Review Article

Need of quality control in point of care glucose monitoring devices

Thakurdas BR[1], Ghosh Y[2]

[1]Dr Bhavana R Thakur Das
Assistant Professor, Biochemistry
bhavana.ghosh@yahoo.com

[2]Dr Yatin Ghosh
Assistant professor, General Surgery
yatinghosh@gmail.com
[1,2]Punjab Institute of Medical Sciences
Jalandhar, Punjab, India

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Correspondence to:
Dr Bhavana R Thakur Das
bhavana.ghosh@yahoo.com

ABSTRACT

Point of care testing is also referred to as near patient, bedside, or extra laboratory testing. It helps in bringing the test immediately to the patient via convenient handheld, portable, or transportable devices. POCT devices facilitate ways to improve the quality and outcomes of care while decreasing cost and length of stay especially for critical care practitioners. One of the oldest applications POCT is for self-monitoring of blood glucose (SMBG) devices They were originally designed for home self-monitoring of blood glucose (SMBG) for diabetic patients to improve glucose control during regular life activities. However, ease of use of a POCGMD and its rapid reporting of BG information led to its utilization in the inpatient setting. POCGMD represents the largest commercial market for POCT. The newer POCT devices have an advanced level of connectivity with laboratory information system (LIS). They electronically capture and transmit results to a central management point (a central data station and/or a clinical or laboratory information system), ensuring that post-analytical errors are minimized.

QC is an immediate check on the integrity of the POCT device. There should be regular review of QC and EQA results as part of quality improvement. The global POCT field is in need of whole-blood standards, harmonization among methods, and improved QC. Granting these 3 wishes will facilitate common sense consistency among measurement procedures performed at the point of care and, in our opinion, will ultimately improve diagnoses, treatment decisions, and patient outcomes. EQA is both desirable and required for POCT devices.

***Key words**: Point of care devices, self monitoring, blood glucose, laboratory, information system*

Introduction

Point of care testing, otherwise also referred to as near patient, bedside, or extra laboratory testing, is not new. Over the past few years, analytical systems have been developed that enable a wide range of tests to be done quickly and simply without the need for sophisticated laboratory equipment. [1] The ability to move testing closer to the patient, has been possible for some three decades with continuing advances in technology that have produced steadily more sophisticated devices measuring an increasing range of analytes. [2] Point of care tests have great potential for facilitating faster decision making. [3] It helps in bringing the test immediately to the patient via convenient handheld, portable, or transportable devices. Many of POCT devices use whole-blood samples for results. The rapid technological advances in POCT permit measurement of multiple analytes in whole-blood samples. Additionally, whole-blood analysis in POCT decreases therapeutic turnaround time and facilitates shorter time to treatment. [4]

POCT devices facilitate ways to improve the quality and outcomes of care while decreasing cost and length of stay especially for critical care practitioners. Evaluation of point-of-care testing for application in each institution requires information about the devices available; knowledge of the advantages and disadvantages of the technologies, the clinical impact, and cost of the process change; and strategies for

successful implementation. Point-of-care testing is a technological innovation with the potential for improving patients' care without increasing costs. It most likely will soon become part of the standard of care. [5]

In primary care POCTs are usually delivered during a clinical visit; the results are available quickly without the need to send samples to a laboratory. This offers alternatives to traditional laboratory testing, with the potential to maintain or improve patient convenience, satisfaction and health outcomes thus saving time and costs. [6-10] Point-of-care testing devices and technology are increasingly used in the delivery of care and therapeutic decision making. [11]

Two broad types of technology support point of care testing: small bench top analysers (for example, blood gas and electrolyte systems) and hand held, single use devices (such as urine albumin, blood glucose, and coagulation tests). The bench top systems are smaller versions of laboratory analyzers in which operator dependent steps have been automated by automatic flushing of sample after analysis, calibration, and quality control. Hand held devices have been developed using microfabrication techniques. They are outwardly simple but internally complex devices that do several tasks—for example, separate cells from plasma add reagents, and read colour or other end points. [12] Most PoCT devices utilise a disposable single-use testing unit. The sample is inserted into the testing unit and the analyte to be measured is recognised most commonly through the use of chemical or biological sensors (that is, a reaction takes place). The second component of the PoCT system is the device, which in simple terms is just a reader of the signal generated as a result of the reaction. [13, 14]

