Accred Qual Assur (2016) 21:143–149
DOI 10.1007/s00769-015-1188-2

PRACTITIONER'S REPORT

Analytical performance of glucometers in a tertiary care hospital

Angela Somavilla Higioka[1,2] · Renata Cristina Messores Rudolf-Oliveira[2,3] · Flavia Martinello[1,4] · Maria Luiza Bazzo[1,2,3]

Received: 16 June 2015 / Accepted: 11 December 2015 / Published online: 2 January 2016

Abstract Point-of-care (POC) testing of glucose (glucometers) represents a convenient alternative to monitor glycemia since the measurement procedure is performed without delay after sampling of the capillary blood, thereby avoiding the metabolism by the blood cells of glucose present in plasma. Likely because of sample instability, there is no proficiency test provider in Brazil for this type of POC sample. In this context, this study aimed to evaluate the analytical performance of glucometers used in a tertiary care hospital. The glucometers used were the Accu-Chek Performa® model from Roche Diagnostics, which use the principle of amperometry. The reference method was the reaction with modified hexokinase/glucose-6-phosphate in a Dimension® device. The stability evaluation of the control samples showed that it can be performed up to 90 min after the collection of whole blood samples. In the two rounds performed, only one result of the 17 glucometers evaluated was out of the threshold of two standard deviation. Thus, this method for control of glucometers met the expectations and enabled comparing the glucometers in a hospital. Given the current quality guidelines, daily internal quality control of glucometers is recommended, besides at least two annual comparisons between the results of the glucometers and the reference method and one EQA every 3 months.

Keywords Point-of-care tests · Capillary glucose · Glucometer · Accuracy assessment

✉ Maria Luiza Bazzo
m.l.bazzo@ufsc.br

[1] Residência Multidisciplinar em Saúde, University Hospital, Federal University of Santa Catarina, Florianópolis, Brazil

[2] Laboratório de Pesquisa III (segundo andar), Divisão de Análises Clínicas, Hospital Universitário Professor Polydoro Ernani de São Thiago - Universidade Federal de Santa Catarina, Campus Universitário, s/no, Trindade, Florianópolis, SC CEP 88040-900, Brazil

[3] Program of Post Graduation in Pharmacy, Department of Clinical Analysis, Federal University of Santa Catarina, Florianópolis, Brazil

[4] Departamento de Análises Clínicas, Centro de Ciências da Saúde, Universidade Federal de Santa Catarina, sala 109, bloco JK, Trindade, Florianópolis, SC CEP 88040-900, Brazil

Introduction

The persistence of high blood glucose levels raises the chances of complications in inpatients, just as hypoglycemia is harmful and should be avoided [1–3]. In this sense, point-of-care (POC) tests for glucose, the so-called glucometers, represent a convenient alternative for monitoring capillary glycemia in inpatients given its easy handling and low volume requirement of the biological sample. Moreover, they yield quicker results compared to the conventional methodology with plasma, which speeds up the medical decision regarding the treatment. Nevertheless, it is crucial that POC results have a good correlation with the results of reference laboratory equipment [4, 5]. POC handling seems simpler; however, the professionals that operate such devices do not have laboratory training and do not easily detect analytical sources of error. Hence, there is great concern in hospitals regarding the errors in these devices due to the large number of operators and POCs that must be supervised [6]. Furthermore, evidence shows the need for education, training, and oversight of these activities by healthcare professionals [7]. In Brazil, the National Health Surveillance Agency (ANVISA) mandates internal and external quality

control for all laboratory tests [8]. Nonetheless, likely due to the instability of the samples, there is no proficiency test provider in Brazil that supplies control samples for this type of POC.

In this context, this study aimed to systematize the production of control samples and to standardize an alternative form of accuracy assessment for capillary glycemia performed in glucometers. The purpose of this control is not to replace or to compete with the internal quality control, but allow comparing the results of glucometers from different units of the hospital considering that the inpatients are transferred among them.

