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Evaluation of the analytical and clinical accuracy of four blood glucose meters in pregnant women with hyperglycaemia

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Abstract

Aims: Physiological changes during pregnancy can infuence the performance of blood glucose meters. This study aimed to evaluate the analytical and clinical accuracy of glucose meters in pregnant women with hyperglycaemia.

Materials and Methods: Glucose was measured by four commonly used meters among consecutive women with diabetes in pregnancy. Capillary and venous samples were collected concurrently and compared with i-STAT (amperometry) and laboratory (hexokinase) glucose as reference methods. Bland–Altman plot, International Organization for Standardization criteria, surveillance error grid (SEG) and haematocrit influence were assessed.

Results: In total, 824 paired samples from 103 women were analysed (GDM 57%, mean i-STAT capillary glucose 6.7 ± 2.3 mmol/L [121 ± 41 mg/dL], laboratory glucose 6.6 ± 2.4 mmol/L [119 ± 43 mg/dL], median haematocrit 0.36 L/L). Mean capillary glucose measured on all meters was significantly different from that measured on i-STAT (all $p < 0.001$), whereas venous glucose measured on Contour Next, Accu-Chek Guide and the laboratory (plasma) was similar. Contour Next had the lowest bias when using both reference methods (mean bias [95% limits of agreement] meter vs. i-STAT: Contour Next 1.3% [−8% to 10.6%], Accu-Chek Guide −3.2% [−11.4% to 5%], FreeStyle Optium Neo −11.9% [−24.7% to 0.8%] and LifeSmart 6.8% [−5.8% to 19.4%]; meter versus laboratory: −0.2% [−8.1% to 7.7%], −0.2% [−10.2% to 9.8%], −3.8% [−17.6% to 10%] and 6.1% [−5.9% to 18.2%]), respectively. Only Contour Next and Accu-Chek Guide had ≥97% of pairs within the SEG no-risk zone during both comparisons. Meters did not show haematocrit-related bias.

Conclusions: Accuracy of meters was higher when using venous samples than when using capillary samples. Contour Next and Accu-Chek Guide meters met accuracy standards in all analyses.

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KEYWORDS
accuracy, Bland–Altman plot, blood glucose meters, haematocrit, pregnancy, surveillance error grid

1 | INTRODUCTION

Self-monitoring of blood glucose (SMBG) is routinely recommended for women with gestational diabetes mellitus (GDM), and inclusion of SMBG in GDM care has been found to reduce pregnancy complications such as caesarean section, large-for-gestational age babies and macrosomia.[1] In addition, women who perform SMBG achieve glycaemic control faster, with reduced need for insulin therapy, than those who do not perform SMBG.[1] SMBG has a significant role in GDM management; the decision on initiating and titrating medication is often guided by meter glucose values and also facilitates self-care behaviour among women. Potential concerns related to SMBG include lack of adherence with glucose monitoring instructions and inaccuracies in the meter reading due to operator errors, factors intrinsic to devices and strips and the patient's physiological state.[2] Accuracy testing performed in a laboratory setting has shown that glucose meters do not perform equally with some showing superior performance over others.[3] Moreover, in those studies the inaccuracies were greater in hypoglycaemic samples.[3] Studies conducted in real-life situations also showed suboptimal performance of certain meters.[4]

Pregnancy is a state characterized by transient changes in physiological parameters, including expansion in blood volume and decrease in haematocrit, potentially affecting the performance of glucose meters.[5] Although glucose meters are used for monitoring glycaemia in women with GDM, they are not usually recommended for diagnosing GDM because of their bias[6] and low sensitivity compared to the gold standard oral glucose tolerance testing (OGTT)[6,7]; however, findings vary between studies.[6–10] There have been limited studies that compared the accuracy of glucose meters in a real-world setting in pregnant women.[5] Therefore, we have undertaken this study to test the analytical performance of the four most commonly available blood glucose meters in Australia (Ascensia Contour Next, Roche Accu-Chek Guide, Abbott FreeStyle Optium Neo and LifeSmart meter), focusing on their accuracy in pregnant women with varying degrees of hyperglycaemia. We have also examined how changes in physiological parameters, such as low haematocrit and serum iron concentrations, influenced the performance of these meters.

