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Point of care testing to improve glycemic control

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Abstract

Purpose—The purpose of this paper is to pilot-test the feasibility and impact of protocol-driven point-of-care HbA1c testing on levels of glycemic control and on rates of diabetic regimen intensification in an urban community health center serving low-income patients.

Design/methodology/approach—The paper suggests a primary care process re-design, using point of care finger-stick HbA1c testing under a standing order protocol that provided test results to the provider at patient visit.

Findings—The paper finds that the protocol was well received by both nurses and physicians. HbA1c testing rates increased from 73.6 percent to 86.8 percent ($p = 0{:}40$, $n = 106$). For the 69 patients who had both pre- and post-intervention results, HbA1c levels decreased significantly from 8.55 to 7.84 ($p = 0{:}004$, $n = 69$). At baseline, the health center as a system was relatively ineffective in responding to elevated HbA1c levels. An opportunity to intensify, i.e. a face-to-face visit with lab results available, occurred for only 68.6 percent of elevated HbA1c levels before the intervention, vs. 100 percent post-intervention ($p < 0{:}001$). Only 28.6 percent of patients with HbA1c levels >8.0 had their regimens intensified in the pre-intervention phase, compared with 53.8 percent in the post-intervention phase ($p = 0{:}03$).

Research limitations/implications—This was a pilot-study in one urban health center. Larger group-randomized controlled trials are needed.

Practical implications—The health center's performance as a system, improved significantly as a way of intensifying diabetic regimens thereby achieving improved glycemic control.

Originality/value—This intervention is feasible, replicable and scalable and does not rely on changing physician behaviors to improve primary care diabetic outcomes.

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Keywords

Diabetes; Primary care; Quality improvement; Redesign

Introduction

More than 18 million Americans have diabetes (CDC, 2003), which is the sixth leading cause of death in America. It is a leading cause of blindness, lower extremity amputation, and end-stage renal and cardiovascular disease (CDC, National Center for Health Statistics, 2005). For each of these micro- and macro-vascular complications, higher levels of risk have specifically been linked to levels of glycemic control among diabetics (Eberly *et al.*, 2003; Stamler *et al.*, 1993). Intensive therapy and glycemic control can reduce diabetic complications (Stratton *et al.*, 2000). Glycemic control is most commonly measured using the glycosylated hemoglobin or HbA1c test, which reflects the level of control of blood sugar levels over the previous four to 12 weeks. Clinical guidelines from the National Diabetes Education Program at the time of this study recommended glycemic control defined as a HbA1c of <7 percent, with HbA1c levels of > 8 percent indicating a definitive need for change in therapy (NDEP, 2005). This requires HbA1c testing at least twice yearly in patients with stable glycemic control and quarterly testing if therapy changes or glycemic goals are unmet.

Unfortunately, there is a significant gap between usual care and recommended or optimal care (Saaddine *et al.*, 2002). In 2003, only 24 percent of diabetic patients received three or more glycosylated hemoglobin tests in a two-year period (McGlynn *et al.*, 2003). Racial/ethnic and socioeconomic disparities have been demonstrated in diabetic self-care (Rhee *et al.*, 2005), medical care (Bonds *et al.*, 2003), pharmacologic treatment (Allsworth *et al.*, 2005), complications (Jiang *et al.*, 2005; Karter *et al.*, 2002) and mortality (Wong *et al.*, 2005; Wong *et al.*, 2002), not only in uninsured and low-income diabetic populations (Cook *et al.*, 1999; Chin *et al.*, 2000), but also to varying degrees among the insured, even in managed care in academic practice settings (Gary *et al.*, 2004; Karter *et al.*, 2002; Schneider *et al.*, 2002; Bernard *et al.*, 1999; Cook *et al.*, 2001). Obstacles to achieving optimal primary care for diabetes patients have also been documented (Barnes *et al.*, 2004; Phillips *et al.*, 2001). Miller *et al.* 2003 were able to demonstrate that point of care rapid-result HbA1c testing could increase the rate providers intensified diabetic therapy and improve glycemic control for patients with type 2 diabetes in an urban neighborhood clinic staffed by academic physicians. Their conclusion was that immediate results improved provider behaviors, i.e. intensifying therapeutic regimens in the face of poor glycemic control. A series of focus groups by Brown *et al.*2004 with health professionals suggested openness to point-of-care testing (POCT) among practicing clinicians, nurses and health educators, if concerns about accuracy and cost could be adequately addressed.

