



Quality assurance: a benefit or burden?

Quality assurance (QA) is a means for verifying the accuracy of testing procedures, the results that they produce, and the interpretation of those results.

In Australia, QA is mandatory for laboratories for accreditation and can therefore be viewed as a burden, providing yet another task in a busy environment. Alternatively, laboratory management and staff can use QA as a beneficial and valuable tool to foster a culture of excellence. The achievements of a well-performing laboratory should be acknowledged, and a supportive and educational system developed for a laboratory that is performing poorly in QA programs.

QA programs have a responsibility to provide quality specimens, but there may be occasional testing problems with some kits, as, out of necessity, some QA specimens are diluted, pooled or converted from plasma to serum.

Reports must be issued promptly so that the information and results are still relevant to the situation in place when testing for the survey was performed (that is, same lot number in use, same operator performing the testing). Assessment of performance from past surveys must be available in the current survey report so that laboratories can accurately assess performance. A single erroneous result sent to an external QA program is a 'snapshot' of a laboratory's performance and may not be a true reflection of performance over time, but it is still an indication of a problem.

For example, apart from results that are not in agreement with a consensus of $\geq 80\%$, the problems most commonly seen in the RCPA serology QAP surveys are mixing specimens (so that results of two specimens are reversed), use of

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expired kits, transcription errors, non-detection of clerical errors and use of units that are incorrect/inappropriate for the specimen values and/or methodology.

Errors should be assessed through a "diagnostic journey... those activities of the quality improvement process which start with the outward symptoms of a quality problem and end with determination of the cause(s)"¹. Corrective action strategies must be established and results from the next and subsequent surveys utilised to monitor progress. Poor performance in two surveys or more is indicative of a systemic error, as opposed to a random 'one-off' error, and must be tackled through both short and long-term objectives and strategies.

To ensure that QA results provide ongoing benefits, there must be one individual who is ultimately responsible for overseeing QA results to establish a point of responsibility (with appropriate authority) to make changes and/or give acknowledgements, and then provide ongoing monitoring.

QA results need to be assessed on a number of levels. First, is the result in agreement with the consensus established through agreement of 80% of participating laboratories? Are the interpretative comments appropriate and in agreement with the consensus? If the result is not in agreement with the consensus, the kit user group in the raw data summary must be checked to assess if the problem is kit or batch related.

The skills, experience, training and knowledge of the scientists and technicians involved with the specific area of work are invaluable – and they should be included in the assessment and all stages of the 'diagnostic journey' (Figure 1) and subsequent corrective action strategies.

Poor performance needs to be discussed in a non-judgmental atmosphere where problems and issues are identified, categorised and addressed in an appropriate way – depending on whether the error is due to the operator (training issue), equipment (maintenance, calibration) process or choice of methodology. Errors that may appear to be due to staff error may in fact be due to an inherent problem that is built into the system of operation.

