RANDOX

EDUCATIONAL GUIDE

The Cost of Poor Quality in the Clinical Lab

QUALITY CONTROL

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Background

In the clinical laboratory, the term 'Quality' refers to the standard of one lab's results compared to others. Generally, every lab or test system could be made more efficient, and labs seeking to achieve a good standard of quality will need to engage in ongoing process evaluation and improvement.

Good quality is like a reputation; it takes a long time to build, but it can be ruined in an instant.

What is the Difference Between Good Quality and Poor Quality?

In simple terms, a good quality (GQ) test system will produce very few failures or adverse events. Conversely, poor quality (PQ) will result in more adverse events and failures, which will ultimately need to be corrected.

Both GQ and PQ have associated costs, and the overall cost of quality in the lab is calculated by adding the cost of good quality and the cost of poor quality. Where GQ costs are relatively easy to anticipate and account for, PQ costs can be more complex.

Costs of Good Quality – In order to attain or maintain a good quality test system, additional costs are required to prevent test system failures. Some examples include:

- **Staff Training** – All staff must be adequately trained to carry out their roles effectively. Although there may be costs associated with staff training, it can help to reduce future costs associated with poor training.
- **Equipment Maintenance** – All equipment and instruments should be maintained to a high standard and serviced regularly in order to avoid potential issues or failures.
- **Quality Management System (QMS)** – A complete quality management system should be adopted comprising Third Party Control, External Quality Assessment and Data Management. There are some factors that should be considered when choosing a QC or EQA supplier.
- **Accreditation** – Achieving accreditation is proof of the lab's commitment to quality, however, it can be expensive and time-consuming.

Costs of Poor Quality – While the costs associated with GQ are associated with preventing potential issues, costs of PQ are incurred as a result of test system failure.

- **Repeated Testing** – The most obvious issue with poor quality is the need to re-test both QC and patient samples when errors are detected. This can be extremely difficult to do in the case of patient samples, and has the added effects of increased cost and reduced patient/physician confidence in the lab's results.
- **Root Cause Analysis** – Labs may spend a significant amount of time and resources determining the root cause of a failure and implementing preventive actions.
- **Misdiagnosis and Inappropriate Treatment** – The most severe outcome from erroneous lab results is the potential for misdiagnosis and inappropriate patient treatment, which can have severe medical repercussions for the patient and significant cost/reputation implications for the lab.

When comparing GQ and PQ, it is plain to see that costs associated with GQ are much easier to forecast and plan for, whereas PQ costs are much more scenario-dependent. Both GQ and PQ incur additional costs, but the main difference is that labs will **spend** money on GQ practices and **waste** money correcting issues arising from PQ practices.

Examples of Poor Quality Practices

Case Study 1 – A lab was using QC material with non-human source material for their entire Immunoassay panel, despite ISO 15189 and CLIA recommendations to use QC material with a matrix as close to the patient sample as possible. Due to matrix effects associated with the non-human material in the QC, the lab had to reassign QC reference ranges upon every reagent batch change due to significant shifts in QC performance, resulting in unnecessary time and QC wastage.

Conclusion: *Using commutable QC material would have prevented any significant shifts in QC performance, eliminating the need to reassign target values.*

Case Study 2 – A laboratory using the Acusera Assayed Chemistry Premium Plus control contacted Randox Technical Services after observing a consistent negative bias for ALT which was not replicated by the instrument control. They had previously contacted their instrument manufacturer who advised that the problem was with the control and not the reagent or instrument. Randox investigated the problem and demonstrated that patient results were also incorrectly reported low. This later led the instrument manufacturer to recommend a wash stage to eliminate any interference.

Conclusion: *The use of a third-party control in this instance enabled the identification of a procedural error with the instrument that the recommended control did not.*

How to Improve Quality in the Laboratory

There are many methods of improving quality in the laboratory. The most obvious methods are to ensure staff are adequately trained, and that all materials and instruments are properly maintained, and of sufficiently high quality. Some key areas to improve quality include;

- Use of commutable QC materials
- Use of Third Party Controls
- Use of QC materials which cover clinically relevant levels
- Peer Group Reporting Software
- Six Sigma analysis of QC performance
- External Quality Assessment

Commutability – According to ISO 15189, labs should ***"use quality control materials that react to the examining system in a manner as close as possible to patient samples".*** Control materials which react in the same manner as patient samples are known as 'Commutable' controls.