There is a need to assess the feasibility and effectiveness of such point-of-care testing in other settings providing primary care to the underserved with non-academic clinicians. Therefore, our study aimed to determine if point-of-care HbA1c testing with immediate results could be replicated in a non-academic, urban community health centers. We aimed also to assess its impact on rates of HbA1c testing, intensification of regimens when indicated and glycemic control.

Methods

Our study design was a before-after trial of a practice-based process re-design, using point of care finger-stick HbA1c testing under a standing order protocol that offered results to the

provider at the time of the patient visit. The intervention site was the main clinic of an urban community health center in Atlanta's low-income and low empowerment zone. In 2003, the health center and its various satellite clinics provided 75,195 medical visits to 29,161 individuals, most of whom are poor (46 percent) or near-poor (54 percent) individuals of African-American race or culture (96 percent). Approximately 5 percent of encounters are for a primary diagnosis of diabetes (GAPHC, 2005). The providers, whose intensification behaviors were being evaluated, included three family practitioners and three physician assistants. The intervention used point of care finger-stick HbA1c testing under a standing order protocol consistent with National Diabetes Education Program recommendations for HbA1c testing on all diabetic patients. Providers received results at the patient's visit. Testing was performed using an on-site DCA 2000 + Analyzer for point of contact (finger stick HbA1c testing). Additionally, physicians and nurses received education on the importance of glycemic control, evidenced-based guidelines on optimal HbA1c values and what constituted diabetic regimen intensification. Chart audits were performed on randomly selected records from among all diabetic patients with a baseline visit in the three-month pre-intervention period and a visit during the intervention period. Principal outcome measures were:

- Percentage of patients receiving HbA1c test before and during the intervention period.
- Percentage of patients with elevated "action-indicated" HbA1c (>8.0) levels whose diabetic regimens were intensified (defined by criteria listed below) before and during the intervention period.
- Mean and median HbA1c levels from pre- to post-intervention.

Chart reviews told us whether HbA1c was performed during the pre-intervention and post-intervention periods and whether those values had improved. When HbA1c levels were greater than 8 percent, charts were further reviewed to see whether or not providers had intensified the diabetic regimen. Regimen intensification was defined as a change in prescription (medication dosage increased, additional medication, change in medication), referral to a nutritionist and/or a health educator and/or a written exercise prescription. Informal interviews with each provider and nurse at the health center sought feedback on the intervention's feasibility and practicability. Differences in pre- and post-intervention HbA1c testing (yes-no) rates were evaluated using the chi-square test for non-independent observations. Differences in pre- and post-intervention HbA1c mean values were tested for significance using a paired *t*-test only on the 69 individuals who had both a pre- and post-intervention HbA1c values measured. Differences in rates at which clinicians intensified the diabetic regimen in the face of an elevated HbA1c level >8.0 were measured using two alternative denominators – all patients with elevated HbA1c levels (measuring performance of the health center as a system) and only those patients with elevated HbA1c levels who also had a face-to-face clinical encounter within 90 days of the elevated HbA1c result (measuring performance of the clinician in a moment of opportunity). All statistical tests were performed using SPSS statistical software, version 11.0.

Results

A total of 106 adult diabetic patients met our inclusion criteria – having both a baseline visit in the three month pre-intervention period and a visit during the post-intervention period. Patients' average age was 60 years, 72.9 percent were women and 98.1 percent African American (1.9 percent whites but no Asian or Hispanic/Latino diabetic patients). Patients were excluded if they received diabetes-related visits at non-intervention satellite clinic sites, or if they had night clinic visits (the standing order was only established during the day shift, because night clinic included nurses and providers from various satellite clinics). The

point of care testing protocol was implemented successfully, with positive feedback from nurses and physicians. The mean HbA1c values and physician intensification behavior for these patients in both pre- and post-intervention periods are summarized in Table I.

