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# User competency is still a major factor affecting analytical performance of glucose meters in patient service

Yun Huang[a,*], Edward Campbell[b], Bonita Colbourne[b], Jeanette Power[b], Edward Randell[b,c]

[a] Kingston General Hospital, Department of Pathology and Molecular Medicine, Queen's University, 76 Stuart Street, Kingston, ON, Canada
[b] Discipline of Laboratory Medicine, Eastern Health Authority, St. John's, NL, Canada
[c] Faculty of Medicine, Memorial University of Newfoundland, 300 Prince Philip Dr., St. John's, NL, Canada

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ABSTRACT

*Objectives:* This study investigated the analytical performance of glucose meters while in use for 1.5 years in a hospital setting. The effect of user competency, strip stability and strip lot number variation on the performance of blood glucose meters was investigated.

*Design and methods:* The studies for linearity, accuracy, imprecision, and method comparison were conducted according to Clinical and Laboratory Standards Institute (CLSI) guidelines Point of Care Testing (POCT) 12-A3. Proficiency testing results were used for meter-meter comparison. Quality control (QC) data, strip lot and users' identification were extracted from the data management system 1.5 years after the new systems were implemented. The frequency of users QC testing was used as the indicator of user competency.

*Results:* The average total imprecision based on 20 glucose meters with QC materials targeting 2.5 mmol/L and 17.05 mmol/L increased by 2.4 fold and 1.83 fold, respectively, over that from initial evaluation studies. When the glucose levels were < 5.6 mmol/L, the absolute bias ranged from −0.75 to +0.55 mmol/L relative to the core laboratory analyzer and the accuracy goal was met by 96.3% of samples. When the glucose levels were ≥5.6 mmol/L, the percentage bias ranged from −17.8% to +9.4% and 79.3% of samples met the accuracy goal. The users who performed QC checks less frequently (< 10 times/year) showed significantly different QC mean and greater variation than users who performed QC checks > 20 times/year, especially for QC targeting 2.5 mmol/L.

*Conclusions:* Poorer analytical imprecision of POCT blood glucose meters following introduction to patient service is mainly due to the low level of user competency.

## 1. Introduction

Point of care testing (POCT) blood glucose meters are used widely at the patient bedside for quantitative measurement of glucose for monitoring the effectiveness of glycemic control. The analytical performance of blood glucose meters can impact patient management and especially the insulin dosage given to patients [1–3]. Before new glucose meters are implemented into patient service, comprehensive studies to assess linearity, imprecision and accuracy are conducted to verify acceptable analytical performance. This initial verification process is usually performed by a small number of laboratory technologists using test strips or other materials that are usually of a single lot number. In patient service, glucose meters are operated by a large number of non-laboratory professionals using different lot numbers of strips stored at multiple sites and potentially different conditions. This creates significant challenges to maintain acceptable analytical performance of glucose meters.

User competency is an important potential source of error in POCT [4]. Lack of competency during sample collection and handling results in higher pre-analytical error rates by POCT compared with core lab testing [5]. In three adult critical care units, differences in quality of test results were observed using identical analyzer systems (blood gas analyzers) depending on the organization of the intensive care units (ICUs), but bias was reduced by focusing quality management efforts on pre-analytical processes [6]. Effective interventions included defining the upper time limit for the pre-analytical phase according to existing guidelines and local constraints; using technology to standardize mixing of blood samples; and implementing a short checklist to confirm user competency during each testing step.

Altitude, temperature, and humidity are common factors that affect

* Corresponding author at: Kingston General Hospital, 76 Stuart Street, Kingston, ON K7L 2V7, Canada.
*E-mail address:* yun.huang@kingstonhsc.ca (Y. Huang).

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the measurement made by glucose meters. The enzymes on the strip can be inactivated at temperature extremes. Exposure to humidity can prematurely rehydrate the enzyme and limit its reactivity when the strip is utilized for patient testing [7]. In the hospital setting, in order to avoid frequent change of strip lots a large number of sequestered strips are usually ordered for use up to one year. The stability of the strips in long term storage at various sites is monitored as part of the quality management program for glucose meters.

