Opinion

The Conduct of Quality Control and Quality Assurance Testing for PoCT Outside the Laboratory

*Janice P Gill,1 Mark DS Shephard2

1RCPA Quality Assurance Programs Pty Ltd, Adelaide, SA 5000, 2Community Point-of-Care Services, Flinders University Rural Clinical School, Flinders University, Bedford Park, SA 5042, Australia.

*For correspondence: Ms Janice Gill jan.gill@rcpaqap.com.au

Introduction
Within pathology laboratories, quality assessment, internal quality control (QC) and external quality assurance (EQA) are integral components of a laboratory’s quality system. They are tools to ensure that the quality of results being produced by laboratory testing will not compromise the clinical care of the patient. This criterion applies equally when the testing environment changes from the laboratory to the point of care, and the large laboratory instrument becomes a smaller device.

While the principles of quality assessment should be the same in the point-of-care testing (PoCT) environment, the methods by which they are applied will be different, depending on factors such as frequency of testing, complexity of the device, inbuilt checks manufactured into the device, cost and practicality of providing the quality management system, and the fact that non-laboratory-trained operators will most likely be performing the tests. As the use of PoCT increases, it is laboratory-trained professionals who understand the principles of quality assessment that are best positioned to set guidelines for PoCT application.

The Role of Professional Organisations
Professional organisations such as the Australasian Association of Clinical Biochemists (AACB), through the laboratory expertise of its members, have a role to play in providing guidance on the use of PoCT conducted outside the laboratory environment. The AACB believes that PoCT can make significant and positive clinical, economic and social contributions to society if used appropriately. However, all PoCT should be accessed and conducted within formal quality frameworks to ensure such testing is conducted to professional standards that assure fitness for medical purpose. The AACB PoCT Working Party has previously developed documents on the principles of conduct of PoCT,1 and at the time of writing is completing minimum guidelines specifically targeted at non-laboratory-trained operators for the use of QC and EQA in the PoCT environment. This article provides a descriptive supporting commentary on selected issues featured in these guidelines.

Scope
Globally, the scope and application of PoCT has grown exponentially in the past decade principally due to significant technological improvements in the design and manufacture of PoCT device and reagent systems as well as advances in connectivity standards.2

The clinical settings in which PoCT is conducted are numerous, including hospitals (emergency departments, wards, clinics, operating theatres), doctors’ surgeries, indigenous medical services, pharmacies, sports medicine clinics, workplaces, veterinary clinics and, with patient self-monitoring, the home.

Within Australia, PoCT has come of age in the community setting with the successful implementation of large scale national PoCT programs such as the Quality Assurance for Aboriginal and Torres Strait Islander Medical Services (QAAMS) Program and the PoCT in General Practice Trial, together with state-wide models including Pathology Queensland’s i-STAT program and the iCCnet SA PoCT model for cardiac care.3-12

The element common to most of the aforementioned clinical settings is that a non-laboratory-trained person is performing PoCT. However, except in the case of patient self-monitoring, this person is usually a healthcare professional. The QC and EQA guidelines that have been developed by the AACB PoCT Working Party focus on the use of PoCT by healthcare professionals rather than on patient self-monitoring.

The Need for Quality Frameworks
In the laboratory setting, analytical quality is usually assessed by QC and EQA. The aim of conducting QC and EQA testing...
is to monitor the stability of the analytical measurement system and to alert the operator to a change in stability (notably a shift or trend in performance, or poorer reproducibility of testing) that may lead to a medically important error.

While these traditional quality processes serve the laboratory well, a key issue which is the subject of considerable debate among the medical scientist fraternity worldwide is: are these processes relevant, transferable, practical and cost effective for monitoring analytical quality on PoCT devices?9,13,14

There is no simple answer or solution to this question. In attempting to address the issue, it is necessary to:

(i) have an understanding of the difference between laboratory and PoCT testing systems
(ii) assess the degree of technological sophistication that individual PoCT systems have, particularly their ‘inbuilt’ or ‘onboard’ quality checks and level of connectivity
(iii) find the appropriate balance between ensuring safety and analytical quality of PoCT, and implement a quality framework that is practicable in the field and cost effective.

