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Review Article

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Importance of External Quality Assurance (EQA) and Quality Control (EQC) programs in Clinical Laboratories: Review

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Abstract External Quality Assurance (EQA) programs are essential to have a standardized reputable clinical laboratory that ensures reliability, precision, accuracy, best turnaround time and reproducibility of its test results. Since long, established and highly regarded clinical labs all around the world are strongly following EQA programs, inclusive of internal quality controls, calibration and acquiring quality management systems and accreditation such as from College of American Pathology (CAP), JCIA and CLSI. Present review briefly described the importance, understanding, several rules of EQA and its sustainable benefits.

Keywords External Quality Assurance EQA, College of American Pathology CAP, quality management systems QMS, CLSI

Short title: EQA and EQC in clinical laboratories

Introduction

External quality assurance programs, generally known as EQA/EQC are a significant component to asses accuracy, precision, quality of the results and/or the parameters, whether biochemical, hematological, microbiological, or histopathological origin, been analyzed and as of now, mandatory part of running a clinical Laboratory [1]. Off course and essentially, a good reputable clinical lab stand by rules of quality, precision and better services to its patients and peers; and to achieve that, put every effort viz human resource, technology, management, administration, trainings etc, to sustain its quality assured services [2-5]. More emphasis received in last 15 years or so because of significance and practice of evidence based medicine, where chances of medical decision errors shall remain negligible [6,7] Clinical Laboratories, governed by quality management system, internal and External QC, EQA and any other type of quality assurance programs such as accreditation from JCIA, CLSI, College of American pathology (CAP), ISO 15189, ISO 9001:2015 etc, ensure long term sustainable reliability, accuracy and precision of lab results [8]. This review article describes few important QMS/EQA/EQC/QC components that all reputable clinical laboratories have established to perform better, precise, reproducible results and continual services.

Revolution: from internal and national QA/QC programs to International EQA/EQC and accreditation, certification: 20th century experience, post World War II:

It is well documented that it's late 1940s, when EQA was pioneered by two scientists Dr Belk and Dr Sunderman [9]. Since then, clinical laboratories came a long way from development of huge mammoth analyzers to present day, hand held analyzers; very efficient turnaround time (TAT) nowadays-seconds to minutes; from hours of analytical

steps and preparation of samples during earlier days; hazardous chemicals and burners 1950s till 1980s to battery fitted portable analyzers, which can easily be used by patients as well [6,8]. EQA, is now a essential part of any good clinical laboratory that pledged quality assured, efficient service to its patrons and patients [2,7]. Additionally, it became an integral part of QMS, accreditation or certification, without EQA, efficacy, credibility and precision of analytical steps, parameters and maintenance became questionable. Using EQA, in addition to labs own internal QA and QC, improves working, efficiency, management, analysis, maintenance, calibration of pledged services that a patient needs or a physician requires. Several EQA services are now been offered by national and international organization such as College of American Pathology (CAP), WHO programs, RIQAS (Randox), Biorad 3rd party EQA, some certifications programs offered by CLSI (clinical lab standard institutes, USA). As development of EQA, QMS and clinical lab standardization progresses in western world, our own Asian countries didn't stay behind and progressed in standardization and EQA programs, for example Indian NABL (The national accreditation Board for testing and calibration laboratories; & Christian Medical College, Indonesian The national accreditation committee (KAN), Thai-The Bureau of laboratory quality and standards (BLQS), International laboratory accreditation cooperation (ILAC) and Asia Pacific laboratory accreditation cooperation (APLAC) [1]. In general, EQA, entwined with QMS, ensures timeline, accuracy, precision of analytical parameters, and the resultant data, that guaranteed by laboratory, for physicians and clinicians to make medical decision and saves live. Quality of a lab product, which is its reports, directly dependent on its analytical steps, which can only be assured if it adhered to prescribed SOPs, when the lab has a strong EQA program.

Purpose and how an EQA program works

Purpose of having an EQA program always portray a strong management commitment, good lab team and ethical adherence to QMS and pledged services to patients. Having an EQA program, doesn't automatically absolve labs in using internal QA/QC or QMS programs, having multi level, variable outcome programs, ensures management at every level and 3D compliance. Steps in a routine EQA program always starts with sending (or receiving) unknown samples (with hidden results) to participating labs, analysis and reporting the results to the system, data analysis Z score, SDs etc and then interpretation of analyzed results/data and taking corrective action, correction and preventive actions (CPA). Implementation of CPA is as important as actual analysis and data interpretation, which ensures management of deviation and rectification where needed, including staff training, reagents checking, maintenance, calibration, methodology evaluation and analytical ranges [10-13]. Most of EQA programs not only provide data regarding accuracy and precision of existing analytical system in a lab, but also helps in verification of precision, accuracy, sensitivity, specificity, interfering components, analytical and reference ranges. Having an EQA program with atleast one cycle per year (mean testing samples sent once per years) is a minimal measure a good clinical laboratory can do to ensure its professional practices and sustainable results/reporting. Validation and verification of analytical procedures is also a component well addressed since many years by JCIA, WHO, CAP, CLSI and thus a significant part of quality assured service. EQA also provides confirmation of analytical procedures to some extent, however, separate methods, procedures should be employed to check and then ensure proper, standardized analytical steps and principals.

Components that qualify an EQA program as good with 360^{o} 3D attributes

EQA program, both national and international, are entities accredited by government and/or a competent authority of international repute such as CLSI and WHO. CAP, one of the very famous EQA program with extensive menu of parametric tastings in 1000s, quality to be known as EQA program of higher standard as it provides verification of precision, accuracy, sensitivity, specificity, interfering components, analytical and reference ranges. However, every lab must choose an EQA program keeping in view their convenience of financial, analytical, administrative bindings that such program needs essentially. Been done with choosing an EQA program, doesn't absolve labs in not having routine internal quality control and assurance programs. Similarly, routine maintenance, calibration is a must to sustain credibility and even having a good results after utilizing an EQA program. Few points that should be taken into consideration before choosing an EQA program by clinical lab;

- No financial burden thus sustainability of EQA sample supply every year
- Coverage of majority of testing profile that clinical lab offers to patients
- Scientific and clinical reliability, relatable, reproducible and sustainable
- Easy to understand, follow and implement methodologies for EQA sample receiving, storage, analysis and data documentation
- Reliable data interpretation, returning of results, easy to read and follow EQA reports
- Chances of CPA and training where needed, means continual education
- Scientific and technical support

During last 2 decades, pre-analytical, analytical and post-analytical errors of clinical laboratories has decreased drastically due to more modern advanced technology, trainings, scientific and technical awareness, availability of education and sustainable and off course stringent EQA programs and focus on internal quality control and assurances. Less and less errors mean more and more reliability and trust of patients and physicians on lab data/results. Therefore, having an EQA program in a good, tertiary care clinical lab should be mandatory, in addition to strong internal QA/QC activities, including maintenance and calibration.

Conclusion

The review described briefly importance of EQA and EQC programs, its modules, requirements and systemic modalities. Clinical Lab having an effective EQA programs are reputable, known for their precision, accurate and reliable results and have a better share of services regarding patients care and peer reliance.

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