A Prospective Evaluation of Point-of-Care Measurements of Maternal Glucose for the Diagnosis of Gestational Diabetes Mellitus

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BACKGROUND: Point-of-care (POC) measurement of glucose is currently recommended only for the monitoring of gestational diabetes mellitus (GDM). This prospective observational study evaluated the use of POC measurements of maternal glucose to diagnose GDM in women being screened selectively with a 1-step 75 g oral glucose tolerance test (OGTT).

METHODS: The strictest preanalytic and analytic international laboratory standards were applied to measure maternal plasma glucose at fasting and at 1 and 2 h post glucose load. The recent International Association of Diabetes and Pregnancy Study Groups diagnostic criteria were used. At the same time, maternal capillary glucose was measured. Because of differences in plasma and capillary glucose measurements, regression analysis of POC capillary glucose results vs laboratory plasma glucose results was conducted. The regression equations for plasma glucose were derived in a derivation cohort (n = 102). These equations were applied in the validation cohort (n = 100). Predicted and actual plasma glucose values were compared.

RESULTS: Of the 202 women screened, 36.6% were nulliparous, 56.4% were obese, and 81.2% were Irish-born. Two thirds had a single risk factor for GDM, and a third had multiple risk factors. Based on the plasma measurements, 53.5% had GDM. As a predictor of GDM, the diagnostic accuracy of POC measurement was 83.0% (95% confidence interval, 74.2–89.8).

CONCLUSIONS: In high-resource settings where measures to inhibit glycolysis are implemented, the use of POC measurements for the diagnosis of GDM is not justified based on this study. In low- and medium-resource settings, where measures to inhibit glycolysis are not achievable, regression analysis using POC measurements may be acceptable compared with plasma samples subject to glycolysis.

Based on an analysis of the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study, the International Association of Diabetes and Pregnancy Study Groups (IADPSG) recommended more sensitive criteria for the diagnosis of gestational diabetes mellitus (GDM) *(1, 2)*. This approach was endorsed by the World Health Organization (WHO) in 2013, and implementation has led to a major increase in the number of cases diagnosed and an increase in resource requirements for maternity services in Ireland *(3, 4)*.

However, there is no national or international consensus about the IADPSG criteria *(5)*. The United States and Canada both recommend that physicians can adopt the IADPSG criteria or a 2-step approach with less sensitive thresholds *(6–8)*. The United Kingdom recommends the guidelines of the National Institute for Health and Care Excellence (NICE) *(9)*, which also has less sensitive thresholds for diagnosis of GDM.

A major diagnostic challenge in measuring glucose is glycolysis by the glycolytic enzymes in blood cells in the sample *(10)*. All 15 centers in the HAPO study adhered to the National Academy of Clinical Biochemistry protocol for the handling of glucose blood samples *(11)*. However, since 2011, the standards have become stricter, which avoids potential underdiagnosis of diabetes mellitus *(12)*.

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Using a sample tube with a fluoride additive at room temperature will not inhibit glycolysis for up to 30–90 minutes *(13)*. Immediate placement of glucose samples collected in a fluoride additive on an ice-water slurry and prompt centrifugation are necessary to prevent glycolysis. The updated guidelines advise that centrifugation of samples should take place within 30 minutes, not 60 *(12)*. An alternative to a fluoride additive on an ice-water slurry is the use of citrate buffer, which is a rapid inhibitor of glycolysis *(14)*.

Glucose meter devices are not recommended currently for diagnostic purposes *(12)*. An important factor to consider is that almost all of the prior studies evaluating the diagnostic capability of point-of-care (POC) measurement for GDM compare the POC results with venous glucose samples as the reference standard with suboptimal sample handling *(15)*.

