A simple tool to identify at risk assays using EQA data

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SUMMARY

We describe an objective procedure to use laboratory EQA performance to identify poorly performing assays compared to their peers and determine risk based on a calculated capability index, error detection of matching QC algorithms (analytical reliability), and biological variation.

INTRODUCTION

Maintaining the quality of clinical assays continues to challenge pathology laboratories despite improvement in data handling and analyser capabilities. To achieve commutable and precise results requires suppliers providing appropriate calibrators, an effective laboratory QC system and careful interpretation of External Quality Assurance (EQA) results which identify if the laboratory or analyser method group perform poorly compared to peers and achievable best practice.

Clinical laboratories must also have targeted processes in place to reduce patient risk, including risk from poorly performing assays. Risk is a function of the clinical application of a test result in patient diagnosis or monitoring and is therefore dependent on the frequency of errors in test results and reliability of the QC system in identifying those errors.

Our tool relies on three concepts: imprecision performance based on Assay Capability, a 3 x 3 matrix to grade peer performance against the 20th percentile laboratory, and calculation of a risk score based on analytical reliability and performance compared to biological variation targets.

METHOD

ASSAY CAPABILITY

We calculated Assay Capability (Cpa) as the ratio of AACB RCPA QAP Allowable Limit of Performance to laboratory end of cycle imprecision: Assay Capability Cpa = ALP/SD (or ALP/CV if ALP is expressed as a percentage) and represents the number of SD inside ALP.

PEER MATRIX

We placed assays in a matrix based on laboratory capability versus 20th percentile, allowing calculation of laboratory performance with achievable performance of a large number of laboratories.

We graded the standard components of risk (detection, frequency and harm), then multiplied the factors to achieve a risk score.

1. Detection of (analytical) error = the ease of achieving 90% Ped from QC algorithms matched to laboratory assay capability. That is, the worse the capability, the poorer the error detection of your chosen QC algorithm.

Where Cpa < 4 the assay cannot achieve 90% Ped and so fails reliability if fails PROACTIVE QC which tries to achieve <5% errors when QC flags a critical shift, eg 2SD. At Cpa < 4 reliability is scored relative to 20th percentile until Cpa < 2 at which point the assay fails even reactive QC because a 2 SD shift causes >50% analytical errors. Where the analytical goal matches or is wider than the biological goal, this causes >50% errors in patient results.

2. Frequency of (patient) error is predicted by the ratio of BV to ALP. That is, multiplying Assay Capability by the ratio of BV/ALP gives SD inside BV (ALP/SD x BV/ALP = BV/SD). This allows scoring to be logically graded according to BV targets of optimal, desirable, minimal (or fail).

3. Harm from error (patient impact). Assays were graded (in/out) according to clinical significance. Multiply the three factors to achieve a risk score.

RESULTS & DISCUSSION

20th percentile laboratory Cpa - General Serum Chemistry cycle 97

<table>
<thead>
<tr>
<th>Lab A Cpa</th>
<th>4-6</th>
<th>4-6</th>
<th>4-6</th>
</tr>
</thead>
<tbody>
<tr>
<td>VALP</td>
<td>CL, ALP, K</td>
<td>FE, I, HDL, CHO, LACT, ALP, TRIG</td>
<td>Urate</td>
</tr>
<tr>
<td>UREA</td>
<td>LDH, CK, SAA, ALP</td>
<td>20-50%</td>
<td>Laboratory</td>
</tr>
<tr>
<td>GGT/TRIG</td>
<td>&lt;20% Prof</td>
<td>&lt;20% Peer group</td>
<td>50-80%</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>&lt;2</td>
<td>10</td>
<td>10</td>
</tr>
</tbody>
</table>

The table above uses Assay Capability to show end of cycle performance for more than 35 analytes from one laboratory, rated according to 20th percentile performance. The right hand column explains how the detection of analytical errors is scored: low scores where imprecision matches the best QC algorithms have good error detection, poorer imprecision is scored higher but according to achievable peer performance, until imprecision is unacceptable low i.e. where the best QC algorithm has only a 50% (or less) chance of detecting a 2SD shift.

The table at bottom of page shows the calculation of patient monitoring risk for six assays from one laboratory using EQA results from RCPA QAP General Serum Chemistry cycle 97. The assay of greatest concern for this laboratory is sodium because it is a clinically important assay with high frequency of biological/patient errors (due to the poor ratio of within subject BV to Lab CV). Glucose has poor analytical performance but is in 20th percentile with >2 SD inside ALP, but has increased risk because of moderate performance in producing patient errors. GGT, Creatinine and Troponin I have good performance. Chloride is clinically irrelevant.

CONCLUSION

We have suggested an objective procedure for laboratories to identify poorly performing assays when compared to their peers and a method of determining risk based only on performance in an EQA. The technique compares laboratories to each other, to analytical goals (RCPA QAP Allowable Limit of Performance) and to relevant biological goals. This allows a laboratory to effectively use the EQA peer assessment to identify and stratify by risk those assays which require attention due to increased performance or increased clinical risk.