The HbA1c testing rates increased from 73.6 percent to 86.8 percent (78 pre-intervention tests and 92 post-intervention tests on 106 individual patients, $p = 0{:}397$). For the 69 patients who had both pre- and post-intervention results, HbA1c levels decreased significantly from 8.55 to 7.84 ($p = 0{:}004$ by paired *t*-test, $n = 69$). The proportion of patients with HbA1c levels greater than 8 percent (among all patients with HbA1c levels drawn) decreased slightly from 44.9 percent in the pre-intervention phase to 42.4 percent. At baseline, the health center as a system was relatively ineffective in responding to elevated HbA1c levels. Only 28.6 percent of patients with HbA1c levels >8.0 had their regimens intensified in the pre-intervention phase, compared with 53.8 percent of patients with elevated HbA1c levels in the post-intervention phase ($p = 0{:}028$). Before intervention, only 68.6 percent of patients with an elevated HbA1c level completed a follow-up visit within 90 days, whereas 100 percent of the patients with an elevated HbA1c in the intervention phase were seen by a primary care provider at the moment when their HbA1c results became available ($p = 0{:}001$). Provider intensification behaviors, during patient encounters when elevated HbA1c results were available, improved only modestly from 41.7 percent before intervention to 53.8 percent during the intervention ($p = 0{:}348$).

Discussion

Our results demonstrate that making HbA1c testing automatic through point-of-care testing is feasible and acceptable to physicians, nurses and patients in the safety net primary care setting of a federally funded community health center. It also resulted in a significant decrease in HbA1c levels, despite only a modest improvement in physician intensification behaviors. This is a key point because Miller *et al.*'s (2003) study emphasized improvements in provider behavior and "overcoming clinical inertia" (Ziemer *et al.*, 2005, p. 564). Our results suggest that glycemic control is not just the outcome of doctor behaviors or the "inside-the-exam-room" patient-provider interaction but that there is an essential third dimension, which is the practice or process of care as a micro-system. Our intervention was designed to change this provider-patient-system triad and indeed appears to have had its greatest impact by making care better as a process within the practice system.

In this study, the health center as a system, was delivering intensified diabetic regiments to less than three out of ten patients who had elevated HbA1c levels. This improved to 53.8 percent with the intervention, an improvement that could only partially be attributed to a modest improvement in clinician intensification behaviors (from 41.7 percent to 53.8 percent, not statistically significant). More important were changes in the care process. In the pre-intervention phase only two-thirds (68.7 percent) of clients with an elevated HbA1c had a face-to-face "opportunity-to-intensify" encounter with their provider within 90 days of the lab results being available. In the intervention phase, 100 percent of patients with elevated HbA1c results saw a provider the same day results were produced. This is an example of what Wagner and others have referred to in their chronic care model as re-setting the default process to make best-practice care automatic (Bodenheimer *et al.*, 2002). How does this work? Figure 1 demonstrates the pre- to post-intervention reduction in discretionary steps required for a clinician to reach that moment of opportunity in the exam room face-to-face with a patient whose HbA1c level is elevated.

In the old system no test was performed until the clinician decided to order it. The patient then could choose to go or not to go downstairs to the laboratory for the blood draw. The test results then were returned to the clinic the next day and routed to the ordering physician,

who then decided the test was sufficiently elevated to require a call-back. Nurses then had to contact the patient by telephone or by mail, documenting these contacts in the medical record. Assuming contact was made the patient might make and keep the appointment at which time there would finally be an opportunity for the provider behavior (i.e. intensification of the regimen) to take place. We count at least nine discretionary steps in this usual care process, at which point a failure by any participant (patient, provider, nurse, laboratory, medical records, appointment system, etc.) misses an opportunity to improve glycemic control.

During our intervention the first two steps (only do an HbA1c test if the doctor orders it and then send the patient to the laboratory) were eliminated by implementing a standing-order protocol for nurse-managed, automatic finger-stick HbA1c testing on all diabetic patients. This alone resulted in a modest increase in HbA1c testing rate from 73.6 percent to 86.8 percent. A rate that compares favorably to that found in benchmark Veteran's Health Centers and in Medicare managed care populations (Heisler *et al.*, 2003; McBean *et al.*, 2005) and substantially better than that found in primary care practices serving uninsured and low-income patients (Nelson *et al.*, 2005; Harwell *et al.*, 2002; Chin *et al.*, 2001). The next six discretionary steps eliminated involve the patient contacting when HbA1c was elevated and getting him or her to return for a doctor visit in which the therapeutic regimen could be intensified. All these steps were eliminated when the nurse put the finger-stick HbA1c results on the chart before the clinician stepped into the exam room, so that 100 percent of the patients whose HbA1c was elevated in the intervention phase were seen by a primary care provider within minutes of their HbA1c results becoming available. It was also helpful that the same nurses who previously had to do the patient call-back work were now doing the "extra work" of finger-stick HbA1c testing. They not only recognized that they were providing better care but also that their overall workload did not increase because the time they invested in finger-stick HbA1c testing saved time and frustration spent on the often unsuccessful attempts at patient call-backs. Therefore, the largest impact of this intervention appeared not to be in improving clinician's discretionary behavior but rather eliminating discretionary steps that were unnecessary and which did not require clinical judgment. A similar Australian rural health center study found that patients, doctors and nurses all reported high levels of satisfaction with a similar strategy using point-of-care testing to improve diabetes care and outcomes in community-based practices (Shephard *et al.*, 2005).