As with core laboratory testing there is often lot-to lot variation of test strips on glucose results, which affects the accuracy of patient testing [8]. Between-lot variation of test strip is also known to influence external quality assurance (EQA) results and method assessments [9]. The size of variation is manufacturer and lot dependent, therefore verifying each new lot of strips before use is necessary.

New blood glucose meters were implemented in our city hospitals in 2015 and managed under a quality management system since then. An initial comprehensive evaluation was conducted on representative meters following the protocols and standards recommended by CLSI guidelines POCT 12-A3 [10]. This evaluation demonstrated that the analytical performance of the new glucose meters met requirements proposed in CLSI guidelines. In this study we investigated if the analytical performance of blood glucose meters is maintained once placed into patient service at 1.5 years afterward. We also investigated the effect of user competency, strip stability and strip lot number change on the performance of blood glucose meters. The results provide information important to quality assurance and quality improvement of POCT programs involving use of blood glucose meters.

## 2. Method and design

### 2.1. Glucose meter and measuring principle

In May of 2015, ACCU-CHEK Inform II glucose meters (Roche Diagnostics) were implemented into two city hospitals, the Health Sciences Centre (a 346-bed tertiary care centre) and St. Clare's Mercy Hospital (a 201-bed tertiary care centre), both located in St. John's, Newfoundland. The enzyme on the test strip was a mutant variant of quinoprotein glucose dehydrogenase that converts glucose in blood samples to gluconolactone. This reaction creates a direct electrical current by a patented electrochemical method that is proportional to blood glucose concentration in the sample, and measures glucose in the range of 0.6–33.3 mmol/L.

### 2.2. Data management system

All glucose meters were connected to a manufacturer provided data management system (Cobas IT; Roche Diagnostics). The results of linearity and accuracy assessments, quality control testing and proficiency testing were recorded in the system for data extraction and analysis. The glucose meter strip lot number, expiration date and users' identification were also recorded in the data management system.

### 2.3. Accuracy standards of glucose meter

Analytical specifications based on CLSI POCT12-A3 were adopted, including total allowable error of ± 0.67 mmol/L for blood glucose concentration < 5.6 mmol/L, and total allowable error of ± 12.5% when blood glucose concentrations were ≥5.6 mmol/L. The error budgets for random and systematic error were both set at 25% of the total allowable error, which generated the allowable random error and allowable systematic error of 0.168 mmol/L for glucose < 5.6 mmol/L and 3.13% for glucose ≥5.6 mmol/L.

### 2.4. Linearity and accuracy

Linearity was determined using kits obtained from the manufacturer containing six levels of glucose material with assigned levels ranging from 1.6 to 31.0 mmol/L. Each level of glucose material was tested four times on each glucose meter. Twenty glucose meters (not the same meters as those tested in the initial validation) were tested at 1.5 years after implementation by a limited number (< 3) of laboratory technologists. Accuracy was determined by the absolute bias (mmol/L) between the average of measured results and assigned values for level 1 and level 2 (1.6 mmol/L and 2.5 mmol/L), and by bias (%) for level 3, 4, 5 and 6 (6.5, 17.0, 28.4 and 31.0 mmol/L) of the linearity specimens provided.

### 2.5. Precision

Two levels of quality control (QC) (assigned value: 2.5 mmol/L with range 1.7–3.3 mmol/L and 17.05 mmol/L with range 14.5–19.6 mmol/L) provided by the manufacturer were tested on each glucose meter every 24 h while in service and by different end users (3795 different users according to records in the data management system for city hospitals in 2017). The QC test results from analyses performed on 20 meters, with > 200 QC data points collected in 2017, were extracted from the data management system for analysis.

### 2.6. Method comparison

Each month two different glucose meters were used for meter to core laboratory chemistry analyzer comparisons. This was performed involving two to three laboratory technologists. Randomly, five different patient whole blood samples were measured on two glucose meters. Plasma was promptly prepared within 5 min and measured on the core laboratory chemistry analyzers (any one of five Abbott, Architect c8200i analyzers) for method comparison.

