Tel: +44 (0) 2920 314750
E-mail: contact@weqas.com
Web: www.weqas.com

Weqas
Unit 6, Parc Tŷ Glas
Llanishen, Cardiff, UK
CF14 5DU

Weqas Problem Solving Algorithm – Troubleshooting Performance Issues; A Case Study

Gareth Davies, Sam Jones, Annette Thomas

Introduction

EQA in medical laboratories has evolved over the past 50 years to provide more sophisticated systems compared with the simple analytical performance evaluation of earlier years.

Utilising problem-solving tools are pivotal to help resolve laboratory performance issues and improving quality. The Weqas troubleshooting algorithm leads the participant through a series of questions using their EQA reports to identify errors (Figure 1).

Imprecision is identified using metrics that measure dispersion of the data about the best fit line (Coefficient of Linear Correlation, (r) and the Standard Deviation of the Residuals, (Sy.x)).

Inaccuracy is identified using the linear regression equation, y = mx + c whereby y is the lab result, x is the target value, m is the slope of the line, and c is the y-intercept.

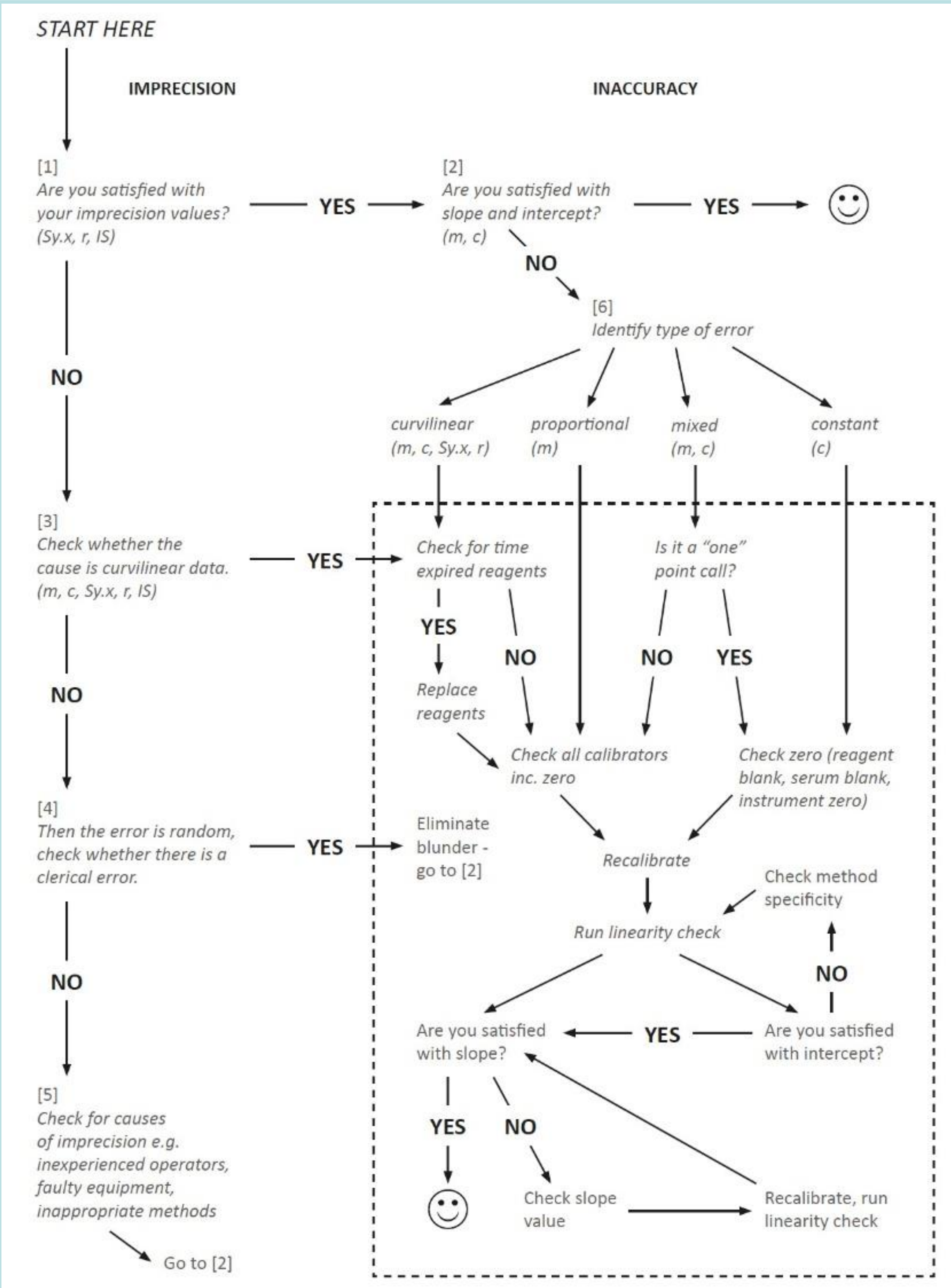

Figure 1 – Weqas Troubleshooting Algorithm

Causes of imprecision can include inappropriate operators, faulty equipment, inappropriate methods and others.

Inaccuracy can be categorised into proportional, constant and mixed errors and each one can be caused by different issues.

Systematic proportional: Identified from the slope m, usually due to calibration.

Systematic constant: Identified from the intercept, c, usually due to blanking error from reagent, serum or instrument zero.

Mixed systematic: Identified from combined errors of both m and c. For a one-point calibration with a cross-over at or near a calibration point (pivoting about calibration point), check zero calibration point, i.e. reagent blank, serum blank, instrument zero and then follow guide as for proportional systematic error. For a multi-calibration with cross-over at or near one point, check other calibrators and/or zero point.

Curvilinear data: Identified from m & c and poor r & Sy.x values, usually due to reagent deterioration or deterioration in calibrators if multiple calibration curve used.

Case Study: Serum Calcium performance

A first Scheme Organiser Letter was sent to a laboratory regarding Total Calcium on the Weqas Serum Chemistry programme.

The laboratory had 3 distributions in a row of unacceptable SDI scores (SDI > 2). Results showed a significant positive bias to the reference value, method mean, the instrument mean and the overall mean. The SDI scores are calculated based on Reference Target Values measured in-house (Flame Atomic Absorption Spectrometry, Varian FS 220 Spectrometer).

Recent performance (SDI scores) over last 7 distributions (current distribution and previous 6) is shown in Figure 2. Results from SC0622, the distribution preceding the letter, are shown in Figure 3.

