Quality Assurance of Single Use Point of Care (POC) Testing Products

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Assuring the quality of test results is a crucial element of diagnostic test provision across the healthcare landscape. Following the rigorous quality control processes in the laboratory is relatively straight forward when performed by well trained, experienced laboratory staff in protected environments. Implementing the same approach in the point of care setting comes with its own challenges.

Key Article Elements

- **What are the considerations for POC quality control?**
- **What additional challenges do single use tests pose?**
- **What systems should be in place to assure good governance and quality?**
- **Who should be providing the checks?**
- **Logistical points for consideration**
- **Ongoing monitoring and compliance with ISO standards**

There are a number of POC solutions on the market which require single use strips, cards or cartridges to be used in order to generate the clinical result. This poses the question as to how to perform sufficient quality checks in order to assure that performance levels are high.

Many point of care devices have on board quality control material, internal electronic checks and some equipment follows a similar quality control process to that deployed in the laboratory. This is mainly reserved for bench top equipment offering a minilab approach to POC.

Where these features are absent a well designed quality assurance programme needs to be introduced. This article will cover many of the considerations required when introducing such programmes. Examples of IVDs include handheld blood gas analysers, urinalysis test strips, and glucose/ketone test strips.

So what is different about single use tests? Firstly, you cannot run quality control material at the same time or with the same product that is being used for the patient test. The conditions for each card or cartridge may be different every time you perform the test. This means that a standardised way of performing quality checks is required to minimise any risk to the accuracy of results produced.

Which quality material to use?

Where possible a third party quality control (QC) material covering multiple levels at appropriate concentrations must be used. The manufacturer's own material may be used where there are no other options, or the quality of third party material is shown to be sub-optimal.

The material should reflect the composition of the sample type to be tested where possible, although this can be difficult to achieve. It should also be analysed by the same method or process that patient samples go through.

Batch testing and lot numbers

Once the material has been selected and a record of the selection criteria recorded, the next consideration is how often to test. All levels of quality control material should be tested periodically and this will be informed by the pattern of device use. If the equipment is in use throughout the day, every day of the week, this will indicate a more frequent testing of the device performance.

At the very least each lot number change must be checked to verify it can perform to the manufacturer's claims. In order to limit the number of lot changes you may consider ordering in larger quantities, and where possible, reserving lot numbers for your site. The size of order will be based on test capacity, storage capabilities and shelf life of the products.

Service providers such as the POC team should ensure that each consignment of consumables is also checked in order to give assurance that the batch has not been compromised from a performance point of view. Even if the consignment contains the same lot number, the delivery may have been stored or shipped incorrectly or been subjected to conditions that may alter the performance characteristics.

A record of lot number acceptance and consignment acceptance processes must be kept. In some cases it will be more efficient for the POCT team to take delivery of all consignments and issue stock after these checks have been made.

External Quality Assurance (EQA)

Where available the device and each associated test must be enrolled in external quality assurance programmes. If there is no scheme available for the test then other ways of assuring the quality of results should be considered to include quality control material, samples sharing schemes, and repeat testing of previous samples. These approaches can be difficult when dealing with point of care equipment due to the nature of the sample but should be considered and recorded if not adopted.

EQA allows for peer comparison and blind assessment of performance across platforms. Most schemes allow the recording of lot numbers of consumables, so there is an opportunity to look at lot number specific deviations, or assess whether devices of the same type are behaving differently.

Critical Review of Quality Data and Measurement Uncertainty (MU)

A critical review of quality data must be performed on a monthly basis by the POCT team. There should also be bespoke audits throughout the annual calendar which are designed to assess the on-going quality challenge.

To provide sufficient oversight of the quality of device performance, there must be an appropriate number of quality control results, generated regularly enough, to be valid.

For instance, if lot number changes are minimised and consignment frequency reduced then there could be an argument that quality control material doesn't need to be run very often at all, with internal checks being sufficient along with monthly EQA participation.

This is short sighted and the absence of quality control data restricts the service provider's ability to sufficiently govern the activity.

One output all providers should be reviewing is Measurement Uncertainty (MU). There are many calculations available for establishing MU but you need to generate enough data points to make it meaningful. The MU of a test is important as it informs the user about the accuracy of the result produced, and whether there could be a deviation from the value reported. For instance, a sodium result of 140 mmol/L with an MU of 1 mmol/L would inform the user that the result could be between 139-141 mmol/L. This is critical to know when results are reported near clinical decision limits.

Critically reviewing quality control data across multiple devices of the same type in your service is also important for establishing variation within the service. It will allow investigations into performance if a device is indicated to be failing or malfunctioning. Regular review will pick up bias and quality control failures, so that action can be taken to troubleshoot, replace or remove devices from service.

Patient Test vs QC Ratio

There is always a debate around the economic viability of performing quality control and the number of patient samples analysed. For instance, if a device is not used every day then analysing QC material each day is not warranted. The other end of the spectrum is when lot number changes or consignments are infrequent which would not prompt a set of QC samples to be performed.

Striking a balance between the economic viability of a service and maintaining quality assurance is key. This should be clinically led and agreed with the service lead. A process should be in place that meets the following:

- Ensures that a device is regularly checked for performance issues
- Enables MU to be calculated regularly
- Checks lot number changes
- Checks that consignments are received in the condition expected and that performance characteristics of those consumables haven't been impacted on
- Devices can be monitored for changes in performance and compared to other devices of the same type within the service
- Offers an assessment of the operator capabilities and competence

In low use areas there should be no deviation from performing quality checks just to make a service more economical. Quality of results must and always will come first.

Who should be performing IQC?

The quality programme should include all users where possible, and as many as possible over the course of a year. There is often a technique to performing these tests and every system employs a range of technologies. Without appropriate training and regular competency assessment, users can form habits which can affect results. They can also damage or affect the performance of the device through employing poor technique which will introduce further uncertainty around result accuracy.

All operators should be involved in the following:

- Have an understanding of the quality requirements and how to interpret the results
- Perform regular QC measurements
- Participate in EQA analysis
- Be aware of the MU value for each test they use
- Have sight of the review of quality assurance report (may be submitted to the POCT Management or Governance Group for review)

Parting message

Quality assurance is everyone's responsibility within any clinical service and should be backed up by knowledge, experience and implementation of ISO standards. There must be a fully engaged management team and governance group that will ensure that the quality management system is implemented effectively and critically reviewed.

For further support contact us through the following channels-

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