2 | RESEARCH DESIGN AND METHODS

This point-of-care comparison study was conducted at the diabetes in pregnancy clinic at Campbelltown Hospital from November 2022 to December 2023. Pregnant women with any type of hyperglycaemia (type 1 diabetes, type 2 diabetes or GDM), aged above 18 years, attending the Thursday afternoon clinic (1:00–4:00 PM) were consecutively approached for participation in this study. Women who were non-English speaking and unable to provide consent were ineligible. Women who consented to participate in the study subsequently underwent capillary and venous blood sampling simultaneously in the specimen collection room. Trained researchers and hospital phlebotomists performed finger-sticks and the venipuncture, respectively. The glucose meter specifications are provided in Table S1. All meters passed the QC testing. The manufacturers' instructions for QC testing were followed where QC was not repeated unless error values were suspected.

2.1 | Capillary blood collection

The first drop of capillary blood was wiped away using swabs, and the second drop was applied to the meter strips in random order. A random list was generated in Excel for determining the order of blood glucose meters prior to the start of the study. Duplicate measurements were taken using two devices for each meter brand. The average of the values was used for accuracy analyses. Capillary blood glucose was also measured using the Abbott i-STAT device, which served as the reference method. i-STAT was found to have good correlation to the laboratory equipment ($r > 0.975$) with a measuring range of 1.1–38.9 mmol/L and a coefficient of variation (CV) of 1.1% (calculated).[11] The sequence of the meter and i-STAT tests followed a randomized list.

2.2 | Venous blood collection

A tube of venous blood was collected during venipuncture to test venous whole blood glucose on glucose meters immediately. Duplicate measurements were taken as per the protocol and the average was computed for further comparison with laboratory plasma glucose. Laboratory plasma glucose was measured from venous blood collected in a lithium heparin tube. The specimens were then immediately taken to the laboratory in an ice pack by the research staff, where they were centrifuged and separated within 30 min and analysed immediately. Plasma glucose was measured using the hexokinase method with a Roche Cobas 8000 analyser with an analytical sensitivity of 0.11 mmol/L. The imprecision was 1.9% at 4.7 mmol/L and 11.5 mmol/L.

The demographic and medical information were collected using a study questionnaire. Ethics approval was obtained from the Southwestern Sydney Local Health District Human Research Ethics Committee (2021/ETH12490).

2.3 | Statistical analysis

The sample size was estimated to be 103, which would provide a power of 80% (2-tailed alpha 0.05) with an effect size of 0.29, using

the mean difference of 0.2 mmol/L and standard deviation (SD) of difference 0.7 mmol/L reported by Perera et al.[12] There were two accuracy comparisons: capillary meter glucose with i-STAT glucose and venous meter glucose with laboratory venous (plasma) glucose. Accuracy was determined using the Blood Glucose Monitoring System Surveillance Program provided by Diabetes Technology Society (https://www.diabetestechnology.org/seg/).[13] The accuracy measures included bias, mean absolute relative difference (MARD), CV, Bland–Altman tools, the percentage of meter values that meet the International Organization for Standardization criteria (ISO) 15 197:2013 range and surveillance error grid (SEG) analysis. Percentage of meter values above the reference values across meters were compared using Cochran's Q, and the differences in mean glucose and mean bias across the meters were assessed using a one-way repeated measures ANOVA. Bonferroni correction was applied for multiple comparisons. The influence of haematocrit and iron status on the mean bias was assessed using an independent *t*-test by dichotomizing haematocrit and serum iron concentrations at the median value. Data were analysed using IBM SPSS for Macintosh version 28.0 (IBM Corp., Armonk, NY, USA).

3 | RESULTS

Of the 118 women approached for participation in the study, 15 declined to participate. The characteristics of the study population are presented in Table 1. The mean age ± SD of the women was 33.0 ± 4.9 years with a mean gestation of 24.3 ± 10.3 weeks. Almost one-third (36%) of the study cohort was of European background, more than half of them (57.3%) had GDM and 33% were recruited before 20 weeks' gestation. There were 206 capillary samples and 206 venous samples for each meter. After computing the average of duplicate measurements, 824 paired measurements from 103 women were analysed. The average time from last meal to blood collection was 3 h. The average turnaround time (from sample collection to centrifugation to measurement) for venous plasma glucose was 1 h and 10 min. The samples were collected at a mean room temperature of 26°C. The mean (±SD) capillary glucose by i-STAT was 6.7 ± 2.3 mmol/L, and the mean (±SD) venous glucose by laboratory method was 6.6 ± 2.4 mmol/L. The mean capillary glucose of each meter brand (Table 1) was significantly different from i-STAT glucose and significantly different from one another (all $p < 0.001$ except i-STAT vs. Contour Next, $p = 0.02$), whereas the venous glucose measured using the Contour Next and Accu-Chek Guide meters was similar to that measured using the laboratory method (6.5 ± 2.3 vs. 6.6 ± 2.4, $p = 1.00$ and 6.5 ± 2.1 vs. 6.6 ± 2.4 mmol/L, $p = 0.15$, respectively). The venous glucose of the FreeStyle Optium Neo and LifeSmart meters was significantly different from all other meters and laboratory glucose (all $p < 0.001$). In the correlation analysis, i-STAT glucose and laboratory glucose were highly correlated with Pearson's correlation coefficient (r) of 0.984 (Figure S1). In addition, there was a strong positive correlation between meter measurements and the respective reference methods (all $r > 0.975$) (Figure S2).