Finally we are left with the discretionary step of the doctor or nurse practitioner deciding to intensify the therapeutic regimen in the face of an elevated HbA1c. Only this last discretionary step remained discretionary in our re-designed process, making excellent care up to this point almost automatic. If we isolate clinician behavior in the moment of opportunity to intensify the regimen during a face-to-face encounter at a time when elevated HbA1c results are available then there was only a modest and not statistically significant improvement from 41.7 percent before intervention to 53.8 percent during the intervention. This is consistent with meta-analysis of studies evaluating interventions to improve preventive service delivery, which found that provider and patient-level interventions were only modestly effective (odds ratios 1–2.6), while organizational change (including process and systems change) was dramatically more effective (odds ratio >10) (Stone *et al.*, 2002).

Regimen intensification was the one step that clinicians in this practice believed should remain within the realm of clinical judgment. However, leaving this phase to the clinician's discretion means that POCT alone cannot assure a best-practice outcome. Just because the physician has the lab result does not mean that he/she will automatically do the right thing clinically, i.e. aggressively intensifying the diabetic treatment regimen, a specific and measurable physician behavior that is highly correlated with improved glycemic control as

an outcome (Ziemer *et al.*, 2005). Changing physician clinical decision-making behavior is hard. Physicians adopt widely varying targets for fasting blood glucose levels in patients with type 2 diabetes (Belfiglio *et al.*, 2001). Provider-centered interventions may improve the provision of some diabetes care elements and still not improve glycemic control (Renders *et al.*, 2001). Combining physician education with patient education seems to have greater impact, reinforcing the importance of the patient-provider-system triad (Renders *et al.*, 2003). The physician education intervention in our project was weak, consisting only of one lecture-discussion followed by monthly educational mailings. In effect, our results confirm that practice-based, micro-process re-design can work even with minimal physician education.

Would there be a way to make even the most discretionary therapeutic decision-making step more automatic? Some clinical decisions like influenza vaccination seem clearly amenable to decision-making rules that could drive standing-order protocols (Dexter *et al.*, 2004). However, attempting to reset the default to intensify the diabetic regimen automatically would be much more complex. One could imagine automatic referrals to diabetic group education or to a health educator or nutritionist, but medication changes would require a much higher level of physician buy-in. Kennedy *et al.* (2006) recently combined HbA1c POCT with algorithmic basal insulin titration in a study of 7,893 adults with type 2 diabetes requiring insulin because glycemic control with oral agents was inadequate. While improvements were seen in all arms of the trial (including POCT plus usual care adjustment of medication regimens), the best improvements were achieved among patients who also received algorithm-driven titration of insulin dosing. The study is especially relevant because it was conducted in 2,164 practices sites, with predominantly primary care practitioners. Thus, POCT testing strategy, with or without therapeutic protocols or algorithms, appears to be not only replicable, but also scalable, i.e. able to be rapidly implemented in a large number of practice sites simultaneously with no additional staffing.

Unfortunately, our study did not demonstrate the financial sustainability of this POCT testing in resource-limited safety-net health centers. Even though the clinic could bill third party insurers (predominantly Medicare and Medicaid) for these tests, roughly 40 percent of their patients were uninsured and the cost of the test cartridges was a new cost for the center, which was not entirely covered by new revenues. At the time of writing the center had suspended POCT because of the per-test costs, despite clinician preference for having results available at the time of the visit.

Conclusions and recommendations

Our quasi-experimental study demonstrates feasibility (within financial constraints) and potential effectiveness of this practice-level intervention in safety-net primary care settings. However, it lacks the scientific rigor of a group randomized controlled trial. It also reinforces previous evidence that POCT can improve testing rates, intensification behaviors, and ultimately glycemic control. Specifically, we achieved a significant practice-level improvement in diabetic regimen intensification, in spite of relatively modest physician performance improvement, by eliminating missed opportunities for face-to-face counseling with patients once the HbA1c results became known. Rigorous trials of replicability and scalability of this model across large numbers of safety net primary care centers are needed if we are to improve glycemic control in the highest-disparity populations and practice settings.