Differences Between Laboratory and PoCT Systems

Most laboratory instruments are closed (or self-contained), multi-use systems that have the ability to measure large numbers of samples in batches throughout the day. For these types of analysers, the testing of multi-level QC throughout the day combined with monthly EQA testing and regular maintenance is considered standard practice.

In contrast, most PoCT devices utilise a disposable single-use testing unit. The sample is inserted into the testing unit and the analyte to be measured is recognised most commonly through the use of chemical or biological sensors (that is, a reaction takes place). The second component of the PoCT system is the device, which in simple terms is just a reader of the signal generated as a result of the reaction.15,16

There are many different types of single-use testing units including the cartridges used with the Abbott i-STAT, Siemens DCA and Axis Shield Afinion devices, the cassettes used with the Inverness Cholesterol LDX, and the test strip-based systems that use a code chip for calibration, including the Roche CoaguChek XS, Roche Cobas h232 and Nova Biomedical NovaStat devices. Other examples of single-use testing units include the cuvette with the HemoCue haemoglobin device and the rotor or disc with the Abaxis Piccolo device.

Traditional batch-based QC and EQA practices are not necessarily applicable to these systems as each testing unit is discrete and disposable, and checking the performance of a single testing unit does not guarantee with any certainty the quality of the next unit (unlike multi-use laboratory instruments).

QC Checks for PoCT Systems

How then have manufacturers of such systems approached the problem of quality management? With most modern PoCT devices, there has been significant technological investment by manufacturers in the development of sophisticated inbuilt quality checks within the testing unit itself. (These checks have been described variously as onboard QC, intelligent QC and internal checks.) Manufacturers have recognised that in the future the main consumers of PoCT will be health professionals from a non-laboratory background, and they have deliberately tried to make the devices as simple as possible for the operator and, at the same time, as well-controlled internally as possible. For example, the Abbott i-STAT cartridge has a calibration solution contained in a pouch in every cartridge and performs a calibration before each sample is tested. Inbuilt checks of the calibration fluid include its freedom from bubbles, its integrity during handling and its correct concentration. With the Roche CoaguChek XS, every test strip has inbuilt control checks for strip deterioration due to exposure to excessive temperature and humidity (with the reduction of resazurin to resorufin, a highly fluorescent dye, correlating with the degree of strip damage). The Piccolo rotor quantifies interference and verifies chemistry, optics and electronics with every run.

In terms of the device component of the PoCT system, most PoCT devices feature processes by which the quality/reliability of signal generation is monitored (known as the electronic QC check).17 For example, the Abbott i-STAT has an electronic simulator which specifically measures electrical signal generation and ensures that these signals are within tight specification limits.

It should also be noted that state-of-the-art PoCT devices now have advanced levels of connectivity and the ability to electronically capture and transmit results to a central management point (a central data station and/or a clinical or laboratory information system), ensuring that post-analytical errors are minimised.

Clearly, the best unit-use PoCT systems are those with the highest degree of built-in QC checks to monitor the analytical steps and the most advanced level of connectivity.

Finding the Balance

With this level of technological sophistication in PoCT devices today, the role of traditional QC and EQA has come
under question. A training manual for a widely-used PoCT device currently contains the following statement: ‘Quality control and system checks using control test solutions that you may be familiar with from other systems are no longer required …’ Certainly this is not the view of the authors, nor most likely the vast majority of laboratory professionals. For us, unquestionably, there remains a continuing place for traditional QC and EQA as an independent check of the quality of PoCT systems, but one needs to match the degree of technical sophistication of the device with a QC/EQA frequency regimen that is cost effective and practicable.

There is no ‘one size fits all’ policy that can be applied universally across all PoCT testing systems, and it is for this reason that the AACB PoCT guidelines focus on minimum requirements for conducting QC and EQA testing. Certainly, it is a given that QC on a PoCT device should be conducted on a new delivery of reagents, when there is a change in reagent lot number, when a patient result does not fit the clinical presentation, and when a major maintenance or repair procedure has been enacted. Beyond these scenarios, frequency of QC testing, in particular, should take into account the actual volume and nature of patient testing conducted in the field. For example, some sites will conduct weekly clinics for patients with diabetes but the number of patients may vary widely. It is our experience that a considerable amount of PoCT in community settings is opportunistic, making broadly applicable frequencies for QC testing difficult to set.

