A Perspective on the Accuracy of Blood Glucose Meters During Pregnancy

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Diabetes Care 2018;41:2053–2058 | https://doi.org/10.2337/dc18-0833

Blood glucose monitoring is fundamental for hyperglycemia management during pregnancy, but are the devices up to the job? Studies assessing the accuracy of 10 commercially available glucose meters during pregnancy showed that although >98–99% of the meter values were in the acceptable zones of the error grid for the majority of the meters, the meter performance varied, with the majority showing positive bias and a few showing minimal negative bias. The mean difference between meter and laboratory plasma values varied between −0.33 and 0.73 mmol/L. Three meters showed deviations from laboratory results with a change in maternal hematocrit levels. No meters had a total analytical error <5%, and no studies evaluated meters using recent International Organization for Standardization 15197:2013 criteria. The Continuous Glucose Monitoring in Women With Type 1 Diabetes in Pregnancy Trial (CONCEPTT) recently showed that an antenatal continuous glucose monitoring system (CGMS), as an adjunct to capillary monitoring, was associated with a lower incidence of large-for-gestational-age babies, fewer neonatal intensive care unit admissions (>24 h), and a lower incidence of neonatal hypoglycemia. The flash glucose monitoring system shows good accuracy in pregnant women but has not been marketed widely in the U.S. We suggest that meters cannot be assumed to be sufficiently accurate during pregnancy and that manufacturers should ensure a total error <5%, with bias and imprecision <2% during pregnancy. Large studies are needed to evaluate the usefulness of CGMS among pregnant women with type 2 diabetes and gestational diabetes mellitus.

Blood glucose monitoring is an integral part of hyperglycemia management. The American Diabetes Association recommends the use of self-monitoring of blood glucose (SMBG) for pregnant women with gestational diabetes mellitus (GDM) and preexisting diabetes for achieving better glycemic control (1). This testing can augment the use of HbA_{1c} (2,3), which is unable to monitor day-to-day changes in glycemia, particularly when the level is significantly lower in pregnant women than in nonpregnant women (4). Current new-generation meters have features that enhance their accuracy profile, making them more accurate than older devices (5). However, despite technical advancement, many newer glucose meters fail to perform well in real-world situations (6). Numerous factors influence the accuracy of meter values, including meter and strip technology, operator knowledge and performance technique, underlying clinical conditions (e.g., high triglyceride and uric acid concentrations and changes in oxygen and hematocrit levels), environmental factors (e.g., temperature, altitude, and humidity), and interfering substances (7). Because new meters are able to perform with a blood volume as small as 0.3 μL, any hand

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Received 17 April 2018 and accepted 28 June 2018.

contamination with sweat, moisture, and traces of fruit may also interfere with the accuracy of meter values.

Glucose monitoring targets in pregnancy need to be tight (1), with low thresholds for commencing pharmacotherapy or increasing the insulin dosage. The Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) study showed that a fasting glucose of 5.1 mmol/L in the oral glucose tolerance test at 24–28 weeks of gestation was already associated with a 75% increased risk of adverse outcomes (8). Since the initiation of insulin/metformin/glyburide therapy and the related dosage adjustments depend solely on the SMBG results, inaccurate results may lead to insulin dosage errors and a greater chance of hypo- or hyperglycemia and may even fail to detect hypoglycemic episodes. Therefore, accurate SMBG results are crucial for management of hyperglycemia during pregnancy. The capabilities of continuous glucose monitoring systems (CGMS) during pregnancy have advanced with the technical aspects of glucose meters, and therefore considering these aspects is important in this Perspective on SMBG during pregnancy.