Many of the early “diagnostic tests” were first done at the bedside—for example, urine testing. [1] Point of care tests has great potential in the accident and emergency department. The main studies in accident and emergency have been on tests for measuring blood gas and electrolyte concentrations. [3] Rapid analysis of cardiac markers help improve the recognition of patients who will benefit from early treatment as well as those who are at greatest risk of a later cardiac event. [15] Similarly, point of care tests for D-dimer can help identify patients at risk of a pulmonary embolism or deep vein thrombosis, with improved outcomes. [16] Rapid testing during surgery may reduce the length of an operation, which could reduce the clinical consequences of an extended operative period or time spent in a postoperative intensive care unit. For example, point of care tests for ionized calcium during the liver transplantation could reduce the adverse effects of the citrate load from transfused blood. Similarly, assessment of coagulation status by point of care testing during cardiopulmonary bypass surgery reduces the requirement for blood products, postoperative blood loss, and the time spent in postoperative high dependency care. [17] Intraoperative measurement of parathyroid hormone concentration improved the success of reoperative parathyroidectomy from 76% to 94%. [18]

Reduction in the length of hospital stay has been seen as one of the main advantages of point of care testing. The rapid availability of a result reduces the time to make decisions, thereby allowing more rapid triage, treatment, or discharge.

In addition, point of care testing can be used to guide whether a patient needs admitting to hospital, as has been suggested for patients with chest pain. [19] The key objective of point of care testing is to generate a result quickly so that appropriate treatment can be implemented, leading to an improved clinical or economic outcome. [12] Even with the most sophisticated device, reliable results can be obtained only if the patient is prepared appropriately and the correct technique is used. As point of care testing is likely to be done by staff with limited technical background, proper training of the staff and quality control are critical. [20] Point of care testing should be organized by laboratory staff and should follow a set line of protocols. [21]

Wherever possible, point of care testing equipment should be linked to the laboratory information system to enable real time monitoring of performance and integration of results into the patient's electronic record. This approach should meet all the requirements associated with clinical risk management and clinical governance. [21] The cost of point-of-care testing is greater than traditional laboratory testing, but the increased cost may be offset by improvements in the management of patient care, improvements in patient outcomes, and decreased utilization of the healthcare system. [11]

Mahoney and Ellison [1] pointed out the various challenges faced in any diagnostic point of care testing e.g. variations in hematocrit, oxygen tension, pH, and temperature, and myriad other factors, such as drugs, may affect measurements unpredictably. All diagnostic tests, including the tests performed at the bedside, should be highly accurate. Point-of-care testing is no excuse for inaccuracy. Apart from inaccurate testing there are potential disadvantages including time needed to use tests, and inappropriate testing. [8, 22] The effect of point of care testing can be assessed in terms of the benefit to the diagnostic or treatment strategy and thus overall health outcome. [23] As seen the technological aspects of PoCT have tended to receive more attention but there is an increasing need to focus on how and where PoCT should be applied and the potential outcomes from PoCT. [2] The emphasis on need to focus on application and potential outcome has helped to adopt an evidence-based approach to the introduction of new technology. In addition, healthcare reform being pursued by many western countries including Australia is encouraging the need to provide better and more convenient access to healthcare for all patients, particularly those with chronic diseases. [24] Any test will be beneficial only if appropriate action is taken on the result. Thus, the rate limiting step in reducing length of hospital stay or initiation of treatment may not be delivery of a test result, [3] but acknowledgement of the result (communication, appreciation, and action). [25] However there is limited data to indicate that point-of-care testing, when combined with changes in healthcare delivery systems, may improve patient outcomes and decrease the overall cost of health care. There is a great need for additional investigation into the use of point-of-care testing in patient care. [11]

Point-of-care Glucose Monitoring Devices (POCGMD)

