WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 5.045
Volume 3, Issue 9, 1449-1457. Review Article ISSN 2277 – 7105

QUALITY CONTROL ASPECT OF POCT

***Dr. Jayesh P. Warade**

Consultant Biochemistry and Quality Manager, Department of Laboratory Services, Meenakshi Mission Hospital, and Research, Centre, Madurai, India

Article Received on
10 Sept. 2014,

Revised on 04 Oct. 2014,
Accepted on 28 Oct. 2014

***Correspondence for Author**
Dr. Jayesh P. Warade
Consultant Biochemistry and Quality Manager, Department of Laboratory Services, Meenakshi Mission Hospital, and Research, Centre, Madurai, India

ABSTRACT

Number of Point of care tests (POCT) have evolved in the recent years. The field of POCT is rapidly developing and the market share is constantly increaseing. POCT devices are beneficial in providing bed side testing and rapid reporting of the tests that helps in managing patients in emergency situation. However theses POCT instrument are only reliable if the results provided are reliable and accurate. Quality controls (QC) exists to ensure accuracy and reliability. For many of the healthcare workers using POCT instruments, QC will be unfamiliar territory, as these staffs are not trained in testing the QC material as well as the analysis of the QC results. Many of the standard QC procedures applied in laboratories cannot be applied to POCT devices. Although there are many benefits of using POCT devices in terms of their convenience, these benefits are only true if the results produced are both accurate and reliable. Ensuring accuracy and reliability is the primary responsibility of Quality Control.

KEYWORDS: Training, External Quality Assurance, Electronic QC, Instruments, Split Sampling.

INTRODUCTION

Quality Control Aspect of POCT

Number of Point of care tests (POCT) have evolved in the recent years. The field of POCT is rapidly developing and the market share is constantly increaseing. POCT devices are beneficial in providing bed side testing and rapid reporting of the tests that helps in managing patients in emergency situation. However theses POCT instrument are only reliable if the results provided are reliable and accurate. Quality controls (QC) exists to ensure accuracy and reliability. For many of the healthcare workers using POCT instruments, QC will be

unfamiliar territory, as these staffs are not trained in testing the QC material as well as the analysis of the QC results. Many of the standard QC procedures applied in laboratories cannot be applied to POCT devices. However, it is essential that both primary and community care settings apply well-structured QC procedures to ensure the accuracy and reliability of results, minimizing risk to patients and improving patient outcomes. In recognition of this, there is now an international standard for POCT, namely ISO 22870, which, in conjunction with ISO 15189, lays out the requirements for quality and competence.

Quality Control (QC) – the set of procedures designed to monitor the test method and the results to ensure the test system is performing correctly. QC includes testing control materials, charting the results and analyzing them to identify sources of error, and evaluating and documenting any remedial action taken as a result of this analysis.

External Quality Assurance (EQA) – an external program that allows sites to check the quality of their results in comparison to other sites by testing an identical sample with an unknown value.

Quality Testing Recommendations

According to ISO 22870 5.6, the quality manager is responsible for the design, implementation, and operation of quality control that ensures POCT conforms to the quality standards of the central laboratory.(1) In the laboratory setting, QC and EQA are used to assess analytical quality. These tools of quality assessment should also apply to the PoCT instruments and be performed on all PoCT devices by routine operators. Laboratory professionals are best able to set quality testing recommendations practicable in the field. They should tailor programs without excessive complexity adapted to be performed by non-laboratory operators in a non-laboratory environment. The degree of technological improvement of the PoCT devices, the level of connectivity and the volume of patient testing are major elements to be taken into account.

Table No.1: Challenges of POCT Quality Control - Unique vulnerability to error(2)
Underestimation of risk by the user 1. False perception of infallibility 2. Pressures of a busy clinical environment
Training and competency verification 1. Large number of users 2. Diverse educational backgrounds
Technical consideration

1. Many locations to control (metrology, documents) 2. Adequate storage space to store specimens to repeat the tests between the last successful QC and a failed QC. 3. Clinical management on receipt of results does not allow the system to be out of control.

The goal of QC testing is to ensure that the POCT system and the operator are performing correctly (testing reliability and routine work quality) and that results correspond to the expected values of the control material. The QC procedure includes control material testing, immediate results analysis and identification of errors to undertake remedial actions. If QC results fail, patient testing should not be performed until the problem is resolved.

Table No.2: Factor Affecting Methods for IQC and EQA in POCT
1. Complexity of the devices 2. Inbuilt checks 3. Frequency of testing 4. Non laboratory operators 5. Cost

IQC plan according to the device complexity(3)

Laboratory type instruments

Full size instruments, for example blood gas analyzers. Similar to instruments found in a laboratory, the QC procedures for these types of analyzers should follow full laboratory QC protocol. Multi-level QC samples should be run on these instruments every day a patient test is performed and the accuracy and reliability of those results should be monitored over time by participating in a frequent PT scheme.