TABLE 1 Characteristics of the study population.

Characteristics	N	Mean ± SD/%
Mean age	103	33.0 ± 4.9
Weight	102	92.3 ± 21.1
European ethnicity (self-identified)	103	36 (35%)
Type of diabetes		
Type 1 diabetes	9	8.7
Type 2 diabetes	32	31.1
GDM	59	57.3
MODY	3	2.9
Duration of diabetes		
Type 1 diabetes	9	18.8 ± 9.2
Type 2 diabetes	31	5.1 ± 4.5
Gestation (weeks)	103	24.3 ± 10.3
<20 weeks	34	33
≥20 weeks	69	67
i-STATcapillary glucose	103	6.7 ± 2.3
Meter capillary glucose		
Contour Next	103	6.8 ± 2.4
Accu-Chek Guide	103	6.4 ± 2.1
FreeStyle Optium Neo	103	5.9 ± 2.2
LifeSmart	103	7.1 ± 2.5
Venous plasma glucose	103	6.6 ± 2.4
Meter venous whole blood glucose		
Contour Next	103	6.5 ± 2.3
Accu-Chek Guide	103	6.5 ± 2.1
FreeStyle Optium Neo	103	6.3 ± 2.2
LifeSmart	103	6.9 ± 2.3
Haemoglobin (g/L)	103	120.0 ± 10.0
Haematocrit (PCV) (L/L)	103	0.36 ± 0.03
Median (IQR)		0.36 (0.34–0.38)
Range		0.29–0.41
Mean corpuscular volume (fL)	103	86.5 ± 5.0
C-reactive protein (mg/L)	102	9.2 ± 10.3
Ferritin (μg/L)	103	48.5 ± 46.4
Iron (μmol/L)	103	13.3 ± 5.6
Median (IQR)		12.0 (9.0–17.0)
Range		3.0–30.0
HbA1c (%)	103	5.9 ± 1.1
eGFR (mL/min)	102	89.7 ± 2.6

3.1 | Comparison between capillary meter glucose and capillary i-STAT glucose

While comparing capillary meter glucose against the i-STAT method (Table 2), the majority of the LifeSmart meter measurements were above the reference method (Contour Next 58%, Accu-Chek Guide 20%, FreeStyle Optium Neo 4.9% and LifeSmart 90%, $p < 0.001$). The CV of meters ranged from 4.2% to 6.5%. The Contour Next and

TABLE 2 Comparison between capillary meter values and i-STAT.

Parameters	Contour Next	Accu-Chek Guide	FreeStyle Optium Neo	LifeSmart
Total *N*	103	103	103	103
Meter < i-STAT	31	79	96	8
Meter = i-STAT	12	3	2	2
Meter > i-STAT[a]	60 (58%)	21 (20%)	5 (4.9%)	93 (90%)
Bias (%)[b]	1.3%	−3.2%	−11.9%	6.8%
MARD	3.4%	4.3%	12.3%	7.4%
CV	4.8%	4.2%	6.5%	6.4%
Lower 95% limit of agreement	−8%	−11.4%	−24.7%	−5.8%
Upper 95% limit of agreement	10.6%	5%	0.8%	19.4%
ISO range ≤5% or 5 mg/dL *n* (%)	84 (81.55)	67 (65.05)	13 (12.62)	41 (39.81)
5%–10% or mg/dL	15 (14.56)	33 (32.04)	32 (31.07)	43 (41.75)
10%–15% or mg/dL	3 (2.91)	3 (2.91)	30 (29.13)	15 (14.56)
15%–20% mg/dL	1 (0.97)	NA	23 (22.33)	3 (2.91)
>20% or 20 mg/dL	NA	NA	5 (4.85)	1 (0.97)
Compliant pairs	102 (99%)	103 (100%)	75 (72.8%)	99 (96.1)

