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Point-of-Care Hemoglobin A1C Testing System in Community Settings: Challenges, Opportunities, and Measurement Characteristics

Morgan Smith, MS, RN, CDE[1], Sophie Rosenmoss, BA[2], and Hilary K. Seligman, MD, MAS[1,2]

(1) Feeding America; (2) Division of General Internal Medicine, University of California San Francisco, Center for Vulnerable Populations, University of California San Francisco

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Abstract

Background: Point-of-care (POC) hemoglobin A1c (A1C) testing provides clinicians and diabetic patients real-time information on glycemic control. POC testing in community settings may expand reach, but feasibility is underexplored. We sought to describe challenges, opportunities, and quality control results of POC testing conducted in community food pantries.

Methods: Food bank staff who were directly involved in POC testing provided feedback in telephone interviews, weekly team calls, and quarterly open-ended surveys. We evaluated device performance using test-retest comparisons (n = 58) and comparisons between POC results and laboratory results from medical records (n = 72).

Lessons Learned: Study staff performed 1,771 POC A1c tests. Barriers were administrative, regulatory, and operational. Opportunities included ease of training and high participant satisfaction. There was high test-retest correlation (r = 0.97) and high correlation between POC results and laboratory results from medical records (r = 0.85).

Conclusions: Community POC testing programs are feasible and relatively accurate, but implementation requires resources and capacity building.

Trial Registration: This trial is registered at www.clinicaltrials.gov with identifier NCT02569060, registered October 6, 2015, https://clinicaltrials.gov/ct2/show/NCT02569060.

Keywords

Community health partnerships, health disparities, community health research, health promotion, diabetes mellitus, United States, public health, poverty, medically uninsured, food, food insecurity

More than 30.3 million people in the United States have diabetes.[1] Diabetes disproportionately affects racial/ethnic minorities and low-income populations—groups that experience more barriers to clinical care and worse outcomes.[1–7] Reducing diabetes-related health disparities will require innovative strategies tailored to the needs of vulnerable populations.

A1C tests reflect average plasma glucose levels over a period of approximately three months. A1C testing is a critical component of diabetes diagnosis and management. A diabetes diagnosis can be made with a single A1C value. The American Diabetes Association recommends routine A1C testing for all patients with diabetes.[8] A1C values are correlated with risk for diabetes complications, which impact quality of life and drive care costs.[9–11]

POC A1C testing is common in clinical settings,[10,12–14] where POC results correlate highly with laboratory measurements.[15,16] While previous studies have evaluated the use of

POC A1C testing in underserved populations, these studies focused on recruitment of ethnic minority populations for research or occurred in clinical settings.[17] One study recruited Korean-American research participants with diabetes by conducting POC A1C testing at a resource center and referring potential participants to a laboratory for confirmatory diabetes testing.[15] The authors concluded the strategy was successful because it "reduc[ed] costs, recruitment time, and effort, and . . . satisf[ied] an important principle of mutuality in the community." A quality improvement program implemented in Australia expanded access to A1C testing among Indigenous patients with diabetes by integrating POC A1C systems into remote health centers. The authors found significant improvements in frequency of A1C testing, lag between A1C testing and clinical follow-up, and mean A1C.[18] These studies suggest that POC A1C testing in diverse settings for the purposes of diabetes screening and/or monitoring of glycemic control might be successful, particularly for low-income populations less connected to clinical care.

Despite this promise, little is known about barriers and facilitators to implementation of POC A1C programs in community settings. Increasingly, efforts to move clinical care "upstream," or more intentionally focus on social determinants of health within clinical care systems, have emphasized strategies to better link clinical care with community resources.[19] Because this work is centered in the health care sector, the assumption is that patients will be referred from health care settings into the community. Such frameworks hypothesize that screening for a social determinant of health (e.g., food insecurity) in the clinical setting and referring patients who screen positive into community-based programming will result in improved health behaviors, disease risk, and clinical satisfaction, ultimately improving health outcomes and utilization patterns.[20,21] In contrast, screening for diabetes and poor glycemic control in community settings create opportunities to reverse the direction of this engagement; that is, community-based A1C testing may identify diabetes among people without access to clinical care, create opportunities for community settings to tailor programming, and support engagement with clinical care for those with or at high risk of diabetes by providing personalized information about disease risk.