The prevalence of diabetes mellitus continues to increase with approximately

12.9% of the population in the United States diagnosed with diabetes and 29.5% of population estimated to be living in a prediabetic state. [26] Control of blood glucose (BG) in an acceptable range remains a target for diabetes patients in both the hospital and outpatient environments. [27] One of the oldest applications PoCT is for self-monitoring of blood glucose (SMBG) devices with the first patents for glucose strips being lodged in 1963. [28] They were originally designed for home self-monitoring of blood glucose (SMBG) for diabetes patients to improve glucose control during regular life activities. However, ease of use of a POCGMD and its rapid reporting of BG information led to its utilization in the inpatient setting. [27] POCGMD also represents the largest commercial market for PoCT. [28] In an observational study done on patients who self-monitored their blood sugar to those who did not monitor their sugar a pooled reduction of HbA1c of 0.22% (CI 0.34 to 0.11%) was seen this was analysed using meta-analysis of seven RCTs of SMBG in type 2 diabetes. [29] The NHS Diabetes Working Group in the UK has published a report including a further Systematic Review separating trials into those which determined the effects of just SMBG and those where the intervention was SMBG plus education and follow-up. [30] In the former, termed 'simple SMBG', the pooled reduction in HbA1c was 0.21 % while in the latter trials, the reduction was 0.52%. These findings have emphasized the importance of therapy adjustment following testing as well as education, points now in the guidelines issued by bodies such as the International Diabetes Federation. [31] Depending on the specific glucose measurement technique of a POCGMD, the measurements can be influenced by various circumstances. [27]

POCT glucose in critically ill patients

Glycemic control using an insulin infusion in critically ill patients requires frequent and rapid BG monitoring with devices available for bedside use. [32-36] The accuracy of the BG measurements plays an important role for treatment decisions when aiming for glycemic control. [27] Because of concerns about accuracy in critically ill patients, the FDA held a public meeting about clinical accuracy requirements for POC glucose meters and tight glycemic control. [37, 38] A need for improved performance of POC glucose meters and greater attention to human factors affecting device accuracy were articulated at the meeting. Moreover, it was suggested that different populations should have separate analytical standards as well as separate clinical performance standards. This is true especially in critically ill patients on tight glycemic control. [38] Several studies have reported poor performance of POC glucose meters in critically ill patients in the intensive care unit (ICU) environment. [20, 39]

POCT glucose in anesthetized patients

In anaesthetized patients accuracy of blood glucose (BG) determinations is even more important as the patients cannot report symptoms of hypoglycemia due to general anesthesia or the patient's capacity to inform may be impaired during procedures which are performed under sedation. The autonomic responses may be masked by anesthetic agents and other drugs (e.g., beta blockers, opioids), making it even harder to recognize hypoglycemia. [40] Concerns have been raised about the safety and accuracy of peri-operative use of POC

meters. [41, 42] However there is insufficient data on POC glucose meters performance in the operating room (OR) a. Point-of-care glucose meter accuracy perioperatively and in the ICU has been reviewed. [41-43] Rice and colleagues identified a number of factors in the form of medications (e.g., ascorbic acid, mannitol, acetaminophen, and dopamine), hematocrit, oxygen concentration, pH, hypothermia, and hypotension that could influence the accuracy of POC measurements. Rice and colleagues also commented on the lack of studies in the OR environment, they identified that the exact spectrum of POC glucose meter accuracy is unknown in the operating room due to insufficient studies done in OR. They also concluded that POC glucose meter accuracy is also affected by the training of the particular operator. [41] Performance of POC glucose meters in patients during anesthesia may be even less accurate than in ICU patients, in whom such concern already exists. Perioperative clinicians should be aware of the limitations of specific POC glucose meters, and routine use of POC glucose meters as sole measurement devices in the intraoperative period should be carefully considered. [44]

Different types of commonly used devices and their methods

There are many different types of single-use testing units including the cartridges used with the Abbott iSTAT, Siemens DCA and Axis Shield Afinion devices, the cassettes used with the Inverness Cholestech LDX, and the test strip-based systems that use a code chip for calibration, including the Roche CoaguChek XS, Roche Cobas h232 and Nova Biomedical NovaStat devices. Other examples of single-use testing units include the cuvette with the HemoCue haemoglobin device and the rotor or disc with the Abaxis Piccolo device. [45]

Methods of POCGMD devices

Glucose Oxidase per Oxidase (GOD-POD)

In this technique glucose oxidase (GOX/GOD) acts as an enzyme which oxidizes glucose to gluconic acid and hydrogen peroxide; the amount of hydrogen peroxide produced is proportional to the glucose concentration in the blood sample. This change in the hydrogen peroxide concentration is measured by using a color change as an indicator using a photometric technique or in newer devices, which rely on the production of an electrical current (amperometric technique). [46]

