

https://dspace.org/

Performance of pointofcare glucose testing for the diagnosis of gestational diabetes in South Africa

Lungile Khambule; Chemedzai Chikomba; Yasmin Adam; Lubayna Khan; C Haldane ...

https://hdl.handle.net/10539/46277
WOS

Downloaded from a DSpace repository. https://dspace.org/

Received: 27 March 2024 | Revised: 14 August 2024 | Accepted: 3 September 2024 | Published online: 22 September 2024

DOI: 10.1002/ijgo.15914

CLINICAL ARTICLE

Obstetrics

Performance of point-of-care glucose testing for the diagnosis of gestational diabetes in South Africa

L. Khambule[1] | C. Chikomba[2,1] | Y. Adam[3] | L. Khan[1] | C. Haldane[4] | B. Vetter[4] | J. George[5]

[1]Department of Chemical Pathology, University of the Witwatersrand, Johannesburg, South Africa

[2]Department of Chemical Pathology, National Health Laboratory Service, Johannesburg, South Africa

[3]Department of Obstetrics and Gynaecology, Chris Hani Baragwanath Academic Hospital, University of the Witwatersrand, Johannesburg, South Africa

[4]FIND, Geneva, Switzerland

[5]Wits Diagnostic and Innovation Hub, National Health Laboratory Service, Johannesburg, South Africa

Correspondence
J. George, Wits Diagnostic and Innovation Hub, Wits Health Consortium and University of Witwatersrand, 31 Princess of Wales Terrace, Parktown, Johannesburg 2193, South Africa.
Email: jaya.george@nhls.ac.za

Funding information
Swiss Agency for Development and Cooperation

Abstract

Objective: Lack of accessibility to oral glucose tolerance tests (OGTTs) in South Africa means many pregnant women go without testing for gestational diabetes mellitus (GDM). This study evaluated point-of-care (POC) glucometers against the laboratory-based glucose method in pregnant women.

Methods: This was a cross-sectional study on pregnant women attending the prenatal clinic in Johannesburg who were recommended for the OGTT. OGTTs were conducted as per International Association of Diabetes and Pregnancy Study Groups (IADPSG) guidelines. Women who consented to the study donated both venous and capillary blood for laboratory-based and POC glucose measurements using seven POC glucometers: I-STAT, Xpress, LDX, VivaChek-Ino, Accu-Chek Active, StatStrip, and Codefree. By assessing sensitivity, specificity, and area under the receiver operating characteristic curve (AUC) and comparing Bland–Altman plots, the diagnostic accuracy of each glucose meter was compared with the reference method, the laboratory-based glucose method.

Results: Data were analyzed for 1076 pregnant women. Based on OGTT testing, 83 women had GDM (7.7%). Overall, the POC glucometers performed poorly, with sensitivity ranging from 17.6% to 87.18% and specificity ranging between 62.7% and 99.8%. The AUC ranged from 0.59 to 0.79. All POC glucometers showed moderate to poor reliability. Laboratory-based fasting plasma glucose (FPG) surpassed the POC glucometers in sensitivity, specificity, and AUC, with values of 94.0%, 100%, and 0.98, respectively.

Conclusion: We demonstrated that laboratory-based FPG has the potential to be used as a diagnostic test for GDM and that the POC glucometers cannot replace OGTT laboratory-based measurements.

KEYWORDS
diagnostic accuracy, fasting plasma glucose, gestational diabetes mellitus, point-of-care testing

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.
© 2024 The Author(s). *International Journal of Gynecology & Obstetrics* published by John Wiley & Sons Ltd on behalf of International Federation of Gynecology and Obstetrics.

1 | INTRODUCTION

Gestational diabetes mellitus (GDM), defined as hyperglycemia first discovered in pregnancy, is one of the most common complications of pregnancy, affecting about 16% of pregnant women worldwide,[1] with the majority of cases (87.6%) occurring in low- and middle-income countries (LMICs).[2] In 2011, the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study showed that blood glucose thresholds below the conventional GDM diagnostic criteria were linked to adverse maternal and neonatal outcomes.[3] Since then, large-scale meta-analyses have demonstrated that women with GDM are more likely to develop type 2 diabetes mellitus (T2DM) and cardiovascular diseases (CVD).[4] Children born to women with GDM are at risk of macrosomia and hypoglycemia after birth, as well as long-term complications such as childhood obesity, early onset of T2DM and CVD.[5] The first step to optimum GDM care and T2DM prevention/delay is the diagnosis.[6] In 2015, the International Federation of Gynecology and Obstetrics (FIGO) published GDM consensus guidelines recommending a universal screening approach, the oral glucose tolerance test (OGTT) being the gold standard for screening and diagnosing GDM.[6] While these recommendations are widely recognized, LMICs like South Africa face many challenges to GDM screening, including individual, healthcare work-related, and health-system barriers.[7]

In South Africa, the prevalence of GDM is estimated to be about 10%.[8] However, this may be an underestimate because only women at high risk for GDM are screened.[8] Diagnosis of GDM in South Africa is made based on an OGTT conducted at 24–28 weeks of gestation.[8] However, the test involves laboratory-based glucose readings and there are only a few facilities that provide this service.[9] The point-of-care (POC) testing offers many operational advantages to the OGTT such as reduced turnaround time, eradication of pre-analytical sample handling, stability errors, and prompt health interventions.[10] In South Africa, strip-based glucometers are readily available for self-monitoring among diabetics; however, strips are affected by external variables such as humidity, temperature, hematocrit, medicines, and hypotension.[11] Cassette-based devices minimize the limitations of strips.[12] However, the evidence for the performance of the glucometers in the various clinical scenarios has been inconsistent.[13,14] Therefore, this study aims to determine the accuracy of seven POC glucometers in diagnosing GDM among pregnant women in South Africa. We anticipate that the study will identify POC glucometers that accurately detect GDM.

2 | MATERIALS AND METHODS

2.1 | Study design

This cross-sectional study was conducted between July 13, 2022 and February 28, 2023 among pregnant women who attend the antenatal clinic at Chris Hani Baragwanath Academic Hospital (CHBAH).

Institutional ethics approval was obtained at the University of Witwatersrand Human Research Ethics Committee (Medical) (clearance no: M220219). All women provided written informed consent (Figures S1 and S2). The study followed the Standards for Reporting Diagnostic accuracy studies (STARD) guidelines (see Table S1 for the checklist).

2.2 | Study population

Based on an estimated GDM prevalence of 10%,[8] the minimum sample size was 1070, to detect sensitivity and specificity of at least 0.80 with a power of 80% and alpha threshold of 0.05.[15] Eligible women were between 24 and 32 weeks of gestation and had one or more conventional risk factors for GDM as per the Society of Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA) guidelines.[16] The women had to fast the night before blood withdrawal for at least 8 h.

