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Utility of a Point-of-Care Device in Recruiting Ethnic Minorities for Diabetes Research with Community Partners

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Abstract

Background—Recruitment of hard-to-reach ethnic minorities such as Korean Americans (KAs) requires substantial time, cost, and strategic effort. A point-of-care (POC) A1c test could facilitate the recruitment of such populations for diabetes research in community settings.

Methods—A two-step approach for participant screening was employed: Potential participants were first screened using the POC A1c test at a community location. Only those with POC A1c levels $\geq 7.5\%$ were referred for a confirmatory lab test within two weeks.

Results—In total, 237 KAs were screened using the POC A1c test; 92 were referred for confirmatory testing and 83 who got the laboratory A1c measurement were confirmed eligible (A1c $\geq 7.5\%$). There was a strong positive correlation between the POC and reference laboratory measurements ($\rho=0.83$, $p<.001$).

Conclusion—Using a POC A1c method as a front-line screening test can facilitate the recruitment of KAs with type 2 diabetes, while saving cost, time, and effort.

Keywords

Korean Americans; community-based participatory research; type 2 diabetes mellitus; recruitment; point-of-care; A1c

The prevalence of type 2 diabetes has continued to increase over the past decade, with ethnic minority populations suffering a disproportionate burden of the disease.¹ Even though recruitment of underserved ethnic minorities for diabetes research is important to improving the generalizability of study findings and ultimately to reducing health care disparities, the recruitment of ethnic minority groups for diabetes research continues to prove challenging.

Korean Americans (KAs), one of the most underserved and understudied minority populations in the United States, have a notably greater prevalence of type 2 diabetes than their counterparts in Korea.^{2–5} Being predominantly first-generation immigrants, KAs experience a number of significant barriers that can limit their ability to participate in a study: insufficient English proficiency, unfamiliarity with research protocols, lack of time or transportation, and intimidation by and distrust of the mainstream health care system.

Korean Americans are often called a hard-to-reach population due in part to recruitment and retention challenges; in turn, many research projects or health programs have not been adequately evaluated among KAs. This limited research participation contributes to a widening of the health gaps between this vulnerable group and mainstream communities. Researchers must become more creative in addressing the barriers to research participation by traditionally understudied groups to reduce health disparities.⁶

Recruiting ethnic minorities in community settings for diabetes research involves the expenditure of substantial time and resources to determine eligibility. Potential participants often lack primary care providers and lab data; therefore more time is required to verify their diagnosis and study eligibility. The American Diabetes Association (ADA) recently endorsed using glycosylated hemoglobin (A1c) as one of the diagnostic criteria for diabetes.⁷ A1c measures a patient's average glycemia over the preceding two to three months and does not require fasting. However, the conventional A1c test requires the patient to visit a certified reference laboratory, which may be inconvenient and even challenging for some participants. This is particularly true for individuals from linguistically isolated ethnic communities (such as many KAs) because of challenges posed by appointment-making, transportation, distance from the lab, and language barriers.

The point-of-care (POC) capillary blood glucose test provides immediate results of A1c testing in any location and provides timely feedback on clinical practice. The availability of on-the-spot testing results can facilitate the interaction between the clinician and the patient with diabetes.^{8,9} Studies have supported a high level of concordance in A1c values between laboratory venous blood glucose and POC capillary blood glucose measurements.^{10–12}

To date the potential utility of the POC A1c test in screening underserved populations for diabetes research in community settings and the impact of such testing on the recruitment process have not been evaluated. The purpose of the present study was to test the utility of the POC A1c test as a creative recruitment tool for diabetes research targeting KAs. The criterion validity of the POC method was tested against well-established laboratory measurements in a convenience sample of KAs who participated in a community-based intervention trial. Our paper discusses the recruitment-related lessons learned from the trial and implications for future research targeting ethnic minorities with type 2 diabetes in the community.