### 2.7. Meter-meter comparison

An external Quality Assessment (EQA) program, run by the Institute for Quality Management in Healthcare (IQMH), was used for monitoring the performance of glucose meters; the results also reflected the variation between glucose meters. Two surveys with three samples in each survey were tested in 2017 on 238 meters (survey 1 on 124 meters, survey 2 on 114 meters) and involved different end users for each survey and meter.

### 2.8. Statistical analysis

The linearity and accuracy of glucose meter were analyzed in the EP Evaluator (Data Innovation, EE 12.0). The calculation of the average/mean and variation of the data were performed by using Excel software (Microsoft, 2013). Statistically significant differences between groups of data were determined by the Student *t*-test in Excel. Statistical significance was determined at $p < 0.05$.

## 3. Results

Results from the initial evaluation of the blood glucose meters are provided as supplementary data.

### 3.1. Analytical performance of glucose meter in patient service

The linearity of all 20 blood glucose meters examined following 1.5 years in service was maintained. The systematical error for the 20 meters ranged from 0.4–1.7% with an average of 0.96%, meeting the allowable systematic error (3.13%) target.

The proportion of glucose meters meeting the accuracy goals of systematic error were 95%, 90%, 50%, 45%, 55% and 60% for levels at 1.6, 2.5, 6.5, 17.0, 28.4 and 31.0 mmo/L, respectively.

Total imprecision (SD) at a target mean of 2.5 mmol/L ranged from

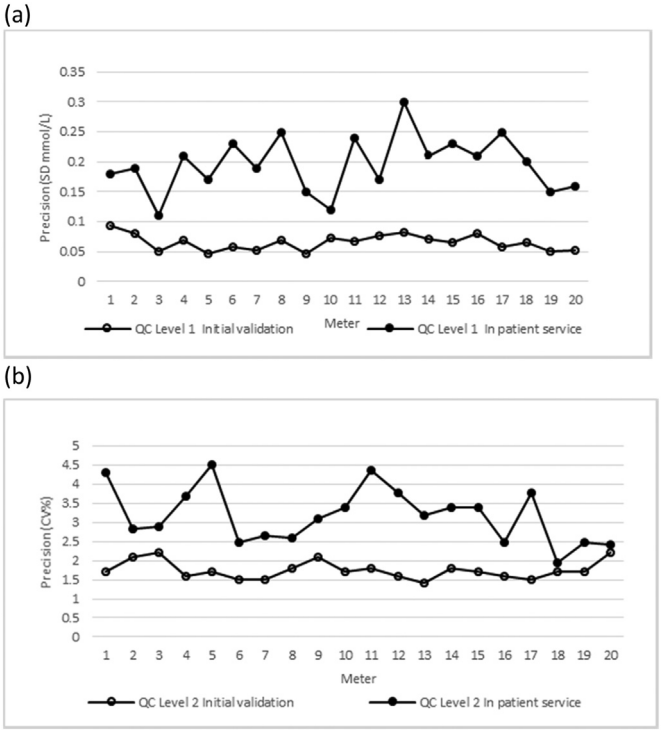


**Fig. 1.** Total imprecision of glucose meters in patient service used by different users. Total imprecision of QC level 1 on 20 glucose meters used in patient service comparing to initial evaluation. (b) Total imprecision of QC level 2 on 20 glucose meters used in patient service comparing to initial evaluation. Note: The 20 meters in patient service were not exactly the same 20 meters in the initial evaluation.

