The *P* values were taken as the number of reshuffled samples where the difference between the POCT and control groups was greater than or equal to the observed difference. *P* values comparing total patients, sex, and percentage with comorbidities were calculated using a two-tailed Fisher exact test.

Results

Table 1 summarizes the demographic data, visit type, and disease prevalence among the POCT and control groups. There were no significant differences in sex or prevalence of hypertension, dyslipidemia, or diabetes between the POCT and control groups, either by overall comparison or when grouped by visit type. No significant differences in age were seen between the two overall study groups, although among the subgroup of "new" patients, control patients were older than POCT patients (46 vs 40 years).

Table 2 summarizes the effect (percent reduction) following implementation of POCT on the number of ordered laboratory tests and the number of phone calls, letters, and follow-up visits generated as a result of the testing. The results are structured by visit type as described in the Materials and Methods section. Following POCT, there was a 21% decrease in the total number of tests ordered per visit ($P < .0001$), an 89% decrease in the number of telephone calls to patients ($P < .0001$), an 85% decrease in the number of results letters sent to patients ($P < .0001$), and a 61% reduction in the number of follow-up visits for an abnormal laboratory result ($P = .002$). Significant reductions in each of these metrics were seen across all visit types with the exception of the number of tests ordered per visit for new patients, the number of calls made to patients coming for return annual physical examinations, and the number of additional visits required for new patients due to abnormal test results; the latter two outcomes approached statistical significance (Table 2).

The average cost for testing, including reagents, consumables, and labor, was $25.25 per patient vs estimated revenues of $31.87, yielding a net per-patient margin of $6.62 **Table 3**.

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Table 2
Practice Metrics for Control Patients and Those Who Received Point-of-Care Testing

Metric and Visit Type	Mean (95% CI)		% Reduction With POCT	*P* Value
	Control	POCT		
Tests/patient				
New patient	2.45 (2.32-2.61)	2.35 (2.13-2.57)	4	.45
Annual	2.59 (2.38-2.84)	1.88 (1.62-2.14)	27	.0006
Follow-up	1.95 (1.69-2.21)	1.32 (1.13-1.47)	32	.0002
Total	2.34 (2.22-2.47)	1.85 (1.71-1.99)	21	<.0001
Calls/patient				
New patient	0.11 (0.02-0.18)	0	100	.03
Annual	0.19 (0-0.38)	0	100	.08
Follow-up	0.49 (0.26-0.72)	0.08 (0-0.13)	85	.0004
Total	0.23 (0.13-0.32)	0.03 (0-0.05)	89	<.0001
Letters/patient				
New patient	0.86 (0.74-0.98)	0.19 (0.07-0.28)	79	<.0001
Annual	0.81 (0.66-0.97)	0.1 (0-0.17)	88	<.0001
Follow-up	0.62 (0.46-0.77)	0.08 (0-0.13)	88	<.0001
Total	0.78 (0.7-0.86)	0.12 (0.07-0.17)	85	<.0001
Additional visits/patient (due to abnormal laboratory results)				
New patient	0.42 (0.26-0.58)	0.24 (0.11-0.35)	43	.13
Annual	0.31 (0.16-0.47)	0.12 (0.02-0.21)	62	.05
Follow-up	0.41 (0.21-0.59)	0.09 (0.02-0.17)	77	.0029
Total	0.39 (0.28-0.5)	0.15 (0.09-0.21)	61	<.0002

CI, confidence interval; POCT, point-of-care testing.

The revenues actually collected would depend on the payer mix of the practice. Based on this analysis, a clinic panel size of approximately 2,645 patients with the testing patterns represented in our study would recover the cost of the instruments. However, in most situations, the cost of the instrumentation would be included in the reagents and therefore there would be no capital acquisition cost. The estimated cost for initial setup of the POCT using the midpoint salary and benefits of a POCT coordinator was $958, including operator training and establishing regulatory compliance documentation. If this cost was allocated to the 149 patients who were tested, the per-patient cost would be $6.43. However, in an ongoing continuous operation, the per-patient cost would decrease as the number of patients tested accumulated. The cost for ongoing monitoring of testing quality and compliance was $871. Again, the per-patient cost for 149 patients would be $5.84, but this number would also decrease over time in an ongoing operation. We did not include these costs in the analysis because the study included only 149 patients. In actual practice, the per-patient cost would be spread out over a large number of patients and therefore would not be significant. Other cost savings in the practice that would enhance the financial benefits of the POCT program include costs/time incurred for writing and processing letters, costs/time incurred with phone calls to patients, and costs incurred for follow-up visits. The net financial benefit resulting from improvements to practice efficiency was $24.64 per patient (Table 3), roughly the same amount as the testing cost. Overall, the total financial benefit to the practice (net testing margin plus net practice efficiency margin) was $31.26 per patient.