TECHNICAL ACCURACY OF SMBG DEVICES IN PREGNANCY: EVIDENCE FROM RECENT STUDIES

We conducted an electronic search of four databases (PubMed, CINAHL, Embase, and Scopus) from January 2007 to April 2017 to identify studies that evaluated the technical performance of glucose meters during pregnancy. The search was performed using key words including "blood glucose meter," "glucometer," "self-monitoring of blood glucose," "blood glucose monitoring," "accuracy," "precision," "performance," "evaluation," "gestational diabetes," "antenatal," and "pregnancy." A manual search was also performed using the reference lists of the articles obtained from the search. Any studies that assessed the accuracy of glucose meters against laboratory plasma measurements as a reference or comparative values during pregnancy were eligible for inclusion regardless of the type of device or diabetes (type 1 diabetes, type 2 diabetes, or GDM). Studies that assessed the accuracy of glucose meters for any clinical outcome during pregnancy, including the screening, diagnosis, or treatment of hyperglycemia, were also eligible for inclusion. Studies that were published prior to 2007 were excluded due to the progressive improvements in technology. Animal studies, studies performed outside the pregnant population, and non-English publications were ineligible. The primary outcome measure for this review was the frequency of meters that met the analytical and clinical accuracy criteria as per International Organization for Standardization (ISO) 15197:2003 (9) or the ISO 15197:2013 recommendations (10). The mean difference, mean bias, stability to hematocrit changes, and percentage of meter values within 5% or 10% error were also reviewed and summarized.

A literature search identified 355 articles, of which only a few were relevant to the review objective. Four studies (11–14) met the eligibility criteria and were selected for the review. A total of 10 different glucose meter devices manufactured by 5 different companies were reviewed, 2 of which were available in the U.S. The glucose meters evaluated in the studies were as follows: Accu-Chek Active, Accu-Chek Advantage II, Accu-Chek Performa (Roche Diagnostics); Ascensia EliteF (Bayer HealthCare); CareSens 505B (iSENS); Optium, Optium Xceed 5s, Optium Xceed 20s, Freestyle Lite (Abbott Diabetes Care); and Stat-Strip (Nova Biomedical). Table 1 summarizes the bias and clinical accuracy observed for each glucose meter. Our review of the studies during pregnancy showed that the accuracy of the glucose meters varied, with the majority showing positive bias and a few showing minimal negative bias. The mean difference varied between −0.33 and 0.73 mmol/L. The three glucose meters evaluated using ISO criteria met the ISO 15197:2003 recommended targets. We did not identify any studies that evaluated the recent ISO 15197:2013 criteria or any glucose meters with a total analytical error <5%. The Roche Accu-Chek Active glucose meter exhibited the lowest mean bias and thus demonstrated the best analytical accuracy. With the exception of one study (14), most glucose meters had a large proportion (>98–99%) of the meter values in zones A and B of the error grid analysis, which led to clinically appropriate treatment. Three devices (Optium, Optium Xceed 20s, and Optium Xceed 5s) showed a discrepancy from the reference values with a change in the maternal hematocrit level that rendered them unsuitable for use during pregnancy. One study (12) reported that only one-third of the meter values were within 5% of the plasma values for all four meters evaluated. Three glucose meters (Accu-Chek Advantage II [Roche Diagnostics], Accu-Chek Performa [Roche Diagnostics], and FreeStyle Lite [Abbott Diabetes Care]) were evaluated in two different studies, and a significant variation in the accuracy profiles was noted between the studies.

SMBG DEVICES: EXPECTATIONS DURING PREGNANCY

Performance Goal of Glucose Meters During Pregnancy

Meters have no specific performance "goal" for pregnancy alone. Current quality specifications by different organizations allow a maximum of 15% performance error for 95% of the meter results in the nonpregnant population (10,15,16). A simulation modeling study (17) using a Monte Carlo method outside of pregnancy reported that 8–23% of the insulin doses were incorrect for meters with a total analytical error of 5% and that the dosage error rate was 16–45% for meters with a total error of 10%. Additionally, large insulin dosage errors were reported when the coefficient of variation (CV) and/or bias was >10–15%. The study recommended that both the bias and CV needed to be <1% or <2% to ensure a rate of insulin dosage error <5%. Because pregnancy demands such tight glycemic control and pregnant women have a lower glucose threshold for insulin therapy initiation than the nonpregnant population, the performance goal of glucose meters during pregnancy should be to attain the lowest error possible to prevent insulin dosage errors.