Glucose-1-dehydrogenase (GDH)

In this technique glucose-1-dehydrogenase (GDH) converts glucose to gluconolactone using a coenzyme to convert nicotinamide adenine dinucleotide (NAD) to NADH (reduced form of NAD). The NADH concentration is measured which is proportional to the BG concentration. The NADH concentration can be measured using a photometric or amperometric technique. Newer POCGMDs use the coenzyme pyrroloquinoline quinone (PQQ) because of less sensitivity to ambient oxygen and electrochemical interference. [47]

Both these techniques based on GOX and GDH measurement have many limitations. The GOX method is extremely specific for BG concentration. Blood oxygen concentrations influence GOX devices, but not the GDH technique. [47, 48] When there are high levels of dissolved oxygen in the sample (e.g hyperoxia), oxygen is readily available for the GOX reaction and can cause an underestimation of blood glucose;

conversely, hypoxemia may falsely elevate GOX glucose measurements. The significance of the oxygen influence is relatively small compared to other potential interferences. Critically ill patient with circulatory shock may exhibit a significant difference caused by increased glucose extraction and poor tissue perfusion. Blood oxygenation significantly affects POCGMD glucose measurement techniques more with GOX and not with GDH. [47-49]

Table1: Various POCGMD their methodology

COMPANY	METHOD		RANGE (mg/dl)	INFORMATION
	Enzyme	analytical		
Roche				
AccuchekII	GOR	Photo		Discontinued
Accuchek adv	GDH	Amp	10-600	
Accuchekcompact plus	GDH	Amp	10-600	
Accuchek comfort	GDH	Amp		Discontinued
Acc trend	GDH	Amp		Glu/lac/TG
HemoCue (Cypress, California)	GDH	Photo		
Abbott/MediSense(Alameda, California)				
Precision QID	GDH	Amp	20-600	
Precision PCX	GDH	Amp	20-600	
FreeStyleFlash	GDH	Amp	20-500	
Optium	GDH	Amp	20-500	
Optium Xceed	GDH	Amp	20-500	
Bayer (Leverkusen, Germany)				
Elite XL	GOX	Amp	20-600	
Ascensia contour	GDH	Amp	20-500	
LifeScan (Milpitas, California)				
OneTouch II/Ultra	GOX	Photo	0-600	
SureStep Pro/Flex	GOX	Photo	0-500	
DDI Prodigy (Charlotte, North Carolina)	GDH	Amp		Voice controlled
Menarini GlucoMen PC (Berlin, Germany)	GOX	Amp	20-600	

GOR- glucose dye oxidoreductase mediator reaction; photo- photometric; amp- amperometrics

Although within the normal oxygen range values may not differ significantly but errors with GOX measurement techniques can be 15% or more when PaO2 (blood oxygen content) exceeds 100 mm Hg or falls below 44 mm Hg depending on the type of test strip and measurement method. [47, 50] GOX test strips using peroxide/meta [3-methyl 2 benzothiazoline hydrazine] N-sulfonyl benzene sulfonic acid (MBTH) are less vulnerable to oxygen presence than the GOX/ferrocene method. On the basis of a comparative analysis of several POC test strips by Tang and colleagues, [49] using ±15% of reference value from CLD as tolerated error, the GOX/ferrocene strips had the highest glucose measurements outside of the error tolerances (20.1–31.6%), while 14.3% of the GOX/MBTH measurements were outside of the set

limits. The impact of oxygen tension on accuracy worsened when blood glucose concentration fell below 100 mg/dl and the oxygen tension was above 100 mm Hg. Only one study investigated the influence of extremely low oxygen tension on POC glucose measurements and found that GOX-based techniques might be inaccurate at extremely low oxygen tensions (PO2 less than 20 mm Hg). [50] Although the impact of oxygen tension on the overall accuracy of POCGMD in the cited studies can be minimal, it is not negligible. Therefore, it has been recommended to minimize the oxygen tension effect on glucose testing variability by using oxygen-insensitive test methods in critically ill patients with PaO2 >100 mm Hg or patients with unpredictable blood PO2 levels. [49]