Discussion

The literature concerning the impact of POCT on clinical, operational, and financial outcomes was recently reviewed[1] and demonstrates a paucity of studies evaluating improved practice efficiency via primary care POCT. Specific examples include the use of rapid streptococcus A testing to guide decisions on antimicrobial therapy,[12] rapid fingerstick prothrombin time–international normalized ratio (PT-INR) to improve anticoagulation management,[8] and in-office HbA_{1c} testing to improve glycemic control in patients with diabetes mellitus.[7] Each of these studies evaluated the effect of POCT on a *medical outcome* as opposed to *practice efficiency*. As a result, the cost-effectiveness of primary care POCT has been questioned.[13] An Australian study evaluating the cost-effectiveness of POCT in a general practice setting concluded that the *per-patient* cost to the health sector was less than that through a central laboratory for the urine microalbumin-creatinine ratio but greater for PT-INR, HbA_{1c}, and the lipid panel.[14] None of these differences, however, were significant. One factor may be that they evaluated only the cost of the tests without consideration of the economic impact of improved work efficiency. In another study, Delaney et al[15] performed a systematic review of near-patient testing in primary care and concluded there was no evidence justifying expansion of primary care POCT. The authors noted that the quality of most of the studies they reviewed was poor, and cost and outcome assessments were heavily biased. In the current study, we demonstrated that POCT in the primary

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Table 3
Cost/Revenue Analysis for Point-of-Care Testing in a Primary Care Setting

Item	$US per Patient
Cost of testing[a] (reagents, consumables, labor)	25.25
Cost of instrumentation[b]	0.00
Cost of site set up and oversight[c]	See below
Revenue from visit[d]	31.87
Net per-patient margin	6.62
Estimated savings from improved practice efficiency[e]	24.64
Total financial impact	31.26

[a] The average cost for testing includes reagents, consumables, and labor. Because patients could receive one, two, or three tests, the value of $25.25 was calculated from the actual costs incurred for each of the 149 study patients divided by the total number of patients.
[b] The cost of the instruments would be included in the consumables in a nonclinical trial situation.
[c] Site setup and regulatory oversight were provided by the clinical laboratory. The cost per patient would depend on volume. Because this was a clinical study with only 149 patients, the cost of site setup and compliance would appear to be high (see text). However, in an ongoing operation, the cost per patient would be much lower because it would be spread over a much larger number of patients.
[d] Potential revenues were estimated using Medicare fee schedules for a level 3 visit, including a phlebotomy charge of $3.00. The revenues actually collected would depend on the payer mix of the practice. This number does not include revenues from the point-of-care test itself.
[e] Estimated savings from improved practice efficiency (using activity-based costing). 1. We calculate that a simple letter detailing normal findings costs the practice $7.03, a letter with minor abnormal findings costs $15.52, and a letter with major abnormal findings costs $29.67. 2. The cost of a typical phone call was estimated to be $28.30, including repeat call attempts. 3. We used the Medicare fee schedules for a level 3 visit, including a phlebotomy charge of $3.00, to estimate the cost of a revisit. For each patient who received point-of-care testing, there was an average reduction of 0.49 tests, 0.66 letters, 0.20 telephone calls, and 0.24 revisits. Assuming most letters to patients are of the "simple variety ($7.03 per letter), a per phone call cost of $28.30, and a typical revisit time of 15 minutes (at $3.24 per minute), a minimum estimate of the potential cost savings to the practice would be (0.49 test × $25.25/patient/1.85 tests/patient) + (0.66 letters × $7.03/letter) + (0.20 calls × $28.30/call) + (0.24 visits × $31.87/visit[d]) = $24.64.

care setting was associated with a significant reduction in the number of tests ordered, letters and phone calls made, and follow-up visits compared with conventional central laboratory testing. Most of these outcomes were significant at the visit subgroup level.

The lack of significant reductions in the number of tests ordered for *new* patients with POCT vs usual laboratory testing suggests that tests ordered for these patients, about whom relatively little is known prior to the visit, are not determined by the specific convention of testing. In other words, providers are not preferentially using POCT on new patients simply because the tests are more readily available. A significant difference in the number of tests ordered for all other visit types using POCT suggests that having results available at the time of the encounter for *established* patients allows providers to actually order fewer tests.

Regardless of the actual test results, the positive impact of POCT on follow-up phone calls, letters, and revisits is self-explanatory and offers potential financial savings opportunities for primary care practices. That we did not see 100% reduction in letters and phone calls among the POCT group or subgroups reflects elements of real-world primary care practice, where there may not be enough time to review POCT results with patients at every visit. This may be due to practice-dependent factors (eg, work flow—whether the test was performed at the beginning or end of the visit) or patient-dependent factors (eg, the patient might not have time for test results discussion regardless of when, during the visit, the test was performed).