Hematocrit Influence

In addition to the technical capabilities of meters outside of pregnancy as well as the tighter glycemic targets required within pregnancy, hemodilution lowers the hematocrit level, which can influence the accuracy of glucose meter measurements. Blood glucose meters have been shown to overestimate the glucose concentration when the hematocrit level is low, leading to positive bias (18). Currently, 26 different companies have marketed more than 90 glucose meter devices in the U.S. These meters differ in glucose measurement technology and sensitivity to hematocrit changes. Table 2 summarizes the assay and hematocrit specification of each glucose meter device. Evidence has shown that meters using coulometric and colorimetric techniques are less sensitive to

Table 1—Bias and clinical accuracy of blood glucose meters in pregnant women with diabetes

Author, year (ref.)	Devices	Mean difference (mmol/L)	95% limits of agreement	Mean bias (%)	Imprecision CV (%)	Mean total analytical error (%)	Values affected by hematocrit changes (yes/no)	ISO 15197:2003 criteria met (yes/no)	Values within 5% error (%)	Values within 10% error (%)	Values that met clinical accuracy criteria (%)
Dhatt et al., 2011 (11)	Accu-Chek Active		—	−0.2	2.9% (at 3.2 mmol/L), 1.8% at (9.0 mmol/L)	—	—	Yes	—	—	100
Kong et al., 2010 (12)	Elite	−0.30	−1.46 to 0.87	—	—	—	No	—	28.6	58.0	99.8
	Accu-Chek Advantage II	0.14	−0.99 to 1.26	—	—	—	No	—	43.4	73.8	99.0
	CareSens	0.03	−1.15 to 1.22	—	—	—	No	—	36.6	66.0	99.3
	Optium	0.17	−1.08 to 1.43	—	—	—	Yes	—	35.6	63.7	98.1
Parwaiz et al., 2014 (13)	FreeStyle Lite*	−0.33	−1.22 to 0.57	—	4.6	—	No	Yes	—	—	100
	Accu-Chek Performa	−0.02	−0.91 to 0.86	—	3.1	—	No	Yes	—	—	100
Perera et al., 2011 (14)	Accu-Chek Advantage II	0.36	−0.75 to 1.47	8.99	—	14.87	No	—	—	—	<50
	Optium Xceed 20s	0.57	−0.75 to 1.89	13.08	—	26.21	Yes	—	—	—	<50
	Accu-Chek Performa	0.38	−0.76 to 1.53	9.04	—	15.65	No	—	—	—	<50
	Optium Xceed 5s	0.73	−0.52 to 1.97	15.76	—	32.14	Yes	—	—	—	<50
	FreeStyle Lite*	0.23	−1.16 to 1.62	6.37	—	17.07	No	—	—	—	<50
	StatStrip*	0.26	−0.82 to 1.33	6.10	—	12.29	No	—	—	—	<50

Bias was described as mean difference (95% CI). Mean difference = mean of the meters − plasma glucose. Mean percentage bias = ([meter value − reference value]/reference value) × 100. Mean total analytical error = % bias + 1.96 CV. The table also shows meters that met the ISO 15197:2003 criteria (95% of the meter values should be within 0.83 mmol/L [15 mg/dL] of the reference values at blood glucose levels ≤4.2 mmol/L [75 mg/dL] and within 20% for blood glucose levels >4.2 mmol/L [75 mg/dL]). Clinical accuracy criteria as per the ISO 15197:2013 recommendations: 99% of the meter results should be within zones A and B of the consensus error grid, leading to clinically appropriate treatment. The empty cells denote data not reported. *Meter currently available for use in the U.S.