Methods

Study sample and setting

Research team meeting minutes, research staff daily activity logs, and relevant medical record reviews were used as the source of data related to the screening and recruitment of KAs for a community-based randomized clinical trial to improve glycemic control among KAs with type 2 diabetes. To be eligible for the trial, participants had to be KA, 30 years of age or older, with A1c $\geq 7.5\%$, and resident in the Baltimore-Washington Metropolitan Area. Individuals with type 1 diabetes and those with hemoglobinopathies that would affect the A1c assay were unfit to sign a consent form and were thus excluded. Participants were recruited *via* Korean churches, referrals from Korean physicians, word-of-mouth, and advertising in ethnic media. Detailed information about study design and methods has been published.³

Screening/verification procedures

A number of effective recruitment strategies targeting the KA community have been identified: conducting research in familiar settings or in a place conveniently located for the research participants, working with culturally sensitive researchers, and using bilingual

research staff.^{3,6,13} In accordance with community-based participatory research (CBPR) principles, we also held several recruitment strategy meetings with members of the KA community, including community health workers, patients, and their families. To address their needs (i.e., minimizing the participants' financial and psychological burdens) and to implement a fiscally prudent recruitment program, we took a two-step approach to participant screening and recruitment: Following study approval by the Institutional Review Board, potential participants were first asked to come to our community partner site, the Korean Resource Center (KRC), which is located in an area with a dense population of KAs. At the center, A1c levels were initially checked *via* a POC A1c test (A1CNOW+[®]). A1CNOW+[®] is a five-minute assay, and there was no initial instrument cost. Each monitor contained 10–20 test cartridges; no maintenance or calibration was required since the monitor is disposed of after 10–20 uses. A1CNOW+[®] is certified by the National Glycohemoglobin Standardization Program (NGSP) and produces a result within 1% A1c of the standardized result 95% of the time. As an additional outreach effort, researchers also visited local health fairs and local health education centers for on-site POC A1c testing and screened individuals interested in participating in the intervention trial.

Only those with A1c levels of 7.5% or higher through the POC A1c test were scheduled to receive additional venous A1c tests within 1–2 weeks at a NGSP-certified laboratory to confirm study eligibility (for details about NGSP-certified methods: <https://www.ngsp.org/>). At the time of research participant recruitment, there was a lack of agreement on screening criteria using A1c, and the ADA had not endorsed the use of the A1c as a diagnostic test. Therefore, we conservatively set the cut-off point for study eligibility at 7.5%, using the POC device to identify KAs with uncontrolled diabetes and to minimize the false-positive rate from the POC A1c test. The confirmatory blood draw was also conducted at our community partner site (KRC) by trained phlebotomists dispatched from the academic research center on scheduled days as agreed upon among the research team, the community partner, and the academic research center. Those with A1c levels 7.5% or higher from this confirmatory blood draw were included in the study.

Statistical analysis

Participant characteristics were summarized with descriptive statistics. Spearman's rho correlation coefficient was calculated to determine the strength of the association between the POC A1c and the reference laboratory A1c values. A p-value of less than .05 was considered significant. To predict the laboratory A1c value (dependent variable) from the POC device (independent variable), a linear regression analysis was performed. The mean difference (bias) between the A1c as determined by the POC test and that obtained by the laboratory measurement of venous plasma glucose was determined using the Bland-Altman technique.¹⁴ The difference between the two measurements was plotted against the mean of the two measurements. It is recommended that 95% of the data points lie within ± 2 standard deviations (SD) of the mean difference.¹⁴

Results

Recruitment and sample characteristics

Patients were recruited from September 2007 to March 2008; study enrollment was completed in April 2008. To enroll the targeted sample size of 80 KAs, we screened 237 KAs using the POC A1c test during the recruitment period. Of these, 145 were excluded based on their POC A1c test values (<7.5%); 92 people with POC A1c 7.5% or greater were scheduled to have blood samples drawn for laboratory A1c measurement. Table 1 presents the demographic characteristics of the 92 individuals who received both the POC and lab-based A1c tests. More than half of the 92 were male, and nearly three-fourths were married.

The majority had at least a high school level of education and an annual household income less than \$60,000. Eighty-three of the 92 were confirmed eligible (laboratory-based A1c 7.5%).

Criterion validity of the POC method

The mean ($\pm$ SD) A1c as measured with the POC device was $8.89 \pm 1.21\%$. The mean ($\pm$ SD) A1c value as determined by the reference laboratory was $9.1 \pm 1.47\%$. Overall, the absolute mean difference ($\pm$ SD) between the POC method and laboratory measurement was $0.59 \pm 0.55\%$ (Table 2). The A1c values from the two methods were strongly correlated ($\rho=0.83$, $p<.001$) (Figure 2). Of the 92 individuals tested, six had laboratory results identical to those obtained from the POC device. Thirty-seven percent of the participants had POC results that read higher than those obtained through laboratory measurement.