Materials and methods

A brand-new glucometer (reference glucometer), model Accu-Chek Performa® from Roche Diagnostics, Germany, was used to determinate the reference concentration of sample panels for the accuracy assessment. This device was approved in the internal quality control performed with the control sample provided by the manufacturer. For the capillary glycemia test, a drop of fresh blood (venous, capillary, or arterial) collected with EDTA or heparin is required. The principle of the glucometer test is based on amperometry, in which the enzyme glucose dehydrogenase impregnated onto the test strip converts the glucose from the blood sample into gluconolactone in the presence of the coenzyme pyrroloquinoline quinone (PQQ). This reaction creates a harmless continuous electric current that the monitor interprets as the glycemia [9]. In order to employ the new glucometer as reference glucometer, the results from whole blood samples were compared with results produced simultaneously by the reference equipment from the plasma of the same samples. The reference method used in the comparison was the reaction with modified hexokinase/glucose-6-phosphate in the Dimension® (Siemens, USA) equipment, which is assessed by an External Quality Assessment program for the glucose measurement. The variation between the results of both methods was within the range admitted according to the criteria defined by the International Organization for Standardization (ISO) [10] and by the Clinical and Laboratory Standards Institute [11].

For the purpose of comparing the analytical performance of the 17 glucometers of the hospital, the average result yielded by the control sample panel obtained with the reference glucometer was considered the target value for the glucometers evaluated. For the production of control sample panels, blood samples were collected with vacuum EDTA tubes through venipuncture in the anterior surface of the arm (cubital, median, or cephalic veins) from healthy volunteers that signed a term of free and informed consent and whose hematocrit levels were within the reference range (between 36 % and 47 % for women and between 40 % and 52 % for men). Samples whose hematocrit levels were out of these ranges were excluded from the study.

In order to determine the correlation between capillary glycemia and plasma glucose and the stability of the control samples in the panels regarding the glucose consumption by the blood cells over time, glucose concentration was measured with the reference glucometer and with the reference method in 20 venous blood samples at the initial (zero) time and at 30 min, 60 min, and 90 min after collection with the samples stored at room temperature (20 °C–25 °C). At each time, an aliquot was taken from the whole blood sample for analysis by the glucometer and another aliquot, for centrifugation (3500*g* for 10 min) for plasma obtention and evaluation by the reference method. Thus, the percentage of glucose level reduction in the samples was verified according to the contact time of the plasma with the cells and the maximum time between collection and accuracy assessment with no significant change in the glucose level was defined. The analysis of the samples at time zero was performed 10 min after collection, the time needed for sample centrifugation to obtain the plasma.

To evaluate the 17 glucometers of the University Hospital (UH) of the Federal University of Santa Catarina (UFSC), two panels were prepared with control samples with different glucose levels (high and low). Each panel required 10 ml of venous blood. The whole blood sample was split into two 8-ml aliquots using two 15-ml polystyrene tubes. In one of the tubes, a quick glucose test was performed with the reference glucometer and, as the result was above 3.892 mmol/l, the sample was left to sit at room temperature for long enough so that the glucose was naturally consumed by the blood cells, which yielded the low-glucose control sample (control sample 1). The time required to obtain control sample 1 depended on the initial glucose level and was calculated from the information that the initial glucose level in the sample decreases by 5 %–7 % per hour at rest at room temperature [12, 13]. The control sample with high glucose level (control sample 2) was prepared shortly before the beginning of the accuracy assessment tests by adding a concentrated glucose solution (18.515 mmol/l) (Glucup 100, NewProv, Brazil) to the sample. By the end of sample preparation, their concentrations were measured in triplicate with the reference glucometer. Afterwards, 1 ml of the reference sample was separated and centrifuged to obtain the plasma, and then the glucose concentration was measured using the reference method.