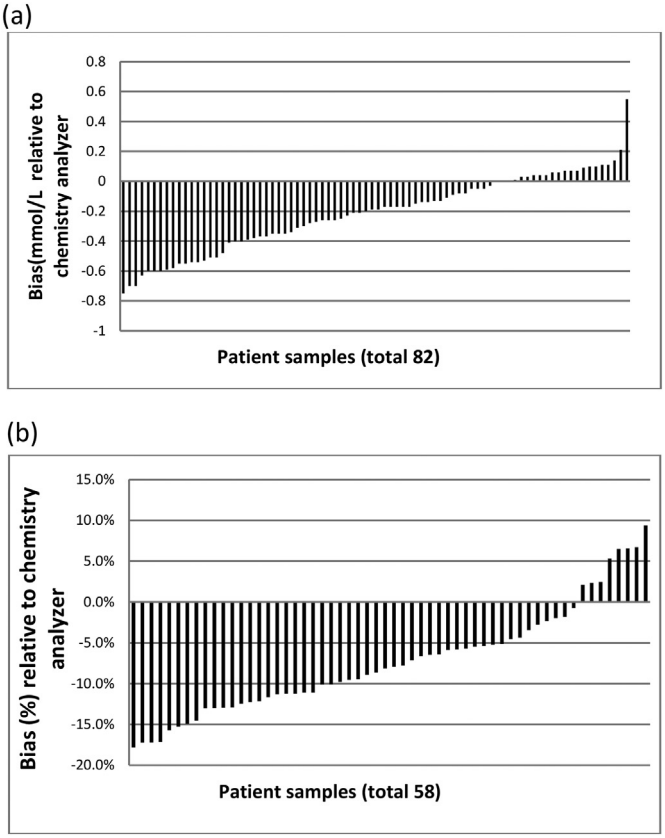


**Fig. 2.** Bias between glucose meter in patient service and core lab chemistry analyzer. Bias (mmol/L) when glucose is < 5.6 mmol/L, (b) Bias % when glucose is ≥5.6 mmol/L.

0.11 to 0.3 mmol/L based on 209 to 388 data points, on the 20 meters. Total imprecision (CV%) at a target mean of 17.05 mmol/L ranged from 1.94–4.52% based on 179–381 data points. These represented increases of 2.4 fold and 1.83 fold for low and high concentration QC samples, respectively, when compared with results from the initial evaluation studies (Fig. 1). The total imprecision of the low concentration QC sample on 15 meters, the high concentration QC sample on 10 meters failed to meet the random error goals, compared with all 20 meters meeting the random allowable error goal during the initial evaluation.

Method comparison between the glucose meter and core laboratory chemistry analyzers was conducted, involving 140 data points from 28 meter to core laboratory glucose comparisons performed by laboratory technologists. The glucose concentrations ranged from 1.3 to 27.6 mmol/L with 82 results < 5.6 mmol/L and 58 samples ≥5.6 mmol/L. The absolute bias ranged from −0.75 to +0.55 mmol/L for glucose concentrations < 5.6 mmol/L, with 96.3% of samples meeting the accuracy requirement (absolute bias < 0.67 mmol/L). The percentage bias ranged from −17.8% to +9.4% for glucose concentrations ≥5.6 mmol/L, with 79.3% of samples meeting the accuracy requirement (< 12.5%) (**Fig. 2**). However, 100% of results were within ± 0.8 mmol/L for glucose < 4.2 mmol/L or ± 20% for glucose ≥4.2 mmol/L, required by a second criteria of CLSI guidelines [10].

The glucose results on 238 glucose meters from two PT surveys were compared to survey targets. Only two out of 714 (0.28%) results fell outside of acceptable limits (20% for all methods for glucose > 5 mmol/L, or 1 mmol/L for glucose ≤5 mmol/L). For samples with glucose concentrations < 5.6 mmol/L, 99.2% of blood glucose meter results met the accuracy requirement ( ± 0.67 mmol/L). For samples with glucose concentrations ≥5.6 mmol/L, 99.2% of results met the accuracy requirement ( ± 12.5%). The variation across blood glucose meters for the six samples were 2.3%, 2.3%, 2.0%, 3.4%, 4.0% and 3.3%, for 5.3, 8.2 and 11.9 mmol/L samples in survey 1, and 10.3, 3.5 and 6.6 mmol/L samples in survey 2, respectively.