The GDH technique using PQQ also has limitations. The coenzyme NAD reacts with other sugars (e.g., maltose, galactose, mannose, xylose, and ribose) and detects them as glucose some other alternate techniques should be used when these other sugars are present. [51, 52] The Food and Drug Administration (FDA) issued a public health notification in 2009, secondary to a number of deaths, for the use of the GDH-PQQ glucose monitor because of the potential fatal error related to the interference of other sugars with this methodology. [53]

Drugs may interfere with both GOX and GDH glucose measurement methods, including but not limited to ascorbic acid and acetaminophen. [54, 55] The presence of high doses of ascorbic acid has the potential to read falsely low in GOX- and GDH-based devices. Acetaminophen, in therapeutic concentrations, results in lower and higher glucose measurements with the GOX and GDH POCGMD techniques, respectively. [51]

Central Laboratory Devices

Central laboratory devices (CLD) have higher accuracy as compared to the POCT devices. Studies assessing POCGMD accuracy often employ CLD comparison. Measurement techniques of CLDs vary by device type, and most frequently utilize either the GOX or, more commonly, the glucose hexokinase reaction to measure blood glucose concentration. According to a proficiency report surveying U.S. laboratories, the majority of CLDs use a hexokinase-based method, and the remaining facilities use GOX-based assays. Glucose hexokinase phosphorylates glucose to glucose-6-phosphate which is then oxidized by glucose-6-phosphate dehydrogenase using NAD as a cofactor. This results in production of NADH, and the concentration is measured with a spectrophotometer (absorption 340 nm) to determine BG concentration. [56]

Sample Source and Collection Site

Methodologies involved with the collection site and storage can significantly impact BG measurements. Glycolysis is typically not an issue for a POC measurement, but can cause falsely lower values in CLD results with delayed analysis. One should be aware of fact that at room temperature glucose is metabolized at the rate of 5-7% per hour this can cause falsely lower values in CLD results if there is delay in processing of the samples in CLD. [57] The serum POCGMD measurements typically involve whole blood samples with results usually internally converted to plasma values. Glucose concentrations are higher in the plasma than whole blood because the water content (and thus the glucose concentration) is higher in plasma than in

erythrocytes. The water content of the plasma can be affected by the concentration of other components. Hypertriglyceridemia and paraproteinemias decrease the water concentration in the whole blood sample, potentially causing a "pseudohypoglycemia," measured by POCGMDs. [58] Sample source also have a significant impact on glucose concentration measurements. The common sampling sites include arterial, venous, or capillary (e.g., finger tips, ear lobes, etc.). As a general rule, the highest concentration glucose by sampling site is artery the capillary, and then venous. [59] The patient's metabolic state alters in glucose concentrations between capillary and venous blood with insignificant differences in the absence of stress and fasting. In a critically ill patient, the presence of a hypermetabolic state and other stressors, including fasting, can cause significant differences between these values. [59, 60]

Quality control (Qc) checks for PoCT Systems

QC is an immediate check on the integrity of the PoCT device the operator should record the result and take appropriate action at the time of testing. There should be regular review of QC and EQA results as part of the cycle of quality improvement. Improper follow-up can be an area of weakness in PoCT, but it is an opportunity for laboratory professionals with expertise to provide such training to PoCT coordinators or for them to consult directly. [45] The global POCT field is in need of whole-blood standards, harmonization among methods, and improved QC. Granting these 3 wishes will facilitate common sense consistency among measurement procedures performed at the point of care and, in our opinion, will ultimately improve diagnoses, treatment decisions, and patient outcomes. [61]

The latest PoCT devices are more advanced as they have more sophisticated inbuilt quality checks present within the testing unit these inbuilt devices are called as on board QC, intelligent QC or as internal checks. [45] Most PoCT devices also feature processes by which the quality/reliability of signal generation is monitored (known as the electronic QC check). [62] As the consumers/users of PoCT devices are people who have a non-laboratory background the manufacturers recognized the need of inbuilt quality control checks, this has made the newer PoCT devices more simple to operate and also better controlled internally For example, the Abbott i-STAT cartridge has a calibration solution contained in a pouch in every cartridge and performs a calibration before each sample is tested. Inbuilt checks of the calibration fluid include its freedom from bubbles, its integrity during handling and its correct concentration. In Roche CoaguChek XS, every test strip has inbuilt control checks for strip deterioration due to exposure to excessive temperature and humidity (with the reduction of resazurin to resorufin, a highly fluorescent dye, correlating with the degree of strip damage). The Piccolo rotor quantifies interference and verifies chemistry, optics and electronics with every run. [45] The Abbott i-STAT has an electronic simulator which specifically measures electrical signal generation and ensures that these signals are within tight specification limits. [62]