Two accuracy assessment rounds were carried out in the hospital, in December 2013 and January 2014, following this standardized control sample preparation. The rounds evaluated 17 Accu-Chek Performa® glucometers from Roche Diagnostics, Germany. For each round (Gluco1 and Gluco2), 17 panels were produced, made up of two Eppendorf tubes

with 0.4 ml whole peripheral blood each (one with low concentration and the other with high concentration of glucose), two 1-ml Pasteur pipettes, two gauzes, and one sheet to write down the results. The panels were stored in polystyrene boxes with recyclable ice, so that the ice did not contact the samples, and each box was sent to one sector of the hospital. Each panel was handed to a nursing staff professional, who ran the tests and wrote down the results. All panels were sent out and measured within 30 min of preparation. The analyses were performed within as short time as possible in order to minimize the analytical difference due to variations in the samples' glucose concentration. Every control sample were tested in duplicate with each of the 17 glucometers using reactive strips from three different batches in order to decrease the chance of interference of a particular lot. In order to compare the results produced in each glucometer, the result of each one was compared to the mean of all glucometers, as an External Quality Assessment.

Statistical analysis

Sample stability was assessed using analysis of variance (ANOVA) with a significance level of $p < 0.05$. A study was performed to detect outliers results using the SPSS (Statistical Package for the Social Sciences) Statistic Data Editor version 17.0, IBM (Chicago, USA) and then the average, standard deviation, errors (mmol/l and percentage), and standard deviation index (SDI) were calculated. This index is the classic method to compare results from different devices and represents the number of standard deviations that separate the result of the glucometer evaluated from the average obtained by all glucometers. In general, an SDI variation in range of ±2 is considered acceptable [14]. Bland–Altman test was performed to compare groups, using MedCalc version 12.0.3.0, Microsoft Partner (Ostend, Belgium).

Results

The analysis for detection of outliers was carried out for all the data, but no results were excluded from the study. The Bland–Altman analysis showed no statistically significant difference between the three different batches of test strips used in this work (results not showed). In the stability analysis of control samples, the reduction in glucose concentration in the 20 blood and plasma samples read at 0, 20, 60, and 90 min from collection can be seen in Table 1.

ANOVA showed that these variations are not statistically significant ($p > 0.05$). Thus, the present study considered that the distribution of the glucometer assessment panels performed within 90 min does not significantly impacts the precision of the results.

Moreover, the comparison between the glucose concentration measurements in the normoglycemic samples with the reference glucometer (whole blood) and with the reference method (plasma) showed results 7.3 % lower, on average, in the glucometer. The glucose results obtained with the 17 glucometers evaluated were also compared to the value obtained in the plasma glucose concentration measurement of the samples that made up the panels (Table 2). This comparison aimed to verify whether the difference in the results is within the one admitted by the guidelines. The result of each glucometer is the mean of six repeated measurements with the same sample.

The differences in the results shown in Table 2 were compared with those admitted by the guidelines (prepared by several organizations such as the International Standards Organization (ISO) [10], the Clinical and Laboratory Standards Institute (CLSI, USA) [11], the American Diabetes Association (ADA, USA) [5], and the Food and Drug Administration (FDA, USA) [15] for glucometer performance) (Table 3).

Two accuracy assessment rounds were carried out, labeled Gluco1 and Gluco2. The former evaluated 15 glucometers, while the latter evaluated 17. In Gluco1 (Table 4), the results obtained with the glucometers evaluated with control sample 1 had maximum differences of ±0.167 mmol/l (±3.8 %) when compared with the average result of all glucometers evaluated. With control sample 2, the differences varied between +0.964 mmol/l (6.2 %) and −1.037 mmol/l (−6.7 %). Regarding the SDI data of the results produced by the glucometers tested compared with the average of all tested devices, all results have a SDI within the range of ±2.

Table 1 Reduction in glucose concentration in whole blood and plasma samples left to sit for 30, 60, and 90 min from the first measurement

Sample	Percentage of reduction in glucose concentration after the first measurement (time zero)		
	Reduction in 30 min mean ± SD (%)	Reduction in 60 min mean ± SD (%)	Reduction in 90 min mean ± SD (%)
Whole blood[a] (reference glucometer)	3.5 ± 1.5	4.2 ± 1.7	7.9 ± 2.1
Plasma (reference method—Dimension[a])	2.5 ± 3.2	4.9 ± 4.1	7.1 ± 4.7

SD Standard deviation

[a] Blood anticoagulated with disodium EDTA

Table 2 Result of the glucose concentration performed with the glucometers with whole blood and the difference from the plasma glucose concentration performed with the reference method (automated equipment—Dimension®)