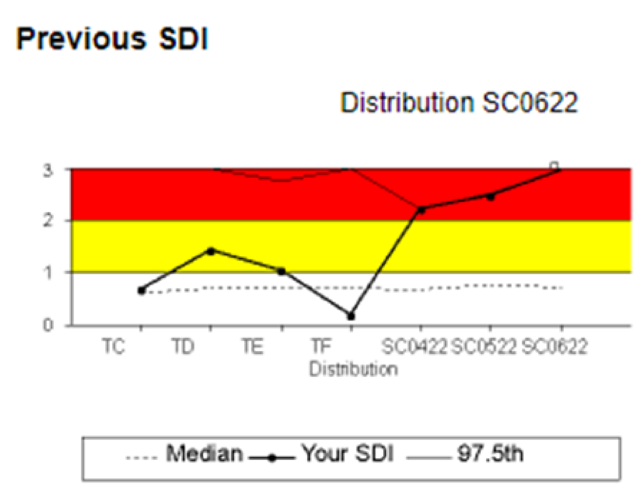

Figure 2 – Previous SDI scores

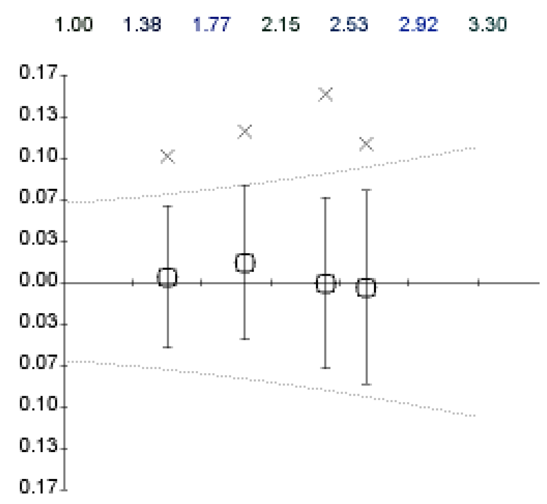

Figure 3 – SC0622 Results Bias Plot

The precision metrics were good or acceptable for SC0422 – SC0622, indicating no issue with precision.

For inaccuracy the linear regression analysis showed proportional errors (m) of 4.7%, 3.9% and 2.2% for the 3 distributions. The 3 distributions previous to this showed proportional errors of <1%. The linear regression analysis also showed systematic constant errors (c) of -0.005, 0.017 and 0.07mmol/L. The predominant error over this period is a proportional error. The troubleshooting algorithm suggests 'check all calibrators including zero'.

The laboratory responded with their investigations (RCA), and found that the 'higher calcium values related to a specific calibration'. This was noted on both of their analysers but more pronounced on Line 1. This was also related to a change in lot number of reagents (this was the predominant reagent in use for the period of poor performance). IQC trend fell closer to the mean on re-calibration after SC0622. This can be seen in Figures 4 and 5.

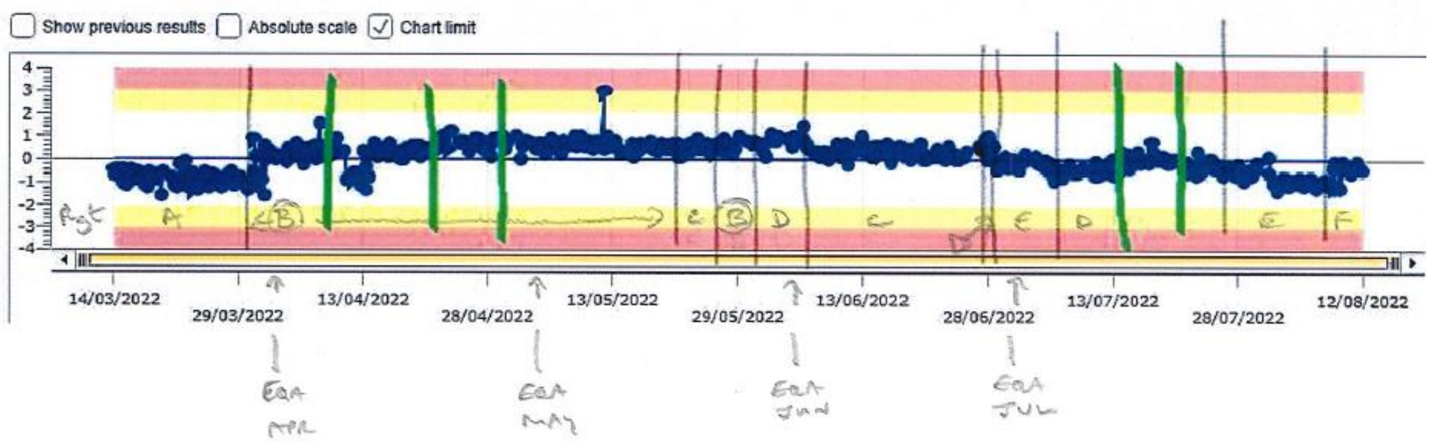

Figure 4 – Annotated IQC chart showing reagent lots (A, B, C etc) and time of EQA analysis

