Quality Assurance and Fungal Diagnostics

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PHE

Question: What does QA mean to you?

- 1. Quality Assessment
- 2. Quality Assurance
- 3. Quality Accreditation
- 4. Question and Answers

Quality Assurance-Definition

- QA is the total process whereby the quality of laboratory results can be guaranteed.
- The reliability of results is improved by undertaking QA therefore minimising the variability of results.
- The variability may arise from biological or analytical sources,

  -fundamental in all qualitative and quantitative investigations.

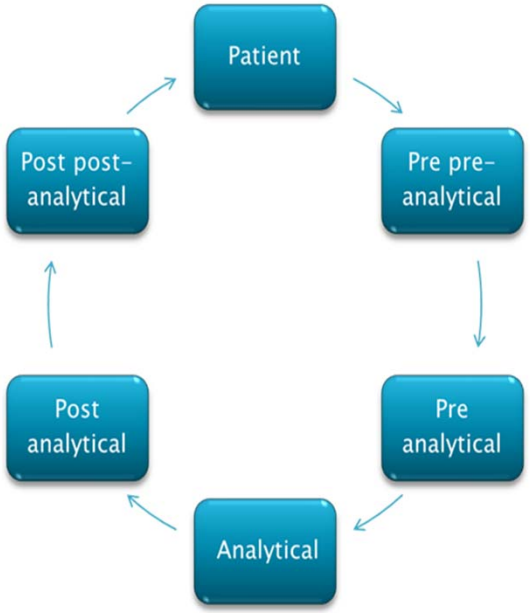
Components of QA

- good laboratory practice
- internal quality control (IQC)
- audit
- validation
- internal quality assessment (IQA)
- accreditation
- evaluation
- education
- external quality assessment (EQA)

Total Testing Process (TTP)

- The total testing process is the unique framework in revealing and resolving errors in laboratory medicine.
- Several stages in the TTP can be assessed and evaluated via IQC, IQA and EQA procedures.
- Presently there are EQA schemes available to assess the analytical and post analytical stages of the TTP.

Total Testing Process



Analytical stage

- Conventional testing may be used alone or in combination with various modern analytical systems e.g MALDI-ToF-MS and VITEK™.
- The quality of results from new technologies is not guaranteed and appropriate quality assurance and analytical quality control measures need to be taken
- training and assessment, in just the same way as traditional testing methods.

Post-analytical stage

- Reporting of results using modern information technology or manual authorisation requires appropriate quality assurance and implementation of quality control measures to ensure the accuracy and timely release of reports to the requesting clinician.

Internal quality control (IQC)

- IQC is carried out continuously within the laboratory to ensure the systems are performing to pre-defined specifications.
- IQC assesses and monitors test performance in real time to ensure consistent performance and reproducible results.
- This process monitors or measures reproducibility, but not necessarily the accuracy.
- The majority of IQC procedures involve the analysis of the control material or international standards where available, and compares this to the accepted levels predetermined at the validation stage of the test procedure.

Internal quality assessment (IQA)

- IQA is a system in which clinical specimens are anonymously re-introduced back through the diagnostic laboratory process.
- This ensures the processes are operating at an acceptable level and monitors performance of staff and test procedures, ensuring they are consistent

External quality assessment (EQA).

- The terms EQA or Proficiency Testing (PT) are used to describe a method that allows comparison of a laboratory's competence in testing, to an external source.
- process can be defined as a system for objectively checking the laboratory's performance using an external provider.
- main objectives of an EQA are to provide inter-laboratory comparability, standardisation of diagnostic testing and fundamentally as an educational tool.
- EQA can provide laboratories with the following necessary information to help them:

Question: What does EQA entail?

- 1.Testing the recipient laboratory with undisclosed contents of a clinical specimen
- 2. Comparison of performance with other laboratories participating in the EQA
- 3. Detect equipment faults, identify reagent problems and review staff training
- 4. Assurance of results determined
- 1,2,and 3
- 1 and 2
- 2 and 3
- 1 and 3
- 12,4
- 134

- All of the them

- Maintain and improve analytical quality
- Improve inter-laboratory agreement and raise standards
- Detect equipment faults, identify reagent problems and review staff training
- Initiate and evaluate corrective actions
- Compare performance to different analytical methods
- Ongoing monitoring of EQA performance using an accredited EQA scheme will help to reduce laboratory errors, produce accurate patient test results and most importantly improve patient care.

What is the most useful diagnostic test for fungal diagnosis?

- Direct microscopy
- Culture
- Histopathology
- Antibody
- Antigen
- Molecular techniques
- Proteonomics
- WGS/NGS

EQA schemes

Range of tests available for mycology services has been expanding and now encompasses

- identification and susceptibility testing of yeast and moulds, including dermatophytes
- antibody testing for candidosis and aspergillosis
- antigen testing for cryptococcosis
- DNA detection for Aspergillus and Candida,
- antifungal assays, there are some notable gaps.

- Participation in external quality assessment (EQA) plays a vital role in the quality management and improvement of services offered by clinical laboratories, thereby furthering the ultimate aim of ensuring a high standard of patient care. Increasingly, bodies that provide accreditation of clinical laboratory performance are looking for participation in a range of EQA schemes that encompass the entire repertoire of tests undertaken by a laboratory.

Interpretative comments

The role of interpretative comments in improving patient outcomes has been acknowledged

UK NEQAS for Microbiology deliver an interpretative comments scheme to provide the opportunity for medical personnel to participate in inter-laboratory communication on previous clinical case reports

The results obtained indicate that interpretation provided by laboratory professionals with inadequate expertise can be detrimental to the care of the patient, and highlight the need for improvement in the standard of interpretation

The possibility of Interdepartmental cooperation (Round robin testing) may help avoid errors in medical laboratories

Pan UK NEQAS
(pre and post monitoring- PREPQ)

- Assessing provision of a pre and post analytical monitoring service in all disciplines of laboratory medicine.
- An aspect of the quality management to investigate post analytical errors.
- Investigate variable factors:

  age of specimen

  quality of specimen e.g correct specimen type

  volume received

  type of test performed (appropriate tests requested)

  turn around time (time taken to reporting results)

  interpretation of results (correct/incorrect)
- Data collated presently on the pre-pilot distributions

Summary

- All laboratories are strongly advised to integrate QA procedures as part of maintaining professional standards of service.
- Full and regular participation in appropriate EQA schemes is a necessary and integral part of the rational provision of a reliable clinical laboratory service.
- EQA should be viewed as educational and utilised as a tool to help drive improvement efforts in the laboratory and is one of the critical elements of a laboratory quality management system.
- Ultimately EQA specimens must be treated as patient samples following the routine testing methods and the procedure must involve personnel who routinely perform the testing.