Note: Bias (Mean relative difference between meter and i-STAT) = Meter–i-STAT/ i-STAT; MARD (Mean absolute relative difference) = |Meter-i-STAT|/i-STAT; CV (Coefficient of variation) = Standard deviation of relative difference between meter and i-STAT; Lower 95% limit of agreement = Bias− 1.96 × CV; Upper 95% limit of agreement = Bias + 1.96 × CV; ISO (International Organization for Standardization) = difference between meter and i-STAT as percentage of i-STAT for i-STAT >100 mg/dL and in mg/dl for i-STAT ≤100 mg/dL. (https://www.diabetestechnology.org/seg/).[13]

[a]Cochran's Q 169.54, df 3, $p < 0.001$.

[b]One-way repeated measures ANOVA was performed for comparison of mean bias across the meters $p < 0.001$. Bonferroni correction was made for multiple comparisons; pairwise comparisons all $p < 0.001$.

TABLE 3 Surveillance error grid.

		Capillary meter values versus i-STAT Number of pairs (%)				Meter results (venous blood) versus laboratory plasma Number of pairs (%)			
SEG Risk level	SEG risk category	Contour Next	Accu-Chek Guide	FreeStyle Optium Neo	LifeSmart	Contour Next	Accu-Chek Guide	FreeStyle Optium Neo	LifeSmart
0	No risk	101 (98.1%)	103 (100%)	92 (89.3%)	95 (92.2%)	102 (99%)	100 (97.1%)	101 (98.1%)	98 (95.1%)
1	Slight, lower	2 (1.9%)		11 (10.7%)	7 (6.8%)	1 (1%)	3 (2.9%)	2 (1.9%)	4 (3.9%)
2	Slight, higher				1 (1%)				1 (1%)
3	Moderate, lower								
4	Moderate, higher								
5	Severe, lower								
6	Severe, upper								
7	Extreme								

LifeSmart meters showed positive bias, whereas the Accu-Chek Guide and FreeStyle Optium Neo meters showed negative bias (Table 2): Contour Next (mean bias [95% limit of agreement]) 1.3% (−8% to 10.6%), Accu-Chek Guide −3.2% (−11.4% to 5%), FreeStyle Optium Neo −11.9% (−24.7% to 0.8%) and LifeSmart 6.8% (−5.8% to 19.4%). The modified Bland–Altman Plots are shown in Figure S3. Bias and MARD were highest for the FreeStyle Optium Neo meter and lowest for the Contour Next meter. The Accu-Chek Guide meter had 100% of values within the ISO acceptance criteria (Table 2). The Contour Next and Accu-Chek Guide meters demonstrated good clinical reliability with ≥97% of pairs within the SEG no-risk green zone (Table 3 and Figure S4).

TABLE 4 Comparison between meter results (venous blood) and laboratory plasma glucose.

Parameters	Contour Next	Accu-Chek Guide	FreeStyle Optium Neo	LifeSmart
Total *N*	103	103	103	103
Meter < Laboratory	47	53	69	11
Meter = Laboratory	12	4	3	1
Meter > Laboratory[a]	44 (43%)	46 (45%)	31 (30%)	91 (88%)
Bias[b]	−0.2%	−0.2%	−3.8%	6.1%
MARD	3%	4.1%	6.7%	6.8%
CV	4%	5.1%	7%	6.1%
Lower 95% limit of agreement	−8.1%	−10.2%	−17.6%	−5.9%
Upper 95% limit of agreement	7.7%	9.8%	10%	18.2%
ISO range ≤5% or 5 mg/dL *n* (%)	90 (87.38%)	75 (72.82%)	47 (45.63%)	47 (45.63%)
>5%–10% or mg/dl	11 (10.68%)	25 (24.27%)	39 (37.86%)	42 (40.78%)
>10%–15% or mg/dl	2 (1.94%)	3 (2.91%)	14 (13.59%)	13 (12.62%)
>15%–20% mg/dl	NA	NA	3 (2.91%)	1 (0.97%)
>20% or 20 mg/dL	NA	NA	NA	NA
Compliant pairs	103 (100%)	103 (100%)	100 (97.1%)	102 (99%)

Note: Bias (Mean relative difference between meter and laboratory values) = Meter−laboratory/ laboratory; MARD (Mean absolute relative difference) = |Meter-laboratory|/laboratory; CV (Coefficient of variation) = Standard deviation of relative difference between meter and laboratory; Lower 95% limit of agreement = Bias−1.96 × CV; Upper 95% limit of agreement = Bias + 1.96 × CV; ISO (International Organization for Standardization) = difference between meter and laboratory as percentage of laboratory for laboratory >100 mg/dL and in mg/dl for laboratory ≤100 mg/dL. (https://www.diabetestechnology.org/seg/).[13]

[a]Cochran's Q 94.260, df 3, $p < 0.001$.