Cost of purchasing QC and EQA materials is a factor that is of particular relevance (and concern) both to small health centres with limited financial budgets that wish to practice PoCT and to large PoCT networks (possibly servicing 50 or more sites) where costs of conducting QC and EQA at every site could consume a large percentage of the consumables budget.

In terms of practicality in the field, laboratory scientists should never lose sight of the complexities faced by a PoCT operator performing QC and EQA in a non-laboratory environment. For example, operators in the national QAAMS Program, who are required to conduct two levels of QC testing in the first fortnight and two EQA samples in the second fortnight of each month, must work with a range of different sealed vials, liquid solutions and pipetting equipment to fulfil their quality testing requirements. The realities of PoCT conducted in the field by busy health professionals who are not familiar with laboratory practice are often overlooked or misunderstood by the laboratory-based scientist.

EQA Checks for PoCT Systems

EQA programs are a component of a continuous quality assessment and improvement cycle and under International Organization for Standardization (ISO) are a mandatory requirement for medical laboratories. The benefits of participation in EQA include an assessment of the accuracy of results against an assigned value, comparison with all instruments, peer comparison with the same instrument, assessment of performance over time, and providing confidence that the results reported on patients are correct. These benefits apply equally to PoCT. Therefore EQA is both desirable and required for PoCT devices. The requirement is reflected in the international standard, ISO 22870 Point-of-care testing (POCT) - requirements for quality and competence, and in The National Academy of Clinical Biochemistry Evidence-Based Practice for Point-of-Care Testing.

An alternative to formal EQA testing is ‘split’ or ‘parallel’ patient sample testing in which the same patient sample is tested by PoCT and by the laboratory. Potential advantages of split sample testing are: (a) like EQA, it provides a delayed external check of quality; (b) testing utilises a sample of identical matrix (e.g. whole blood) to that of routine patient samples rather than a lyophilised EQA material; (c) it can be a cost-effective external assessment of quality; and (d) with samples equivalent to routine specimens, it can check the pre-analytical component of testing. However, potential drawbacks of split sample testing include: (a) testing only a limited range of concentrations vs EQA with its ability to test an analytical method across the range of concentrations seen in health and disease; (b) a lack of peer comparison; (c) the need to define appropriate acceptability criteria that recognise measurement uncertainty; and (d) problems associated with transport and delivery of patient samples to the laboratory from geographically isolated rural and remote locations.

Who Should Perform the Quality Testing?

There is still a tendency at some PoCT sites, especially in hospitals, to consider that laboratory staff or the PoCT co-ordinator, for example a diabetes educator, should run the QC and EQA samples. The reasoning behind this can be time considerations or the desire to get the ‘best’ result. However if we go back to the ultimate purpose of these checks – to ensure that the quality of results will not compromise patient care – then it follows that the operator who is performing the testing should be the one performing the quality checks. Where there are multiple operators, all should be rotated through this process.

Who Should Review the Quality Testing?

QC is an immediate check on the integrity of the PoCT device and therefore the operator should record the result and take appropriate action at the time of testing. However there should be regular review of QC and EQA results as part of the cycle of quality improvement. This follow-up can be an area
of weakness in PoCT, but it is an opportunity for laboratory professionals with expertise to provide such training to PoCT co-ordinators or for them to consult directly.

Conclusion
This article is designed to provide readers with a brief discussion of some of the issues relevant to the conduct of PoCT outside the laboratory. The article acknowledges that there is no single strategy that can be universally adopted across all of the clinical settings in which PoCT is now conducted in Australasia. Rather, a tailored, flexible and balanced approach taking into account technological sophistication, practicality, cost and size/scope of PoCT networks is required. The discussion presented is consistent with and supportive of the guidelines for the conduct of QC and EQA being developed by the AACB PoCT Working Party.

Competing Interests: Ms Janice Gill and Associate Professor Mark Shephard are on the Committee for the AACB PoCT Working Party.

References