A previous study from our research group of 108 women selectively screened with a 75 g oral glucose tolerance test (OGTT), which examined POC capillary glucose measurements for the diagnosis of GDM, found that 17.6% of the cohort had GDM with customary preanalytical sample handling, 47.2% had GDM based on strict preanalytical sample handling of venous samples, and 49.1% had GDM based on POC *(16)*. Because glucose is distributed differently in capillary and venous samples, an arbitrary cutoff of 87 mg/dL (4.8 mmol/L) was selected for adjustment of the POC fasting cutoff value compared with 92 mg/dL (5.1 mmol/L) for the venous reference sample. The accuracy for the POC method used was 82.4%.

The aim of this prospective study was to evaluate the use of POC measurements for the diagnosis of GDM in women being screened selectively with a 1-step 75 g OGTT at 26–28 weeks using a regression method to predict laboratory plasma glucose. The POC method was benchmarked against venous samples measured at the same time using the latest international laboratory standards.

Materials and Methods

The study was conducted prospectively in a single, large, university, maternity hospital. Women aged ≥18 years who could understand English, who had sonographic confirmation of a singleton ongoing pregnancy, who did not have established Type 1 or 2 diabetes mellitus, and who had ≥1 risk factor for GDM were eligible for inclusion. Women were screened selectively based on risk factors as recommended in national guidelines *(17)*.

Women were recruited at their first hospital visit, and demographic and clinical information was recorded by a midwife trained on the hospital's medical records (Euroking K2). Written informed consent was obtained. The obstetric and neonatal details were updated immediately after delivery and before postpartum discharge from the hospital.

Women who agreed to participate were followed up with an OGTT (mean [SD] gestation, 27.5 [1.0] weeks) after an overnight fast (≥8 hours) between October 2017 and November 2018. A 2-h 75 g OGTT was conducted to screen for GDM with strict adherence to international guidelines and recommendations for laboratory analysis in the diagnosis of diabetes mellitus *(12)*. This involved collection of the venous samples in a sodium fluoride additive tube (Sarstedt Fluoride EDTA S-Monovette, 2.7 mL) with immediate placement on an ice-water slurry for transportation to the laboratory within 30 minutes for prompt centrifugation to prevent glycolysis. Glucose was measured by the hexokinase method (Beckman Coulter AU640 analyzer) with a CV percentage (CV%) of 2.0% at 103 mg/dL (5.7 mmol/L) and 234 mg/dL (13.0 mmol/L). The hospital laboratory is nationally accredited with International Organization for Standardization (ISO) 15189 by the Irish National Accreditation Board. The preanalytic standard was followed for all samples.

Before the collection of each venous sample (and after hand washing), a single-use lancet was used to collect a drop of capillary whole blood from a distal fingertip to measure POC capillary glucose using the Bayer Contour XT meter. This meter uses a flavin adenine dinucleotide glucose dehydrogenase measuring system and was selected for its performance over a wide hematocrit range. All testing was conducted according to the same protocol by a single researcher (E.OM.) with the same meter. The performance of this meter was confirmed daily using the quality-control solution Contour Next Normal (110–137 mg/dL [6.1–7.6 mmol/L]), with a CV% of 3.6% at a mean concentration of 126.1 mg/dL (7.0 mmol/L). The meter was also enrolled in an external quality assessment (EQA) scheme where a standardized sample was received quarterly in 2018. This sample was tested using the POC device, and the result was compared with the group mean for the same device (n = 303–1269) with all EQA results falling within the acceptable range.

SPSS version 24.0 (IBM Corp) was used for statistical analysis. Descriptive statistics were derived for the general characteristics of the cohort. SPSS was used to randomly select 102 cases from the cohort of 202 women who attended for testing. Linear regression analysis of the POC glucose results vs the laboratory plasma glucose results was conducted using the derivation cohort (n = 102). These equations were applied to the remainder of the cohort (validation cohort, n = 100) to determine the values that the equations predicted for the laboratory plasma glucose results based on the POC capillary result for the fasting and 1- and 2-h tests. These predicted laboratory results were compared with the actual laboratory plasma glucose results. The

IADPSG thresholds were applied and the predicted result correlated with the actual result to derive the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy (and confidence intervals [CIs]) for each time point (fasting, 1 and 2 h) and the overall GDM result. The adherence of the POC results with the ISO standard 15197:2013 was calculated in accordance with the thresholds stipulated by the standard *(18)*.

