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Evaluation of point-of-care algorithms to detect diabetes during screening for latent TB infection

A. Largen[1], **A. Ayala**[2], **R. Khurana**[2], **D. J. Katz**[3], **T. K. Venkatappa**[3], **R. Brostrom**[1,3]

Tuberculosis Epidemiologic Studies Consortium

[1]Tuberculosis Control Program, Hawaii Department of Health, Honolulu, HI

[2]Maricopa County Department of Public Health, Phoenix, AZ

[3]Centers for Disease Control and Prevention, Atlanta, GA, USA

SUMMARY

BACKGROUND: Individuals with both diabetes mellitus (DM) and TB infection are at higher risk of progressing to TB disease.

OBJECTIVE: To determine DM prevalence in populations at high risk for latent TB infection (LTBI) and to identify the most accurate point-of-care (POC) method for DM screening.

METHODS: Adults aged ≥25 years were recruited at health department clinics in Hawaii and Arizona, USA, and screened for LTBI and DM. Screening methods for DM included self-report, random blood glucose (RBG), and POC hemoglobin A1c (HbA1c). Using HbA1c ≥6.5% or self-reported history as the gold standard for DM, we compared test strategies to determine the most accurate method while keeping test costs low.

RESULTS: Of 472 participants, 13% had DM and half were unaware of their diagnosis. Limiting HbA1c testing to ages ≥30 years with a RBG level of 120–180 mg/dL helped identify most participants with DM (sensitivity 85%, specificity 99%) at an average test cost of US$2.56 per person compared to US$9.56 per person using HbA1c for all patients.

CONCLUSION: Self-report was insufficient to determine DM status because many participants were previously undiagnosed. Using a combination of POC RBG and HbA1c provided an inexpensive option to assess DM status in persons at high risk for LTBI.

RÉSUMÉ

Les patients atteints à la fois de diabète (DM) et d'infection tuberculeuse courent un risque plus grand de progression vers la TB maladie.

Déterminer la prévalence du DM dans des populations à risque élevé d'infection tuberculeuse latente (ITL) et d'identifier les méthodes de dépistage du DM les plus exactes sur les lieux d'intervention (POC).

Correspondence to: Angela Largen, Tuberculosis Control Program, Hawaii Department of Health, Honolulu, HI, USA. angela.largen@doh.hawaii.gov.

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Des adultes âgés de ≥25 ans ont été recrutés dans des structures de santé de Hawaii et en Arizona et ont bénéficié d'un dépistage d'ITL et de DM. Les méthodes de dépistage du diabète ont inclus l'auto déclaration, la glycémie aléatoire (RBG) et le dosage d'hémoglobine glyquée (HbA1c) à POC. En utilisant l'HbA1c ≥6.5% ou l'auto déclaration, nous avons comparé les stratégies afin de déterminer la méthode la plus exacte tout en gardant des coûts de tests faibles/raisonnables.

Parmi 472 participants, 13% avaient un DM et la moitié n'était pas au courant du diagnostic. En limitant les tests de HbA1c aux personnes de ≥30 ans avec une RBG de 120–180 mg/dl (soit 1,2 à 1,8 g/l) a identifié la majorité des participants atteints de DM (sensibilité 85%; spécificité 99%) pour un coût moyen de test de 2,56 US$ par personne comparé à 9,56 US$ par personne en utilisant l'HbA1c pour tous les patients.

L'auto déclaration a été insuffisante pour déterminer le statut en matière de DM car beaucoup de participants ont été diagnostiqués jusque-là. L'utilisation combinée d'une RBG et de l'HbA1c à POC ont fourni une option peu coûteuse pour évaluer le statut en matière de DM chez des personnes à risque élevé d'ITL.