This article describes challenges and opportunities encountered in implementing POC A1C testing during a research trial (Feeding America Intervention Trial for Health—Diabetes Mellitus [FAITH-DM]) conducted in food pantries.[22] While the feasibility of POC A1C testing was not the trial's primary objective, our experiences may help illuminate the potential role of community-based POC A1C testing in vulnerable communities.

PARTNERSHIPS

Feeding America (FA) is the largest hunger relief organization in the United States. In addition to advocating for policies to address food insecurity in the United States, FA engages a national network of 200 food banks. These food banks source, warehouse, and distribute donated and purchased food to more than 60,000 agencies (such as food pantries) located in every U.S. county. For almost a decade, FA has collaborated with researchers at the University of California San Francisco (UCSF) and the Urban Institute (among numerous others) to better understand who is reached by their services, evaluate programming, and measure impact. FAITH-DM leveraged these deep, collaborative relationships. The partnering food banks, selected through a competitive application process, were Houston Food Bank, Gleaners Community Food Bank (Detroit), and Alameda County Community Food Bank (Oakland). These food banks operate robust networks of agency partners, including food pantries; these pantries are embedded in their communities and are trusted service sites for their clients.

After successful completion of a large pilot,[23] staff from FA, the three partnering food banks, and academic researchers co-developed a diabetes intervention study they felt to be both feasible for implementation in pantry settings and adequately rigorous to inform future broad-scale implementation efforts, should the study be successful. All partners agreed upon the mission, goals, and outcomes for the trial. Although all processes were collaborative, staff from FA led development of recruitment and tracking processes and intervention components. FA staff also initially developed and maintained the study Manual of Operations. Revisions to the Manual of Operations resulted from ongoing conversation between food bank and FA staff and addressed site-specific challenges that arose during trial implementation (primarily related to regulatory requirements that differed by state, and environmental factors that differed by region and time of year). Staff from UCSF led randomization processes, survey

development, data tracking and quality control, and data analysis. Food bank staff, in collaboration with pantry staff and volunteers, implemented the intervention, including conducting outreach to pantry clients, helping promote and implement trial activities, providing diabetes education and diabetes-appropriate boxes of food, and conducting free, on-site POC A1C testing.

This article emerged because of feedback from food bank staff that participants highly valued the POC A1C testing, despite operational challenges being encountered. In response, the study's authors (partners from FA, UCSF, and the Urban Institute) sought published information about similar models, but little published information was available. We seek to address this gap in the literature and support future implementation efforts by sharing our collective experiences.

METHODS

Parent Study

FAITH-DM is a randomized, controlled trial investigating the effects of a multi-component diabetes intervention (supplemental food, diabetes self-management education, clinical care referrals, and blood glucose and A1C monitoring) on diabetes outcomes in adults with poorly controlled type 2 diabetes. Food bank staff visited affiliated local food pantries ($n = 27$) in Houston, Detroit, and Oakland to recruit and enroll adults queuing for food. Primary results from the trial and a full description of the intervention are published elsewhere.[24]

Study participants provided written informed consent and authorized their care providers to release medical records data to study staff. The research protocol was approved by the Western Institutional Review Board (WIRB Protocol No.: 20151569). Additional review (for data analysis only) was provided by UCSF's Committee on Human Research and the Urban Institute Institutional Review Board. Clients were offered a free POC A1C test if they had a fasting blood glucose of 140 mg/dL or greater, non-fasting blood glucose of 160 mg/dL or greater, or self-reported history of type 2 diabetes. Those with a POC A1C of 7.5% or greater were eligible for study participation. Study participants were also offered a POC A1C test approximately four times over their 12-month study period. All tests were conducted between October 2015 and September 2017. This study was approved by an independent institutional review board, the Western Institutional Review Board.

Data Collection

Facilitators and barriers to implementation. Data on facilitators and barriers to implementation of the POC testing was collected as part of study implementation, coordination, and quality improvement. Themes described in this manuscript were documented in notes from three sources. The first was weekly calls between FA staff and food bank staff, where implementation themes (e.g., environmental challenges to testing) were discussed and problem-solved. The second was notes from site visits conducted by FA (and sometimes UCSF) staff to participating food banks both early in implementation and at the implementation mid-point. Site visits provided FA staff with opportunities to observe testing practices, provide feedback, and address testing challenges in-person with food bank staff. The final source was quarterly surveys filled out by food bank staff and designed to inform progress reporting to the funder. These surveys included open-ended questions about implementation successes and challenges.