Women who were <18 years old, non-fasted, acutely ill, or on high-dose vitamin C (>2000 mg/day) or corticosteroid therapy were excluded, as were those with previous bariatric surgery, prediabetics, and those who smoked or vomited during the OGTT. Prediabetics were defined as fasting plasma glucose (FPG) >7 mmol/L and/or glycated hemoglobin (HbA1c) >6.5% and/or glucose level >11.1 mmol/L at 2-h post-glucose load.[16]

2.3 | Medical history and sample collection

Data on women's age and gestational age by last date of menstrual cycle, confirmed by ultrasound scans, parity, gravidity, history of miscarriages, medication, and body weight were collected on the day of the OGTT test by L.K. and L.K.

2.4 | Sample collection

Capillary and venous plasma glucose samples were collected at three OGTT time points: fasting, and 1 and 2 h post-glucose load. Each time, a finger was pricked once, and the blood was collected using a capillary tube to analyze the glucometers except for I-STAT and LDX glucometers as these required a larger volume of blood. Venous blood was collected in sodium fluoride and sodium citrate tubes, immediately analyzed on I-STAT and LDX, and the rest of the blood was used for laboratory-based glucose measurement. Information on the POC glucometers is reported in Table S2.

2.5 | Oral glucose tolerance test

The OGTTs were conducted by qualified nurses and diagnosed as per International Association of Diabetes and Pregnancy Study Groups (IADPSG) guidelines.[17] However, in this study, samples were kept in an ice slurry and separated within 10 min after the end of the OGTT. Glucose was measured in the central laboratory using the Roche Cobas 8000/502 (Roche Diagnostics, Mannheim, Germany).

2.6 | Statistical analysis

Statistical analyses and graphical representations for method agreement and reliability were conducted using MedCalc software v. 22.021 (Belgium, Germany) and the rest was performed using STATA 18 software (StataCorp, College Station, TX, USA). A *P*-value <0.05 was assumed to be statistically significant. Shapiro–Wilk test was used to test for normality, normally distributed data was reported by means ± standard deviation, and non-normally distributed were reported as medians and interquartile range (IQR). Categorical variables were expressed as sample numbers and percentages. Demographic and clinical characteristics in the GDM and non-GDM groups were compared using Student *t*-test (for normally distributed data) or the Wilcoxon rank-sum test (for skewed data). Categorical data were analyzed using a chi-squared or Fisher exact test where expected frequencies were <5.

Methods were compared by Pearson correlation coefficient (PCC) and scatterplots with the least-squares best-fit line and 95% confidence interval (CI) band, intra-rater class coefficient (ICC), and Bland–Altman (BA) plots.[18] The ICC estimates and their 95% CIs were based on single-measurement, absolute-agreement, two-way random-effects model.

Sensitivity, specificity, negative predictive values (NPVs), positive predictive values (PPVs), and area under the receiver operating characteristic curve (AUC) were calculated to determine the diagnostic accuracy of each POC glucometer. The laboratory-based OGTT method and GDM diagnosis by IADPSG criteria were used as the reference method. Three criteria for GDM diagnosis were analyzed: (1) GDM diagnosis by OGTT (as per IADPSG criteria); (2) FPG at 5.1 mmol/L; and (3) FPG at 4.8 mmol/L. Both reference and classification methods were binary variables (classified as GDM yes/no). Criteria 2 and 3 were guided by reports in the literature indicating that FPG can potentially diagnose GDM.[9,10]

An ICC, PCC, and AUC near the value of 1.0 suggest a high degree of method reliability, correlation, or accuracy, respectively. For BA plots, POC glucometers with a mean difference of 1.3% or less and with narrow 95% limits of agreements were deemed optimum.[19]

3 | RESULTS

3.1 | Study population

In total, 1144 women were recruited, of whom 68 (5.94%) were excluded from the study. Reasons for exclusion were: incomplete OGTT (6, 0.52%), withdrew from the study (2, 0.17%), vomited (1, 0.09%), <18 years (1, 0.09%), and prediabetic (9, 0.79%). Among the 1125 women included in the study, 49 (4.36%) had incomplete laboratory-based glucose measurements for the following reasons: the specimen was insufficient, grossly hemolyzed, lipidemic, or clotted. Therefore, data were analyzed for 1082 women (Figure 1).

The mean age of this population was 35 years (IQR 29–39). Mean gestational age was 25 weeks (IQR 21–29). Based on OGTT testing using the IADPSG criteria, 83 (7.7%) women had GDM.

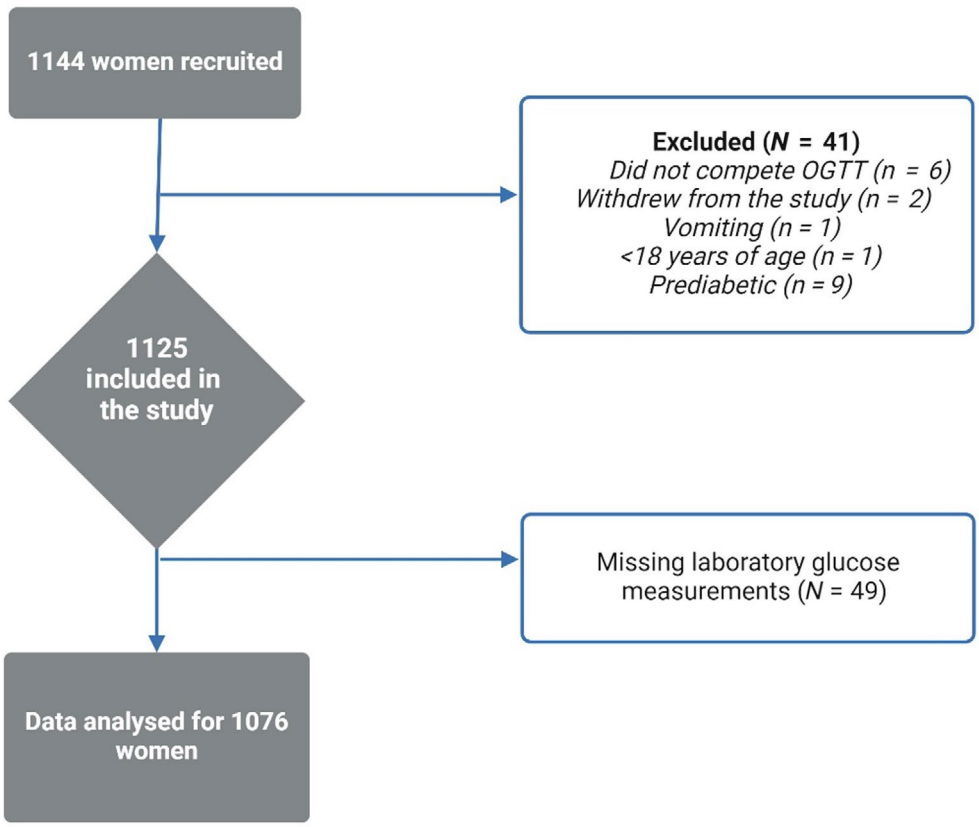


FIGURE 1 Diagram of participant recruitment. OGTT, oral glucose tolerance test.