Keywords

hemoglobin A1c; random blood glucose; TBESC; Hawaii; Arizona

TB DISEASE INCIDENCE in the United States has remained at 2.7 to 2.8 cases per 100,000 population for the past 4 years.[1] Analysis of TB surveillance data suggest that >80% of TB cases in the United States are the result of reactivation of infection acquired in the past.[2] Latent TB infection (LTBI) is the diagnosis of exclusion when an individual tests positive for TB infection but has no detectable evidence of TB disease. The detection and treatment of LTBI, especially among individuals at high risk for progression to TB disease, is part of efforts to further decrease the national TB rate and accelerate progress towards TB elimination in the United States.[1]

The association between diabetes mellitus (DM) and TB disease is well established, with a 2- to 3-fold increased risk of progression to TB disease among individuals with LTBI and DM compared to those without DM.[3,4] Because people with DM may require extended TB treatment,[5] and are at increased risk of poor outcomes, some experts recommend that adult patients with TB disease be screened for DM.[6]

DM may also be associated with higher LTBI prevalence.[7,8] Incorporating DM status in the decision to offer LTBI treatment may help providers prioritize individuals at risk for progression to TB disease. Furthermore, emphasizing the increased risk of TB progression to patients with DM may encourage LTBI treatment acceptance and adherence.

To diagnose DM, the American Diabetes Association (ADA) recommends a laboratory-based glucose or hemoglobin A1c (HbA1c) test certified by the National Glycohemoglobin Standardization Program.[9] However, laboratory-based tests are resource-intensive and may require additional follow-up encounters that may reduce adherence. More convenient point-of-care (POC) options such as finger-stick HbA1c or random blood glucose (RBG) are cheaper and easier to implement to screen for DM. POC HbA1c provides a more accurate

assessment of long-term glucose control than RBG but is more expensive. Undiagnosed patients, as well as patients who are unwilling to disclose their DM diagnosis, are missed when self-report is used. A recent study of refugees screened for both LTBI and DM in the state of Georgia, USA, found over half (55.6%) of patients with DM were previously undiagnosed;[10] national reports estimate 21.4% of adults with DM in the United States are undiagnosed.[11]

The aims of the present study were 1) to estimate the prevalence of pre-DM (no self-reported history of DM and HbA1c of 5.7–6.4%) and DM (self-reported DM or HbA1c ≥6.5%) in populations screened for LTBI at two health department clinics; 2) to identify the most accurate POC DM screening algorithm for these populations while minimizing test costs; 3) to estimate the number and proportion of individuals with DM who were previously undiagnosed; and 4) to determine how often participants with a screening result of new pre-DM or DM reported changes in diet or exercise and scheduled or completed a follow-up appointment for medical evaluation.

METHODS

Patient recruitment

The Tuberculosis Epidemiologic Studies Consortium (TBESC) is a partnership of academic institutions and health departments in 11 states of the United States funded by the Centers for Disease Control and Prevention (CDC). As part of a large TBESC prospective cohort study to compare the three commercially available tests for LTBI in individuals at high risk for infection and/or progression to TB disease, we screened a subset of adults aged ≥25 years for TB infection and DM. Individuals under age 25 were not enrolled due to low prevalence of DM in younger age groups.[7] Participants were recruited at two TBESC sites that were able to participate: the Hawaii Department of Health (HDH) in Honolulu, HI, USA, and the Maricopa County Department of Public Health (MCDPH) in Phoenix, AZ, USA, between December 2015 and February 2017. Both health departments are in states with average or higher-than-average DM prevalence among patients with TB disease: 21.9% in Arizona and 40.0% in Hawaii, compared to 19.8% in the United States.[12]

Persons eligible for the TBESC study were at high risk for TB infection and included close contacts to persons with infectious TB disease; individuals born in countries whose U.S. populations had high (≥100/100,000 population) TB incidence; recent arrivals (within 5 years) from countries whose U.S. populations had medium (10–99/100,000 population) TB incidence; those with recent travel for ≥30 days to a high-incidence country; and persons with HIV infection. All participants were tested for LTBI using two interferon-gamma release assays (QuantiFER-ON®-TB Gold In-Tube, Qiagen, Hilden, Germany; and T-SPOT®.*TB*, Abingdon, UK) and the tuberculin skin test (TST). A structured interview assessed demographics, TB history, and medical and social risk factors for LTBI and TB disease.

The large cohort study and associated sub-study were approved by institutional review boards at CDC (Atlanta, GA, USA) and at local sites; participants provided written informed consent for both studies.