An alternative approach to determine the cutoff points for the OGTT using the POC meter was also considered. A ROC plot was constructed for the fasting and 1- and 2-h tests in the derivation cohort (n = 102), benchmarked against the criteria from the corresponding venous measurements at the same time point based on the IADPSG diagnostic criteria. The ROC curves were used to derive the cutoff points for the diagnosis of GDM for the POC method. The sensitivity, specificity, and accuracy of these cutoff points were then calculated for the remaining women (validation cohort, n = 100). These results are not presented because they were similar to the results of the regression method and can be found in the online Data Supplement.

The general characteristics and the GDM rate did not differ significantly between the derivation and validation cohorts. The study was approved by the Hospital's Research Ethics Committee (Study 14-2017).

Results

A total of 275 women agreed to participate in the study, and 202 (73.5%) attended for the OGTT. Of the 73 women who did not attend, 39 failed to attend the scheduled appointment, 7 could not attend on a date convenient for the laboratory, 10 were diagnosed with GDM before the OGTT (at the time of early testing because of a history of GDM), 6 attended a satellite clinic for their OGTT, 4 had a miscarriage, 3 were excluded because of a twin pregnancy, 2 were lost to follow up, 1 delivered elsewhere, and 1 was excluded because she had gastric bypass surgery, which compromises the oral glucose load.

The general characteristics of the 202 women studied are shown in Table 1. The majority (68.8%, n = 139) had 1 risk factor for GDM, and the most common risk factor was a body mass index (BMI; calculated as kg/m^2) >29.9 (56.4%, n = 114). Mean (SD) gestation at the first prenatal visit was 12.5 (1.5) weeks when maternal risk was stratified.

The mean (SD) time between collection of the reference standard venous samples on ice-water slurry and transportation to the laboratory for centrifugation was 17 (9.7), 13 (9.0), and 13 (8.9) min for the fasting, 1-h, and 2-h samples, respectively, confirming adherence to international guidelines. Based on the plasma sample, the rate of GDM was 53.5% using the IADPSG criteria.

Table 1. General characteristics and risk factors for gestational diabetes mellitus for the study population (n = 202).

Characteristic	Result
Age, years, mean (SD)	31.5 (5.3)
BMI, mean (SD)	30.6 (6.1)
Nulliparous, % (n)	36.6 (74)
Married, % (n)	47.0 (95)
Current smoker, % (n)	12.4 (25)
Irish nativity, % (n)	81.2 (164)
Gestational age at recruitment, weeks, mean (SD)	12.5 (1.5)
Gestational age at OGTT, weeks, mean (SD)	27.5 (1.0)
Positive OGTT result at 26–28 weeks, % (n)	53.5 (108)
RFs[a] for gestational diabetes mellitus (GDM)	
BMI >29.9, % (n)	56.4 (114)
Family history of diabetes mellitus, % (n)	42.1 (85)
History of polycystic ovary syndrome, % (n)	13.4 (27)
History of GDM, % (n)	11.7 (15)[b]
Age ≥40 years, % (n)	7.4 (15)
Ethnicity as an RF for GDM, % (n)	7.4 (15)
No. of RFs, % (n)	
1	68.8 (139)
2	24.3 (49)
3	6.4 (13)
4	0.5 (1)

[a]RF, risk factor.
[b]Of the 128 multiparous women.

The correlation between POC capillary and laboratory plasma glucose was >0.9 at all 3 time points in the derivation cohort ($P < 0.001$, n = 102) (Table 2). The linear regression equations to predict the laboratory plasma glucose derived for each time point are shown in Table 2.