Women with GDM had a significantly higher median (IQR) weight (89 [76–104] vs 80 [67–95] kg, $P=0.001$). Of note, there were no significant differences between groups in age, parity, and miscarriages ($P>0.05$) (Table 1).

3.2 | Method agreement and reliability analysis

Average glucose levels measured with the seven POC glucometers are shown in Table 2. Data were normally distributed, and the PCC

TABLE 1 Clinical characteristics, overall and by gestational diabetes mellitus (GDM) status.

Variable	Total observations	All	Non-GDM	GDM	*P*-value
Age (years)	1048	35 (29;39)	35 (29;39)	37 (31;39)	0.125
Gestational age (weeks)	1015	25 (21;29)	25 (21;29)	24 (20;28)	0.492
Miscarriages (*n*)	1034	0 (0;1)	0 (0;1)	0 (0;1)	0.889
Parity (*n*)	1034	2 (1;3)	2 (1;3)	2 (1;2)	0.198
Gravidity (*n*)	1034	4 (2;5)	4 (3;5)	3 (2;4)	0.255
Weight (kg)	1062	80 (68;95)	80 (67;95)	89 (73;101)	0.001
Fasting glucose from the laboratory (mmol/L)	1076	4.2 (3.9;4.5)	4.1 (3.9;4.4)	5.5 (5.2;5.8)	<0.0001
OGTT, 1-h glucose from the laboratory (mmol/L)	1076	5.7 (4.9;6.8)	5.6 (4.9;6.6)	8.2 (6.2;9.7)	<0.0001
OGTT, 2-h glucose from the laboratory (mmol/L)	1076	5.2 (4.5;6.0)	5.1 (4.5;5.8)	7.0 (5.8;8.6)	<0.0001

Note: Data presented are median (IQR) unless stated otherwise.
Abbreviation: OGTT, oral glucose tolerance test.

TABLE 2 Average glucose measurements of the point-of-care (POC) glucose testing at each oral glucose tolerance test (OGTT) time point.

		Median glucose level (mmol/L)		
Device	Time point	All participants	Non-GDM	GDM
Laboratory	Fasting	4.2 (3.9–4.5)	4.1 (3.9–4.4)	5.5 (5.2–6.0)
	OGTT, 1 h	5.8 (6.9–5.8)	5.7 (4.9–6.6)	8.2 (6.2–10.4)
	OGTT, 2 h	5.2 (4.5–6.0)	5.1 (4.5;5.8)	7.1 (5.9–8.8)
I-STAT	Fasting	3.7 (3.4–4.0)	3.6 (3.4–3.9)	4.5 (4.1–5.1)
	OGTT, 1 h	4.9 (4.1–5.9)	4.8 (4.1–5.7)	7.2 (5.6–8.8)
	OGTT, 2 h	4.4 (3.9–5.1)	4.3 (3.8–5.0)	5.9 (4.9–7.4)
Xpress	Fasting	4.5 (4.1;4.9)	4.4 (4.1–4.9)	5.7 (4.9–6.3)
	OGTT, 1 h	7.2 (6.3–8.3)	7.0 (6.2–8.0)	9.0 (7.7–11.2)
	OGTT, 2 h	6.4 (5.7–7.3)	6.3 (5.6–7.0)	8.4 (7.0–10.1)
LDX	Fasting	3.8 (3.5–4.1)	3.7 (3.5–4.0)	4.6 (4.2–5.2)
	OGTT, 1 h	5.1 (4.2–5.9)	4.9 (4.2–5.7)	7.2 (5.7–8.5)
	OGTT, 2 h	4.5 (3.9–5.1)	4.4 (3.9–5.0)	6.0 (5.1–7.3)
VivaChek Ino	Fasting	4.7 (4.3–5.1)	4.6 (4.3–5.0)	6.1 (5.2–6.5)
	OGTT, 1 h	7.5 (6.5–8.6)	7.3 (6.5–8.3)	9.7 (8.3–11.3)
	OGTT, 2 h	6.6 (5.9–7.5)	6.5 (5.8–7.3)	9.0 (7.3–10.6)
Accu-Chek Active	Fasting	4.5 (4.1–4.9)	4.4 (4.1–4.8)	5.5 (4.8–6.3)
	OGTT, 1 h	7.1 (6.1–8.2)	7.0 (6.0–8.0)	9.6 (8.1–10.9)
	OGTT, 2 h	6.2 (5.4–7.1)	6.2 (5.3–6.9)	8.1 (6.8–10.0)
StatStrip	Fasting	4.3 (3.9–4.8)	4.2 (3.8–4.7)	5.4 (4.9–5.9)
	OGTT, 1 h	6.9 (6.0–8.0)	6.3 (5.9–7.8)	9.0 (7.6–10.7)
	OGTT, 2 h	6.1 (5.4–7.0)	6.1 (5.3–6.8)	8.0 (6.8–9.5)
Codefree	Fasting	4.8 (4.5;5.3)	4.7 (4.4–5.2)	5.8 (5.3–6.6)
	OGTT, 1 h	7.6 (6.6, 8.9)	7.5 (6.5–8.6)	10.0 (8.0–11.7)
	OGTT, 2 h	6.7 (6.0–7.6)	6.6 (6.0–7.4)	8.7 (7.5–11.0)

Note: Data are presented as median (interquartile range).
Abbreviation: GDM, gestational diabetes.

ranged from 0.62 for Codefree at fasting to 0.87 for I-STAT and LDX at the 1-h time point ($P < 0.001$ for all; Figures 2–4).

According to the BA plots, StatStrip had the optimum mean differences (0.20%) at fasting and a desirable mean difference (−2.82%) at 1-h post-glucose load. Codefree had the highest mean difference (23.1%) at 1-h post-glucose load. All POC glucometers, including StatStrip, had wide 95% limits of agreement at all time points. The postprandial glucose readings showed the biggest mean percentage difference. According to the ICC estimates, all POC glucometers had moderate to poor reliability with a wide 95% CIs (Table 3; Figures 5–7).

3.3 | Accuracy of POC glucometers

For criterion '1', GDM diagnosis by OGTT (as per IADPSG criteria, sensitivity [95% CI] varied from 17.57 (15.17–19.96) for I-STAT to 87.18 (85.14–89.22) for Codefree) (Table 4). Specificity (95% CI) was poorest for Codefree at 62.71 (59.76–65.66) and was highest for I-STAT at 99.78 (99.48–100). The NPVs (95% CI) were good for all POC devices and ranged from 93.76 (92.24–95.15) for LDX to 98.35 (97.58–99.13) for the Codefree. PPVs (95% CI) ranged between 16.08 (13.83–18.32) for Codefree and 86.67 (84.53–88.81) for the I-STAT. The AUC (95% CI) ranged from 0.59 (0.54–0.63) for I-STAT to 0.79 (0.74–0.85) for Accu-Chek.