Diabetes screening

Participants were screened for DM using self-report, POC HbA1c and RBG on the day of LTBI testing. In addition to the interview for the larger study, participants in the sub-study were asked about time of last meal and personal and family history of DM.

Self-reported history of DM was incorporated in all screening strategies; in other settings, self-reported DM and medical record review showed high agreement.[13,14] Cutoffs for POC glucose and HbA1c were chosen because they were similar to or the same as the ADA-recommended glucose and HbA1c thresholds for laboratory-based diagnosis of DM: 126 mg/dL (fasting glucose), 200 mg/dL (RBG), and 6.5% (HbA1c); additional diagnostic criteria such as symptoms of hyperglycemia were not assessed in this study.[9]

DM and LTBI results were given at the second clinic visit. Participants with HbA1c values indicating pre-DM (5.7%–6.4%) or DM (≥6.5%) were briefly counseled, which included a brief description of DM and the importance of primary care follow-up. Participants with DM or pre-DM, including those with a history of DM not currently established in care, were given a list of low-cost primary care clinics (HDH) or assigned a primary care provider (MCDPH) for confirmatory testing and follow-up care. Newly diagnosed participants were contacted after 2 months to determine if they followed-up with a primary care provider or reported changes in diet or exercise.

To identify the most accurate low-cost DM screening strategy, four algorithms were explored that included combinations of self-report, RBG testing, and HbA1c testing (Table 1): 1) self-reported history of DM or HbA1c value ≥6.5% (gold standard); 2) self-reported DM status (yes or no) alone; 3) self-reported history of DM or RBG thresholds of a) 200, b) 180 or c) 120 mg/dL, chosen to span the ADA cutoffs, and 4) a tiered strategy (Figure 1) of self-reported history of DM or RBG ≥180, or RBG 120–179 and HbA1c ≥6.5% (Table 1, Figure 1).

Calculation of test cost

Glucose (US$1.30) and HbA1c (US$10.30) costs were based on local supplier prices for the state of Hawaii in 2015; a single test price was chosen to focus on any impact the population characteristics of the two sites may have on testing algorithms. The average per patient cost for each strategy was calculated by multiplying the number of people who received the test by the price of the test divided by the total number of participants.

Data analysis

Site-specific descriptive participant characteristics were generated, including frequencies of pre-DM and DM using the study gold standard. To assess the association between age and the presence of pre-DM or DM, risk ratios (RRs) were calculated using an unadjusted log-binomial model; age was categorized as ≥45 and <45 years for this analysis.

To compare screening strategies within and between sites, we calculated sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) compared to the gold standard, as well as accuracy (true-positives + true-negatives/total results). Summary frequencies were generated for 2-month follow-up results.

Data management and analyses were performed using Microsoft Excel (Microsoft, Redmond, WA, USA) and SAS v9.4 (SAS Institute, Cary, NC, USA).

RESULTS

Descriptive characteristics

The 472 participants enrolled in the DM study included 375 (79%) at HDH and 97 (21%) at MCDPH (Table 2). Approximately half (*55*%) were female, 40% were 25–39 years old, 52% had a positive LTBI test, and 85% were born in countries with TB incidence of ≥100/100,000.[15]

Using the study gold standard, 13% of participants (62/472) had DM and 29% (137/472) had pre-DM (Tables 1–3). Increasing age was associated with increasing prevalence of DM and pre-DM (Table 3). No participant in the 25–29 years age group had DM. Compared to those aged <45 years, persons aged ≥45 years were more than twice as likely to have pre-DM (RR 2.1, 95% CI 1.6–2.8) and more than five times as likely to have DM (RR 5.5, 95% CI 3.0–10.0).

Participants at the two sites differed by country of origin, and by combined pre-DM/DM prevalence, but not by DM prevalence alone or pretest knowledge of DM status. MCDPH enrollees were primarily born in Somalia (26%), Syria (26%), Iraq (13%), and the Democratic Republic of Congo (10%). A majority of HDH participants (83%) were born in the Philippines. At HDH, 14% (95% CI 10–17) of participants had DM compared to 10% (95% CI 4–16) at MCDPH. More than half (56%, 95% CI 13–69) of participants with DM at HDH were undiagnosed prior to TB screening, as were 40% (95% CI 10–70) at MCDPH. MCDPH had more participants without either pre-DM or DM (72%, 95% CI 63–81) than HDH (54%, 95% CI 49–59).