These newer PoCT devices have an advanced level of connectivity with laboratory information system (LIS). They electronically capture and transmit results

to a central management point (a central data station and/or a clinical or laboratory information system), ensuring that post-analytical errors are minimized. [63] In the absence of global harmonization, the likelihood that a result may be misinterpreted and the patient may be misdiagnosed is increased because of different assays exhibiting nonequivalent analytical responses. A spectrum of different values may result from testing of the same specimen by different methods. Data reporting comparisons of global SRMs show an international bias resulting in noncomparable patient outcomes due to different field methods. Bias in measurements has also shown to impact medical decision making. [64, 65]

External quality assurance (EQA) programs in PoCT Devices

EQA programs are a part of a continuous quality assessment and improvement cycle these programmes are mandatory requirement for the medical laboratories as per International Organization for Standardization (ISO) standards. [63] The benefits of participation in EQA include an assessment of the accuracy of results against an assigned value, comparison with all instruments, peer comparison with the same instrument, assessment of performance over time, and providing confidence that the results reported on patients are correct. These benefits apply equally to PoCT. Therefore EQA is both desirable and required for PoCT devices. The requirement is reflected in the international standard, ISO 22870 'Point-of-care testing (POCT) - requirements for quality and competence', [66] and in The National Academy of Clinical Biochemistry 'Evidence-Based Practice for Point-of-Care Testing'. [67]

An alternative to formal EQA testing is 'split' or 'parallel' patient sample testing in which the same patient sample is tested by PoCT and by the laboratory. Potential advantages of split sample testing are: (a) like EQA, it provides a delayed external check of quality; (b) testing utilizes a sample of identical matrix (e.g. whole blood) to that of routine patient samples rather than a lyophilized EQA material; (c) it can be a cost-effective external assessment of quality; and (d) with samples equivalent to routine specimens, it can check the pre-analytical component of testing. However, potential drawbacks of split sample testing include: (a) testing only a limited range of concentrations vs EQA with its ability to test an analytical method across the range of concentrations seen in health and disease; (b) a lack of peer comparison; (c) the need to define appropriate acceptability criteria that recognize measurement uncertainty; and (d) problems associated with transport and delivery of patient samples to the laboratory from geographically isolated rural and remote locations. There is still a tendency at some PoCT sites, especially in hospitals, to consider that laboratory staff or the PoCT coordinator, for example a diabetes educator, should run the QC and EQA samples. The reasoning behind this can be time considerations or the desire to get the 'best' result. The ultimate purpose of these checks is to ensure that the quality of results will not compromise patient care – then it follows that the operator who is performing the testing should be the one performing the quality checks. Where there are multiple operators, all should be rotated through this process. [45]

Point-of-Care Glucose Monitoring Devices Accuracy

The impact of patient factors on POC glucose accuracy has been investigated by assessing POCGMDs during tight glycemic control for critically ill patients. The FDA MAUDE (Food and Drug Administration Manufacturer and User Facility Device Experience) database has been searched for reports related to glucose monitors, revealing 189 records for the year 2011. An inquiry of the FDA recall database indicated 30 recalls related to glucose monitors in the time frame 2004–2011. Based on the review of the databases mentioned earlier, the POCGMD technology is not always the cause of inaccuracy. Additional effects can come from sample sources, collection sites, and patient factors, and may include the glucose meter cleaning solution or the disinfectant wipe interfering with the measurement. [68, 69]

There are two ways to assess the accuracy of glucose measurement techniques: technical or clinical. Technical accuracy assesses the agreement between the measured and reference glucose values. Clinical accuracy judges how the differences in the measurements impact clinical decision processes. Both have clinical implications. [70] Traditional batch-based QC and EQA practices are not necessarily applicable to these systems as each testing unit is discrete and disposable, and checking the performance of a single testing unit does not guarantee with any certainty the quality of the next unit (unlike multi-use laboratory instruments). [45]