Table 2—List of glucose meter devices with hematocrit specification and assay method

Hematocrit range (%)	Glucose meter device (manufacturer)
20–60	AgaMatrix Presto,* AgaMatrix Premium,*§§ Jazz Wireless 2* (AgaMatrix); GLUCOCARD Shine,† GLUCOCARD Shine XL,† ReliOn Premier VOICE† (ARKRAY); Dario Smart Glucose Meter‡ (DarioHealth); Advocate Redi-Code+ Speaking,‡ Advocate Redi-Code+ Non-Speaking‡ (Diabetic Supply of Suncoast); MyGlucoHealth Wireless‡ (Entra Health); FIFTY 50 Glucose Meter 2.0† (FIFTY 50 Medical); FORA Premium V10 and FORA Premium V10 BLE,‡ FORA V30a,† FORA Premium V12,† FORA D40d and D40g 2-in-1,‡ FORA MD† (ForaCare); CareSens N,‡ CareSens N POP,‡ CareSens N Voice‡ (i-SENS); OneTouch Verio IQ,‡§§ OneTouch Verio,‡§§ OneTouch Verio Flex‡ (LifeScan); EasyMax NG,† EasyMax LTC,† FortisCare MU,† FortisCare V3† (Oak Tree Health); EmbracePRO† (Omnis Health); One Drop Chrome§ (One Drop); Prodigy Connect,‡ Prodigy AutoCode,‡ Prodigy Voice,‡ Prodigy Pocket† (Prodigy); Clever Choice Voice HD,‡ Clever Choice HD,‡ Clever Choice Pro+‡ (Simple Diagnostics); Infinity‡ (US Diagnostics)
30–55	*On Call* Express,‡ *On Call* Plus,‡‖‖ *On Call* Pro‡ (ACON Laboratories); GLUCOCARD 01,‡ GLUCOCARD Expression‖ (ARKRAY); OneTouch UltraMini,¶ OneTouch Ultra 2,¶‖‖ OneTouch Ping† (LifeScan); EasyMax EMV,† EasyMax EMV2,† FortisCare T1‖ (Oak Tree Health); Embrace,† EmbraceEVO† (Omnis Health); Telcare‡ (Telcare); TRUEtrack‡ (Trividia Health, formerly Nipro Diagnostics); EasyGluco‡ (US Diagnostics)
15–65	FreeStyle Freedom Lite,#‖‖ FreeStyle Lite,# FreeStyle Precision Neo‡ (Abbott Diabetes Care); ReliOn Premier BLU† (ARKRAY); CONTOUR NEXT,‡ CONTOUR NEXT EZ,‡ CONTOUR NEXT LINK,‡ CONTOUR NEXT LINK 2.4,‡ CONTOUR NEXT ONE‡ (Ascensia Diabetes Care); VeraSens‖ (US Diagnostics)
20–70	*On Call* Vivid,†† *On Call* Vivid Pal†† (ACON Laboratories); Livongo InTouch† (Livongo); TRUE METRIX AIR,‡‡ TRUE METRIX GO,‡‡ TRUE METRIX‡‡ (Trividia Health, formerly Nipro Diagnostics)
10–65	Accu-Chek Aviva,**‖‖ Accu-Chek Aviva Nano,‡‖‖ Accu-Chek Guide‡ (Roche Diagnostics)
33–52	GLUCOCARD Vital,‡ ReliOn Prime† (ARKRAY)
30–54	ReliOn Confirm,‡ ReliOn Micro‡ (ARKRAY)
30–60	GE100,‡ Rightest GM550‡ (Bionime)
25–60	Nova Max Plus,‡§§ Nova Max Link‡§§ (Nova Biomedical); TRUE FOCUS‡ (Trividia Health, formerly Nipro Diagnostics)
25–55	FortisCare EM66† (Oak Tree Health)
NA	MyGlucoHealth Cellular,‖ BLE Smart Wireless System‖ (Entra Health); FIFTY 50 Glucose Meter 2.0 Sport‖ (FIFTY 50 Medical); FORA TN'G,† FORA TN'G VOICE,† FORA GD50,† Fora Gold Advance Plus‖ (ForaCare); GHT Blood Glucose Meter‡ (Genesis Health Technologies); iHealth Smart Wireless Glucose Monitoring,‡ iHealth Align‡ (iHealth Labs); 2-in-1 Glucose and Blood Pressure Monitor‖ (Simple Diagnostics)