Diabetes screening strategies

Compared to the gold standard of self-reported history of DM or HbA1c ≥6.5%, the accuracy of the tiered testing strategy (Figure 1) was equal or superior to the other strategies across all age groups (Figure 2). In general, accuracy decreased as age increased until the >60 years age category. As no participants were identified with DM in the 25–29 years age category, further analyses exclude participants under age 30.

DM screening strategies for participants aged ≥30 years were compared by average per-participant test cost and test characteristics for each site (Table 4). A self-reported history of DM was free but had low (≤60%) sensitivity. Combining self-report with a glucose threshold of 120, 180, or 200 mg/dL was inexpensive (US$1.21 per participant screened), but resulted in poor test performance, including low PPV for the 120 mg/dL threshold (49–75%) and low sensitivity (≤80%) for the 180 mg/dL and 200 mg/dL cutoffs. The gold standard had the highest average cost (almost US$10) per participant. The combined method of self-report, RBG, or HbA1c for participants with glucose 120–179 mg/dL (tiered testing) had good test performance at relatively low cost. (<US$3). All strategies performed similarly at both sites (Table 4).

Two-month follow-up

Follow-up interviews with participants newly diagnosed with DM or pre-DM revealed substantial positive changes; nearly half (47%) of participants with DM who were contacted for 2-month follow-up had completed or scheduled a primary care appointment, and 93% reported changes in diet or exercise practices (Table 5).

DISCUSSION

DM has become increasingly prevalent in the United States and is a common comorbidity among persons with TB disease.[16] Global estimates of the population attributable fraction suggest that 10–20% of TB cases can be attributed to DM, and that this proportion may be higher in areas with high rates of both conditions.[17] While the impact of DM on TB progression is widely recognized, it is unclear how to best implement screening for both LTBI and DM and in which settings it may be beneficial.

In this study, we identified a high percentage of participants with DM among adults at risk for TB infection in two health department settings, 14% at HDH and 10% at MCDPH. Both populations had equal or higher proportions of persons with DM compared to their 2016 state estimates (9.5% and 9.7% in Hawaii and Arizona, respectively).[18]

Among persons with LTBI and no other risk factors for progression to TB, a diagnosis of DM may encourage individuals to start and complete LTBI treatment. However, in our evaluation, about half (53%) of participants at high risk of LTBI with DM were unaware they had the condition, so self-reported status would be insufficient. Of note, many of the participants in this study came from the Philippines, where as many as 40% of persons with DM are undiagnosed.[19]

We identified an inexpensive POC DM screening method for persons at high risk for LTBI or TB. For those without a history of DM, a tiered strategy—RBG, followed by HbA1c for patients with a glucose level of 120–179 mg/dL—performed best against the gold standard of self-report and HbA1c. Quick screening options for DM, such as the method identified in this study, may assist providers with LTBI treatment prioritization.

Risk scores to predict DM have been developed that incorporate glucose and HbA1c, medical history, family DM history, or anthropometric measures. Such scores were used in the TANDEM TB and DM study to screen for DM among persons with TB disease in low- and middle-income countries.[20] Risk scores were not considered for this study as the goal was to identify a quick DM screen for clinics that see a high volume of patients for LTBI and TB disease. However, among patients with TB disease, the best performing risk score identified by Grint et al. included a two-step combination of RBG, followed by POC HbA1c in patients with a glucose level of ≥110 mg/dL,[20] similar to the tiered screening strategy in our study.

Our study also provided referrals to care for participants with newly diagnosed pre-DM or DM. Two months after screening, 47% of individuals with DM had either completed or scheduled a primary care appointment and 93% reported changes in diet or exercise. In

addition to prioritizing LTBI services, this encounter provides an opportunity for programs to use routine TB screening to connect patients with DM to primary care. Providing a list of clinics or direct linkage to services appeared effective at encouraging confirmatory testing and care. Since some participants did not follow up, additional approaches may be required to increase linkage to care.