[b]One-way repeated measures ANOVA was performed for comparison of mean bias across the meters $p < 0.001$. Bonferroni correction was made for multiple comparisons; pairwise comparisons all $p < 0.001$ except Contour Next versus Accu-Chek Guide, $p = 1.00$.

3.2 | Comparison between venous meter glucose and laboratory venous (plasma) glucose

When venous whole blood meter glucose measurements were compared against the laboratory method (Table 4), the percentage of meter measurements above the reference method were as follows: Contour Next 43%, Accu-Chek Guide 45%, FreeStyle Optium Neo 30% and LifeSmart 88% ($p < 0.001$). All meters showed negative bias except the LifeSmart meter (Table 4). The CV of meters ranged from 4.0% to 7.0%. The mean bias and 95% limits of agreement were Contour Next −0.2% (−8.1% to 7.7%), Accu-Chek Guide −0.2% (−10.2% to 9.8%), FreeStyle Optium Neo −3.8% (−17.6% to 10%) and LifeSmart 6.1% (−5.9% to 18.2%). Bias and MARD were highest for the LifeSmart meter and lowest for the Contour Next meter. The Contour Next and Accu-Chek Guide meters had 100% of values within the ISO range ≤15% or mg/dL (Table 4). All meters but LifeSmart showed good clinical reliability with ≥97% of pairs within the SEG no-risk green zone (Table 3 and Figure S4).

Bias was analysed by median haematocrit (<0.36 vs. ≥ 0.36 L/L), iron status (<12.0 vs. ≥12 μmol/L) and gestation (<20 weeks vs. ≥20 weeks), showing no statistical differences (Tables S2–S4). Numbers were too small to check the accuracy in the hypo and hyperglycaemic ranges (<3.9 mmol/L, $n = 7$, 3.9–7.8 mmol/L, $n = 72$, ≥7.9 mmol/L, $n = 24$).

4 | DISCUSSION

This study assessed the analytical performance of blood glucose meters in pregnant women with diabetes using both capillary and venous blood against i-STAT and laboratory methods, respectively. Analyses showed substantial differences in accuracy profiles with bias ranging from −11.9% to 6.8% against the i-STAT method and from −3.8% to 6.1% against the laboratory method. Meters performed better when venous whole blood meter glucose was compared with laboratory values with all four meters meeting the accuracy standard. Meanwhile, the FreeStyle Optium Neo meter failed to meet the accuracy standard when compared with i-STAT capillary glucose. Only two meters, Contour Next and Accu-Chek Guide, met clinical accuracy criteria during both comparisons. Haematocrit, iron and gestational age did not affect meter performance.

Our results agree with those of the previous studies, showing varying accuracy profiles of meters during pregnancy.[5,12,14–16] Among 10 m assessed (Accu-Chek Active, Advantage II, Performa, Elite F, CareSens, Optium, Optium Xceed 5S, 20s, FreeStyle Lite, Stat-strip),[5] the mean difference ranged from −0.33 to 0.73 mmol/L, and only two studies[14,15] used the ISO accuracy standards for the accuracy evaluation. Studies published after 2015 focused primarily on assessing the diagnostic ability of glucose meter for GDM versus laboratory glucose (oral glucose tolerance test). Not all of these studies reported Bland–Altman plots or ISO standards, and none showed SEG analysis.