Concordance. Details on quality control procedures are further described in the Results section. We used data from these quality control procedures to assess two types of POC A1C device concordance. In the first type, we assessed concordance between simultaneous POC A1C testing results by simultaneously completing two A1C tests on the same participant using two different monitors (blood samples from the same puncture site). We aggregated the three sites' test results ($n = 58$ test pairs) and used Pearson's correlation to assess agreement between the two sets of measurements. In the second type, we assessed concordance between POC A1C results and abstracted medical record A1C results. We performed Pearson's correlation to assess concordance between POC A1C values and medical record A1C values for 72 dyads.

RESULTS

POC Test Selection, Training, and Administration

We selected the PTS Diagnostics A1CNow®+ POC testing system because it is portable, battery-powered, requires no maintenance, and is reasonably accurate according to

manufacturer reports.[25] We also used this product during the pilot project on which the FAITH-DM intervention was modeled.[23] Each disposable monitor can complete up to 20 POC A1C tests.

Before study implementation, FA and UCSF staff worked with each food bank to develop testing programs that met local and federal regulations. During a 2-day in-person training and regular remote in-service trainings, FA staff built food bank staff capacity to operate the program safely and with fidelity to the research protocol.

POC A1C testing was conducted by trained food bank staff and volunteers at community food pantries (either traditional pantries or food bank-operated mobile distributions in locations such as parking lots and open spaces in apartment complexes). Testing was generally conducted at tables located on the periphery of food distribution activities, both indoors and outdoors.

Study Participants

Food bank staff conducted POC A1C eligibility screening tests on 1,771 individuals queuing at food pantries. Among these individuals, 17.8% ($n = 315$) had results in the prediabetes range (5.7%–6.4%) and 70.1% ($n = 1241$) had results in the diabetes range (≥ 6.5%). Among 878 adults (49.6%) with an A1C result of 7.5% or greater, 568 elected to enroll in the study (Table 1). The average baseline A1C value among enrollees was 9.75 ± 1.79%, and the majority of participants (93.4%) reported having a previous diabetes diagnosis.

Table 1. Baseline Characteristics of FAITH-DM Participants

Characteristic	Result
Age, years (mean, SD)	54.81 (11.42)
HbA1c (mean, SD)	9.75 (1.77)
Race/ethnicity, n (%)	
Latino or Hispanic	293 (52.1%)
White or Caucasian	70 (12.5%)
Black or African American	183 (32.6%)
Native American	3 (0.5%)
Asian or Pacific Islander	8 (1.4%)
Other	5 (0.9%)
Education, n (%)	
Some high school or less	269 (48.0%)
HS graduate/GED/some college/AA/tech. school	251 (44.7%)
College graduate/graduate degree	41 (7.3%)
Health status, n (%)	
Excellent/very good	25 (4.4%)
Good	121 (21.6%)
Fair/poor	413 (73.6%)
Has primary care	523 (92.1%)
No previous diabetes diagnosis, n (%)	37 (6.6%)
Food insecure, n (%)	422 (75.5%)

Opportunities

Food bank staff at all three sites noted very high client interest in participating in POC testing. During food distribution activities and diabetes education classes, many participants reported infrequent utilization of clinical diabetes care due to various barriers (e.g., insurance status, cost, time, and transportation challenges). Staff reported that POC testing became a form of proxy health care for clients facing barriers to clinical care. Clients viewed real-time information about their glycemic control as valuable. In study surveys conducted after the intervention ended, participants rated the POC testing as "very" (87.9%) or "somewhat" (11.6%) helpful.

Across the three study sites we observed additional operational advantages to community POC testing. Staff and client burden was minimal because testing procedures are brief and results are available immediately. Although we observed smoother initial implementation of testing at sites with onsite medical professionals (e.g., nurse or diabetes educator), non-clinical food bank staff quickly mastered testing procedures during the in-person training. There are no professional licensure requirements for operating the devices. Food bank staff also reported anecdotes of A1C results motivating participant re-engagement with formal healthcare.