Information obtained from company websites, user guides, communication with customer service departments, and Internet searches. NA, not available (information could not be obtained via the above means). Assay methods: *WaveSense Dynamic electrochemistry, †unspecified electrochemistry, ‡amperometry, §dynamic electrochemistry, ‖NA, ¶colorimetry, #coulometry, **electrical biamperometry, ††amperometry with hematocrit autocorrection, and ‡‡amperometry with TRIPLE SENSE TECHNOLOGY. §§Meter that showed stability in hematocrit evaluation studies (20,21,22). ‖‖Meter that failed hematocrit evaluation (20,21,22).

hematocrit changes than those using the amperometric technique (19). While most glucose meters (>50%) show hematocrit dependence in evaluation studies, meters that use an additional electrode for hematocrit measurement (Nova Biomedical) and those that use dynamic electrochemistry (Sanofi, AgaMatrix) are unaffected by hematocrit changes (20–22). Additionally, certain meters (*On Call* Vivid and *On Call* Vivid Pal [ACON Laboratories]), TRUE METRIX [Trividia Health, formerly Nipro Diagnostics], and Accu-Chek Aviva [Roche Diagnostics]) have been reported to have special technologies that autocorrect for hematocrit interference. When choosing a glucose meter for use during pregnancy, users are expected to follow the manufacturer's instructions regarding the recommended hematocrit ranges and to limit the use of meters only to women who meet the specified ranges. Bias has been reported in glucose meters even after use among women who are within the manufacturer-recommended hematocrit levels (as seen in the study by Kong et al. [12]). Therefore, use of glucose meters with on-strip hematocrit compensation should be encouraged during pregnancy. Currently, it is not routine practice for clinicians to consider a low hematocrit when deciding on the next change in pharmacotherapy; perhaps we should?

Why Pregnancy May Be Different

Insulin dosage errors, leading to greater chances of hyperglycemia or hypoglycemia, can detrimentally affect a fetus, whereas maternal underrecognition of hypoglycemia can lead to reduced hypoglycemia awareness. Pregnant women with type 1 diabetes exhibit frequent fluctuations in their glycemic profiles and variation in their insulin requirements throughout pregnancy. Therefore, additional caution should be taken when titrating an insulin dosage for these women based on SMBG results to prevent hypoglycemic episodes, particularly during early pregnancy. Strict metabolic control via accurate SMBG data is vital to improve outcomes among pregnancies complicated by type 2 diabetes because of the high risk of serious adverse perinatal outcomes. In addition, the glycemic thresholds used for the diagnosis and management of any hyperglycemia in pregnancy are lower than those used outside of pregnancy. Therefore, meters with good accuracy profiles for lower glycemic ranges should be the ideal choice for use during pregnancy.

CLINICAL USE OF CGMS DURING PREGNANCY

CGMS appear to be a better option for monitoring glucose if cost and technical issues (e.g., wearability and accuracy) are addressed. CGMS use in the nonpregnant population has been shown to improve glycemic control (23). Studies in pregnant women show benefits from CGMS for tracking glucose fluctuations as well as

predicting and detecting asymptomatic hypoglycemia and postprandial peaks, which otherwise may go unnoticed with the use of SMBG alone (24–27). Studies also show a good correlation between CGMS values and reference measurements during pregnancy (24,28) except when rapid changes in glycemia occur (28,29). Recent evidence supports the use of CGMS as an adjunct to SMBG for managing pregnant women with type 1 diabetes. The CONCEPTT (Continuous Glucose Monitoring in Women With Type 1 Diabetes in Pregnancy Trial) multicenter randomized controlled trial (30) involving 215 pregnant women with type 1 diabetes reported improved neonatal outcomes with a small reduction in HbA_{1c} among those in the CGMS group. The incidence of large-for-gestational-age infants (odds ratio 0.51, 95% CI 0.28–0.90), neonatal intensive care admissions lasting >24 h (0.48, 95% CI 0.26–0.86), and neonatal hypoglycemia (0.45, 95% CI 0.22–0.89) were significantly lower with CGMS. CGMS use was associated with an increased time in the target range and less time in hyperglycemia without any improvement in hypoglycemic events (30). Previous smaller trials in pregnant women with type 1 and 2 diabetes have reported conflicting outcomes (31,32).