The accuracy of POC glucometers when using FPG glucose alone was lower than when all three time points were used (Tables S3 and S4). However, for laboratory-based FPG at 5.1 mmol/L threshold, sensitivity (95% CI) and specificity (95% CI) were 100 (100–100) and 99.50 (99.08–99.2), respectively (Table S4).

4 | DISCUSSION

This study, conducted among pregnant women in a tertiary care hospital in South Africa, investigated the accuracy of seven POC

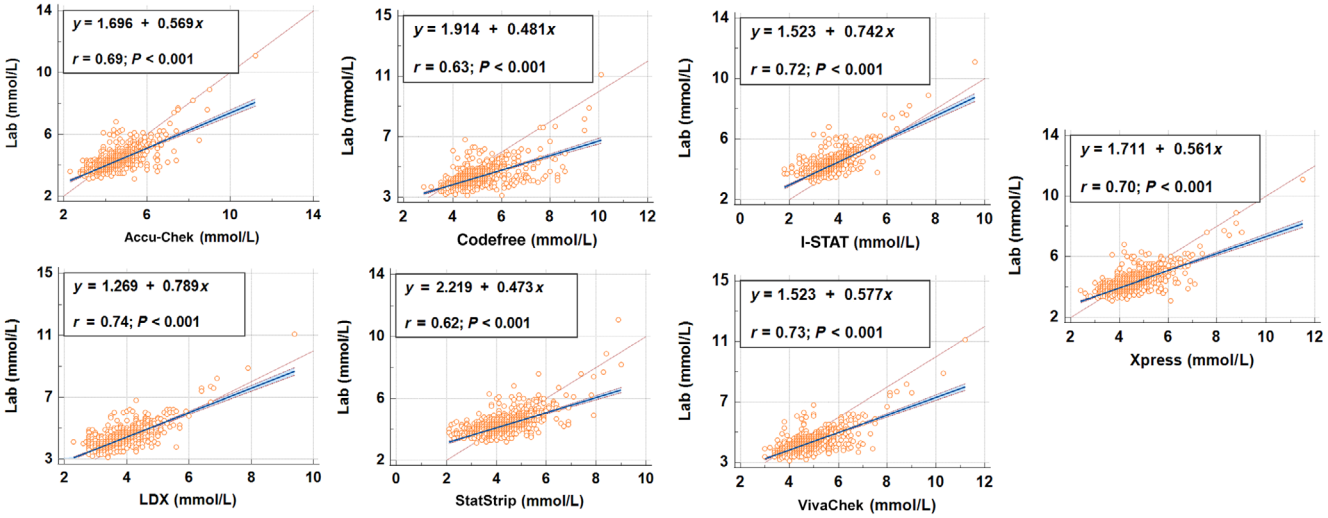


FIGURE 2 Scatterplots with the least-squares best-fit line +95% confidence band (blue) and line $y = x$ (orange) for each point-of-care glucometer against laboratory-based glucose measurements at fasting/0 h.

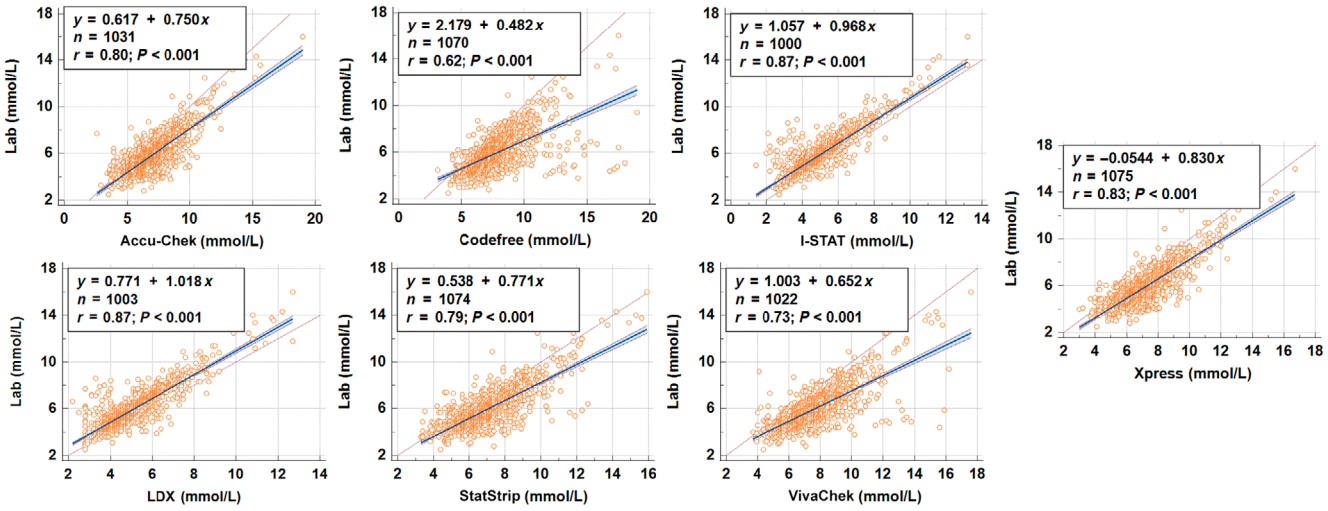


FIGURE 3 Scatterplots with the least-squares best-fit line +95% confidence band (blue) and line $y = x$ (orange) for each point-of-care glucometer against laboratory-based glucose measurements at 1-h post-glucose load.