Administrative Barriers

While food banks recruited some trained volunteers with clinical skills and licensures (e.g., registered nurses, medical assistants) to conduct POC A1C testing, most staff and volunteers at the three sites had no clinical experience. We planned for and worked to address this barrier by developing comprehensive training for study staff covering basic diabetes pathophysiology and treatment, Health Insurance Portability and Accountability Act (HIPAA) regulations, universal precautions, sharps safety and disposal, use of the device, quality control, and reporting. Staff instruction included initial skills

training, site visits and observation, and in-service trainings throughout the trial to reinforce key concepts or address new challenges (i.e., weather-related issues) that arose during implementation.

We supported sites in applying for and maintaining a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver. As a "CLIA-waived device," organizations must receive a waiver from the Centers for Medicare and Medicaid Services before using the PTS Diagnostics A1CNow®+ system.[26] While health care organizations are familiar with obtaining CLIA waivers, this process was challenging for community-based organizations (CBOs). The widespread lack of clarity surrounding the waiver process was made clear by differences we observed across CBOs we researched, with several—including some affiliated with government public health programs—operating POC testing without a CLIA waiver.

Because state agencies manage the CLIA waiver application process, procedures and requirements vary between states. This non-uniform application process created additional challenges for organizations conducting testing in multiple states. There are also regional differences in how public health departments regulate the transportation and disposal of used sharps devices. Local municipalities may place additional burdens on CBOs engaged in POC testing. For example, one food bank was required to submit a "Non-Diagnostic General Health Assessment" application to county officials before conducting POC A1C testing. Overall, the scope of and regional variation in regulatory requirements created a complex and often confusing environment in which to conduct POC testing, and we ultimately worked with each site individually to support application for and maintenance of all necessary certifications. Furthermore, organizations maintaining approvals for operating testing programs must pay annual fees associated with CLIA certificates, sharps disposal, and other testing requirements, which placed burdens on those food banks interested in continuing to provide POC testing to their clients after study completion.

Operational Challenges

The use of POC A1C testing in community settings required addressing several operational issues that potentially affect device accuracy and precision. Weather was a significant challenge at all sites at various points throughout the trial, as environmental conditions in food pantries are often quite different from the climate-controlled clinics for which POC A1C devices are primarily designed. According to manufacturer guidelines, obtaining accurate results with the A1CNow®+ system requires that tests are conducted away from direct sunlight, at room temperature (64°F–82°F), and without physical disturbance (e.g., bumping or moving). Tests conducted outside of these parameters complete a standard five-minute test cycle before the monitor produces an error code indicating the need for retesting. Retests required new blood samples, additional test kits (with attendant costs), and additional time, burdening participants and staff and contributing to difficulties with high-volume community-based testing. Hotter temperatures and humidity in the spring and summer months (particularly, for this project, in Houston) and colder temperatures in the winter months (particularly in Detroit) introduced operational challenges. While staff used portable coolers to transport and store test kits during warmer weather, temperature-related testing challenges occurred much of the year. Maintaining optimal conditions during storage and transportation of test kits required staff to develop site-specific procedures and occasionally destroy unused kits due to suspected heat exposure. We responded to operational challenges with a number of in-service trainings and encouraged site staff to use device customer support to identify sources of error and improve test administration. These challenges also prompted increased quality testing of the system.

POC Quality Control and Concordance Testing

Because of the unique environmental conditions in which the POC device was being used, we implemented two strategies to assess device performance. In the first, staff completed two A1C tests from the same participant using the same puncture site, but a different monitor. Staff recruited a convenience sample of participants for this sub-study during two formal testing periods (November-December 2015 and December 2016–March 2017). Double testing of 58 test pairs revealed strong correlation between two sets of values (r = 0.97) (Figure 1). Mean A1C values from the first and second tests were 7.32 ± 1.87% and 7.38 ± 1.92%, respectively. A1C values ranged from 4.8% to 13%.