A review by Krouwer and Cembrowski66details the standards and statistical methods used to characterize accuracy of POCGMDs and highlight the different criteria acceptable for accuracy between standard organizations and professional societies (Table 2). In 1987, an American Diabetes Association (ADA) consensus statement recommended that the acceptable error for POCGMDs from all sources (user, analytical, etc.) should be less than 10% for glucoses ranging from 30 to 400 mg/dl at all times. [71] This ADA consensus statement also recommended that glucose measurements should not differ more than 15% from values obtained by a laboratory reference method. The ADA decreased the maximum allowable analytical error to <5% in 1996. [72, 73]

Table 2

Glucose range	ADA(1987)	ADA(1996)	FDA(1988)	ISO(15197) 2001
<100 mg/dl	<10%	±5%	±20mg/dl	At <75 mg/dl, 95% of measurements should be ±15 mg/dl; at >75 mg/dl, 95% of measurements should be ±20%
>100mg/dl	<10%	±5%	±20mg/dl	95% of measurements should agree with the reference method; the regression slope can only deviate by ±5%
	At 100% times	At 100% times	<100% of data	95% of data

The standards set by the ADA (ADA 1987/1996), requiring all glucose measurements with POCGMDs to be within 5% of CLD values, were deemed technically

unachievable by the International Federation of Clinical Chemistry and Laboratory Medicine. [57, 70]

Acceptable Performance Criteria

International Organization for Standardization (ISO) 15197 provided different recommendations in 2003. [74] These state that 95% of the individual glucose measurements compared to the reference measurements are required to be in the range ±15 mg/dl for values less than or equal to 75 mg/dl and ±20% for glucose values greater than 75 mg/dl. [74] This is the standard that the FDA normally uses as the goal for approval of POCGMDs. [57, 60] The ranges of error set by the technical standards and allowable error do not address the possibility that these errors might provide safety concerns for patients by decision-making being based on inaccurate glucose values. [57, 74]

Although the ADA and ISO guidelines have been published for over a decade, few POCGMDs meet these accuracy standards. Two examples of evaluations include [1] Sheffield and colleagues [75] studied four commercially available POCGMDs and reported that only two devices met ISO standard requirements and [2] Florkowski and colleagues [76] evaluated two POCGMDs, and although both passed ISO requirements, they failed to meet ADA 1996 recommendations.

One specific concern with POCGMDs is errors in the hypoglycemic range and the potential impact on clinical decision-making. When errors occur in the lower glucose ranges, it most commonly entails a report of a higher than actual blood glucose value. This can lead to a misdiagnosis of normoglycemia when in fact hypoglycemia exists; placing the patient at risk for neurological sequelae because of a failure of early recognition or aggressive treatment of hypoglycemia. [77-80, 83, 84] Because of the importance of accurate glucose values in the hypoglycemic range, Stork and colleagues [81] focused further evaluation of POCGMDs in these patients. While measurements in the normoglycemic range were acceptable, measurement accuracy decreased significantly in the hypoglycemic range. In neonates, POCGMDs for hypoglycemia screening did not have the required accuracy. [82, 85]

Although less frequent, POCGMDs can report a falsely low value. The error may result in treatment for hypo-glycemic when, in fact, normoglycemia actually exists; the hypoglycemia treatment with additional glucose may lead to hyperglycemia. These examples illustrate some of the limitations of current POCGMDs. The accuracy of POCGMDs in these studies rarely met ADA accuracy recommendations in the hypoglycemia range. These devices were originally designed for outpatient SMBG, not to accurately reflect hypoglycemia in hospitalized ward and critically ill patients, whose condition may mask signs and symptoms of hypoglycemia. [81]

Accuracy can be defined as the variation from the reference value. When assessing laboratory values for glucose, the testing method is accurate if the measurement is within acceptable error compared to the reference method. Within the range of hypoglycemia, if the values reported by the POCGMD are inaccurate (e.g., reported higher than actual values), this inaccuracy could lead to failure to recognize and treat life-threatening values or even more worrisome result in a different treatment (e.g., increasing insulin infusions) that could pose a serious patient safety risk. The

