Initial Implementation of a Risk Based Quality Control Scheme Using Bio-Rad
Mission: Control Software

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ABSTRACT

Background: A robust quality control (QC) program is a balance between detection of critical systematic errors (SEs) and false rejection of an analytical run. Hundreds of patient samples are typically run between QC events and the number of results affected by SEs depends on the likelihood of detecting the error with the next QC event. In the course of converting from a Medically Allowable Limits (MAL) strategy to a risk analysis model, we investigated whether the Bio-Rad Mission:Control software program could guide our analytical risk assessment QC strategy. The objectives were to use the Bio-Rad program to analyze our current MAL strategy for its ability to detect SEs in selected analytes and to design a QC strategy that would reduce the number of QC events needed to detect a shift in assay performance.

Methods: Six high volume serum assays (Sodium, Potassium, Chloride, Bicarbonate, Creatinine and Hemoglobin A1c) were selected for analysis. Current QC data (running QC mean and SD) were loaded into the Mission:Control software. CLIA allowable total error limits and the repeat 1:2s QC rule were used to assess protocol performance. The expected number of QC events until detection (EQCE) of a critical systematic error condition for each assay were calculated by the Mission:Control program. Detection of SEs using the running QC mean and SD were compared to fixed QC mean and SD limits. Finally, new user defined fixed means and SDs were selected in order to improve SE detection while minimizing false rejections.

RESULTS

Example of QC Optimization Process

Original QC Settings

Mission: Control

Medical Allowable Limits (MAL)

EQCE = 7.6

EQCE = 5.4

EQCE = 6.1

Mission: Control

EQCE = 7.7

EQCE = 5.4

EQCE = 6.1

New User Defined QC Settings

Mission: Control

EQCE = 7.7

EQCE = 5.4

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CONCLUSIONS

• Mission:Control software allowed us to choose and verify new QC limits following analysis of our risk of reporting out unreliable or erroneous results.

• The QC limits selected following analysis by the Mission:Control program were more restrictive than the pre-risk assessment limits.

• In this small trial there was no increase in the number of 1:2s rule violations with exception of HbA1c. For HbA1c the 1:2s rule violations should have triggered a calibration event. However a misunderstanding of project intent delayed the required calibration.

• The Mission:Control software is an inexpensive tool that uses laboratory historical data to guide QC limits. There are additional software features that were not explored for this initial investigation.

• The Mission:Control software will be an integral part of our overall quality assurance scheme including delta checks and patient moving averages.