The greatest impact of POCT on follow-up visits due to abnormal test results was seen in the follow-up/urgent visit subgroup. One can assume this patient group has higher risks of having abnormal test results. We show that because further evaluation or testing required as a result of an abnormal test can be initiated at the time of the original visit, POCT results eliminated a greater proportion of follow-up visits for retesting or further counseling.

Several limitations need to be considered in this study. First, the case-control design will not provide as strong evidence for the benefit of POCT in practice efficiency outcomes as would a randomized controlled trial. A randomized controlled trial would require much more financial and logistical resources to carry out and might be more disruptive in a study designed to evaluate office work efficiency outcomes. Second, the case-control design risks a higher likelihood of selection bias. We attempted to control for basic demographics, as well as for some of the more likely possible confounders, such as the prevalence of particularly common diseases that might increase the likelihood of abnormal results with the particular tests that were used in this study. While the age difference among the new visit subgroup was statistically significant, it is unlikely to explain significant variation in outcomes. Third, this study did not control for the degree of disease optimization among patients who received laboratory testing. Patients with diseases that are not optimally controlled are, by definition, at higher risk of having abnormal test results (such as abnormal chemistries and renal function for hypertension, abnormal lipid panels for dyslipidemia, and elevated HbA_{1c} and renal function for diabetes). Since the prevalence of abnormal test results will, to a large effect, drive the prevalence of the need for follow-up testing, phone calls, and/or additional appointments, future studies involving primary care POCT should address this. Last, this study was conducted at a single primary care clinic that cares largely for employees of an urban academic hospital and their partners/spouses and is, therefore, not representative of the more diffusely mixed demographics typical of most primary care clinics. Workflow of appointments and laboratory testing undoubtedly vary significantly between this practice and other primary care clinics. The prevalence of suboptimal disease control and abnormal test results differs widely among primary care clinic settings. We would expect that POCT would have an even more dramatic economic impact on practice efficiency in clinic settings with poorer disease control. Larger studies across a number of practices

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and/or institutions would provide more reliable evidence. Similarly, because the study population consisted largely of commercially insured patients, the estimates on cost savings, using more readily available Medicare reimbursement rates, may not reflect actual realized savings in all primary care clinic environments.

Implementing POCT in a primary care setting may impose a number of burdens on the practice, including the need to offer on-site phlebotomy, reagent and capital equipment costs, costs for regulatory compliance, the labor required to perform the test, and the need to change workflow within the practice to permit test results to be available during the time that the patient sees the clinician. These factors can pose a barrier to pursuing office POCT. Potential factors favoring POCT include improved patient and, possibly, provider satisfaction, improved practice work efficiency, potential new sources of anticipated revenue, and the possibility that POCT could improve clinical outcomes.

Considering the benefits and risks of POCT from the perspective of the practice, it is important to demonstrate that its implementation has a significant enough benefit to justify the cost of the testing and demands on workflow change. Our cost-revenue analysis suggests that POCT for HbA_{1c}, lipid panel, and comprehensive metabolic panel can pay for itself, assuming a sufficient volume of patients and positive margin to cover the cost of the capital equipment. We used the Medicare fee schedule to analyze revenue estimates. In a fee-for-service primary care model, practice revenue from POCT would depend on multiple factors, especially the payer mix (commercial, Medicare, or Medicaid-type reimbursement) of the practice. Other factors would include the POCT itself (eg, CLIA status, which might require further certification and/or personnel costs) and the time required to complete a test.

Under a global payment reimbursement system or accountable care organization–type primary care model, practice revenue from POCT would become less relevant. Eliminating unnecessary testing and repeat visits is particularly attractive in a reimbursement environment that is shifting toward global payments. For this reason, the analysis of the impact of POCT on practice efficiency becomes particularly important.

While most primary care practices do not operate under a global payment system, many clinics and physicians participate in quality-incentive, risk-sharing performance contracts, where a portion of third-party reimbursements are tied to the achievement of certain quality metrics (eg, frequency testing for HbA_{1c}, lipids, and urine microalbumin for patients with diabetes). Under such contracts, if quality incentives are not achieved, payment can be withheld from institutions, practices, or individual providers. The availability of POCT for these particular metrics could help practices achieve higher performance scores.

In conclusion, this study demonstrates that POCT can significantly affect several metrics of primary care practice efficiency, and its utilization appears to be cost-effective. The economic benefits of POCT may be realized in both fee-for-service and global payment environments.

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