The positive test rates at each time point and overall, based on the application of the linear regression equation in the validation cohort (n = 100), are shown in Table 3. The GDM rate based on the actual laboratory results was 56.0% in the validation cohort. This compared with 51.0% based on the predicted laboratory results using the regression equation. The diagnostic sensitivity, diagnostic

Table 2. Correlation between POC capillary and laboratory plasma glucose at each time point and the linear regression equation derived from the derivation cohort to predict laboratory plasma glucose (n = 102).

	Pearson correlation with laboratory plasma glucose	*P* value	Linear regression equation
Fasting capillary POC	0.903	<0.001	Laboratory fasting plasma glucose = 0.893 + (0.877 × fasting POC)
1-h capillary POC	0.926	<0.001	Laboratory 1-hour plasma glucose = −1.301 + (1.100 × 1-h POC)
2-h capillary POC	0.916	<0.001	Laboratory 2-h plasma glucose = −0.352 + (1.031 × 2-h POC)

specificity, PPV, NPV, and accuracy and their associated 95% CIs are shown for these predicted laboratory results at each time point and overall in Table 3. Compared with the reference standard of the actual laboratory results, the performance of POC-derived predicted laboratory results was as follows: diagnostic sensitivity of 80.4% (95% CI, 67.6–89.8%), diagnostic specificity of 86.4% (95% CI, 72.7–94.8%), PPV of 88.2% (95% CI, 77.9–94.1%), NPV of 77.6% (95% CI, 66.8–85.6%), and accuracy of 83.0% (95% CI, 74.2–89.8%).

The diagnostic sensitivity, diagnostic specificity, PPV, NPV, and accuracy were also calculated for each time point corrected for the overall GDM result (Table 3). The false-positive (FP) and false-negative (FN) cases at each time point were reviewed and corrected as outlined; using the 1-h plasma glucose as an example, there were 4 FN results and 3 FP results. Each of these cases was reviewed. Among the 4 FN results at the 1-h test, 1 woman was diagnosed with GDM based on one of the other tests (also correctly identified by this method). Of the 3 FP results using the predicted laboratory value at the 1-h test, 2 women were diagnosed with GDM based on one of the other test results (also correctly identified by this method). This approach resulted in 1 FP and 3 FN results at the 1-h time point in the corrected results.

The ISO standard for glucose meters was last updated in 2013 (ISO 15197:2013). For capillary glucose values <99 mg/dL (<5.5 mmol/L), 95% of POC blood glucose results must fall within 15 mg/dL (0.83 mmol/L) of the reference method. For capillary glucose values ≥99 mg/dL (≥5.5 mmol/L), 95% of POC blood glucose results must fall within 15% of the reference method *(18)*. The performance of the chosen POC meter at these levels is outlined in Table 4 for the validation cohort. The POC meter met these specifications in 3 of the 6 categories outlined and performed best for the fasting samples.

Discussion

This prospective observational study of 202 women screened selectively for GDM at 26–28 weeks of gestation had an incidence of GDM of 53.5% if the latest international preanalytic laboratory standards were strictly implemented and the current IADPSG diagnostic criteria were applied. Apart from the strict preanalytic sample handling, other factors that contribute to the higher prevalence of GDM are the study population characteristics (all women had ≥1 risk factor for GDM) and the IADPSG criteria, which require just 1 abnormal value for diagnosis of GDM. In the validation cohort, the incidence of GDM was 56.0% based on laboratory plasma glucose. This result compares with 51.0% incidence based on the predicted laboratory results derived from the regression equation. Assuming that the actual laboratory plasma samples were correct, the accuracy of the POC measurements in predicting the laboratory plasma glucose was 83.0% (95% CI, 74.2–89.8%).