Diagnostic measures reported were sensitivity, specificity, receiver operating characteristic analysis, kappa statistic and regression plot. Devices tested included Accu-Chek Active (Roche),[6,7,9] Accu-Chek Instant,[8] FreeStyle Optium Neo (Abbott),[9] Glucocheck Classic (TaiDoc Technology),[9] One Touch Select Plus Flex (LifeScan),[9] Contour Plus (Bayer),[9] One Touch Ultra-II (LifeScan),[10] Accu-Chek Aviva (now discontinued),[17] Contour Next One (Ascensia),[17] Bayer Contour XT[18,19] and Accu-Chek Inform II.[20] The methodology used for analysing laboratory glucose varied across the studies, and the selection of meters was often based on popularity. In our study all participants had some form of diabetes; therefore, diagnostic accuracy of meters was not assessed. The main issues reported for the meters previously included low sensitivity,[6,7] high false positive cases,[10,17] high inter-evaluator bias[17] and not meeting ISO criteria at 1 and 2 h of OGTT.[9] Meanwhile, a few studies reported sufficient sensitivity,[8] or suggested a low fasting diagnostic threshold, ≥4.8 mmol/L instead of ≥5.1 mmol/L, for improved diagnostic performance.[18] Some studies recommended using certain meters for screening purposes in resource-limited settings.[8,9,17–19]

The accuracy of the meters can be affected by the time of a meal. García-Claver et al.[17] collected samples at the fasting state, which showed lower mean bias (95% CI) (Contour Next 0.15 [−0.44 to 0.75], Accu-Chek Aviva-0.19 [−0.73 to 0.35]) with the highest bias at 60 minutes after glucose load (1.90 [−0.04 to 3.83], and 1.29 [−0.22 to 2.80], respectively). In our study we did not compare the accuracy in the fasting state. Samples were collected at an average of 3 h post-meal. In our study none of the meters were affected by haematocrit changes. The recommended haematocrit ranges by the manufacturers were 0%–70% for Contour Next and LifeSmart, 10%–65% for Accu-Chek Guide and 15%–65% for FreeStyle Optium Neo. None of the participants had a haematocrit level outside these recommended ranges.

Ensuring the accuracy of devices is important while selecting meters for use during pregnancy. More often, the selection of glucose meters depends on clinician recommendation, cost and insurance coverage, availability and ease of use. Inaccuracies in the glucose meter results can cause medication dosage errors, potentially harming both the mother and baby. In our study, not all meters were found to meet the clinical accuracy criteria. This is significant, and clinicians should be aware of the accuracy profiles of meters before proceeding to shared decision-making with the patient regarding the choice of meter. With the recent developments in continuous glucose monitoring (CGM) technology, many women with type 1 and type 2 diabetes now rely on CGM for hyperglycaemia management in pregnancy. Although there are factory-calibrated devices available, some devices require finger-stick measurements for calibration, reinforcing the need for highly accurate meters to ensure optimal CGM performance.

The major strengths of this study include adequate sample size, strict pre-analytical handling of the laboratory samples and concurrent sampling of capillary and venous blood. We also followed best practice for comparing meter values; finger-stick samples were compared with the same sample measured on i-STAT (amperometry) and venous samples on meters were compared with the same venous sample measured on laboratory instrument (hexokinase). Because the concentration of glucose differs in capillary and venous samples, we avoided comparison of capillary samples with venous samples. Some devices (e.g., Accu-Chek Guide meter) have been calibrated to provide plasma-like values; however, the comparison must be performed in a fasting sample. Ideally, meters should be compared with the method with which the device was calibrated. A major limitation of the study is that to assess the compliance with ISO criteria, multiple testing of the same sample using three strip lots for each test is required. In our study, only duplicate testing was performed for each meter brand to reduce inconvenience to the participants.

In conclusion, blood glucose meters are vital for hyperglycaemia management. In our accuracy analysis of four readily accessible glucose meters among pregnant women with hyperglycaemia, both Contour Next and Accu-Chek Guide fulfilled all accuracy specifications, in comparison with the i-STAT and laboratory methods. Contour Next demonstrated superior performance compared to all other meters. Our study highlights the importance of regular clinical evaluation of all FDA-approved glucose meters in real-world settings. In addition, evidence-based recommendations should be incorporated into the clinical guidelines to endorse the use of the most accurate glucose meters in pregnancy.

AUTHOR CONTRIBUTIONS

R.R. and D.S. conceived the project. D.S. and J.I. designed the study, T.K. assisted with recruitment and data collection. J.I. analysed the data and wrote the first draft of the manuscript. All authors contributed to discussion and reviewed and edited the manuscript. All authors approved the final version of the manuscript. J.I. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest. The glucose meter manufacturers supplied devices for use in the study.

PEER REVIEW

The peer review history for this article is available at https://www.webofscience.com/api/gateway/wos/peer-review/10.1111/dom.16209.

DATA AVAILABILITY STATEMENT

Data available on request from the authors.

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SUPPORTING INFORMATION

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

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