Precision performance and error types observed in the point-of-care glucose testing: an external quality assessment program perspective

Berna Aslan¹, Julia Stemp¹, Paul Yip², Jane Gun-Munro¹
¹Quality Management Program—Laboratory Services/Institute for Quality Management in Healthcare, Toronto, Ontario, Canada; ²University of Toronto and University Health Network, Department of Laboratory Medicine and Pathobiology, Toronto, Ontario, Canada

ABSTRACT

Background: Point-of-care (POC) glucose tests offer opportunities for decreased test turnaround times and sample volumes. However, quality assurance of POC testing is challenging for many institutions and little data is available on associated errors. This study is aimed to describe precision performance, error rates and causes that occurred in Quality Management Program—Laboratory Services (QMP-LS) POC glucose proficiency testing (PT) data in comparison with laboratory glucose surveys.

Methods: Data from Ontario hospitals were assessed on 51839 POC glucose results from 174 institutions in 21 PT surveys and laboratory glucose data on 2601 results from 175 institutions in 6 PT surveys over 21 months between September 2009 and June 2011. Commercially-prepared bovine plasma products and fresh human serum samples were used at PT material in POC and laboratory glucose surveys, respectively. Peer group means and CVs were estimated using the ISO recommended robust algorithm. Allowable performance limits (APLs) for POC glucose were ±1 mmol/L ≤5 mmol/L or ±2% if >5 mmol/L, and for laboratory glucose ±9% if ≤4 mmol/L or ±7.5% if >4 mmol/L. Laboratories with current flags and large deviations from the assigned value were required to submit investigations to report the causes of the flags.

Results: The median of the POC glucose peer group CVs (4.5%; range 0.8%–14.5%) was higher than the median CV obtained in laboratory glucose peer groups (1.6%; range 0.6%–3.2%) at glucose concentrations of 4.6–17.9 mmol/L, based on a total of 166 and 179 assessments by peer group in the POC and laboratory glucose surveys, respectively. The median of the number of participants in the POC and laboratory glucose peer groups were 14 and nine, respectively. All reported laboratory glucose results were within the acceptable limits and no flags occurred except the tighter APLs used. However, 350 (0.6%) results exceeded APLs in the POC glucose survey, investigations from 277 (0.5%) results reported pre- and post-analytical errors that accounted for 77% of the discordant findings. Using wrong PT items, sample mix-up at the time of testing, and reporting results for wrong samples were the most frequent reasons, while 28% of discordant findings identified manufacture issues, and 3% were of unknown origin. Laboratories with glucose APLs were applied to POC glucose results, 488 (1.3%) results would have been flagged.

Conclusions: POC glucose tests vastly outnumbered any errors associated with laboratory glucose measurements. Additionally, the high imprecision reflects the looser performance criteria permitted for POC glucose testing and its impact on laboratory reference values. Although this study is based on PT samples and inter-laboratory data, the findings could approximate the various errors encountered within hospitals when testing patients. In order to decrease pre- and post-analytical errors that are frequent in POC testing, greater attention is needed in the training of personnel and taking precautions to prevent transcription errors. Lastly, tighter analytical requirements for glucose meters are needed to serve hospital patients especially when POC results are used interchangeably with laboratory values.

INTRODUCTION

POC testing is a rapidly developing division of the diagnostic laboratory sector. This technology has increased the accessibility to laboratory tests, decreased test turnaround times (TAT) and allowed the use of lower sample volumes. Because of these advantages, POC testing has become a method of choice in primary care, home care, and locations where access to laboratory services is limited. Additional hospital areas include emergency departments (ED) and intensive care units (ICU) where TAT has vital importance, and in neonatal ICU and pediatric wards where low sample volumes and timely results are crucial. In spite of the frequent use of glucose testing in hospital settings, its quality assurance is still challenging for many institutions. In this study, we investigated the precision of POC glucose methods and causes of errors that have occurred in the QMP-LS POC proficiency testing glucose program.

METHODS AND MATERIALS

Participants: POC glucose and laboratory glucose PT data obtained between September 2009 and June 2011 were assessed from laboratory participants. QMP-LS is a mandatory PT and accreditation provider in Ontario, Canada. The QMP-LS accreditation standard (OLA 151/189)¹ is based on ISO 15189 and ISO 22870:2009 that contain general medical laboratory and POC testing requirements, respectively. All participants in the POC and the laboratory glucose surveys included in this study were accredited laboratories and all POC testing devices in the facilities were managed by the laboratory regardless of the location of the devices within each institution.

Survey materials: Commercially-prepared bovine plasma products (Eurolab WB Glucose, Ede, Netherlands) and pooled human serum samples were used as PT items in the POC and laboratory glucose surveys, respectively.