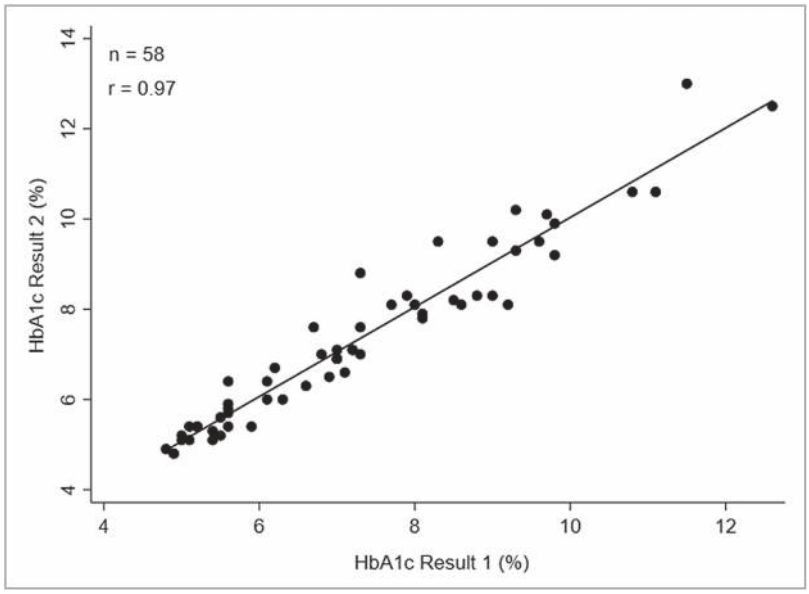

Figure 1. Concordance between two A1CNow®+ tests (different monitors) on single drop of blood at same time.

Two simultaneous A1C tests were conducted on each convenience sample participant (n = 58) using two different A1CNow+ monitors. The two tests were conducted using blood samples from the same finger puncture site. Testing occurred at three participating food banks during two quality assurance testing periods (November and December 2015 and December 2016 to March 2017). Test results (n = 58 pairs) from the three sites were aggregated, and the level of concordance between the two sets of measurements was analyzed using Pearson's correlation. Results of A1C test 1 (%) are displayed on the horizontal access and results of A1C test 2 (%) are displayed on the vertical axis. Scatterplot points represent individual participants' test pair values. The line of best fit shows the concordance between the two sets of A1C tests (r = 0.97).

In the second quality check, we assessed concordance between POC A1C results and abstracted medical record A1C results. As part of the parent study, food bank staff requested medical record data for a subset of participants. Although A1C data was not specifically requested, many records contained A1C results. We extracted A1C values from all medical records received before October 1, 2017. We obtained one or more medical record A1C results for 186 unique FAITH-DM participants, for a total of 451 medical record A1C values. We matched each medical record A1C with participants' POC A1C value(s) from FAITH-DM. There were 72 relatively contemporaneous (within 14 days) medical record/POC A1C dyads (144 unique values). Correlation between POC testing results and contemporaneous medical records results was high (r = 0.85) (Figure 2). Mean A1C value using the A1CNow®+ tests was 9.23 ± 1.80%, and mean A1C value recorded in medical records was 9.28 ± 2.08%. POC values ranged from 5.8% to more than 13%, the maximum possible value using the A1CNow®+ system, and medical record values ranged from 5.4% to 14% in our sample of 72 test pairs.

Sustainability

POC testing at the participating food banks ceased with the formal end of the trial in 2017. Due to high reach and uptake observed during the trial, FA continues to advocate for and test approaches to link community-based programs with health care systems.

DISCUSSION

POC A1C testing may provide a feasible and acceptable option for screening for diabetes and monitoring glycemic control in community settings. Portable, CLIA-waived devices such as the A1CNow®+ system can be used in nontraditional screening environments and require minimal training to operate. Our findings suggest that in real-world, community-based settings, results of A1CNow®+ tests are similar in precision and accuracy to results obtained in controlled, clinical environments and compared to reference laboratory values. Future studies should examine these tests under similar conditions but with larger sample sizes and more rigorous study designs optimized for validity testing, rather than quality improvement.