Preanalytic loss of glucose from samples is considered to be a much greater source of error than the analytic error incurred in clinical laboratories *(10)*. Without strict preanalytic sample handling, glycolysis could result in the loss of 5–10% of the glucose in a sample over a 1- to 2-h period before the sodium fluoride additive becomes active as a glycolytic inhibitor. By comparison, the analytic error expressed as the CV% is typically ≤2% *(10)*. The impact of preanalytic error was minimized in this study by strict adherence to the sample-handling specifications. As in the HAPO study, sodium fluoride additive tubes stored on an ice-water slurry were used to prevent glycolysis, but the samples were centrifuged by a single researcher within 30 min rather than 60 min to meet the revised post-HAPO preanalytic standards *(12)*. The use of citrate in sample tubes as an inhibitor of glycolysis is an alternative, in part, to storage on ice-water slurry and prompt centrifugation. Considerations include the need to fill the sample tube completely and a positive bias of glucose concentration, which may require reconsideration of diagnostic cutoff points *(19)*. The latter may arise if the diagnostic cutoff points were derived in studies with inadequate measures to inhibit glycolysis.

Regression analysis of the POC meter glucose results vs the laboratory plasma glucose results was used

Table 3. Diagnostic sensitivity, diagnostic specificity, PPV, NPV, and accuracy of the predicted laboratory plasma glucose results in the validation cohort compared to the actual laboratory plasma glucose results using IADPSG criteria (n = 100).

	Laboratory Results, % (n)	Predicted Results, % (n)[a]	Sensitivity, % (95% CI)	Specificity, % (95% CI)	PPV, % (95% CI)	NPV, % (95% CI)	Accuracy, % (95% CI)
Fasting	49.0 (49)	48.0 (48)	83.7 (70.3–92.7)	94.1 (83.8–98.8)	93.2 (81.9–97.6)	85.7 (76.0–91.9)	89.0 (81.2–94.4)
Fasting corrected[b]	...	...	84.0 (70.9–92.8)	96.0 (86.3–99.5)	94.5 (84.3–98.9)	85.7 (76.0–91.9)	90.0 (82.4–95.1)
1 h	17.0 (17)	16.0 (16)	76.5 (50.1–93.2)	96.4 (89.8–99.3)	81.3 (58.0–93.1)	95.2 (89.5–97.9)	93.0 (86.1–97.1)
1-h corrected[b]	...	...	84.2 (60.4–96.6)	98.8 (93.3–99.9)	94.1 (69.3–99.1)	96.4 (90.4–98.7)	96.0 (90.0–98.9)
2 h	5.0 (5)	3.0 (3)	60.0 (14.7–94.7)	100.0 (96.2–100.0)	100.0	97.9 (94.2–99.3)	98.0 (93.0–99.8)
2-h corrected[b]	...	...	80.0 (28.4–99.5)	100.0 (96.2–100.0)	100.0	99.0 (94.3–99.8)	99.0 (94.6–100.0)
Overall GDM result	56.0 (56)	51.0 (51)	80.4 (67.6–89.8)	86.4 (72.7–94.8)	88.2 (77.9–94.1)	77.6 (66.8–85.6)	83.0 (74.2–89.8)

[a]Predicted using the linear regression equation derived from the derivation cohort.
[b]FP and FN results in these categories were assessed and corrected for when the overall GDM result was predicted correctly based on ≥1 of the other tests compared with the actual laboratory plasma glucose.

Table 4. Adherence of the POC capillary glucose results (fasting, 1- and 2-h) with ISO 15197:2013 in the validation cohort (n = 100).

	Values <99 mg/dL	Results Meeting ISO 15197:2013 (POC Maximum Deviation ±15 mg/dL vs Venous Laboratory Result)	Values ≥99 mg/dL	Results meeting ISO 15197:2013 (POC Maximum Deviation ±15% vs Venous Laboratory Result)
Fasting, % (n)	92.0 (92)	100 (92)	8.0 (8)	100 (8)
Mean (SD) difference of fasting POC vs venous result, mg/dL	−5.4 (3.6)	...	−1.8 (3.6)	...
1 h, % (n)	2.0 (2)	100 (2)	98.0 (98)	70.4 (69)
Mean (SD) difference of 1-h POC vs venous result, mg/dL	1.8 (10.8)	...	10.8 (16.2)	...
2 h, % (n)	16.0 (16)	93.8 (15)	84.0 (84)	84.5 (71)
Mean (SD) difference of 2-h POC vs venous result, mg/dL	5.4 (5.4)	...	3.6 (10.8)	...