importance of accuracy for clinical treatment assesses whether the measurement value is within a range close enough to the actual value that the clinical approach to therapy remains the same. The current ADA device recommendations for SMBG with POCGMDs include the following: (a) achieve and maintain glycemic control, (b) prevent and detect hypo-glycemia, (c) avoid severe hyperglycemia, and (d) facilitate diabetes therapy adjustment to lifestyle changes (activity, diet changes, etc.). The accuracy requirements set by the professional organizations are still rarely met by POCGMDs. With outpatients and other hospitalized noncritically ill patients, most clinicians appear satisfied with POCGMD accuracy when glucose values avoid the extremes of hypoglycemia and hyperglycemia. This is because, in the range of normal glucose, the accuracy in this range is typically acceptable for clinical decision-making. For the care of critically ill patients, accuracy becomes more important as some of the early signs present with hypoglycemia and hyperglycemia may be difficult to detect in this patient population due to decreased mental status, sedatives, and other patient conditions. For optimal glucose control in high-demand states in critically ill patients, POCGMD technology has yet to provide a high enough degree of accuracy and reliability that leads to appropriate clinical decision-making. Continuous glucose monitoring devices based on invasive, minimally invasive, or noninvasive methodology are being developed to improve blood glucose monitoring. [86] Available technology, including future advances and current limitations, has been reviewed by Vaddiraju and colleagues. Development of a meter with accuracy equal to CLDs should continue to be the industry goal. [87]

Conclusion

Point of care testing is an important aspect of giving faster treatment to the patient by bringing the lab at patients bed side. There are many different parameters which can be done near the patient thereby providing an early diagnosis and facilitating prompt treatment. Diabetes one of the most common non communicable disease still continues to increase in our society with 12.9% of population in United States diagnosed with disease and 29.5% of population estimated to be living in prediabetic state. The most commonly used point of care device is the device used for blood glucose estimation. This device of initially brought into the market for self-monitoring of blood sugars in diabetic patients at home but due to its beneficial effects it made its way for the inpatients in emergency and for critically ill patients. There are many different types of glucose monitoring devices based on different principles are available in the market. The use of point of care glucose monitoring devices (POCGMD) has many advantages but the maximum use of these can be made only if our results are reliable i.e. they are accurate. For the results to be accurate the device has to be calibrated and regular quality control should be performed. QC is the immediate check on the integrity of the PoCT device. Apart from QC, EQA should also be performed regularly for accurate results. An alternate to formal EQA is split or parallel patient sample testing in which the same patient sample is tested by PoCT and by the laboratory

The glucometers should be regularly assessed for their accuracy both technically

as well as clinically. Various laboratories should follow the guidelines laid by American Diabetes Association (ADA) that recommended the acceptable error for POCGMDs from all sources (user, analytical, etc.) should be less than 5% for glucoses ranging from 30 to 400 mg/dl at all times. This ADA consensus statement also recommended that glucose measurements should not differ more than 15% from values obtained by a laboratory reference method. The ISO-15917 in 2003 provided different recommendations according to which 95% of the individual glucose measurements compared to the reference measurements are required to be in the range ±15 mg/dl for values less than or equal to 75 mg/dl and ±20% for glucose values greater than 75 mg/dl. This is also the standard that the FDA normally uses as the goal for approval of POCGMDs. The ranges of error set by the technical standards and allowable error do not address the possibility that these errors might provide safety concerns for patients by decision-making being based on inaccurate glucose values. Accuracy becomes more important in critically ill patients. The current ADA device recommendations for SMBG with POCGMDs include the following: (a) achieve and maintain glycemic control, (b) prevent and detect hypo-glycemia, (c) avoid severe hyperglycemia, and (d) facilitate diabetes therapy adjustment to lifestyle changes (activity, diet changes, etc.). Various professional organizations still rarely meet the accuracy requirements laid for POCGMDs. For the care of critically ill patients, accuracy becomes more important for the critically ill patients as early sign of hypoglycemia or hyperglycemia may be difficult to detect in this patient population due to decreased mental status, sedatives, and other patient conditions. Hence POCGMD technology is still not the test of choice in high demand states and is yet to provide a high enough degree of accuracy and reliability for appropriate clinical decision-making. Newer continuous glucose monitoring devices based on invasive, minimally invasive, or on noninvasive methodology are being developed to improve blood glucose monitoring. Our future in POCGMD for better patient care and prompt treatment still depends on the development of an advanced glucometer with inbuilt QC, calibration and results comparable with the central laboratory devices

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