CHAPTER 13

Quality Control/Quality Assurance

Quality Control/Quality Assurance (QC/QA) can be defined as the set of planned and systematic activities focused on providing confidence that quality requirements will be fulfilled. It covers a wide range of matters that influence the quality of a product or service. In a medical laboratory, the quality can be defined as accuracy, reliability, and timeliness of the reported test results (1). QC refers to those measures that must be included in each assay to verify that the test is working properly. QA is defined as the overall program that ensures that the final results reported by the laboratory are as correct and accurate as possible.

I. Negative consequences of laboratory errors

This broad concept applies to any kind of laboratory testing, including diagnostic testing for bacterial meningitis. Inaccurate meningitis diagnostic results can have significant consequences at the patient care or public health level. At the patient care level, errors can lead to:

- Failure to provide proper treatment to the patient
- Unnecessary treatment, treatment complications, or additional expenses
- Delay in correct diagnosis
- Additional and unnecessary diagnostic testing

At a public health level, laboratory errors on the species, serotype or serogroup identification, as well as antibiotic susceptibility profiles, can impact a cornucopia of public health decisions on the following matters:

- Delay in determining when the epidemic threshold has been reached and implementing public health measures
- Inadequate national control measure recommendations or treatment algorithms
- Inappropriate choice of antibiotics or vaccines

These consequences result in increased cost in time, personnel effort, other resources, and poor patient outcomes in terms of morbidity and mortality.

II. Quality management system

To achieve the highest level of accuracy and reliability, standard QC/QA testing procedures and conditions must be practiced in laboratories on an every day basis. A quality management system, which oversees the entire system, is very important for achieving optimal laboratory performance. Laboratory processes can be grouped into pre-examination, examination, and post-examination categories. Quality management measures should be applied during the entire path of workflow that begins with the patient and ends in interpreting and reporting results. The quality management system is not only concerned with monitoring QC/QA programs, but should also include administrative considerations that may indirectly influence the quality and efficiency of the laboratory operation.

A widely used quality management system model organizes all of the laboratory activities into twelve quality system essentials, which are a set of coordinated activities that serve as building blocks for quality management (2):

1. Organization and supervision
2. Personnel
3. Equipment
4. Purchasing and inventory
5. Documents and records
6. Process control
7. Information management
8. Occurrence management
9. Assessment
10. Customer service
11. Process improvement
12. Facilities and safety

Some of these elements constitute management requirements (i.e., organization, documents and records, and purchasing and inventory) while other constitute technical requirements (personnel, equipment, and process control with the examination procedures) (3). Many of the twelve quality system essentials overlap each other (i.e., there is a close relationship between documents and records, and information management).

A. Quality systems essentials for meningitis diagnostic laboratories

Most of the quality systems essentials described above are not specific to the meningitis diagnostic laboratory and should apply to all laboratory disciplines regardless of the nature of the specimens, pathogens, or assays. However, some specific meningitis laboratory quality assurance measures can be highlighted. Many of them are detailed again in the respective chapters of this manual.

1. Organization and supervision

The structure and management of the laboratory must be organized so that quality management policies can be established and implemented. The laboratory should prepare an organizational chart that reflects the hierarchy and lines of authority with functions and responsibilities of each post. The current duties and responsibilities of staff should be specified in written job descriptions including training required and necessary experience. The director's commitment is crucial. A quality manager should be designated to ensure the implementation and monitoring of the quality policies.

2. Personnel

The most important laboratory resource is a competent, trained, and motivated staff. Continuous education opportunities should be offered to the staff and recorded, especially if new tests or methods are introduced. Regular competency assessment and proficiency testing should be conducted and documented. This can be done by direct observation of the personnel, records monitoring, and/or by analyzing the quality control or the external quality assessment results.

3. Equipment

Specimen identification and characterization requires many types of equipment, such as microscopes, incubators, autoclaves, biosafety cabinets, refrigerators, freezers, water baths, automated identification systems, or antibiotic susceptibility systems. Choosing the right equipment, installing it correctly, assuring that the staff is properly trained to use the equipment, and assuring that the new equipment works properly and receives proper maintenance are crucial. Equipment manuals should be available in the laboratory area for easy reference. An inventory of equipment including records of maintenance and repair should be maintained.

4. Purchasing and inventory

Proper management of purchasing and inventory of reagents, media, and supplies can produce cost savings in addition to assuring accurate and timely reporting of laboratory results. The procedures should be written and implemented to assure that all reagents and supplies are correctly selected, purchased, used, and stored in a manner that preserves integrity and reliability. The inventory should be kept up to date including information on reception, storage, and issuance. Package inserts and Material Safety Data Sheets (MSDS) should be archived as part of records keeping.

5. Documents and records

Documents provide written information about policies, processes, and testing procedures and should be stored in the laboratory quality manual for each laboratory. This manual should serve as a basis for writing the laboratory Standard Operating Procedures (SOPs) which need to be adapted to the laboratory's role and capacity. The SOPs, QC/QA procedures, specimen testing request forms, report forms, and other laboratory forms are all important components of the quality manual, which documents the quality management system.