### 3.2. The factors that influence the analytical performance of glucose meter in patient service

#### 3.2.1. QC testing frequency performed by users

In an investigation of factors influencing the analytical performance of blood glucose meters in patient service the frequency of QC tests performed by users was examined. A total of 59439 QC level 1 (targeted at 2.5 mmol/L)and 58569 QC level 3 (targeted at 17.05 mmol/L) were performed in one year with QC test frequency at 1–240 and 1–242 times respectively. Fig. 3 shows the association between the number of QC testing performed by the users and their QC results. Greater variation in QC results was observed when fewer QC testing were performed by the users. For the low concentration control, 582 (17.8%) of users showed QC variation greater than the allowable random error target. For the high concentration control, 783 (23.9%) of users showed QC variation greater than allowable random error. Table 1 shows the summary of QC performance based on the frequency of QC testing performed by the users. Those who performed QC testing infrequently (≤10 times/year) had significantly different QC mean and greater QC imprecision than the users who performed QC testing (> 20 times/year), especially for the low concentration QC sample. When the users performed QC up to 20 times/year, the QC mean and variation was not significantly different with the users performed QC 30 or 40 times/year, but was significantly different with the users who performed QC > 40 times/year.

#### 3.2.2. Lot variation of test strips

Also test strip lot variation was examined in the investigation of factors influencing the analytical performance of blood glucose meters in patient service. Three different lots of test strips were used during the

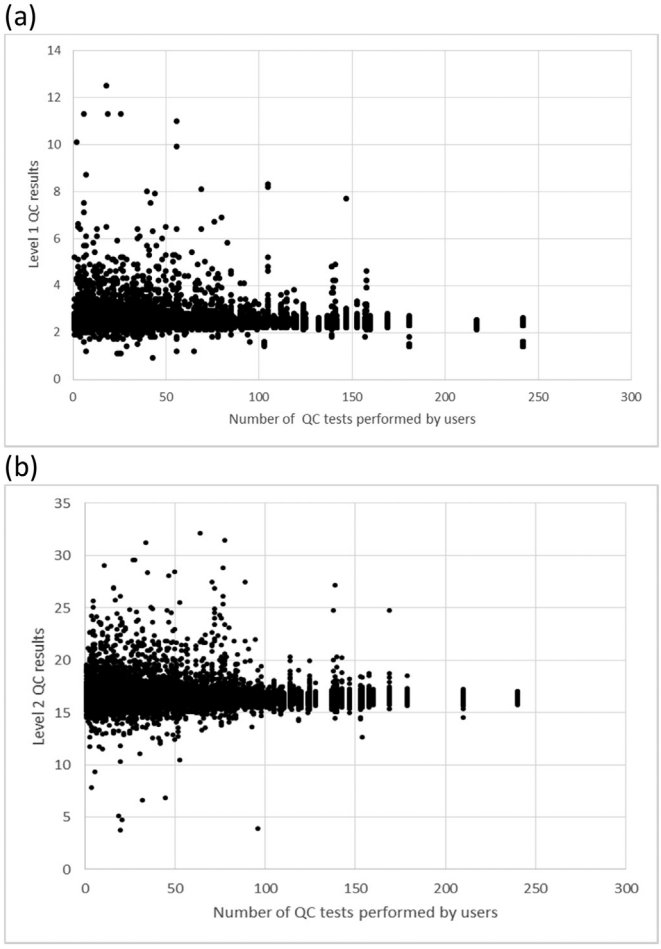


**Fig. 3.** Users' QC variation was associated with users' QC testing frequency. (a) QC level 1, (b) QC level 2.

**Table 1**
Infrequent QC testing of users had poorer QC performance on glucose meter.

| Users' QC testing frequency | QC level 1 | | QC level 2 | |
|---|---|---|---|---|
| | QC number | QC mean (mean ± SD) | User number | QC average (mean ± SD) |
| ~10 QC/year | 8945 | 2.420 ± 0.263 | 8922 | 16.40 ± 0.651 |
| ~20 QC/year | 9690 | 2.415 ± 0.234 | 9599 | 16.41 ± 0.638 |
| ~30 QC/year | 8854 | 2.409 ± 0.200* | 9016 | 16.41 ± 0.600 |
| ~40 QC/year | 7198 | 2.416 ± 0.203* | 7021 | 16.41 ± 0.613 |
| > 40 QC/year | 24,761 | 2.400 ± 0.228*,# | 24,011 | 16.40 ± 0.614 |