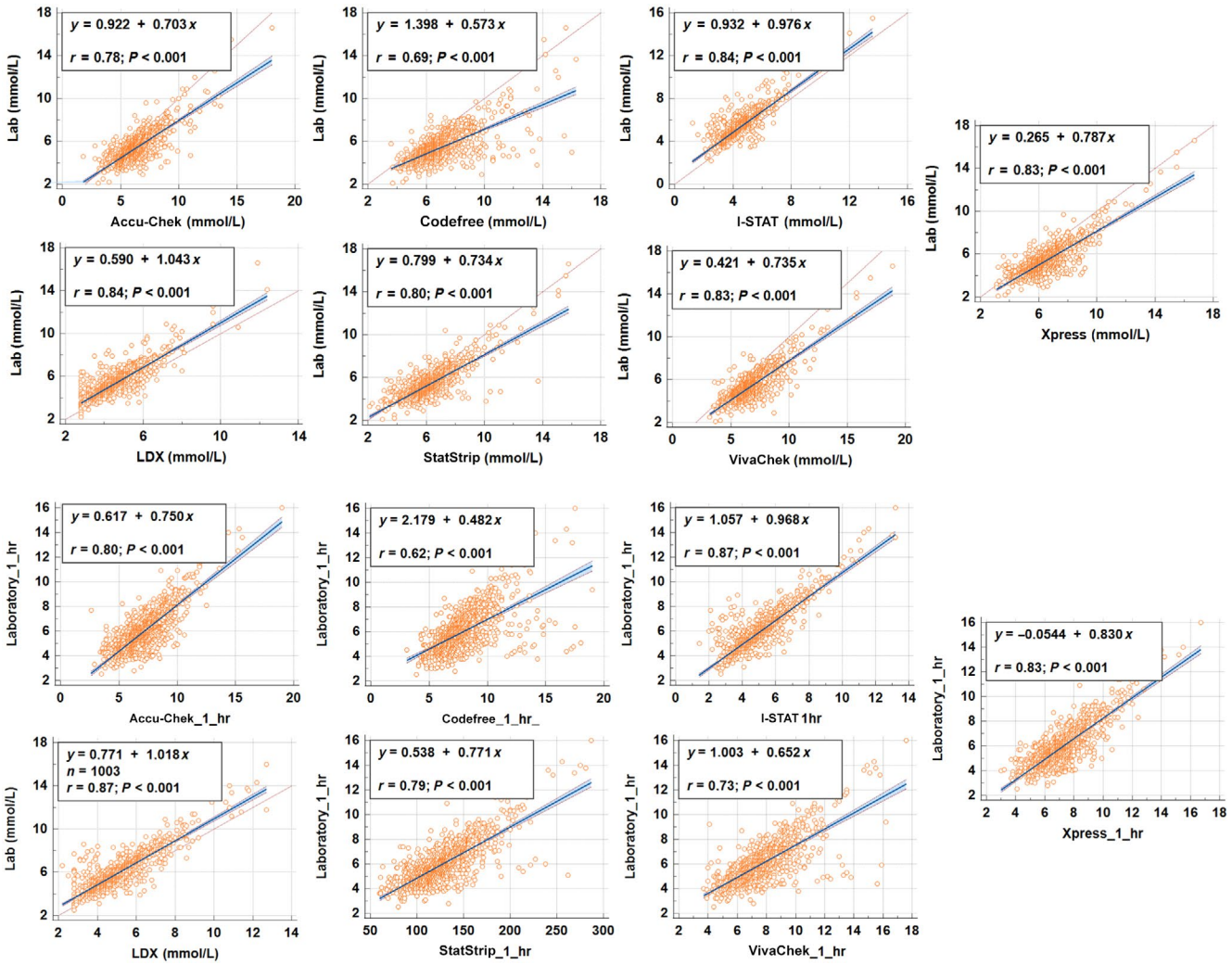


FIGURE 4 Scatterplots with the least-squares best-fit line +95% confidence band (blue) and line $y=x$ (orange) for each point-of-care glucometer against laboratory-based glucose measurements at 2-h post-glucose load.

glucometers in diagnosing GDM. Compared with laboratory diagnosis, the POC glucose testing performed with a sensitivity ranging between 18% and 87% and a specificity ranging between 63% and 99%. The number of diagnoses that would have been missed with the POC glucose testing ranged from 10 to 61.

In vitro glycolysis is a key consideration with laboratory GDM diagnosis and pre-analytical protocols should be designed to minimize glycolysis. As a result, the HAPO research included strict pre-analytical procedures for sample collection and processing.[3] In South Africa, most OGTT testing during pregnancy is performed in tertiary academic or provincial tertiary hospitals with variable proximity to a laboratory. Nurses are unable to centrifuge samples immediately and transport on ice slurry rarely happens. Pre-analytical error is likely significant in these settings, underpinning the need for POC testing. Considering that POC glucometers are readily available and, in most cases, less expensive than conventional laboratory-based measurements, POC testing is an economically viable choice.[20] However, our study shows a lack of diagnostic accuracy among POC glucometers, with the number of GDM cases diagnosed based on glucose meter readings varying widely, which indicates that the POC glucose testing cannot be used interchangeably. Such variation has been reported previously in a comparative performance of five POC glucometers.[13] Our results are in line with several other studies which suggest that POC glucose testing compares poorly with laboratory measures for the diagnosis of GDM.[21,22] In a study among 529 pregnant women attending a primary healthcare clinic in Johannesburg, the Accu-Chek Active glucose meter diagnosed GDM with a sensitivity of 27.0% and a specificity of 89.4%, which is not very different from our PPV and NPV results.[23] In contrast to the above study, Gallardo-Rincón et al. reported a sensitivity and specificity of 89.5% and 66.6%, respectively, for Accu-Chek Instant.[24] According to Daly et al., lowering the diagnostic threshold for FPG from 5.1 to 4.8 mmol/L increased sensitivity from 51% to 92.5% but decreased specificity from 100% to 76.5%.[10] Interestingly, the same authors also used a regression equation to predict plasma glucose levels based on glucose meter readings, indicating that

TABLE 3 Average difference, Bland–Altman 95% limits of agreement, intraclass correlation coefficient (ICC, 95% confidence interval [CI]) of point-of-care glucometers at three time points.

	Observations (*n*)	Differences (% [SD])	95% Limits of agreement (%)	ICC (95% CI)
At fasting (0 h)				
Accu-Chek Active	1021	−4.86 (12.1)	−28.5–19.0	0.525 (0.364–0.639)
Codefree	1036	−12.2 (10.8)	−33.3–9.10	0.332 (−0.024–0.572)
I-STAT	976	16.6 (15.6)	−17.6–50.8	0.385 (−0.067–0.657)
LDX	987	13.0 (13.0)	−12.5–38.5	0.458 (0.013–0.703)
StatStrip	1062	0.20 (17.7)	−34.7–35.1	0.500 (0.452–0.544)
VivaChek	1001	−9.62 (10.3)	−29.9–10.6	0.450 (0.042–0.674)
Xpress	1071	−5.34 (12.2)	−29.2–18.5	0.521 (0.332–0.648)
At 1 h post-glucose load				
Accu-Chek Active	1008	−15.8 (16.2)	−47.5–16.0	0.592 (−0.011–0.811)
Codefree	1049	−23.1 (15.0)	−52.4–6.21	0.344 (−0.066–0.613)
I-STAT	978	20.0 (26.0)	−31.0–70.9	0.706 (0.098–0.875)
LDX	981	18.1 (21.2)	−23.5–59.7	0.708 (0.126–0.873)
StatStrip	1051	−2.82 (22.3)	−46.6–41.0	0.599 (0.058–0.806)
VivaChek	999	−21.2 (14.4)	−49.6–7.03	0.438 (−0.079–0.717)
Xpress	1052	−17.8 (12.9)	−43.1–7.57	0.587 (−0.068–0.830)
At 2 h post-glucose load				
Accu-Chek active	988	−14.1 (15.7)	−44.8–16.6	0.569 (0.049–0.784)
Codefree	1033	−21.7 (13.2)	−47.5–4.0	0.361 (−0.085–0.647)
I-STAT	980	20.0 (23.6)	−26.2–66.2	0.624 (0.015–0.834)
LDX	976	18.0 (18.3)	−17.9–54.0	0.631 (0.045–0.833)
StatStrip	1051	−12.9 (14.4)	−41.1–15.2	0.606 (0.096–0.804)
VivaChek	993	−19.8 (12.0)	−43.3–3.69	0.490 (−0.094–0.777)
Xpress	1057	−16.8 (12.2)	−40.7–7.01	0.559 (−0.073–0.812)