Cartridge - based instruments

For example HbA1c and INR analyzers. These are usually very different from those found in a standard laboratory, consisting of a cartridge based component and an electronic reader, which may have a self-check system built in. Designed to perform QC automatically without the need for operator intervention. The cartridge contains all the necessary components for the analysis of the patient sample while the electronic reader is responsible for converting the results from the cartridge component into a readable numerical value. The difficulty with QC on cartridge-based instruments is that you can only ever test that one particular disposable cartridge and the electronic functioning of the instrument. However, for such devices QC is still essential. The cartridge may have been damaged during transit or the onboard reagents.

Strip - based instruments

For example, electrochemical or reflectance strip-based glucose meters. Designed such that the device will not permit testing unless QC has been performed and the results are in range. These are similar to cartridge-based instruments in that the strips are responsible for the analysis of the sample. However, unlike cartridge devices the electronic component has no self-check feature and without this a faulty analyzer could be producing erroneous results for some time undetected. This makes QC even more important for these types of instruments. Strips should be checked using multi-level QC on delivery and every day of patient testing. Liquid-ready, multi-analyte third party quality controls available from some QC manufacturers are ideally suited for this, as they require no advance preparation and are easy for non-laboratory staff to use.

QC Procedure for Manually read POC Tests.

Manually performed dipstick test share the major fraction of the test performed under POC testing. It is essential to use both IQC and EQA for manually read tests, e.g.: the urine dipstick test. There is a higher degree of human error with manually read tests as results can vary depending on different interpretations and therefore there is a greater need for quality control. Using IQC and EQA will help to standardise results and ensure that reliable results are released. The use of control material can provide reassurance that the dipsticks and automated reader are working correctly and assure the operator of the reliability of patient results.

Electronic QC

1. Electronic QC checks the electronics of the system using surrogate material
2. It does not check the analytical process including issues related to specimen type or application.
3. Electronic QC cannot be a substitute for regular QC
4. It is a supplement to traditional liquid QC requirements
5. It has do be performed according the manufacturer's instruction

"Extreme" built - in IQC: the IQM system

1. Fully automated system in an all in one cartridge (blood gas, electrolytes)
2. Multilevel solutions that contain the actual analytes assessed
3. Monitoring of the whole analytical process in a traditional QC format
4. Free from user intervention

5. No patient test result is released unless the system is within specifications
6. Deactivation of test channels which fail to meet specifications.
7. All patients results are preceded and followed by a successful QC

POCT devices - The role of manufacturers

1. Development of POCT devices that are simple, easy to use, and designed to prevent user andanalytic errors
2. Instrument design to overcome reliance on the user for performing and interpreting IQC
3. Development of built in IQC features
4. auto QC
5. positive/negative controls
6. electronic QC
7. Devices with QC rules built into the software to ensure controlled patient testing

Training in IQC POCT

1. Collaborative approach POCT manager/suppliers
2. Should cover theory and practice:
3. Storage of QC material
4. Preparation of QC material
5. Appropriate QC frequency for each test
6. Principles and practice of QC testing
7. Remedial actions for failures
8. Recording and documentation of actions
9. Proof of assessment (theory and practice):
10. written short questions, multiple choice test
11. Situational to test skills : how to run QC

Table No.3: Characteristics of a QC for Use in POCT	
1. Convenient and easy to use 2. No need for dilution or reconstitution 3. No need to thaw before use 4. Wide range of storage temperature 5. In the clinically relevant range	QC sample included with the test kit may be used Controls from a third party supplier recommended where possible

Table No.4: Frequency of QC Testing
All POC site should establish there own frequency of QC testing according to manufacturers guideline and workload.

In addition to the regular QC program, QC testing should be considered in following situations 1. New delivery of consumables/reagents 2. New lot number of consumables 3. An operator lacks confidence in a patient result 4. The POCT result does not fit the patient ‘s clinical picture 5. Substantial maintenance procedures have been carried out 6. The device has suffered a physical insult
Electronic QC are performed as defined by the manufacturer
Low complexity devices using strip technology - One QC sample per month as a minimum requirement preferably in pathological range; and if 2 levels are available : one normal and another should be abnormal.