An SOP should be written for all procedures in the laboratory, including specimen collection, transport, storage, waste disposal, Gram stain, microscopy, biochemistry measurements, culture, identification, antimicrobial susceptibility testing, typing methods (serological or molecular methods), reagents and media preparation, equipment use and maintenance, and SOP writing.

Examples of records include request forms, report forms, logbooks, quality control results, patient reports, critical communications, and notices from hospitals or public health authorities. See Chapter 3: Results Management and Reporting of Data for items that should be included in the request and report forms.

6. Process control

Process control refers to control of all activities involved in the operation of a laboratory, from pre-examination to post-examination steps.

One of the most familiar process control measures is the use of internal QC to monitor the performance of examination methods. Internal QC of specimen identification and characterization should include:

- Regular QC to check media and reagents, such as agar plates and serogrouping or serotyping antisera. QC should be performed quarterly as well as when a new lot is received in the laboratory.

- Well-characterized reference control strains (gram-positive and gram-negative) should be used to assess the following tests: Gram stain, culture procedures, identification, serogrouping or serotyping, PCR, and antimicrobial susceptibility testing. If access to QC strains is difficult, well-characterized clinical isolates confirmed and characterized in a reference laboratory (such as a WHO Collaborating Center) are available. Isolates received from another laboratory as part of a proficiency testing program received in the scope of External Quality Assessment Schemes can also be used.

- Internal QCs included in rapid diagnostic tests are to be used each time the kit is used.

7. Information management

Written SOPs should be developed for data management, cleaning, and reporting.
See Chapter 3: Results Management and Reporting of Data.

8. Occurrence management

An "occurrence" is an error or an event that should not have happened. A system is needed for detecting and documenting these occurrences, for handling them properly, and for taking corrective action to reduce the chance of recurrence. Common errors include:

- Patient identification error
- Specimen misplacement
- Specimen transport delayed or at insufficient temperature
- Contaminated specimens
- Performing an inappropriate test
- Performing a test inconsistent with the written procedure
- Lack of QC/QA
- Transcription and clerical errors

Occurrences are detected through various means, such as supervisory review, physicians' or patients' complaints, QC/QA results, or findings from external audits. Immediate remedial corrective action should be undertaken before the result is reported to the clinician or public health authorities. Ultimately, corrective actions should be implemented to prevent similar errors from recurring.

9. Assessment

Assessment is a tool for examining laboratory performance and comparing it to known standards or to performance of other laboratories. Assessment may be internal, performed by the laboratory's own staff, or may be external, conducted by an external group or agency outside the laboratory.

- External Quality Assessment (EQA) is a system for objectively checking the laboratory's performance using an external agency or facility. There are three commonly used EQA methods or processes:
    - Proficiency testing (PT) through a panel of unknown specimens sent regularly to the laboratory by an organizer. The laboratory reports the results back to the organizer who will compare the test results with known results and record a pass (all results concordant) or fail (any discrepant results) for the PT.
    - Confirmation by sending a subset of isolates to a reference laboratory for re-identification and characterization.
    - Site visits conducted by inspection, certification, or accreditation bodies.
- Internal audits can be conducted by the staff of the laboratory to identify weaknesses and undertake corrective actions.

- Quality indicators can be defined by the laboratory management and staff to complement the use of internal QC. While internal QC primarily assesses the examination steps, other quality indicators can be designed to monitor the pre- and post-examination steps:

    - Percentage of cerebrospinal fluid (CSF) specimens received from remote areas and not transported in Trans-Isolate (T-I) medium (if T-I was available but not used). This indicator provides information on the pre-examination performance.

    - Percentage of CSF specimens received without appropriate identification, which provides information on the pre-examination performance.

    - Discrepancies between the CSF macroscopic examination and the cell count, which provides information on the examination performance.

    - Inappropriate antibiotic treatment after the antimicrobial susceptibility testing report is given to the physician, which provides information on the reporting system performance, physician error, or if the proper antibiotic is not available.

    - Percentage of results reported on time, which provides information on examination and reporting performance.

10. Customer service

The laboratory should understand who their customers are (the patients, the physicians, or the public health authorities), assess their needs, and use customer feedback for making improvements. Customers' satisfaction can be assessed by means of questionnaire, interviews, or meetings.

11. Process improvement

The primary goal of a quality system is continuous improvement of the laboratory processes in a systematic manner. A number of tools have been described above to identify errors, such as customer service surveys, internal QC, EQA, auditing, and quality indicators. A rigorous analysis of all of these indicators should lead to improvements in procedures and practices. These changes should be recorded and reflected in the SOPs and implemented in the laboratory. Open communication among staff members is also important to encourage suggestions that may improve the quality and efficiency of the laboratory.

12. Facilities and safety

The laboratory should develop SOPs for biosafety, basic safe operating procedures, and waste management that are adapted to their specific role in the laboratory and in conjunction with institutional policies. See Chapter 4: Biosafety.

References

1. WHO/CDC/CLSI. Laboratory Quality Management System Training Toolkit. 2009. http://www.who.int/ihr/training/laboratory_quality/en/index.html.
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3. ISO 15189:2007. Medical laboratories: requirements for quality and competence. Geneva, Switzerland: International Organization for Standardization; 2007.