The regression equation—expected laboratory A1c= $-0.013+1.025 \times$ POC A1c—allowed for prediction of the laboratory A1c value at a given A1c result from the POC device. The most accurate POC A1c values were within 7.5–8.5% based on the results of correlation and absolute mean difference between the POC A1c and laboratory A1c values: The greater the A1c with the laboratory measurement, the greater the absolute difference in A1c value between the POC method and the laboratory measurement. According to the Bland-Altman plot (Figure 3), 6/92 (6.5%) of the points were beyond the ± 2 SD lines, with the most extreme difference being 2.8.

Cost estimation

The retail cost of A1CNOW+® is approximately \$10–\$12 per test, whereas the standardized laboratory test price range is \$40–\$80. Based on the laboratory costs for A1c testing (\$40–\$80), between \$3,500 and more than \$10,000 could be saved by using the two-step approach to screen 237 potential candidates. If other indirect fees such as transportation, parking, and on-site interpreter costs are considered, the costs would be at least an additional \$50 to \$100 per person (not including missed hours from work to travel to the urban research center).

Discussion

To recruit ethnic minorities into clinical trials successfully, it is crucial to identify barriers to research participation in the early phase of a study and to address these barriers accordingly. In the case of KAs, the salient barriers to participating in diabetes research that we observed during the early phases of recruitment included difficulties in communicating with English-speaking providers and reluctance to drive and park in an urban area for safety reasons—both of which presented challenges for the research team when trying to arrange participant visits to an urban academic research center for blood testing to confirm their eligibility based on A1c level. The two-step approach (POC A1c testing initially at various community locations and inviting only those who met the A1c cutoff 7.5% to a community center with bilingual staff for a confirmatory blood draw by a phlebotomist dispatched from the academic research center) was successful in the recruitment of 83 eligible KAs within six months. Given our total number of eligible participants, our recruitment period was shorter than that for a diabetes clinical trial of African Americans in a community setting who already had their A1c results available from their PCPs.¹⁵ In our study most potential participants did not have a previous A1c result; hence we had to screen them to determine eligibility.

Screening for diabetes using a fasting blood glucose or random A1c test in the laboratory requires substantial time and logistical effort to schedule blood draw, and such screening is psychologically stressful.^{16,17} The two-step approach not only reduced the costs associated

with the lab testing but also had other benefits: For example, having a phlebotomist on-site at a community center with easy access from potential participants' residence (the center being located in a Korean-populated suburban area) significantly reduced concerns about travel and parking. Furthermore, the presence of bilingual research staff at the community center and food accommodation after the blood test resulted in a successful and mutually satisfying recruitment process for participants and the research team.

There are some limitations on this study. Since individuals with POC A1c <7.5% did not receive the confirmatory laboratory test, it was not possible to determine the sensitivity and specificity of the POC test; our findings may either overestimate or underestimate without having a sample whose A1c is between 6.5% and 7.5%. However, there was a strong and positive correlation between the POC and the reference laboratory measurements ($\rho=0.83$, $p<.001$). Our results are consistent with previous studies in which correlations between the two A1c test methods ranged from 0.72 to 0.96.^{18–20} The POC values were generally lower than the venous samples. In addition, the bias between the POC test and the reference laboratory measurement was minimal at the lower end of the scale. These observations indicate that the POC A1c test may be more accurate in screening for diabetes than in monitoring for uncontrolled diabetes, implying higher sensitivity than specificity. When used as a primary screening tool, the POC A1c may not be sufficiently accurate, based on the observed level of agreement between the POC test and reference laboratory measurement. However, the strong correlation between the two methods reduces the uncertainty of the POC test as an intermediate screening tool. Rather than supporting the interchangeable use of the POC and reference laboratory measurements, using the POC test to exclude those with normal A1c, followed by the use of confirmatory lab testing, would be an efficient strategy for determining eligibility for community-based diabetes research in an underserved population.

Since we included only KA immigrants in our community-based diabetes intervention, the issue of generalizability beyond our participants is carefully considered based on the characteristics of targeted population. For example, researchers who work with African Americans will face different challenges (probably not, for example, challenges related to inadequate English proficiency).

Despite some limitations, this study has important implications for future research. A series of practical considerations favor the two-step approach using the POC A1c test followed by laboratory testing to screen underserved populations for diabetes research. It not only reduced the cost of screening and confirming eligible KA participants with type 2 diabetes for a community-based intervention trial, it also addressed leading concerns of our community partners such as language barriers, inconvenience, and safety issues associated with travel to an urban research center. The immediacy of the A1c results from the POC test also seemed to increase potential participants' diabetes awareness and led to their interest in participating in the research. Brown et al. suggest that willingness to participate in research is determined by "awareness, acceptability and access."²¹[p.627] Those who were made aware of their elevated A1c levels were willing to move forward to get further testing in the laboratory to confirm the results. This response is understandable, given KAs' tendency to favor crisis-oriented care.^{22,23} Most KAs with asymptomatic diabetes consider that their condition is pre-diabetic and does not require any medical attention. Our two-step approach addressed these beliefs by giving participants both immediate and confirmatory A1C results that raised diabetes awareness. It also served as a community-friendly risk assessment program for diabetes (acceptability) and offered a convenient and rapid test in a convenient research center setting due to the cooperation of the community organization with which we worked (access).