Variation for QC level 1 was presented as SD mmol/L, variation for QC level 2 was presented as CV %. Compared to group ~10 QC/year, *$p < 0.01$, compared to group ~20 QC/year, #$p < 0.01$.

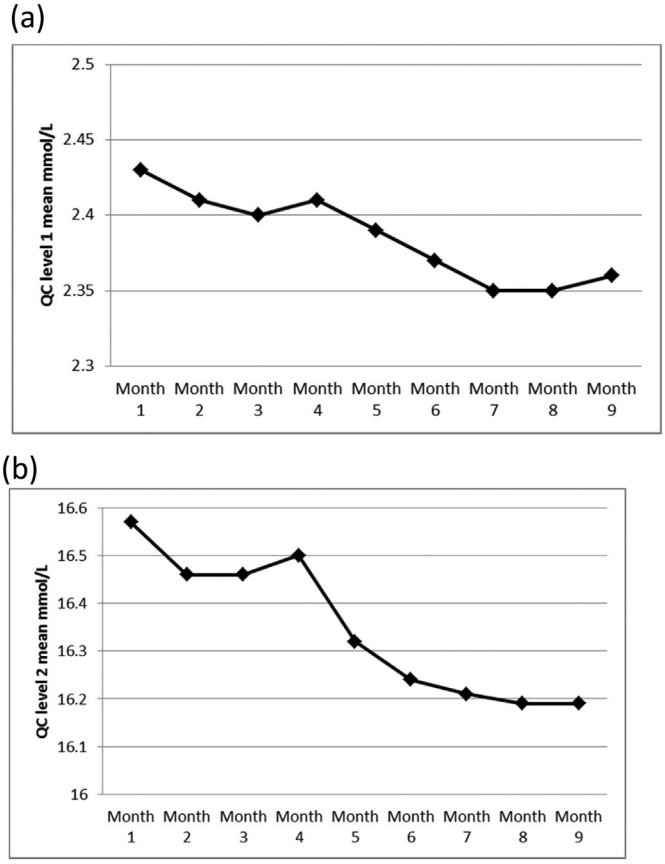


**Fig. 4.** Change in monthly mean QC value for level 1 (a) and level 2 (b) within one lot number of test strip. The monthly QC mean was monitored over a 9 month period.

interval between implementation of the new glucose meters and 1.5 years afterward. The QC mean of low and high concentration QC samples in the first three months of use of each lot number from all meters at the city hospitals was compared. There was no significant shift in the means for the three lots for either level of QC during the three month time periods. The difference between the QC means of the lots fell within acceptable limits for systematic allowable error (Table 2).

### 3.2.3. *Stability of test strips*

Finally the long term stability of test strips was examined. A sequestered strip lot was ordered and stored at multiple hospital sites, based on the manufacturer's instructions. The stability of the strip was monitored by monthly comparing the mean of each level of QC on all meters at the city hospitals. For one lot of strips which was used for 9 months, a minor decrease in QC mean at both levels was observed