At present, there is insufficient evidence to support the use of CGMS among pregnant women with type 2 diabetes and GDM. The number of study participants with type 2 diabetes among existing studies (31,32) is small (total $n = 56$). Moreover, a number of small randomized controlled trials performed among GDM women have reported reduced gestational weight gain (33) and higher detection rates for those who required medication therapy (34) but have found no improvement in glycemic control or pregnancy outcomes with CGMS use (33,35). Conversely, a cohort study performed among 340 GDM women showed better pregnancy outcomes in the CGMS group (36). Regardless, large studies are warranted to evaluate the usefulness of CGMS among pregnant women with type 2 diabetes and GDM.

There are several limiting factors for CGMS. A good correlation with blood glucose values does not mean that either the accuracy or the precision is adequate. This type of monitoring can misrepresent the extent of the hyperglycemic peak and the time period of hypoglycemia during the recovery phase due to the delays in reflecting glucose changes in the interstitial fluid (37). Caution must therefore be exercised when implementing treatment changes in response to CGMS values. In addition, other issues, such as skin site reaction, device discomfort, calibration, and other technical difficulties, may influence user motivation and compliance with CGMS use. Indeed, in the CONCEPTT study, the sensor compliance was only 70%. In the other two randomized controlled trials, compliance was 64% (31) and 80% (32); thus, such devices are not suitable for all women. The new technology in glucose monitoring (the FreeStyle Libre Flash Glucose Monitoring system [Abbott Diabetes Care]), which does not require calibration and eliminates the need for SMBG, has been well received in Europe (38). A recent study in the U.K. and Austria (38) that evaluated the performance and utility of the FreeStyle Libre system reported good accuracy for pregnant women with diabetes with a mean absolute relative difference of 11.8%, and 99.8% of the glucose values within zones A and B of the consensus error grid compared with capillary blood glucose reference values but not laboratory plasma values. This technology recently obtained Food and Drug Administration approval in the U.S. but has not yet been marketed widely for use among the pregnant population.

CONCLUSIONS

Glucose monitoring with tight glucose control is imperative for managing pregnant women with hyperglycemia. Studies have shown that the performance of glucose meters cannot be assumed to be sufficiently accurate during pregnancy. Meters have no quality specification for pregnancy. Efforts should be made to achieve the lowest deviation possible (i.e., a total error <5% with an imprecision [CV] <2%). In addition, the choice of a meter for use during pregnancy should take into account the potential influence of hematocrit changes on the meter values. A meter that features automatic measurement and correction for hematocrit changes is the preferred choice for use during pregnancy. These meters need to have higher accuracy profiles for low glucose ranges; when they do not, efforts must be taken to validate their accuracy in pregnant women prior to making them publicly available. CGMS show promise especially in pregnant women with type 1 diabetes, but further work is required; it remains uncertain whether the technical aspects and cost issues can be addressed sufficiently. Although the new flash glucose monitoring system showed good agreement between SMBG among the pregnant population and was well received in Europe, no recommendations have been made in the U.S. for use among the pregnant population.

Funding. J.I. is supported by a postgraduate research scholarship from Western Sydney University.

Duality of Interest. D.S. has a study for which Roche Diagnostics has provided the Accu-Chek Guide glucose meter at no cost and has been on speakers' bureaus for Roche Diagnostics and Medtronic. The Macarthur Diabetes Service receives all meters (Accu-Chek Guide and Accu-Chek Performa [in the past]) from Roche Diagnostics at no cost with start test strips. No other potential conflicts of interest relevant to this article were reported.