This study had limitations. Results may not be generalizable as enrollment was limited to persons at high risk for LTBI at only two clinics. Self-reported DM was not validated with medical records, although previous studies found high specificity of self-reported DM when compared with medical records (84–97%).[13] Cost estimates did not include staff time and may vary in other settings. POC tests were not compared to laboratory-based tests because the methods used in this study were for initial screening; this underscores the importance of primary care follow-up. As fasting glucose level is more sensitive than HbA1c, using HbA1c as a gold standard may have missed additional undiagnosed DM.[9] While HIV infection was not a significant comorbidity in this sub-study population, HIV antiretroviral medication may reduce the accuracy of HbA1c.[21] Finally, the 2-month follow-up relied on self-report, which may be inaccurate and may not indicate longer-term changes and engagement in care.

Published evidence of the benefits of LTBI treatment in patients with DM is limited.[22] However, as it is well-documented that patients with DM are at increased risk of progression to TB disease and of poor outcomes when TB develops,[16,23] it is likely that patients with LTBI and DM would benefit from LTBI treatment, as well as referral for DM services. A rapid, low-cost screening method, such as the one identified in this study, could be implemented in TB screening clinics to more fully characterize the risk for TB progression, and help patients begin primary care management of DM.

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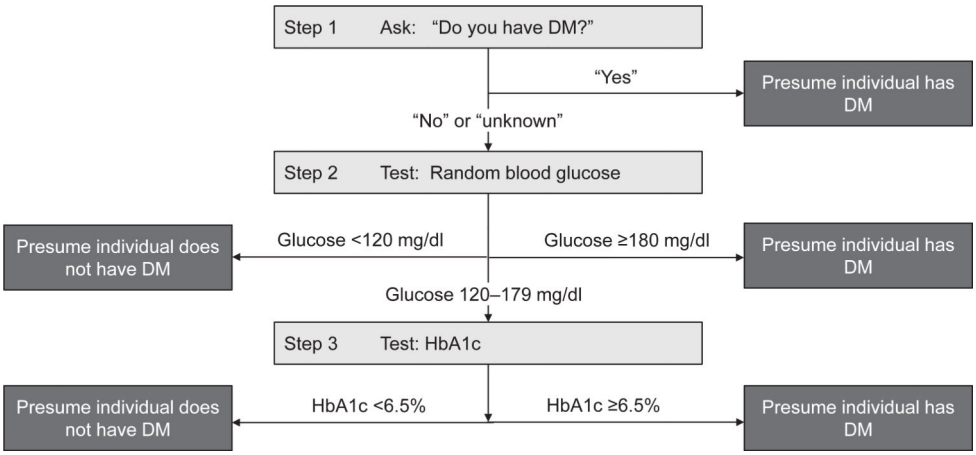

Figure 1.
Tiered DM testing strategy. DM = diabetes mellitus; HbA1c = hemoglobin A1c.

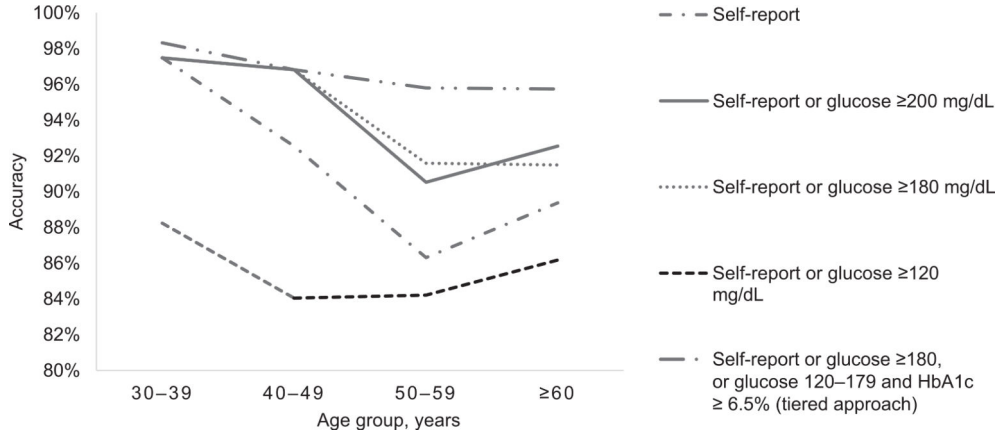

Figure 2.