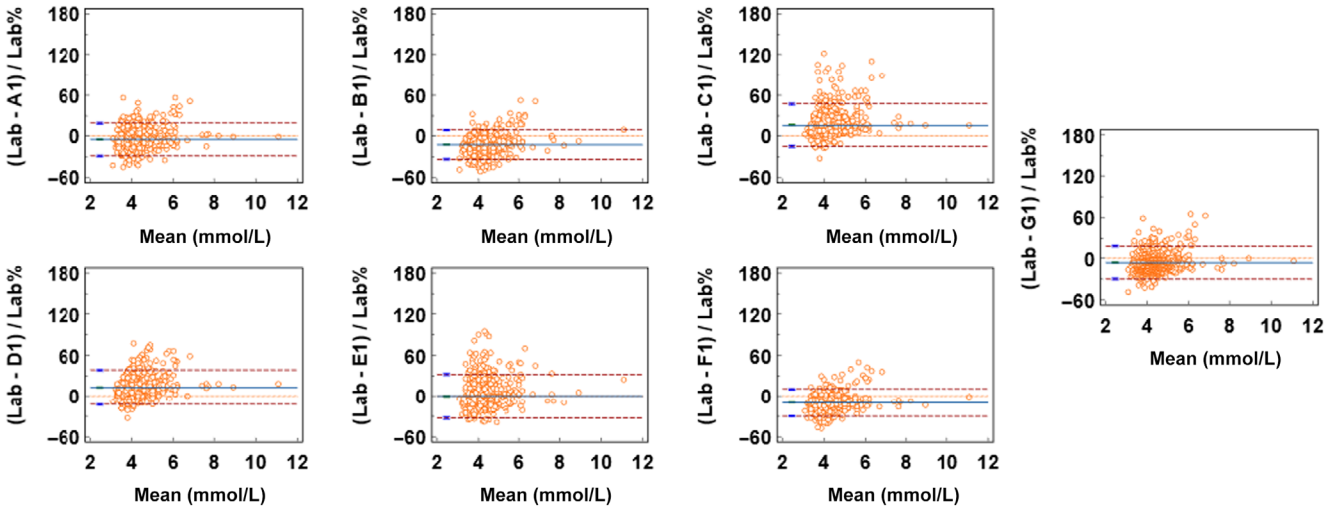


FIGURE 5 Bland–Altman plots (mean difference [blue] and 95% limit of agreement [red]) of each point-of-care glucometer against laboratory-based measurements at fasting. A1, Accu-Chek active; B1, Codefree; C1, I-STAT; D1, LDX; E1, StatStrip; F1, VivaChek; G1, Xpress.

such an approach may be acceptable in LMICs where plasma samples are subject to glycolysis.[10] In the present study, the greatest differences between POC-measured and laboratory-measured glucose levels were at the 1-hour time point which may be an indication of poor performance of the POC glucose testing at higher glucose concentrations.

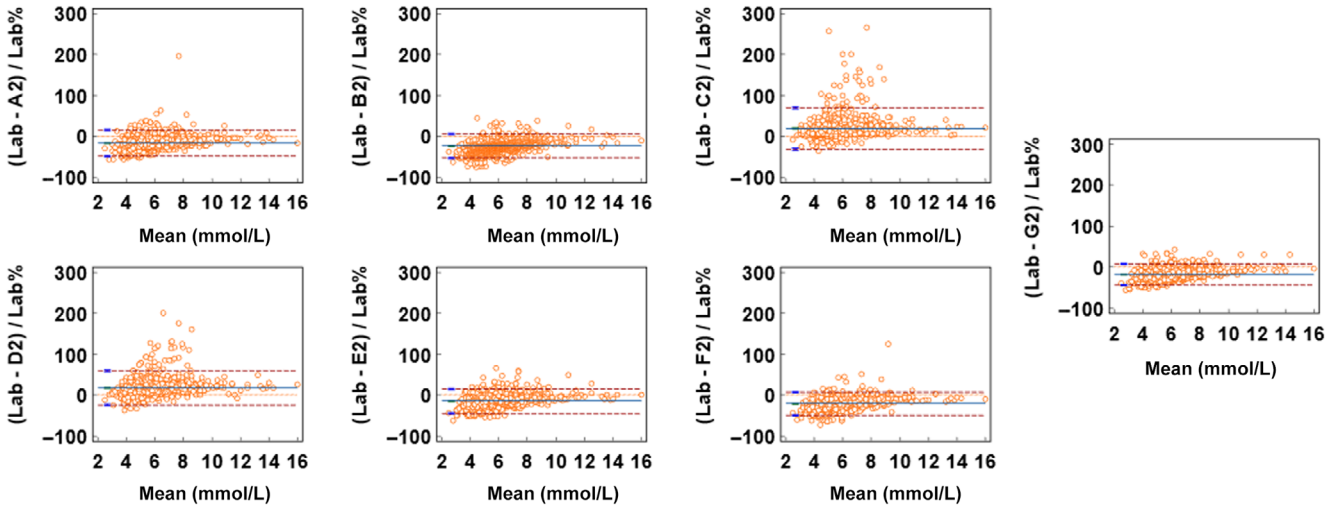


FIGURE 6 Bland–Altman plots (mean difference [blue] and 95% limit of agreement [red]) of each point-of-care glucometer against laboratory-based measurements at 1-h post-glucose load. A2, Accu-Chek active; B2, Codefree; C2, I-STAT; D2, LDX; E2, StatStrip; F2, VivaChek; G2, Xpress.