Processing of POCT quality control samples

QC testing for POCT shall be undertaken by the POCT Operator. All operators who at any time use the device should participate in the quality control program. Ideally there shall be a collaborative approach between POCT Coordinators, suppliers and if appropriate the associated NATA/RCPA accredited laboratory. Minimum acceptable operator training standards shall be documented and available for review. At completion of training, POCT Operators should have their knowledge and technical competency assessed. The POCT Operator undertaking QC testing shall immediately review the QC results and take any appropriate action. The POCT Coordinator or delegate should be responsible for review and trend analysis of QC results, taking appropriate corrective action when required and operator participation. All QC records, reviews and corrective action documentation should be maintained for three years and be available for review

Table No.5: Plan for IQC Recording and Interpretation
1. This step has to be simple and reliable 2. Systematic and immediate interpretation 3. Plotting of result on a control chart with date, values, operator’s name 4. Comparison with limits of acceptability 5. Protocol of actions if QC fails

External Quality Assurance (EQA)

ISO 22870 5.6.5 recommends that where available, participation in an external quality assessment (EQA) shall be required.(1) In the absence of an EQA scheme, the Laboratory Director, or designated person, should establish an internal quality control assessment scheme involving the circulation of samples or replication of the test within the laboratory. However, parallel patient sample testing (correlations) between POCT devices and a central laboratory though could be measure of proficiency testing however is not an alternative of an EQA

program. EQA testing should be performed by PoCT operators but review of results should been undertaken by laboratory professionals. Feedback should be provided to operators. For manually performed dipstick test, it is advisable that all sites using dipsticks undertake the analysis of EQA samples.

Table No.6: Challenges in POCT EQA
Limited period of time to perform testing and to return results on each POCT site
Low frequency of testing
Packaging: sealed glass vials 1. How to safely break open the vial 2. How to reconstitute the material 3. How to pipette the material if necessary
In case of unsuccessful result 1. identifying the cause 2. developing an action plan
Recording of results

Split sample testing

ISO 22870 6.8 states that, split patient samples, or other acceptable QC materials, shall be used to verify performance of POCT systems used in multiple sites (1)

When EQA is not available

At a regular predetermined frequency

POCT sample is also tested in the laboratory

Advantage

Use of patient samples

Test also the preanalytical procedure

Limitation

Level of uncertainty of the 2 methods

You cannot assume that the laboratory results is the true

No peer comparison

Limited range of concentration level

Sample deterioration during transport

Parallel Testing

Parallel testing of a patient sample in the laboratory can provide a QA tool. This needs to be well planned and the comparative data recorded and scrutinised. It has the advantage of using

patient samples which avoids possible matrix effects of control material but it may have the disadvantage of requiring more blood, which might be collected differently to that normally used for the POCT device. POCT managers also need to take into account possible ethical considerations (including patient consent and confidentiality) when planning parallel testing.(5)

EXTERNAL QUALITY ASSURANCE (EQA)

A form of external quality assurance should be undertaken for every PoCT device.

Participation in a recognised EQA program is recommended for each analyte being tested. Monthly split patient sample testing with an accredited laboratory may be considered as an alternative form of external quality assurance. This mode of EQA may be useful when a commercial program is either unavailable or unsuitable for the instrument in question.

However, users must be aware of limitations of using the split patient sample approach which include laboratory method performance, limited range of testing, transport stability and lack of peer comparison.

Processing of POCT EQA

EQA for POCT should be run by the POCT Operator. Processing of EQA also should be considered as collaborative approach between POCT Coordinators, EQA Scheme Organizer, suppliers and if appropriate the associated NATA/RCPA accredited laboratory. Minimal acceptable training standards, including refresher training should be documented and available for review. At completion of training, POCT Operators shall have their knowledge and technical competency assessed. The POCT Coordinator or delegate should be responsible for the review of EQA results and taking appropriate action. All EQA records, reviews and documentation should be available for review and maintained for three years. Review of both QC and EQA should be supervised by a scientist with specialty knowledge of POCT. This may be a scientist in a NATA/RCPA accredited laboratory or a POCT specialist provider. For institutions that are NATA/RCPA accredited this is mandatory.(4)

CONCLUSION

Although there are many benefits of using POCT devices in terms of their convenience, these benefits are only true if the results produced are both accurate and reliable. Ensuring accuracy and reliability is the primary responsibility of Quality Control. Maintaining quality control in POCT is most important for POCT to be prove as useful in bed side testing for patients in

emergency and intensive care units.

REFERENCES

1. International Organization for Standardization (ISO). Point-of-care testing (POCT). Requirements for quality and competence. Document ISO 22870:2006. Geneva.
2. Quality Control issues in point of care testing. C L Martin. Clin Biochem Rev 2008;29 Suppl (i):S79-S82.
3. Assuring quality in Point-Of-Care testing. Evolution of technologies, informatics, and program management. K Lewandrowski, K Gregory, D Macmillan. Arch Pathol Lab med. 2011;135:1405-1414
4. Thinking of Introducing PoCT – Things to Consider 20 March 2014. International Federation of Clinical Chemistry and Laboratory Medicine.
5. Management and use of IVD point of care test devices. IVD POCT devices v1.1 December 2013.