Accuracy of diabetes screening strategies by age group, both sites (age ≥30 years). Accuracy was calculated using self-report or HbA1c ≥6.5% as the gold standard. HbA1c = hemoglobin A1c.

Table 1

Proposed screening strategies for DM

1 Self-reported DM or HbA1c ≥6.5% (gold standard)
2 Self-reported DM status (yes or no) alone
3 a. Self-reported or glucose ≥200 mg/dL (≥11.1 mmol/L)
b. Self-reported or glucose ≥180 mg/dL (≥10.0 mmol/L)
c. Self-reported or glucose ≥120 mg/dL (≥6.7 mmol/L)
4 Tiered testing:
Self-reported, or
Glucose ≥180 mg/dL (≥10.0 mmol/L), or
Glucose 120–179 mg/dL (≥6.7–9.9 mmol/L) and HbA1c ≥6.5%

DM = diabetes mellitus; HbA1c = hemoglobin A1c.

Table 2

Participant characteristics by enrollment site

	HDH (*n* = 375) *n* (%)	MCDPH (*n* = 97) *n* (%)	Total (*n* = 472) *n* (%)
Sex			
Female	205 (54.7)	54 (55.7)	259 (54.9)
Male	170 (45.3)	43 (44.3)	213 (45.1)
Age category, years			
25–29	46 (12.3)	24 (24.7)	70 (14.8)
30–39	80 (21.3)	39 (40.2)	119 (25.2)
40–49	74 (19.7)	20 (20.6)	94 (19.9)
50–59	84 (22.4)	11 (11.3)	95 (20.1)
≥60	91 (24.3)	3 (3.1)	94 (19.9)
BMI, [*] kg/m^2			
Underweight (<18.5)	17 (4.5)	5 (5.5)	22 (4.7)
Normal weight (18.5–24.9)	214 (57.1)	40 (44.0)	254 (53.8)
Overweight (25.0–29.9)	109 (29.1)	26 (28.6)	135 (28.6)
Obese (≥30.0)	35 (9.5)	20 (21.9)	55 (11.7)
TB incidence in birth country, /100,000 [†]			
<100	24 (6.4)	45 (46.4)	69 (14.6)
≥100	351 (93.6)	51 (52.6)	402 (85.4)
Any positive LTBI test [‡]	205 (54.7)	39 (40.2)	244 (51.7)
Family history of DM	114 (30.4)	33 (34.0)	147 (31.1)
DM status [§]			
No DM	203 (54.1)	70 (72.2)	273 (57.8)
Pre-DM	120 (32.0)	17 (17.5)	137 (29.0)
DM	52 (13.9)	10 (10.3)	62 (13.1)
New diagnosis	29 (55.8)	4 (40.0)	33 (53.2)
Glucose, mg/dL, median [IQR]			
No DM	99 [91–108]	89 [83–93]	96 [87–105]
Pre-DM	104 [95–116]	88 [85–109]	103 [94–114]

	HDH (*n* = 375) *n* (%)	MCDPH (*n* = 97) *n* (%)	Total (*n* = 472) *n* (%)
DM, previous diagnosis	219 [160–287]	293 [202–366]	227 [165–313]
DM, new diagnosis	166 [119–293]	167 [116–377]	166 [119–293]

[*] *n* = 6 with unknown BMI from MCDPH.

[†] Based on WHO country profiles;[15] *n* = 1 with unknown birth country from MCDPH

[‡] Includes positive QuantiFERON®-TB Gold In-Tube, T-SPOT®. *TB*, and/or TST; TST interpretation was based on CDC guidelines.[23]

[§] DM = self-reported history of DM or point-of-care HbA1c ≥6.5%; pre-DM = no self-reported history of DM and HbA1c between 5.7% and 6.4%.

HDH = Hawaii Department of Health; MCDPH = Maricopa County Department of Health; BMI = body mass index; LTBI = latent TB infection; DM = diabetes mellitus; IQR = interquartile range; CDC = Centers for Disease Control and Prevention; HbA1c = hemoglobin A1c.