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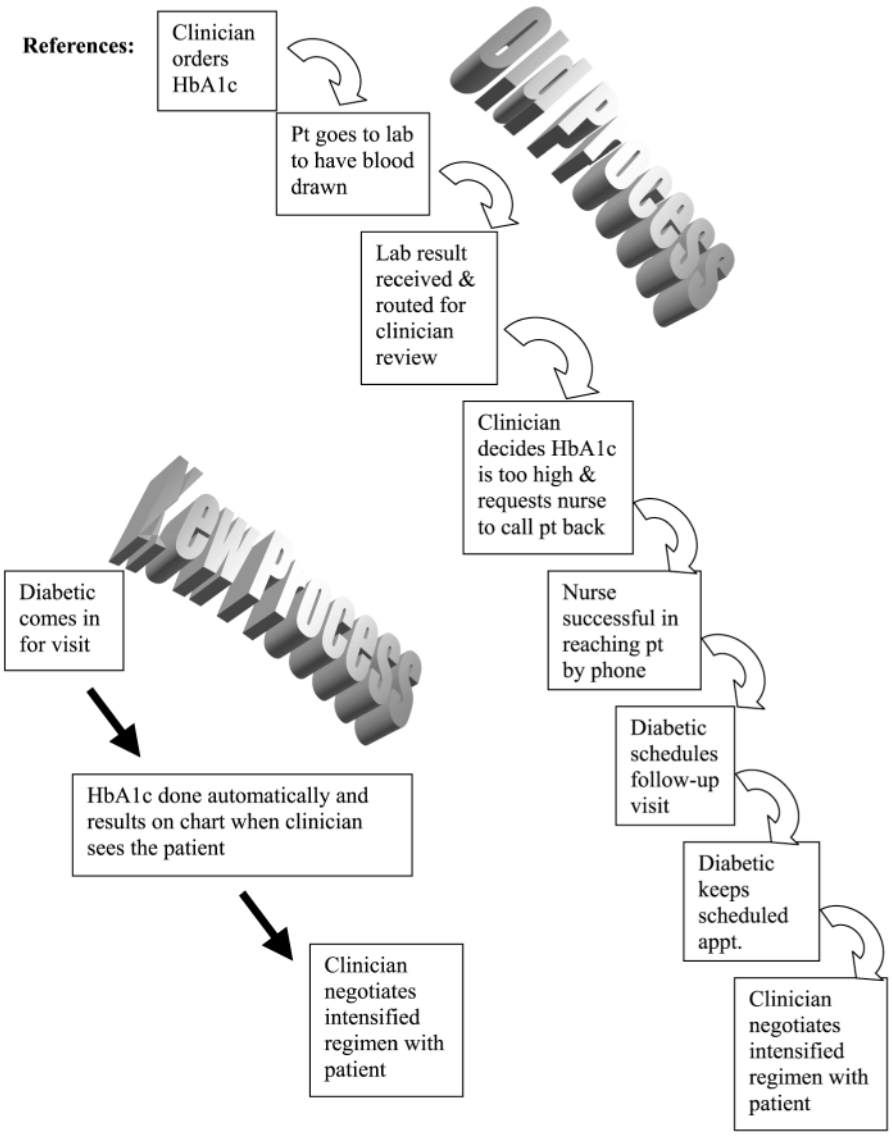

Figure 1.
Process re-design to eliminate un-needed discretionary steps

Table I

Pre- and post-intervention results

	Before		After		
	n	**%**	***n***	**%**	***p*-value**
HbA1c test performed?	78/106	73.6	92/106	86.8	0.397
Mean HbA1c values	8.55[a]		7.84[a]		0.004*
Provider opportunity to counsel patient when HbA1c >8 (face-to-face encounter with results available)	24/35	68.6	39/39	100.0	< 0.001*
CHC as a system: diabetic regimen intensified w/in 90 days after elevated HbA1c > 8	10/35	28.6	21/39	53.8	0.028*
Provider performance in a moment of opportunity: diabetic regimen intensified after HbA1c > 8 and patient had a face-to-face encounter with primary care provider	10/24	41.7	21/39	53.8	0.348

Notes:

[a] $n = 69$

* Statistically significant $p < 0{:}05$

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