References

1. American Diabetes Association. 13. Management of diabetes in pregnancy: *Standards of Medical Care in Diabetes—2018*. Diabetes Care 2018;41(Suppl. 1):S137–S143
2. Church D, Simmons D. More evidence of the problems of using HbA_{1c} for diagnosing diabetes? The known knowns, the known unknowns and the unknown unknowns. J Intern Med 2014;276:171–173
3. Wei N, Zheng H, Nathan DM. Empirically establishing blood glucose targets to achieve HbA_{1c} goals. Diabetes Care 2014;37:1048–1051
4. Nielsen LR, Ekbom P, Damm P, et al. HbA_{1c} levels are significantly lower in early and late pregnancy. Diabetes Care 2004;27:1200–1201
5. Weitgasser R, Gappmayer B, Pichler M. Newer portable glucose meters–analytical improvement compared with previous generation devices? Clin Chem 1999;45:1821–1825
6. Klonoff DC, Prahalad P. Performance of cleared blood glucose monitors. J Diabetes Sci Technol 2015;9:895–910
7. Ginsberg BH. Factors affecting blood glucose monitoring: sources of errors in measurement. J Diabetes Sci Technol 2009;3:903–913
8. Metzger BE, Gabbe SG, Persson B, et al.; International Association of Diabetes and Pregnancy Study Groups Consensus Panel. International Association of Diabetes and Pregnancy Study Groups recommendations on the diagnosis and classification of hyperglycemia in pregnancy. Diabetes Care 2010;33:676–682
9. International Organization for Standardization. ISO 15197:2003: In vitro diagnostic test systems—requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. Geneva, Switzerland, International Organization for Standardization, 2003
10. International Organization for Standardization. ISO 15197:2013: In vitro diagnostic test systems—requirements for blood-glucose