**Table 2**
The effect of lot variation of glucose test strips on QC mean.

| | Lot 1 | | | Lot 2 | | | Lot 3 | | |
|---|---|---|---|---|---|---|---|---|---|
| | Month 1 | Month 2 | Month3 | Month 1 | Month 2 | Month3 | Month 1 | Month 2 | Month3 |
| QC Level 1 | | | | | | | | | |
| QC Number | 3680 | 3651 | 3627 | 4323 | 4295 | 4329 | 4241 | 4247 | 4303 |
| QC Mean | 2.47 | 2.46 | 2.45 | 2.43 | 2.41 | 2.4 | 2.44 | 2.44 | 2.42 |
| QC Level 2 | | | | | | | | | |
| QC Number | 3615 | 3576 | 3615 | 4266 | 4226 | 4255 | 4194 | 4161 | 4267 |
| QC Mean | 16.83 | 16.79 | 16.71 | 16.57 | 16.46 | 16.46 | 16.55 | 16.55 | 16.47 |

QC range level 1: 1.7–3.3 mmol/L, Level 2: 14.5–19.6 mmol/L.

over time (Fig. 4). The differences between the monthly means were also within acceptable systematic allowable error. Compared to the first month, the maximum decrease of QC mean in the following month was 0.08 mmol/L for QC level 1 and 0.36 mmol/L (2.29%) for QC level 2.

## 4. Discussion

The analytical performance of glucose meters during periods of use in patient service was evaluated by examination of linearity, accuracy, imprecision, method comparison and meter-meter comparison at 1.5 years following initial implementation of new blood glucose meters. Results for linearity and accuracy by meter to meter comparison were maintained within acceptable limits. But the blood glucose meter performance for accuracy, imprecision and method comparison against the core laboratory chemistry analyzer was poorer in the follow-up evaluations compared to the initial evaluations, and meters did not consistently meet the accuracy goals. User competency remains a major factor contributing to the poorer analytical performance of meters. Fewer number of QC tests performed by the user was associated with greater QC imprecision for that user. However, variation across glucose measurements relative to changes in strip lot number and strip stability fell within acceptable limits.

During the initial evaluation, the linearity, accuracy, imprecision of the glucose meters, meter to meter comparison and method comparison performed well within targets established by CLSI guidelines. This demonstrated that analytical performance of glucose meters has greatly improved over the years [11,12], and more stringent accuracy standards for POCT blood glucose monitoring seems feasible.

After 1.5 years in service linearity of the blood glucose meters still met requirements for acceptable systematic error, but the percentage bias for 4 linearity materials with glucose ≥5.6 mmol/L did not meet the 25% error budget assigned, although all fell within a 50% of total allowable error budget. The accuracy study for meters in patient service was also performed by laboratory technologists. However, different lots of linearity material and strips were used during the initial evaluation compared with later evaluation, which might result in the difference in accuracy of glucose meters. There is no standard reference material available for this purpose.

The total imprecision of the blood glucose meters were calculated using QC data generated by 20 glucose meters being used by a large number of different users. Imprecision increased 2.4 fold, and 1.83 fold for low and high concentration QC materials, respectively, compared to the initial evaluation. During follow-up investigations, the imprecision of the low concentration QC material on 15 meters and the high concentration QC material on 10 meters failed to meet the targets for allowable random error. Blood glucose meters were used by about 4000 different users in our hospitals. Although user competency is a well know factor contributing to the imprecision of glucose meters, there is no effective approach established to improve the competency. We hypothesized that user competency related to frequency of use may account for the greater imprecision. In Phillipou's study (1990) 12,500 QC tests were performed by approximately 200 accredited users, the results showed marked variation between wards, and with the frequency of patient testing being the major factor influencing test reliability [13]. In our study the QC results and number of QC samples tested by each user was extracted from the data management system, the QC performance based on users' QC frequency was calculated. The results showed that users who performed a greater number of QC tests had lower imprecision than those performing fewer QC tests. Users who tested < 10 QC per year had the highest rates of QC variation which was also significantly higher than users who tested more QC. After the users performed QC > 10 times per year their QC performance started to become stable. The results indicated that user competency is still a significant factor affecting analytical performance of glucose meters with advanced technology in patient service. There is no detailed guideline available in determining user competency over the long term. At our sites, users are required to test two levels of QC and 2 patient samples annually as a minimum to confirm maintenance of competence, which might be inadequate to maintain the competency for using glucose meter. The results of this study suggest that more rigid protocols than this are required to increase the level of user competency to ensure patient safety.