Glucometer	Glucose concentration (mmol/l) Control sample 1[a]	Difference in mmol/l (%) from reference method (plasma)[b] Control sample 1 (3.670 mmol/l)	Glucose concentration (mmol/l) Control sample 2[a]	Difference in mmol/l (%) from reference method (plasma)[b] Control sample 2 (21.184 mmol/l)
1	3.264	−0.406 (−11.1)	18.376	−2.808 (−13.3)
2	3.380	−0.290 (−7.9)	18.448	−2.736 (−12.9)
3	3.392	−0.278 (−7.6)	18.570	−2.614 (−12.3)
4	2.986	−0.684 (−18.6)	18.448	−2.736 (−12.9)
5	3.392	−0.278 (−7.6)	18.609	−2.575 (−12.2)
6	3.375	−0.295 (−8.0)	18.337	−2.847 (−13.4)
7	3.319	−0.351 (−9.6)	18.348	−2.836 (−13.4)
8	3.364	−0.306 (−8.3)	18.476	−2.708 (−12.8)
9	3.297	−0.373 (−10.2)	18.559	−2.625 (−12.4)
10	3.236	−0.434 (−11.9)	18.476	−2.708 (−12.8)
11	3.253	−0.417 (−11.4)	18.237	−2.947 (−13.9)
12	3.186	−0.484 (−13.2)	18.582	−2.602 (−12.3)
13	3.153	−0.517 (−14.0)	18.776	−2.408 (−11.4)
14	3.186	−0.484 (−13.2)	18.921	−2.263 (−10.7)
15	3.180	−0.490 (−13.4)	18.487	−2.697 (−12.7)
16	3.141	−0.528 (−14.4)	18.804	−2.380 (−11.2)
17	3.130	−0.540 (−14.7)	18.748	−2.436 (−11.5)
Average		−0.420 (−11.4)		−2.643 (−12.5)
SD		0.112		0.179

SD Standard deviation

[a] Average of six consecutive glucose concentration measurements from the same sample with each glucometer tested

[b] Plasma glucose concentration from the same sample with the Dimension® device

In Gluco2 round (Table 5), the results obtained with the glucometers evaluated with control sample 1 differed by up to +0.566 mmol/l (13.2 %) and −0.324 mmol/l (−7.6 %) when compared with the average result of all glucometers evaluated. In the comparison between the individual results and the average results of the glucometers using control sample 2, the maximum differences were +0.853 mmol/l (4.2 %) and −0.815 mmol/l (−4.1 %). Regarding the SDI, only one result (glucometer 6), when measuring control sample 1, went over the limits of ±2, which was removed from service and sent to the maintenance.

Discussion

In order to produce the control samples, some aspects of their stabilities were tested and the results of this assessment showed that the decrease in glucose in the sample over time matched the results found by Bruns and Knowler [13]. The glucometer measurement from whole blood had results 7.3 % lower than the glucose concentration with the reference method in the plasma fraction of the same samples. This result was lower than in some studies that show variations between 10 % and 15 % [16, 17]. This discrepancy could derive from the use of normoglycemic samples [18] in the present study. The analysis of the results produced by samples with extreme glucose concentrations (control sample 1 and control sample 2) showed that the difference found was higher (12 %), which is more compatible with the results in similar studies [16, 17]. Therefore, the variation deriving from the matrix must be taken into account when results produced by glucometers and laboratory equipment are used as synonymous [17]. The difference between the plasma and whole blood is the most important variable that physicians must consider when setting glycemia control goals for inpatients [18]. The quality norms for glucometers usually set fixed limits of variation for low glucose concentration and percentage limits for higher ranges (Table 3). According to the quality specifications for glucometers suggested by the CLSI (2013) [11] and by the FDA (2014) [15], 94 % and 41 % of the glucometers, respectively, met the goals for control

Table 3 Comparison of the differences between results obtained with the different glucometers and with the reference method and the performance standard of international organizations