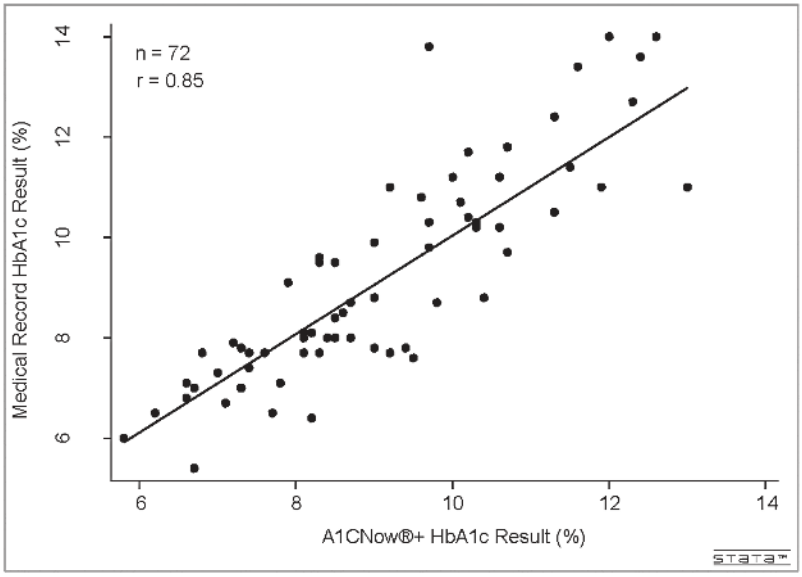

Figure 2. Concordance between A1CNow®+ HbA1c results and medical record HbA1c results within 2 weeks.

A1C values were extracted from participant medical records received between November 2015 and December 2017. Values were aggregated and matched with POC A1C values collected using A1CNow®+ monitors in food pantries. A1C value pairs dated more than 14 days apart were removed. The level of concordance between medical record/POC A1C dyads conducted within 14 days (72 pairs; 144 unique values) was analyzed using Pearson's correlation. The horizontal axis displays POC A1CNow®+ test results (%) and the vertical axis displays medical record A1C test results (%). Scatterplot points represent individual participants' test pair values. The line of best fit shows the concordance between the two sets of A1C values ($r = 0.85$).

There are significant barriers (e.g., cost, time, transportation) to diabetes screening and monitoring for vulnerable populations with limited access to clinical care.[9,17] Our testing program had substantial reach into low-income, food insecure, and minority communities—populations facing barriers to effective self-management, and also at high risk of developing diabetes and diabetes-related complications. High uptake of A1C testing suggests that for these populations, testing in community-based settings—where clients are already accessing other resources—reduces barriers to a much-needed service. For organizations that serve these populations, on-site testing may increase clients' knowledge of their health status and encourage health promotion behaviors and engagement with clinical care. Future studies should be designed to directly evaluate this hypothesis.

As healthcare systems develop deeper partnerships with CBOs to address patients' social needs, exploring how healthcare partners can support training and procurement of supplies for POC testing could assist in making these programs more sustainable. More robust partnerships between healthcare organizations and CBOs could also result in more effective referral systems; while trial participants were provided with resources to establish primary care, deeper partnerships could sustain more effective systems to ensure people actually engaged with healthcare (i.e., through active referral systems, feedback loops, etc.). In the absence of a robust referral and feedback process, a significant limitation of community-based POC testing programs will be an inconsistent ability to effectively drive participant engagement with healthcare, despite demonstrating individuals' elevated test results. Without engagement with healthcare, and therefore without support for medication titration, the capacity of CBOs to have a meaningful impact on glycemic control for people with diabetes will be limited. Thus, more work is also needed to understand how receiving test results in the community may prompt a patient to engage with healthcare (for provider assessment and treatment, pharmaceutical intervention, self-management education and support, etc.), and what systems can be implemented to inform care providers and actively support patient engagement in healthcare services.

Our results have several limitations. We did not ask participants for detailed feedback on POC A1C testing, or how the testing was thought to have impacted their behavior. We compared POC A1C values to values reported in medical records, but the comparison data were obtained using various testing methods in clinic and laboratory settings and taken up to 14 days apart from the POC tests. Additionally, the A1CNow®+ monitor reports a maximum value of 13%, whereas laboratory measurements may report higher values. We did not design the FAITH-DM trial to rigorously assess accuracy or reliability of a testing system. Despite these limitations, our performance results were consistent with those obtained in A1CNow®+ validation and reliability studies conducted in clinical settings.[17,19,27–30]

While developing community-based screening programs is challenging, our experiences demonstrate these programs are feasible for CBOs to operate and highly acceptable to community members. These programs may be particularly effective when robust support exists from local healthcare partners, diabetes educators, and other healthcare professionals working in community settings. Healthcare payors should consider developing and supporting POC testing programs as a public health approach to improving diabetes diagnosis, care integration, and management within vulnerable populations.

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