Glucose conversion factor: 1 mg/dL = 0.0555 mmol/L.

to derive regression equations for the fasting and 1- and 2-h tests in the derivation cohort. These were applied to the validation cohort to predict the laboratory result based on each POC result for the fasting and 1- and 2-h tests. Although the glucose meter used in the study reports that the result displayed is the "plasma equivalent," there are several reasons why this correction method was used. The conversion factor of 1.11 applied by glucose meters has been reported to be valid only for samples that are from the same sample site (e.g., both venous blood); it does not apply for the conversion of arterial or capillary blood glucose to venous plasma glucose *(20)*. POC measurements in this study were taken with capillary blood rather than venous blood because this method of sampling would likely be most practicable and acceptable to the patient compared with venipuncture.

Other sources of error must be considered that may account for differences in the capillary and plasma glucose results. The laboratory-method CV% was 2.0%, and the POC-method CV% was 3.6%. Because of glucose consumption in the tissues, postprandial capillary values are approximately 20% higher than venous blood glucose *(21)*. The glucose meter used does not make any allowances for this difference and treats fasting and postprandial values equally.

Additional factors that are variables in the measurement process include meter maintenance and calibration, variability in the age of strips, their enzyme distribution, and user error *(22)*. Moreover, it is not known whether laboratory plasma glucose samples used to benchmark the POC meter were handled according to recent American Diabetes Association recommendations or if this was conducted in a pregnant population. Strengths of this study are that gold standard preanalytical sample handling of glucose was implemented and that the hospital laboratory is nationally accredited with ISO 15189. Stringent quality control and EQA practices were also adhered to for the POC meter chosen. Nevertheless, it is important to consider that these practices may not be as readily adhered to in a real-world setting. The study cohort was well characterized with sonographic dating of the pregnancy and accurate calculation of BMI at the first antenatal visit. The regression equations were derived in approximately half of the cohort (n = 102) and applied to the remainder of the cohort to assess their performance.

Limitations of this study include convenience recruitment rather than consecutive recruitment; consecutive recruitment was not feasible with a single researcher in a busy service. The test strips for the POC device were not from the same lot, which may affect the POC results *(22)*. The POC measurements were compliant with the ISO 15197:2013 standard (>95% agreement) for 3 of the 6 categories considered (Table 3). In the case of 2-h values <99 mg/dL (<5.5 mmol/L; n = 16), the level of agreement was 93.8%, which is close to the level required (95%). For the 1-h test (n = 98) and the 2-h test (n = 84) with measurements ≥99 mg/dL (≥5.5 mmol/L), the level of agreement was 70.4% and 84.5%, respectively. This suggests that the meter performance is superior for the fasting test. In this cohort, 87.5% (n = 49) of women tested positive based on a positive fasting plasma glucose test in the validation cohort (75.5% [n = 37] with a fasting positive test only and 24.5% [n = 12] with a fasting positive test and at least one other positive value).

Another factor to consider is the variability of results among meters of the same make and model. After reviewing the literature on the variability of one Contour XT meter to another, there appears to be a dearth of information on this topic. A technical report by Bayer Contour XT reported that there was no systematic difference between paired measurements on 2 meters; however, the data were not shown *(23)*. In our study, a second Bayer Contour XT meter was also enrolled in the EQA scheme to serve as a replacement meter. It was not used for measurement of patient samples but exhibited very similar values for the provided EQA samples, which were all in the acceptable range for the scheme (meters 1 and 2, respectively: Quarter (Q) 1: 83 mg/dL [4.6 mmol/L] and 83 mg/dL [4.6 mmol/L]; Q2: 196 mg/dL [10.9 mmol/L] and 193 mg/dL [10.7 mmol/L]; Q3: 209 mg/dL [11.6 mmol/L] and 205 mg/dL [11.4 mmol/L]; Q4: 85 mg/dL [4.7 mmol/L] and 87 mg/dL [4.8 mmol/L]).