A method comparison between the glucose meter and core laboratory chemistry analyzer was conducted monthly using different glucose meters but compared with the same model of chemistry analyzer. For glucose concentration < 5.6 mmol/L, 96.3% of samples met the accuracy standard, while for glucose concentration ≥ 5.6 mmol/L, only 79.3% of samples met the ± 12.5% standard, but all comparisons met the less rigid ± 20% standard. Many factors contribute to the discordance of glucose measurements between a blood glucose meter and core laboratory analyzer. In this study, the comparison was conducted by laboratory technologists who are highly experienced with POCT following standard protocols, and involving steps to minimize glycolysis in the whole blood sample. However medications, pH changes, oxygen concentration or hematocrit, all can potentially interfere with the measurement of blood glucose by glucose meters [7,14,15]. In this study, leftover patient samples were randomly selected for the meter to core laboratory analyzer comparison. It is possible that administered medications and pathological changes might interfere with the glucose measurement obtained by one method more than another in certain patients.

The comparable performance between glucose meters in the same hospital setting is important for standard patient management. Glucose meter to meter variation was evaluated during the initial evaluation study with patient samples and by use of proficiency testing (PT) samples on glucose meters in patient service. The meter to meter comparisons were consistently acceptable. In PT, the result from each meter was compared with the peer mean using the same methodology. The meter performance fell within acceptable limits determined by the EQA Program in most cases. Only 0.28% of PT results exceeded the EQA limits, which was smaller than the 0.53% unacceptable rate in a summary from the EQA program during 2009–2011 [16]. The glucose meter performance also met our accuracy standards in 99.2% of cases at < 5.6 mmol/L or ≥ 5.6 mmol/L. All PT samples were tested by non-laboratory staff users, however; only a small proportion of users (238 in total 3796) did proficiency testing. The most frequent reason for failed PT challenge involves using the wrong PT sample, sample mix-up on the bench and transcription error [16]. The two failed results from our meters might be due to random error at sample preparation, since only one of three samples failed on two different meters. Also, glucose meter variation for 6 PT samples ranged from 2.0% to 4.0%, all of them were below the median method variation in the summary for EQA program [16].

The effect of stability and lot variation of test strips on the QC mean was also evaluated in this study and found to be acceptable. This suggests that improper storage of the test strips was not a major issue in our hospital and accounting for greater result variability.

There are other limitations to this study. We used the number of QC tests that were performed by the users and their QC variation (imprecision) as a measure of user competency. However, while we expect an association between the number of QC tests performed by users and the number of patient tests performed, we have not confirmed this. Nursing staff frequently working at night shifts or on busy units may not have great opportunity to perform the QC tests. Also, the comparison between the initial evaluation and in patient service did not involve the same glucose meters which may contribute to differences in some parameters before versus after implementation, but does not impact the main conclusions of this work. Moreover, the comparative method we used was glucose measurement on a laboratory chemistry analyzer instead of reference method. Hence, the accuracy determined in this report is a relative accuracy only.

In conclusion, this study comprehensively evaluated the analytical

performance of blood glucose meters used in patient service as POCT devices for about 1.5 years after implementation with analysis of large amounts of data extracted from the data management system. Meter variation, strip lot number variation and long term stability of strips had limited negative influence on the accuracy of glucose meter results for the devices examined. Compared to the initial evaluation prior to implementation, the analytical performance of the POCT glucose meter showed diminished performance relative to imprecision following introduction into patient service due to the low level of user competency in the hospital setting. With technological advances in glucose meters, with use of more modern meters in patient service, and under careful monitoring supported by a quality management system, it is likely still an outstanding issue. Establishing more rigorous criteria for maintenance of adequate competency especially for relatively infrequent users of the device may be required in order to improve the quality of service and ensure patient safety.

## Declaration of conflicting interests

The authors declared no potential conflicts of interest with respect to the research, authorship, or publication of this article.

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## Appendix A. Supplementary data

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