Survey of quality assurance practices and clinical locations for POC glucose meter testing in Canadian hospitals

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OBJECTIVE

To evaluate quality assurance (QA) practices for POC glucose meter performance in healthcare facilities participating in proficiency testing (PT) through the Institute of Quality Management in Healthcare (IQMH) and conforming to ISO 22870 standards. This included analytical criteria for glucose meter validation, quality control (QC) monitoring, and locations for POC glucose testing among the participants.

METHODS

Questions were included with the IQMH glucose meter PT survey in May 2017: 1) For replacement glucose meters, what verification studies are performed prior to implementation for clinical use? 2) When comparing results from glucose meters to the central laboratory, what is the total allowable error (TAE) used to determine whether the results are considered comparable? 3) What is the precision goal used to monitor day-to-day quality control results for glucose meters? 4) What sources were used to determine the analytical performance goals above for your institution? 5) In which locations are glucose meters in use in your institution? Additional questions for follow-up were included with the IQMH glucose meter PT survey in May 2018, which asked: In response to the questionnaire and supplemental committee comments on the POCT-1705-GL survey, has your institution made any changes in practice for the glucose meter verification?

RESULTS

A total of 198 sites responded to the 2017 survey, of which 192 responded to the subsequent survey. In both cases, the vast majority of institutions were hospitals with on-site laboratories.

Figure 1 outlines the responses from sites when asked which components are included in verification of glucose meters. Almost all respondents (97%) indicated that analysis of quality control (QC) solutions is part of their process for glucose meter verification. Only 56% indicated that patient sample comparisons are performed.

For precision goals, some respondents indicated that their goals are based on the quality control target values stated by the instrument manufacturer. Others stated identical goals for TAE and precision. The data are summarized in Figure 2.

Of the 197 respondents to the 2018 survey, 36 (18%) indicated changes in practice based on findings and recommendations published by IQMH from the initial survey. Results from a follow-up practice survey indicated that 18% of sites implemented a change in practice based on findings and recommendations published by IQMH from the initial survey.

DISCUSSION AND CONCLUSION

Many institutions noted that patient comparisons were not included for glucose meter validations. It is important for institutions with central laboratories to be conducting regular comparisons between the glucose meters and the method in the main lab to ensure sufficient agreement between methods and/or to advise physicians on expected differences. The survey findings indicated that the majority of users included the manufacturer’s materials for the verification of meter performance, along with acceptance criteria that was higher than the current requirements in the CLSI POCT12-A3 and ISO 15197:2013 documents. Precision targets for quality control on the glucose meters should be set in line with the ongoing meter performance rather than based on the manufacturer’s targets. Total allowable error limits should be set based on published guidelines and clinical need within an organization.

Institutions should work with their meter vendors at improving the performance of meters where necessary and possible.

Results from a follow-up practice survey indicated that 18% of sites implemented a change in practice based on findings and recommendations published by IQMH from the initial survey.