POC testing has previously been compared with venous testing for the OGTT in settings where access to the laboratory or implementation of strict preanalytic sample handling may be difficult. A study in Kenya of 616 women that measured POC capillary glucose and venous glucose for the diagnosis of GDM reported diagnostic sensitivity of 55.6% and diagnostic specificity of 90.6% with the POC method based on the IADPSG criteria *(24)*. The rate of GDM in this low-risk cohort was only 2.9% (n = 18); therefore, the authors were not able to derive POC cutoff thresholds. The venous sample-handling methodology was not described.

Another study that reported poor performance of the POC method compared the Roche Accu-Check Active POC device to venous glucose samples *(15)*. The venous samples of 529 women in South Africa were collected on ice, but the exact mean time to centrifugation was not reported; however, it reported that time as >30 min. The diagnostic sensitivity of the POC device was just 27.0% and diagnostic specificity was 89.4%, with the POC method diagnosing 14.9% of the cohort with GDM compared with 26.7% with the laboratory method.

A study of 1465 women in India compared the performance of the Roche Accu-Check Active POC device

to the venous reference sample (which was centrifuged immediately after phlebotomy) for the diagnosis of GDM with IADPSG criteria *(25)*. The authors compared only the fasting capillary glucose and fasting plasma glucose with an area under the curve of 0.953. A total of 361 (24.6%) and 338 (23%) were diagnosed with GDM based on the fasting plasma glucose and fasting capillary glucose, respectively.

An important factor to consider is the applicability of the results in this study to other settings and situations. It is widely known that the performance of meters will differ according to the make and the model. This has been demonstrated in a study of the comparative accuracy of 17 POC glucose meters that included the Bayer Contour XT meter *(26)*. The same samples were tested on all 17 devices and compared with the reference whole-blood glucose measurements. The reported mean absolute relative difference ranged from 5.6% to 20.8%. It is clear that an analysis similar to the one in this study would be required for different meters from other manufacturers to define the thresholds for a particular meter. This study was conducted with 1 meter of the Bayer Contour XT brand. Additional studies would be required to assess the repeatability between meters of the same make and model. Based on a technical report on the Bayer Contour XT meter and our own experience of the EQA samples, meter to meter variation (witihin the same make and model) seems to be minimal *(23)*.

After correction of the POC results measured with a single meter to derive equivalent plasma glucose values, this study found that the use of this method is not justified when comparing the performance to the results obtained with stringent adherence to preanalytic and analytic standards. However, adherence to these standards may be possible only in high-resource settings. For the maternity services in middle- or low-income settings, where accredited laboratories are not easily accessible and/or strict preanalytic sample handling is not implemented, this approach may be considered. This approach has been advocated by the International Federation of Gynecology and Obstetrics in its initiative on GDM *(27)*. We acknowledge, however, that further studies are required to evaluate it in different populations and different healthcare settings, especially outside of a research setting.

Supplemental Material

Supplemental material is available at *Clinical Chemistry* online.

Nonstandard abbreviations: HAPO, hyperglycemia and adverse pregnancy outcome; IADPSG, International Association of the Diabetes and Pregnancy Study Groups; GDM, gestational diabetes mellitus; WHO, World Health Organization; NICE, National Institute for Health and Care Excellence; POC, point of care; OGTT, oral glucose tolerance test; CV%, coefficient of variation percentage; ISO, International Organization for Standardization; EQA, external quality assessment; PPV, positive predictive value; NPV, negative predictive value; CI, confidence interval; BMI, body mass index; FP, false positive; FN, false negative.

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