Table 3

Gold standard DM and pre-DM prevalence by age

Age category years	Total tested *n*	Pre-DM* *n* (% of age group)	DM† *n* (% of age group)
25–29	70	11 (15.7)	0 (0.0)
30–39	119	25 (21.0)	7 (5.9)
40–49	94	25 (26.6)	13 (13.8)
50–59	95	38 (40.0)	18 (18.9)
≥60	94	38 (40.4)	23 (24.5)

*No self-reported history of DM and HbA1c between 5.7% and 6.4%

†Self-reported history of DM or point-of-care HbA1c ≥6.5%.

DM = diabetes mellitus; HbA1c = hemoglobin A1c.

Table 4

Performance and test cost of DM screening strategies by site for adults aged ≥30 years

	Number that would be tested under each algorithm				Average test cost per participant[†] US$		Sensitivity % (95% CI)		Specificity % (95% CI)		PPV % (95% CI)		NPV % (95% CI)	
	Glucose test		HbA1c test											
Test strategy	**HDH**	**MCDPH**	**HDH**	**MCDPH**	**HDH**	**MCDPH**	**HDH**	**MCDPH**	**HDH**	**MCDPH**	**HDH**	**MCDPH**	**HDH**	**MCDPH**
1 Gold standard: self-reported or HbA1c ≥6.5%	0	0	306	67	9.58	9.45	—	—	—	—	—	—	—	—
2 Self-reported only[*]	0	0	0	0	0	0	44 (32–58)	60 (31–83)	100 (98–100)	100 (94–100)	100 (86–100)	100 (61–100)	90 (87–93)	93 (85–98)
3 a) Self-reported or RBG ≥200 mg/dL	306	67	0	0	1.21	1.19	67 (54–78)	80 (49–94)	100 (98–100)	100 (94–100)	97 (86–100)	100 (68–100)	94 (91–96)	96 (89–99)
b) Self-reported or RBG ≥180 mg/dL	306	67	0	0	1.21	1.19	69 (56–80)	80 (49–94)	99 (96–99)	100 (94–100)	90 (76–97)	100 (68–100)	94 (91–97)	96 (89–99)
c) Self-reported or RBG ≥120 mg/dL	306	67	0	0	1.21	1.19	85 (72–92)	90 (60–98)	84 (79–88)	95 (87–98)	49 (35–64)	75 (43–95)	97 (94–98)	98 (91–100)
4 Self-reported or RBG ≥180, or 120–179 mg/dL and HbA1c ≥6.5% (tiered approach)	306	67	49	4	2.74	1.76	85 (72–92)	90 (60–98)	99 (96–99)	100 (94–100)	92 (80–97)	100 (70–100)	97 (94–99)	98 (92–100)

[*] Don't know/refused/missing: $n = 1$ from HDH, $n = 3$ from MCDPH.

[†] Assuming a unit cost of $1.30 for glucose testing and $10.30 for HbA1c testing.

HbA1c = hemoglobin A1c; RBG = random blood glucose; HDH = Hawaii Department of Health; MCDPH = Maricopa County Department of Health; CI = confidence interval; PPV = positive predictive value; NPV= negative predictive value.

Table 5

Two-month follow-up of patients with new DM or pre-DM

	DM		Pre-DM	
	HDH *n* (%)	**MCDPH *n* (%)**	**HDH *n* (%)**	**MCDPH *n* (%)**
Total attempted, *n*	29	4	120	17
Contacted at 2 months	27 (93.1)	3 (75.0)	110 (91.7)	17 (100)
Lost to follow-up	2 (6.9)	1 (25.0)	10 (8.3)	—
Followed-up with community clinician				
Appointment completed or scheduled	12 (44.4)	2 (66.7)	14 (12.7)	5 (29.4)
No appointment scheduled	15 (55.6)	1 (33.3)	96 (87.3)	12 (70.6)
Reported change in diet or exercise				
Yes	26 (96.3)	2 (66.7)	88 (80.0)	4 (23.5)
No	1 (3.7)	1 (33.3)	22 (20.0)	13 (76.5)

DM = diabetes mellitus; HDH = Hawaii Department of Health; MCDPH = Maricopa County Department of Health.