Community-based participatory research is a collaborative research approach that recognizes community as a unit of identity and features an integrated and iterative process for the mutual benefit of researchers and participants.²⁴ In community-based research, collaboration and reciprocal appreciation between individuals in the community and researchers are essential. For example, providing hands-on services such as outreach health education and screening tests, rather than just taking something away from an underserved population with limited resources (or being perceived to do so) is carefully considered. The hands-on service also provides research results to the community by sharing ownership of the data. A conflict between these perspectives at any level can lead to recruitment failure.²⁵ Most KAs (over 50%) lack health insurance and have not had an opportunity to have regular blood work for diabetes or cholesterol.⁵ For this population who have not received any diagnostic lab test, providing lab tests (i.e., a diabetes screening test for all potential participants and further lab tests such as lipid profile were provided for all eligible participants) is beneficial as an incentive for health research participation. As is true for other underserved populations, flexibility in scheduling appointments with participants and a multidimensional approach are helpful for successful recruitment. We performed the POC test at a local health fair through outreach health services and educational programs. The ease of use of the POC test made it possible to include various study samples from multiple recruitment sites within the community.

Overall, the period required to accrue an adequate number of eligible participants was shortened through the use of the POC test. Our experience with underserved ethnic minorities indicates that participants should begin a research program within two to three weeks of screening to be most effective, in order to preclude a change in potential participants' willingness to participate in the research.

In summary, when used as a front-line, intermediate screening test, the POC A1c method facilitated screening and recruitment of individuals in an underserved population with type 2 diabetes in community-based settings by reducing costs, recruitment time, and effort, and by satisfying an important principle of mutuality in the community. Although we still most understand better the diverse characteristics of a targeted population and the differences between various populations, many of the approaches we have been identifying may be applicable to the greater issue of recruitment of underserved ethnic minorities for community-based health research.

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Notes

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Figure 1.
Recruitment and enrollment for the community-based intervention trial in Korean Americans with diabetes.
POC = Point-of-Care
A1c = Glycosylated Hemoglobin

Figure 2.
Correlation of A1c between point-of-care method and NGSP laboratory measurement (n=92, $\rho=0.83$, $p<.001$).
NGSP = National Glycohemoglobin Standardization Program
A1c = Glycosylated Hemoglobin

Figure 3.
Bland-Altman plot of difference between POC (A1CNOW+[®]) and reference laboratory A1c versus mean values.
POC = Point-of-Care
A1c = Glycosylated Hemoglobin

Table 1**DEMOGRAPHIC CHARACTERISTICS (N=92)**

Characteristics	Frequency (%)
Gender	
Male	50 (54.3)
Female	33 (35.9)
Missing	9 (9.8)
Age (years) (Mean [SD]=56.6 [7.90])	
below 49	20 (21.7)
50–59	35 (38.0)
60 and older	37 (40.2)
Marital status	
Married	73 (79.3)
Single	9 (9.8)
Missing	10 (10.9)
Education level	
less than high school	7 (7.6)
High school graduate	35 (38.0)
More than some college	41 (44.6)
Missing	9 (9.8)
Income Level (\$)	
below 19,999	15 (16.3)
20,000–39,999	19 (20.7)
40,000–59,999	18 (19.6)
60,000–79,999	11 (12.0)
80,000–99,999	7 (7.6)
More than 100,000	10 (10.8)
Missing	12 (13.0)

Table 2

DESCRIPTIVE STATISTICS OF POC A1c AND LABORATORY A1C LEVEL (N=92)

	Mean (SD)	Range
POC A1c	8.89 (1.21)	7.5–12.8
Laboratory A1c	9.09 (1.47)	6.0~14.7
Abs difference (POC A1c—Laboratory A1c) ^a	.59 (.55)	.00~2.80

^a Absolute difference between Point-of-care A1c testing and venous laboratory analysis.

POC = Point-of-Care

A1c = Glycosylated Hemoglobin