Quality assurance and its application in hospital laboratories

A reflection onquality assurance and its application in hospital laboratoriesand in the community (POCT) to indicate competence in understanding the importance in a health care setting

Within hospital laboratories two of the essential components of the quality system are quality assurance and quality control. The quality system is a vital part of a laboratory setting as the produce test results for patients. The patients' health outcome relies on the accuracy of the testing and reporting of these results. If inaccurate results are provided the consequences can be highly significant such as delayed or incorrect diagnosis or the patient being put through the wrong or unnecessary treatment, these errors can cost time, personnel effort and the outcome for the patient.

Quality control is a vital part of quality assurance, its development in a hospital laboratory is the statistical process of detecting, reducing and correcting deficiencies in the analytical process within the laboratory this is to ensure the results are both accurate and reliable before being released to patients. Quality control is a reactive process as it deals with the output of a process after being developed. The responsibility of quality control in a laboratory are the biomedical scientists as these are the ones who are testing the samples.

The goal of quality assurance is to systematically monitor and evaluate the quality appropriateness of test results. It is a proactive process as it aims to prevent the occurrence of defects. The responsibility of quality assurance is of everyone involved. It involves activities both in and out of the hospital laboratory Quality assurance improves the test process and development so

that when a product is being developed defects do not arise. Good laboratory practice and proper management skills are vital part of quality assurance. The main objective of quality assurance is to guarantee the right result is given on the right specimen at the right time, from the right patient and that it is interpreted according to the right reference data. (1)

A Quality care manager is appointed within a hospital laboratory to ensure the quality system functions as it should and sometimes they are involved with external bodies who will check the quality of the results, but all staff are responsible for applying the quality system within the laboratory. Biomedical scientists play a key role in this process as they are responsible for carrying out the relevant laboratory tests to support the diagnosis and treatment of the patient. Processes that biomedical scientists have to follow with quality control are:

- Method validation which confirms that the analytical procedure employed for a specific test is fit for its intended use the eight steps used for method validation are; Accuracy, Precision Specificity, Limit of detection, Limit of quantitation, Linearity and range, Ruggedness, Robustness.
- Standards and reference materials. In order to determine validation parameters, you will need to have reference standards also known as controls containing a known amount of a specific substance. Standards provide a reference that can be used to calibrate instruments or to determine unknown concentrations.

- Monitoring performance with control charts. A control chart is a method that is used in the form of a visual graph this is used for monitoring a cumulative performance. An example of a commonly used control chart is a Shewhart chart. Using charts is a reliable method as it illustrates developing trends and they give an indication of problems that require investigation.
- Monitoring performance with proficiency testing. Proficiency testing is another procedure where laboratories are tested on their continuous performance. This is done by the laboratory along with other laboratories being sent samples which are identical which they then analyse and then report back to an administrator. These results can show how a laboratory is performing.

Point-of-care-testing (POCT) is a way of performing biomedical tests at the patient’s bedside on the ward, outpatient clinics, GP surgeries and even in your own home. POC tests are designed to give a positive or negative qualitative result or in other instances an accurate numerical measurement. Validation of POC instruments is a vital component of an effective POC implementation. The most valuable components of a validation are; accuracy, precision and method comparison, with method comparison being extremely valuable. Biomedical scientists must be able to identify how or if the POC results will differ from results derived from the automated instrumentation in the central laboratory. In addition, quality control should run regularly to maintain competency within the staff and to ensure the devices are performing accurately. The results of a POC test are highly dependent on the person who is carrying out and analysing the results.

Advantages of POC testing are efficiency as the tests are performed at either the patient’s bedside or within a doctor’s surgery it uses efficient work flow process, a fast turnaround time since no specimen transport is required and the test is performed bedside, also only a small volume specimen is required many POC tests require less than 300 microlites of blood or urine, as the result is rapid medical decision can me made an implemented a lot quicker than laboratory based results. Samples do not need processing such as the blood does not need to be centrifuged as the sample is tested as soon as it is obtained

Disadvantages of POC testing are cost; in general, POC testing will come at an increased cost as it is at a cost of each individual test rather than the type of tests that are performed on a large platform within the laboratory. Quality is a concern because the tests are performed by nurses or other non-laboratory personal these people have many other responsibilities aside from laboratory testing which can lead to distractions during testing and things being overlooked. In addition, even if performed correctly some POC devices may not be as precise, accurate and/or analytically sensitive as their automated laboratory counterparts. Compliance is a huge concern with POC tests as documentational results, users and competency can be very difficult when there are a variety of personnel performing the testing. The quality of the result will always depend on the quality of the sample so if a poor-quality sample is taken that will lead to a poor-quality result which in turn can lead to incorrect treatment that could potentially be life threating.

In conclusion POC testing can provide rapid results to patients within the clinical flow although this is seemingly quite attractive and can be beneficial to patient care.

References

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