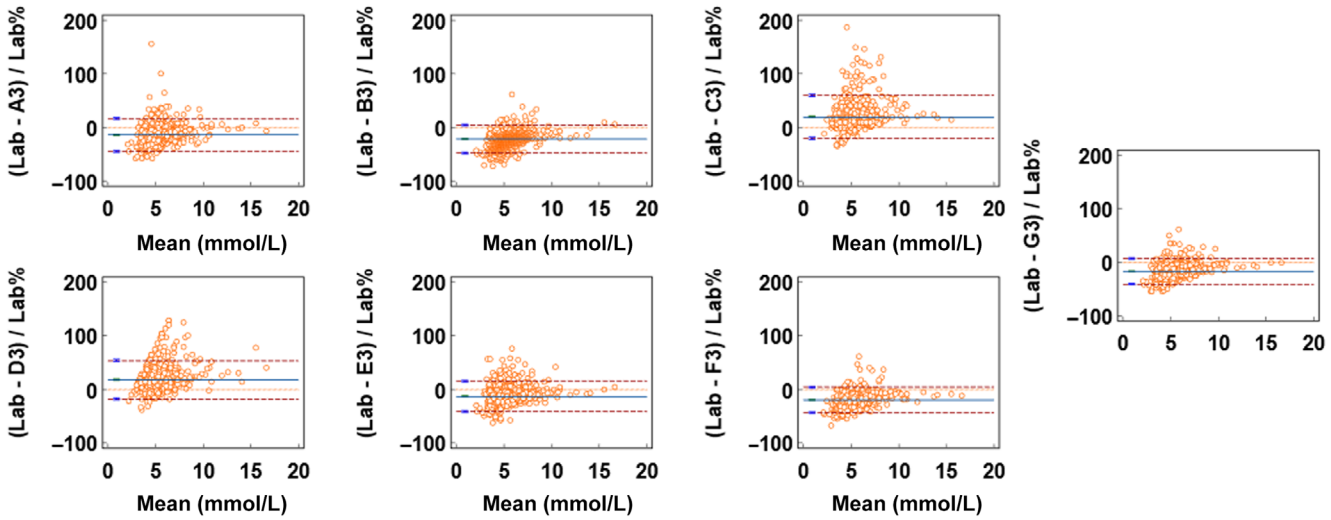


FIGURE 7 Bland–Altman plots (mean difference [blue] and 95% limit of agreement [red]) of each point-of-care glucometer against laboratory-based measurements at 1-h post-glucose load. A3, Accu-Chek active; B3, Codefree; C3, I-STAT; D3, LDX; E3, StatStrip; F3, VivaChek; and G3, Xpress.

Another option for GDM screening is the use of FPG measurements. In the current study, the measurement of FPG showed good sensitivity and specificity for diagnosing GDM when samples were analyzed in the laboratory. These findings are in line with those from several other studies conducted in South Africa which showed high accuracy of laboratory fasting glucose in diagnosing GDM.[13,23] In addition, the FPG may be a better GDM screening test than universal OGTT testing due to its quick turnaround and simplicity of use. However, it is important to determine the diagnostic performance and optimal cut-off of FPG in the screening of GDM. In addition, it must be noted that pre-analytical errors and glycolysis are also risks with laboratory analysis of FPG. In addition, the use of laboratory-based FPG would not address the geographical barriers in the country, as the women would still need to travel to the clinic to get tested.

Given the high NPV of the glucometers at fasting, which suggests the likelihood of not having GDM when tested negative, we recommend the use of POC for screening for GDM using FPG at 5.1 mmol/L and reserve OGTTs (by laboratory-based glucose measurements) for women who test positive. Furthermore, we recommend that future studies should perform modeling analyses to evaluate the impact of having access to POC GDM screening versus being undiagnosed/untreated for GDM entirely. Of note, if POC glucose testing is to be used for diagnosis, manufacturers should meet the performance specifications as recommended by the Milan hierarchy.[25]

Our study had several limitations. The first was the length of time between the collection of blood and analysis in the central laboratory. During this time, there was a risk of glycolysis. POC analysis was sometimes interrupted mid-OGTT due to POC glucometer malfunctions or

TABLE 4 The diagnostic accuracy of each point-of-care glucometer's oral glucose tolerance test (OGTT) results as compared with laboratory-based OGTT measurements.

	Accu-Chek active	Codefree	I-STAT	LDX	StatStrip	VivaChek	Xpress
Observations	982	1030	969	964	1076	983	1052
PPV (% [95% CI])	28.25 (25.44–31.07)	16.08 (13.83–18.32)	86.67 (84.53–88.81)	83.33 (80.98–85.69)	27.06 (24.41–29.72)	17.96 (15.56–20.36)	24.36 (21.77–26.96)
NPV (% [95% CI])	98.02 (97.15;98.89)	98.35 (97.58–99.13)	93.61 (92.07–95.15)	93.76 (92.24–95.29)	97.20 (96.22–98.19)	98.00 (97.12–98.87)	98.07 (97.24–98.90)
Sensitivity (% [95% CI])	80.77 (78.30–83.23)	87.18 (85.14–89.22)	17.57 (15.17–19.96)	20.27 (17.73–22.81)	71.08 (68.38–73.79)	82.19 (79.80–84.58)	81.71 (79.37–84.04)
Specificity (% [95% CI])	82.30 (79.91–84.69)	62.71 (59.76–65.66)	99.78 (99.48–100.00)	99.66 (99.30–100.00)	83.99 (81.80–86.18)	69.89 (67.02–72.76)	78.56 (76.08–81.04)
False-positive (*n*)	160	355	2	3	159	274	208
False-negative (*n*)	15	10	61	59	24	13	15
True-positive (*n*)	63	68	13	15	59	60	67
True-negative (*n*)	744	597	893	887	834	636	762
AUC	0.79 (0.74–0.85)	0.74 (0.69–0.79)	0.59 (0.54–0.63)	0.59 (0.55–0.64)	0.76 (0.69–0.82)	0.74 (0.68–0.80)	0.78 (0.73–0.84)

Abbreviations: AUC, area under the curve; CI, confidence interval; NPV, negative predictive value; PPV, positive predictive value.

insufficient cartridges/strips, especially for I-STAT and LDX, whose cartridges were stored far from the clinic. This contributed to the uneven observations across the POC glucometers. Patient information such as singleton or twin pregnancy, fetal weight, and oligo/polyhydramnios was not collected. Finally, this study was conducted in a high-risk group, which may have skewed the results for the study population compared with the healthy pregnant women. Our study also had several notable strengths, including the number of women participating in the study, as well as the wide range of POC glucometers. As such, these results are a valuable source of information on the accuracy of POC glucose testing in diagnosing GDM among women in South Africa.

5 | CONCLUSIONS

Based on the present study, the use of these POC glucometers for the diagnosis of GDM cannot be recommended. Nonetheless, the POC glucometers have the potential to screen for GDM when a two-step screening process is considered. This may be beneficial in resource-constrained settings where access to laboratory measurement of glucose may be difficult. In addition, laboratory-based FPG has the potential to be used as a diagnostic test for GDM.

AUTHOR CONTRIBUTIONS

JG, CC, and LK contributed to study design. JG, CC, YA, LK and LK contributed to the implementation and analysis plan. LK and LK collected blood samples and study variables. CH, BV, and JG contributed to the management of the project. LK drafted the manuscript, and all authors (LK, CC, YA, LK, CH, BV, and JG) revised and approved the final manuscript.

ACKNOWLEDGMENTS

We are grateful for the support of the patients, nurses, and National Health Laboratory Service staff members from CHBAH.

FUNDING INFORMATION

Funding for the study was provided by FIND through a grant from the Swiss Agency for Development and Cooperation.

CONFLICT OF INTEREST STATEMENT

CH and BV are employees of FIND. The remaining authors have no conflicts of interest.

DATA AVAILABILITY STATEMENT

Data available on request from the authors.