The rationale behind this recommendation is that non-human components of IQC material do not reflect the performance of patient samples, and therefore do not provide an accurate representation of test system performance.

In addition, commutable controls can prevent shifts in QC performance between reagent batches, eliminating the need to reassign QC targets and ranges - saving time and money.

Third Party Controls – ISO 15189 also recommends the ***"use of independent third-party control materials"***. Third party quality controls are manufactured independently of any specific test or system, eliminating potential bias. Some third-party QC manufacturers assign values based on data collected from thousands of independent laboratories, thus ensuring accurate value assignment on a wide range of instruments and methods.

Clinically Relevant Levels – Using control material which covers clinically relevant ranges is key to ensuring accurate diagnosis. For example, Troponin T has a cut-off level of around 0.01 ng/ml. Levels higher than this are indicative of a Myocardial Infarction (MI). For this reason, it is essential that this point of the assay range is adequately tested by way of Quality Control. QC material which does not cover clinical decision levels could mask poor performance, and possibly lead to misdiagnosis. ISO 15189 states ***"The laboratory should choose concentrations of control materials, wherever possible, especially at or near clinical decision values , which ensure the validity of decisions made".***

Peer Group Reporting Software – Peer Group Reporting (PGR) software can be utilised to further optimise QC performance. QC performance can be compared to a global peer group of labs using the same instrument and lot of QC, giving a firm indication of test system performance. Interlaboratory Data Management packages, such as Acusera 24•7, will also automatically calculate advanced statistics and Measurement Uncertainty, improving efficiency and reducing time spent analysing data. They may also help to meet regulatory requirements, ISO 15189 recommends ***"The laboratory shall have a procedure to prevent the release of patient results in the event of quality control failure. When the quality control rules are violated ……the results shall be rejected and relevant patient samples re-examined"***

Acusera 24•7 also offers real-time peer-group statistics, which allows users to compare results with the global peer group instantly; speeding up the troubleshooting process. This has the dual effect of reducing time/money spent troubleshooting, while also providing an increased level of error detection.

Six Sigma – Six Sigma is a method of process improvement which can be employed to improve the efficiency of a lab's QC strategy. Six Sigma analysis allows labs to see which individual tests are performing poorly, so steps can be taken to remedy this. Six Sigma can be laborious to implement, but some peer group reporting software platforms (like Acusera 24•7) can automatically calculate Sigma Scores for each assay, making the entire process quick and easy.

External Quality Assessment – ISO 15189 states that ***"the laboratory shall participate in interlaboratory comparisons such as those organised by external quality assessment or proficiency testing schemes".*** EQA schemes will enable laboratories to objectively review the quality of the results produced and demonstrate competency in medical diagnostics. EQA, when implemented correctly, exposes unexpected areas of underperformance, allowing identification of any potential sources of error. The results measured are then compared against peers from other laboratories on regional, national or international levels. ISO 15189 recommends that, EQA/PT schemes ***"should provide clinically relevant challenges that mimic patient samples… checking the entire examination process…"***, therefore highlighting the need to use clinically relevant levels in laboratory testing.

Conclusion

"Prevention is better than cure" is a statement frequently used in medicine and healthcare, and it also applies to quality in the laboratory. Prevention of adverse incidents is preferable to implementing corrective actions once an issue occurs.

The cost of poor quality is unpredictable and often substantial. It stands to reason that the more logical approach would be to invest heavily in good quality practices, ultimately decreasing the risk of suffering the significant implications of poor quality.

ACUSERA

True third party controls offering complete test menu consolidation

With more than 390 analytes available across the range, and multiple parameters often present in a single control vial, labs can significantly reduce costs and consolidate without compromising on quality. As true third party controls, unbiased performance assessment with any instrument or method is guaranteed.

RIQAS

The largest international EQA scheme with over 45,000 lab participants

Comprising over 360 routine and esoteric parameters in 33 comprehensive and flexible EQA programmes, RIQAS is designed to cover all areas of clinical testing. Each programme benefits from a wide range of concentrations, frequent reporting and informative yet user-friendly reports.

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