	ADA:1996 [5]	ISO 15197:2003	ISO 15197:2013 [10]	CLSI:2013 [11]	FDA:2014 [15]
	Performance limits for glucose concentration measurements (mmol/l)				
Criteria	All ranges/<5 %	<4.17/±0.834	<5.56/±0.834	<5.56/±0.667	<4.17/±0.3897
		>4.17/±20 %	>5.56/±15 %	>5.56/±10 %	>4.17/±10 %
	Percentage (and number) of glucometers that met the expected result range				
Control sample 1	12 % (2/17)	100 % (17/17)	100 % (17/17)	94 % (16/17)	41 % (7/17)
Control sample 2	0 % (0/17)	100 % (17/17)	100 % (17/17)	0 % (0/17)	0 % (0/17)

Table 4 Results of Gluco1 round of glucometers at UH/UFSC

Glucometer	Control sample 1			Control sample 2		
	Glucose concentration (mmol/l)	Difference from the average in mmol/l (%)	Standard deviation index	Glucose concentration (mmol/l)	Difference from the average in mmol/l (%)	Standard deviation index
1	4.392	0 (0)	0.0	14.512	−1.037 (−6.7)	−1.7
2	4.504	0.112 (2.6)	1.1	16.124	0.575 (3.7)	1.0
3	4.448	0.056 (1.3)	0.5	15.735	0.186 (1.2)	0.3
4	4.448	0.056 (1.3)	0.5	16.235	0.686 (4.4)	1.1
5	4.337	−0.055 (−1.3)	−0.5	15.290	−0.259 (−1.7)	−0.4
6	4.281	−0.111 (−2.5)	−1.1	16.513	0.964 (6.2)	1.6
7	4.559	0.167 (3.8)	1.6	15.512	−0.037 (−0.2)	−0.1
8	4.448	0.056 (1.3)	0.5	15.512	−0.037 (−0.2)	−0.1
9	4.281	−0.111 (−2.5)	−1.1	15.179	−0.370 (−2.4)	−0.6
10	4.281	−0.111 (−2.5)	−1.1	15.512	−0.037 (−0.2)	−0.1
11	4.226	−0.166 (−3.8)	−1.6	14.790	−0.759 (−4.9)	−1.3
12	4.337	−0.055 (−1.3)	−0.5	14.623	−0.926 (−6.0)	−1.6
13	4.392	0 (0)	0.0	16.180	0.631 (4.1)	1.1
14	4.392	0 (0)	0.0	15.846	0.297 (1.9)	0.5
15	4.559	0.167 (3.8)	1.6	15.679	0.130 (0.8)	0.2
Average	4.392			15.549		
SD	0.103			0.597		

sample 1 and none of the 17 devices evaluated met the specifications for samples with high glucose concentration (control sample 2). The new quality standards set by the CLSI in 2013 and by the FDA in 2014 could mean better safety for the patient since they would pressure manufacturers to adapt to more rigid criteria by producing more accurate glucometers that yield results with as much quality as laboratory equipment [19].

Regarding accuracy assessment rounds for glucometers, given the time limit between producing the panels and carrying out the glucose tests in whole blood samples, no provider supplies proficiency test panels in Brazil. Hence, each laboratory must create alternative control measures, besides periodically comparing the results obtained with the glucometers using the reference method [5]. In the two rounds performed, only one result was out of the SDI limits of ±2 from the average results with control sample 1 in Gluco2 round. In this sense, many variables may impact the accuracy of the glucometer such as the variation of the equipment operator, incorrect storage of the reactive strips, equipment misuse, among other clinical variables. Thus, the more it is known about the method's limitations and the better glucometers are controlled, the greater the benefits will be for patient safety [20–22]. In addition, the participation in another control program enables assessing the magnitude of the systemic error, i.e., the inexactitude of the analytical system. This way, it is also important to compare equipment among sectors in a hospital, since patients are very commonly transferred between units [23]. Staff training is a requirement to reduce the sources of operational error in such equipment, as well as the daily use of internal controls to verify the performance of the