Statistical methods: Peer group means and CVs were estimated using the robust algorithm recommended in ISO 13528 (±). This non-parametric statistical algorithm minimizes the effects of the outliers on peer group mean, standard deviation and CV. Peer group means are used as assigned values in the QMP-LS POC glucose and laboratory glucose PT surveys, respectively. For this study, laboratory glucose data reassessed using peer group means as assigned values in order to make both evaluations comparable.

RESULTS

The number of institutions participating in POC, glucose surveys ranged between 189–194, and the number of glucose meters used in each institution varied from 1–149. Each POC survey included up to 17 different devices among users. During the study period four PT surveys, including 12 survey challenges, were dispatched and 51379 POC glucose results were assessed in 166 peer groups. For laboratory glucose, a total of 163–179 laboratories participated in six PT surveys comprised of 16 PT samples that were tested on 19 different laboratory instruments. The number of participants, glucose concentration of the survey materials and median of the CVs obtained in each peer group are summarized in Table 2.

Peer group CVs in POC glucose were higher than laboratory glucose CVs at the concentration range of 4.6–17.9 mmol/L, and the difference between groups was statistically significant (p<0.001) (Table 2). Ninety-five per cent of the POC glucose peer group CVs were below 10%, while 95% of laboratory glucose peer group CVs were less than 2.6% (Table 2, Figure 1). Three hundred and five (0.58%) results exceeded the allowable performance limits (±1 mmol/L for ≤5 mmol/L, or ±2% if >5 mmol/L) across the POC glucose surveys. Discordant findings forms were submitted for 277 (0.51%) results. Causes of discordant results are summarized in Figure 2.

CONCLUSIONS

The number of errors observed in POC surveys was drastically higher than errors associated with laboratory glucose measurements. Not surprisingly, imprecision was higher in POC glucose measurement compared to laboratory glucose since the design and intended use of glucose meters cannot match laboratory analyzers in the current state of the art. Also, the observed imprecision is likely a manifestation of looser performance criteria allowed for POC testing.

Although this study is based on PT samples and inter-laboratory data, the findings could approximate the various errors encountered within hospitals when testing patients. In order to decrease pre- and post-analytical errors that are frequent in POC testing, greater attention is needed in the training of personnel and taking precautions to prevent transcription errors, such as connectivity between data management systems. Lastly, tighter analytical requirements for glucose meters are needed to serve hospital patients especially when POC results are used interchangeably with laboratory values.

Table 1. QMP-LS Allowable Performance Limits for Laboratory and POC Glucose Testing

<table>
<thead>
<tr>
<th>Methodology</th>
<th>Allowable Performance Limits</th>
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</thead>
<tbody>
<tr>
<td>Laboratory Glucose</td>
<td>±9% ≤4 mmol/L</td>
</tr>
<tr>
<td></td>
<td>±7.5% &gt;4 mmol/L</td>
</tr>
<tr>
<td>POC Glucose</td>
<td>±1 mmol/L ≤5 mmol/L</td>
</tr>
<tr>
<td></td>
<td>±2% &gt;5 mmol/L</td>
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</tbody>
</table>

Table 2. Comparison of Laboratory and POC Glucose. The range of glucose concentrations in the POC glucose surveys include lower limits than the lab glucose surveys. Therefore, only the data for a similar range of concentrations were compared between the two groups.

<table>
<thead>
<tr>
<th>Concentration range (mmol/L)</th>
<th>POC Glucose</th>
<th>Lab Glucose</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.3–14.5</td>
<td>2.3–4.4</td>
<td>4.6–14.5</td>
</tr>
<tr>
<td>4.5 (0.8–14.5)</td>
<td>4.5 (2.5–10)</td>
<td>4.5 (0.8–14.5)</td>
</tr>
</tbody>
</table>

95th Percentile (CV/%) = 10 7.7 10.7 2.6

No. of results assessed 51379 8173 43206 2661

No. of PT challenges 12 3 9 16

No. of peer groups assessed 166 23 143 179

Comparison of POC and laboratory glucose method peer group CVs

p<0.001

DISCORDANT FINDINGS INVESTIGATIONS:

When PT results demonstrate recurring flags or show a high degree of deviation from the assigned value in QMP-LS surveys, laboratories are required to submit discordant findings investigations to QMP-LS. These discordant investigations are reviewed by the discipline-specific consultant technologist and the associated scientific committee in terms of the cause of the flag(s) and the corresponding corrective action. This information was also reviewed as part of the analysis.

Failure to identify correct EQA samples to use (n=161)
Manufacturer or supplier related issue, problem with reagent performance (n=52)
Sample mix-up on the bench or result reported for wrong sample (n=37)
Wrong analyzer selected, therefore evaluated in the wrong group (n=11)
Unknown or Random number (n=9)
Instrument problem (n=4)
Computer keying errors (n=3)