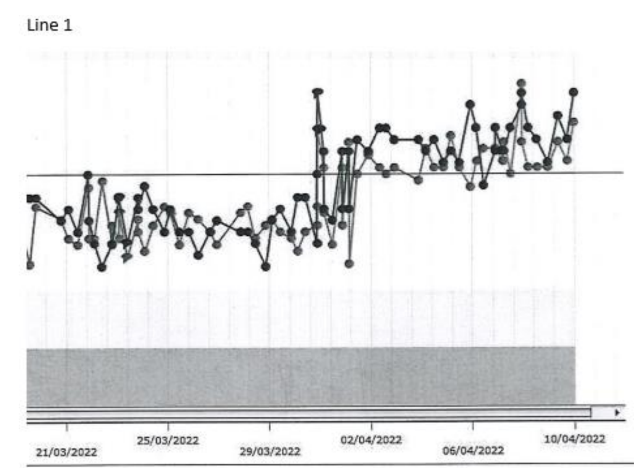

Figure 5 – IQC Chart for Line 1 showing significant change following calibration

Figure 6 shows the Network IQC Chart – The analyser in question (Line 1) is the blue line – a significant shift can be seen in IQC results around late March. This related to a new calibration.

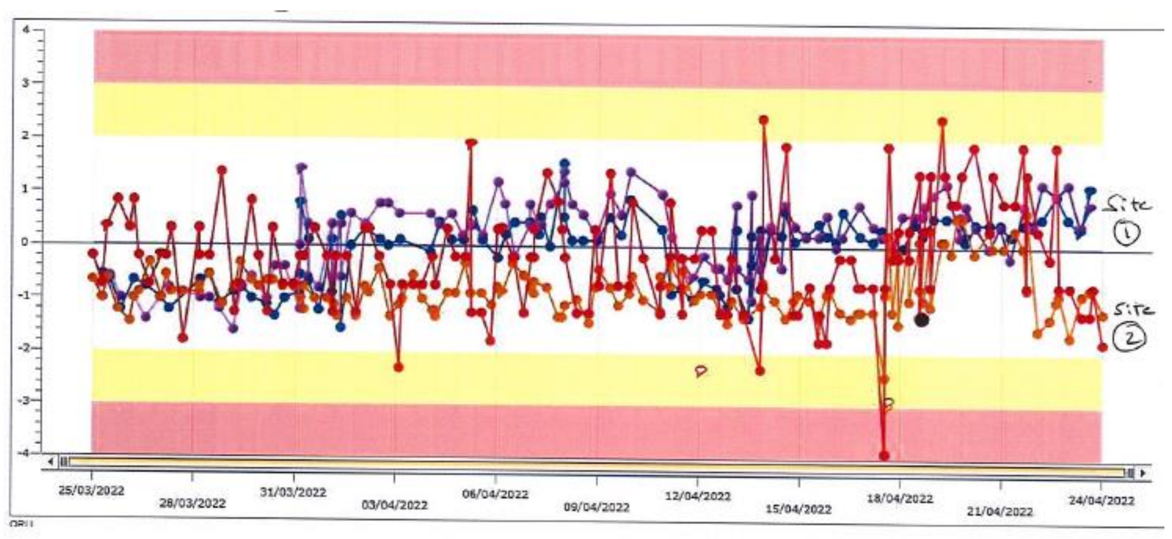

Figure 6 – Network IQC Chart

Using the Weqas Troubleshooting Algorithm helped to identify the cause of the issue as a calibration issue. Laboratory performance improved significantly following re calibration late June and was acceptable for SC0722, and good for SC0822 and SC0922 – therefore there was no requirement to report the laboratory to the NQAAP. Patient results from this period were reviewed and it was felt that no detrimental affects on patient care would have arisen from this performance issue.

This poor performance episode also highlighted other learning points for the laboratory:
Re-training and education of staff reviewing IQC who did not appreciate the significance of the shift in IQC results.
Lab is in discussion regarding the appropriateness of the use of 'wider', 'network wide' IQC limits to accommodate performance of analysers across the network.

Conclusion

The key objective of EQA is in identifying performance issues and providing the necessary tools to help resolve those issues. EQA shouldn't be seen as a 'tick box' or 'pass/fail' exercise but should be used to support laboratories in continuously improving services for the benefit of patients.

This case supports feedback from participants that following the Weqas problem solving guide allows quick and easy error identification and suggestions to correct the error and improve performance.