Table 5 Results of Gluco2 round of glucometers at UH/UFSC

Glucometer	Control sample 1			Control sample 2		
	Glucose concentration (mmol/l)	Difference from the average in mmol/l (%)	Standard deviation index	Glucose concentration (mmol/l)	Difference from the average in mmol/l (%)	Standard deviation index
1	4.059	−0.213 (−5.0)	−0.9	20.572	0.464 (2.3)	0.9
2	4.059	−0.213 (−5.0)	−0.9	20.850	0.742 (3.7)	1.5
3	3.948	−0.324 (−7.6)	−1.4	19.460	−0.648 (−3.2)	−1.3
4	4.337	0.065 (1.5)	0.3	19.905	−0.203 (−1.0)	−0.4
5	4.170	−0.101 (−2.4)	−0.4	20.127	0.019 (0.1)	0
6	4.837	0.566 (13.2)	2.4	20.961	0.853 (4.2)	1.7
7	4.170	−0.101 (−2.4)	−0.4	19.905	−0.203 (−1.0)	−0.4
8	4.170	−0.101 (−2.4)	−0.4	19.905	−0.203 (−1.0)	−0.4
9	4.392	0.121 (2.8)	0.5	20.516	0.408 (2.0)	0.8
10	4.226	−0.046 (−1.1)	−0.2	20.016	−0.092 (−0.5)	−0.2
11	4.226	−0.046 (−1.1)	−0.2	19.794	−0.314 (−1.6)	−0.6
12	4.281	0.010 (0.2)	0	19.905	−0.203 (−1.0)	−0.4
13	3.948	−0.324 (−7.6)	−1.4	20.072	−0.036 (−0.2)	−0.1
14	4.281	0.010 (0.2)	0	20.739	0.631 (3.1)	1.3
15	4.559	0.288 (6.7)	1.2	19.293	−0.815 (−4.1)	−1.7
16	4.281	0.010 (0.2)	0	19.460	−0.648 (−3.2)	−1.3
17	4.670	0.399 (9.3)	1.7	20.350	0.242 (1.2)	0.5
Average	4.271			20.108		
SD	0.239			0.493		

equipment aiming to guarantee reliable results [24]. Given the different variables that may impact accuracy in glucometer results, and since POCs are performed away from the strict laboratory control, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO, USA), the College of American Pathologists (CAP, USA), and the Brazilian Society of Clinical Pathology and Laboratory Medicine (SBPC/ML) recommend comparisons every semester between the results obtained with POCs and those from the clinical laboratory in order to guarantee test quality and competency of the staff that performs them [23, 25, 26].

Conclusion

The stability evaluation of the control samples showed that accuracy evaluation can be performed up to 90 min after the collection of whole blood sample to produce control sample panels. The alternative control method for glucometers fulfilled the needs and enabled comparing the glucometers in a hospital. Finally, given the current quality guidelines, daily internal quality control of glucometers is recommended, besides at least two annual comparisons between the results of the glucometers and the reference method and one EQA every 3 months.

References

1. Umpierrez GE, Hellman R, Korytkowski MT, Kosiborod M, Maynard GA, Montori VM, Seley JJ, Van den Berghe G (2012) Management of hyperglycemia in hospitalized patients in non-critical care setting: an endocrine society clinical practice guideline. J Clin Endocrinol Metab 97:16–38
2. Moghissi ES, Korytkowski MT, DiNardo M, Einhorn D, Hellman R, Hirsch IB, Inzucchi SE, Ismail-Beigi F, Kirkman MS, Umpierrez GE (2009) American Association of Clinical Endocrinologists and American Diabetes Association consensus statement on inpatient glycemic control. Diabetes Care 32:1119–1131
3. Murad MH, Coburn JA, Coto-Yglesias F, Dzyubak S, Hazem A, Lane MA, Prokop LJ, Montori VM (2012) Glycemic control in non-critically ill hospitalized patients: a systematic review and meta-analysis. J Clin Endocrinol Metab 97:49–58
4. Lode PV (2005) Point-of-care immunotesting approaching the analytical performance of Central Laboratory methods. Clin Biochem 38:591–606
5. American Diabetes Association (ADA) (2013) Standards of medical care in diabetes 2013 (position statement). Diabetes Care 36:11–66
6. Nichols JH (2006) Quality in point-of-care testing: taking POC to the next level. Accred Qual Assur 11:273–277
7. Plebani M (2006) Laboratory network of excellence: enhancing patient safety and service effectiveness. Clin Chem Lab Med 44:150–156
8. ANVISA. RDC No. 302, de 13 de outubro de 2005 (2005) Dispõe sobre o Regulamento Técnico para funcionamento de Laboratórios Clínicos. Ministério da Saúde, Brasília
9. Wang J (2008) Electrochemical glucose biosensors. Chem Rev 108:814–825