monitoring systems for self-testing in managing diabetes mellitus. Geneva, Switzerland, International Organization for Standardization, 2013
11. Dhatt GS, Agarwal MM, Othman Y, Nair SC. Performance of the Roche Accu-Chek Active glucose meter to screen for gestational diabetes mellitus using fasting capillary blood. Diabetes Technol Ther 2011;13:1229–1233
12. Kong GW, Tam WH, Chan MH, et al. Comparison in the performance of glucose meters in blood glucose monitoring during pregnancy. Gynecol Obstet Invest 2010;69:264–269
13. Parwaiz M, Lunt H, Florkowski CM, et al. Assessment of glucose meter performance at the antenatal diabetes clinic: exploration of patient-related and pre-analytical factors. Ann Clin Biochem 2014;51:47–53
14. Perera NJ, Molyneaux L, Constantino MI, et al. Suboptimal performance of blood glucose meters in an antenatal diabetes clinic. Diabetes Care 2011;34:335–337
15. Clinical and Laboratory Standards Institute. *POCT12-A3—Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities*. 3rd ed. Wayne, PA, Clinical and Laboratory Standards Institute, 2013
16. Food and Drug Administration. Self-monitoring blood glucose test systems for over-the-counter use: guidance for industry and Food and Drug Administration staff [Internet], 2016. Available from http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm380327.pdf. Accessed 10 May 2017
17. Boyd JC, Bruns DE. Quality specifications for glucose meters: assessment by simulation modeling of errors in insulin dose. Clin Chem 2001;47:209–214
18. Tang Z, Lee JH, Louie RF, Kost GJ. Effects of different hematocrit levels on glucose measurements with handheld meters for point-of-care testing. Arch Pathol Lab Med 2000;124:1135–1140
19. Solnica B, Skupien J, Kusnierz-Cabala B, et al. The effect of hematocrit on the results of measurements using glucose meters based on different techniques. Clin Chem Lab Med 2011;50:361–365
20. Ramljak S, Lock JP, Schipper C, et al. Hematocrit interference of blood glucose meters for patient self-measurement. J Diabetes Sci Technol 2013;7:179–189
21. Pfützner A, Musholt PB, Schipper C, et al. Blood glucose meters employing dynamic electrochemistry are stable against hematocrit interference in a laboratory setting. J Diabetes Sci Technol 2013;7:1530–1537
22. Katz LB, Macleod K, Grady M, Cameron H, Pfützner A, Setford S. A comprehensive evaluation of strip performance in multiple blood glucose monitoring systems. Expert Rev Med Devices 2015;12:263–271
23. Pickup JC, Freeman SC, Sutton AJ. Glycaemic control in type 1 diabetes during real time continuous glucose monitoring compared with self monitoring of blood glucose: meta-analysis of randomised controlled trials using individual patient data. BMJ 2011;343:d3805
24. Chen R, Yogev Y, Ben-Haroush A, Jovanovic L, Hod M, Phillip M. Continuous glucose monitoring for the evaluation and improved control of gestational diabetes mellitus. J Matern Fetal Neonatal Med 2003;14:256–260
25. Yogev Y, Ben-Haroush A, Chen R, Kaplan B, Phillip M, Hod M. Continuous glucose monitoring for treatment adjustment in diabetic pregnancies–a pilot study. Diabet Med 2003;20:558–562
26. Yogev Y, Chen R, Ben-Haroush A, Phillip M, Jovanovic L, Hod M. Continuous glucose monitoring for the evaluation of gravid women with type 1 diabetes mellitus. Obstet Gynecol 2003;101:633–638
27. McLachlan K, Jenkins A, O'Neal D. The role of continuous glucose monitoring in clinical decision-making in diabetes in pregnancy. Aust N Z J Obstet Gynaecol 2007;47:186–190
28. Kerssen A, de Valk HW, Visser GH. The Continuous Glucose Monitoring System during pregnancy of women with type 1 diabetes mellitus: accuracy assessment. Diabetes Technol Ther 2004;6:645–651
29. Kumareswaran K, Elleri D, Allen JM, et al. Accuracy of continuous glucose monitoring during exercise in type 1 diabetes pregnancy. Diabetes Technol Ther 2013;15:223–229
30. Feig DS, Donovan LE, Corcoy R, et al.; CONCEPTT Collaborative Group. Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial. Lancet 2017;390:2347–2359
31. Secher AL, Ringholm L, Andersen HU, Damm P, Mathiesen ER. The effect of real-time continuous glucose monitoring in pregnant women with diabetes: a randomized controlled trial. Diabetes Care 2013;36:1877–1883
32. Murphy HR, Rayman G, Lewis K, et al. Effectiveness of continuous glucose monitoring in pregnant women with diabetes: randomised clinical trial. BMJ 2008;337:a1680
33. Wei Q, Sun Z, Yang Y, Yu H, Ding H, Wang S. Effect of a CGMS and SMBG on maternal and neonatal outcomes in gestational diabetes mellitus: a randomized controlled trial. Sci Rep 2016;6:19920
34. Kestilä KK, Ekblad UU, Rönnemaa T. Continuous glucose monitoring versus self-monitoring of blood glucose in the treatment of gestational diabetes mellitus. Diabetes Res Clin Pract 2007;77:174–179
35. Alfadhli E, Osman E, Basri T. Use of a real time continuous glucose monitoring system as an educational tool for patients with gestational diabetes. Diabetol Metab Syndr 2016;8:48
36. Yu F, Lv L, Liang Z, et al. Continuous glucose monitoring effects on maternal glycemic control and pregnancy outcomes in patients with gestational diabetes mellitus: a prospective cohort study. J Clin Endocrinol Metab 2014;99:4674–4682
37. Cheyne EH, Cavan DA, Kerr D. Performance of a continuous glucose monitoring system during controlled hypoglycaemia in healthy volunteers. Diabetes Technol Ther 2002;4:607–613
38. Scott EM, Bilous RW, Kautzky-Willer A. Accuracy, user acceptability, and safety evaluation for the FreeStyle Libre Flash Glucose Monitoring System when used by pregnant women with diabetes. Diabetes Technol Ther 2018;20:180–188