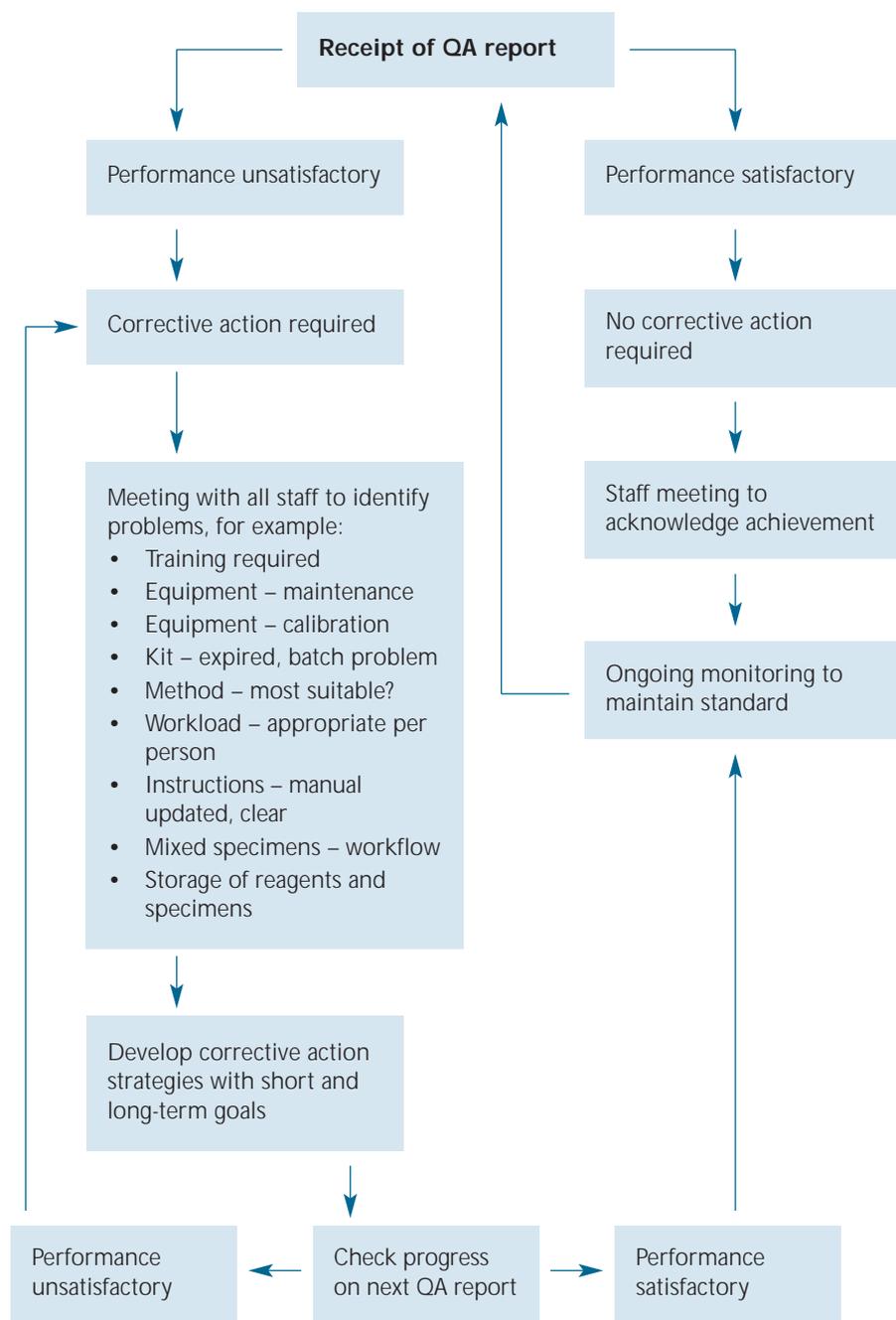
Strategic planning must be both short and long-term, as short-term plans alone are not conducive to developing a quality system. There is a temptation to prioritise problems that can be addressed in the short-term, whereas the means to establish a quality system may be in addressing issues that require long-term objectives and strategies that may not be measurable in the short-term.

For example, a poorly functioning system may require repeat runs, at times issue incorrect results and perform poorly in both QC (quality control) and QA. This in turn increases overheads through wasted labour and purchase of extra kits/reagents as a financial cost, but also there is a potential for misdiagnosis of patient infection, loss of staff morale, job satisfaction and the incentive to strive for excellence.

The 'diagnostic journey' involves flow-charting the entire process from the time the specimen arrives on the premises through to the issue of the result.



Figure 1. The QA diagnostic journey.



Although in the short-term this is time consuming and initially increases overheads, identifying and addressing the issues can provide long-term goals that will ultimately benefit the laboratory financially – both in reduced labour and consumable costs.

This process must have the support of senior management, as scientists and technicians in the laboratory may be aware of the problems – and potentially the solutions, but it is senior management that has the power and authority to effect the change process through both long and short-term goals. When leadership and responsibility for managing the change process has been undertaken and improvements become apparent, staff morale and job interest improves; this in itself increases opportunities and motivation for improvement.

In conclusion, participation in QA can assist laboratories to pinpoint problems that may otherwise be undetected and, through corrective action strategies with both short and long-term objectives, produce results that can effectively diagnose and monitor progress of patients, thus improving patient care. The burden of added work in testing QA specimens is far outweighed by the improvement opportunities and overall benefits.

Reference

1. Juran JM. *Juran on Quality by Design*. 1992; p506.

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<p>Abbott Diagnostics Division</p> <p>Biocene</p> <p>Biolab</p> <p>Bio Mediq (DPC) Pty Ltd</p> <p>BioMérieux Australia Pty Ltd</p> <p>Bio-Rad Laboratories</p>	<p>Blackaby Diagnostics Pty Ltd</p> <p>Dade Behring Diagnostics</p> <p>Diagnostic Technology</p> <p>Don Whitley Scientific Pty Ltd</p> <p>Millipore Australia Pty Ltd</p>	<p>Ortho-Clinical Diagnostics</p> <p>Oxoid Australia Pty Ltd</p> <p>Roche Diagnostics Australia</p> <p>TECRA International</p> <p>Wyeth Australia</p>
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