10. ISO 15197 (2013) In vitro diagnostic test systems—requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. International Organization for Standardization. Geneva, Switzerland
11. Clinical and Laboratory Standards Institute (CLSI) (2013) POCT 12-A3 point-of-care blood glucose testing in acute and chronic care facilities. Approved Guideline—3rd edn, vol 33. CLSI, Pennsylvania
12. Sacks DB, Bruns DE, Goldstein DE, Maclaren NK, McDonald JM, Parrott M (2002) Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus. Clin Chem 48:426–472
13. Bruns DE, Knowler WC (2009) Stabilization of glucose in blood samples: why it matters. Clin Chem 5:850
14. ISO 13528 (2005) Statistical methods for use in proficiency testing by interlaboratory comparisons. International Organization for Standardization, Geneva, Switzerland
15. Food and Drug Administration (FDA) (2014) Blood glucose monitoring test systems for prescription point-of-care use. Draft Guidance for Industry and Food and Drug Administration Staff. http://www.fda.gov. Accessed 15 May 2015
16. Kuwa K, Nakayama T, Hoshino T, Tominaga M (2001) Relationships of glucose concentrations in capillary whole blood, venous whole blood and venous plasma. Clin Chim Acta 307:187–192
17. D'Orazio P, Burnett RW, Fogh-Andersen N, Jacobs E, Kuwa K, Külpmann WR, Larsson L, Lewenstam A, Maas AH, Mager G, Naskalski JW, Okorodudu AO (2005) Approved IFCC recommendation on reporting results for blood glucose. Clin Chem 9:51
18. Dungan K, Chapman J, Braithwaite SS, Buse J (2007) Glucose measurement: confounding issues in setting targets for inpatient management. Diabetes Care 30:403–409
19. Walsh J, Roberts R, Vigersky RA, Schwartz F (2012) New criteria for assessing the accuracy of blood glucose monitors meeting. J Diabetes Sci Technol 6:466–474
20. Ginsberg B (2009) Factors affecting blood glucose monitoring: sources of errors in measurement. J Diabetes Sci Technol 3:903–913
21. Lyon ME, DuBois JA, Fick GH, Lyon AW (2010) Estimates of total analytical error in consumer and hospital glucose meters contributed by hematocrit, maltose, and ascorbate. J Diabetes Sci Technol 4:1479–1494
22. Pfützner A, Schipper C, Ramljak S, Flacke F, Sieber J, Forst T, Musholt PB (2013) Evaluation of the effects of insufficient blood volume samples on the performance of blood glucose self-test meters. J Diabetes Sci Technol 7:1522–1529
23. Sociedade Brasileira de Patologia Clínica/Medicina Laboratorial (SBPC/ML) (2012) Diretriz para a Gestão e Garantia da Qualidade de testes laboratoriais remotos (TLR) da SBPC/ML. http://www.sbpc.org.br/?C=16. Accessed 21 May 2015
24. Blank FS, Miller M, Nichols J, Smithline H, Crabb G, Pekow P (2009) Blood glucose measurement in patients with suspected diabetic ketoacidosis: a comparison of Abbott MediSense PCx point-of-care meter values to reference laboratory values. J Emerg Nurs 35:93–96
25. Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) (2010) Accreditation standards for clinical laboratories. http://pt.jointcommissioninternational.org/enpt/Clinical-laboratory. Accessed 10 July 2013
26. Nakhleh RE (2013) Quality management tools. College of American Pathologists. Surveys & Anatomic Pathology Education Programs http://www.cap.org. Accessed 21 May 2015