REFERENCES

1. Wang H, Li N, Chivese T, et al. IDF Diabetes Atlas: estimation of global and regional gestational diabetes mellitus prevalence for 2021 by international association of diabetes in pregnancy study group's criteria. *Diabetes Res Clin Pract*. 2022;183:109050. doi:10.1016/j.diabres.2021.109050

2. Ogurtsova K, da Rocha Fernandes JD, Huang Y, et al. IDF diabetes atlas: global estimates for the prevalence of diabetes for 2015 and 2040. *Diabetes Res Clin Pract*. 2017;128:40-50. doi:10.1016/j.diabres.2017.03.024
3. HAPO Study Cooperative Research Group, Metzger BE, Lowe LP, et al. Hyperglycemia and adverse pregnancy outcomes. *N Engl J Med*. 2008;358:1991-2002. doi:10.1056/NEJMoa0707943
4. Li Z, Cheng Y, Wang D, et al. Incidence rate of type 2 diabetes mellitus after gestational diabetes mellitus: a systematic review and meta-analysis of 170,139 women. *J Diabetes Res*. 2020;2020:3076463. doi:10.1155/2020/3076463
5. Plows JF, Stanley JL, Baker PN, Reynolds CM, Vickers MH. The pathophysiology of gestational diabetes mellitus. *Int J Mol Sci*. 2018;19:3342. doi:10.3390/ijms19113342
6. Hod M, Kapur A, Sacks DA, et al. The International Federation of Gynecology and Obstetrics (FIGO) initiative on gestational diabetes mellitus: a pragmatic guide for diagnosis, management, and care. *Int J Gynaecol Obstet*. 2015;131(Suppl 3):S173-S211. doi:10.1016/S0020-7292(15)30033-3
7. Hinneh T, Jahn A, Agbozo F. Barriers to screening, diagnosis and management of hyperglycaemia in pregnancy in Africa: a systematic review. *Int Health*. 2022;14:211-221. doi:10.1093/inthealth/ihab054
8. Macaulay S, Ngobeni M, Dunger DB, Norris SA. The prevalence of gestational diabetes mellitus amongst black south African women is a public health concern. *Diabetes Res Clin Pract*. 2018;139:278-287. doi:10.1016/j.diabres.2018.03.012
9. Dickson LM, Buchmann EJ, Janse van Rensburg C, Norris SA. Fasting plasma glucose and risk factor assessment: comparing sensitivity and specificity in identifying gestational diabetes in urban black African women. *S Afr Med J*. 2019;110:21-26. doi:10.7196/SAMJ.2019.v110i1.14089
10. Daly N, Carroll C, Flynn I, Harley R, Maguire PJ, Turner MJ. Evaluation of point-of-care maternal glucose measurements for the diagnosis of gestational diabetes mellitus. *BJOG*. 2017;124:1746-1752. doi:10.1111/1471-0528.14255
11. Macleod K, Katz LB, Cameron H. Capillary and venous blood glucose accuracy in blood glucose meters versus reference standards: the impact of study design on accuracy evaluations. *J Diabetes Sci Technol*. 2019;13:546-552. doi:10.1177/1932296818790228
12. Voglová Hagerf B, Protus M, Nemetova L, et al. Accuracy and feasibility of real-time continuous glucose monitoring in critically ill patients after abdominal surgery and solid organ transplantation. *Diabetes Care*. 2024;47:956-963. doi:10.2337/dc23-1663
13. Dickson LM, Buchmann EJ, Janse van Rensburg C, Norris SA. Accuracy of five plasma calibrated glucometers to screen for and diagnose gestational diabetes mellitus in a low resource clinic setting. *J Clin Transl Endocrinol*. 2018;16:100174. doi:10.1016/j.jcte.2018.12.003
14. García-Claver A, Ramos-Corral R, Laviña-Fañanás C, Solans-Blecua I, Puzo-Foncillas J. Capillary glucose concentration during oral glucose tolerance test for the diagnosis of gestational diabetes. *Int J Gynecol Obstet*. 2020;150:234-240. doi:10.1002/ijgo.13178
15. Bujang MA, Adnan TH. Requirements for minimum sample size for sensitivity and specificity analysis. *J Clin Diagn Res*. 2016;10:YE01-YE06. doi:10.7860/JCDR/2016/18129.8744
16. Veronique N and Kenneth RL Huddle. The 2017 SEMDSA Guidelines for the Management of Type 2 Diabetes. *Journal of Endocrinology, Metabolism and Diabetes of South Africa* 2017; 22(1): S103-S106. http://dx.doi.org/10.1080/16089677.2015.1056468
17. International Association of Diabetes and Pregnancy Study Groups Consensus Panel, Metzger BE, Gabbe SG, et al. International association of diabetes and pregnancy study groups recommendations on the diagnosis and classification of hyperglycemia in pregnancy. *Diabetes Care*. 2010;33:676-682. doi:10.2337/dc09-1848
18. Abu-Arafeh A, Jordan H, Drummond G. Reporting of method comparison studies: a review of advice, an assessment of current practice, and specific suggestions for future reports. *Br J Anaesth*. 2016;117:569-575. doi:10.1093/bja/aew320
19. EFLM. Biological variation. Accessed December 7, 2023. https://biologicalvariation.eu/
20. Lingervelder D, Koffijberg H, Kusters R, IJzerman MJ. Health economic evidence of point-of-care testing: a systematic review. *Pharmacoecon Open*. 2021;5:157-173. doi:10.1007/s41669-020-00248-1
21. Al-Hasani W, Ranasinghe R, Rogers H, et al. Clinical utility of point of care glucose in the assessment of gestational diabetes: Prospective cohort study. *BJOG*. 2024;131(9):1270-1278.
22. O'Malley EG, Reynolds CME, O'Kelly R, Killalea A, Sheehan SR, Turner MJ. A prospective evaluation of point-of-care measurements of maternal glucose for the diagnosis of gestational diabetes mellitus. *Clin Chem*. 2020;66:316-323. doi:10.1093/clinchem/hvz005
23. Adam S, Rheeder P. Evaluating the utility of a point-of-care glucometer for the diagnosis of gestational diabetes. *Int J Gynaecol Obstet*. 2018;141:91-96. doi:10.1002/ijgo.12399
24. Gallardo-Rincón H, Lomelin-Gascon J, Martinez-Juarez LA, et al. Diagnostic accuracy of capillary blood glucometer testing for gestational diabetes. *Diabetes Metab Syndr Obes*. 2022;15:3855-3870. doi:10.2147/DMSO.S389420
25. Milan JG. The new hierarchy: update from the EFLM strategic conference on defining analytical performance goals. Quality specifications for QC and QAP. *Pathology*. 2016;48:S16. doi:10.1016/j.pathol.2015.12.044

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Khambule L, Chikomba C, Adam Y, et al. Performance of point-of-care glucose testing for the diagnosis of gestational diabetes in South Africa. *Int J Gynecol Obstet*. 2025;168:812-821. doi:10.1002/ijgo.15914