EXTERNAL QUALITY ASSESMENT OF MEDICAL LABORATORIES: REQUIREMENT OF MKS EN ISO 15189:2013

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Abstract: One of the main aspects of laboratory quality improvement is participation in external quality assessment schemes (EQAS), proficiency testing (PT) or interlaboratory comparisons (ILC). According to the requirements of the standard ISO EN 15189:2012, participation in EQAS is mandatory for each accredited laboratory. Accreditation is a formal recognition of eligibility to perform certain set of activities. National accreditation body (NAB) can monitor technical competence of the lab through participation in EQAS.
Aim of the study: Assessment of the results of participation in EQAS for Biochemical Analyses Laboratory (BAL).
Material and methods: BAL, within the Institute of Medical and Experimental Biochemistry, Medical Faculty-Skopje, is a medical laboratory accredited according to the International Standard MKC ISO EN 15189:2013.
BAL participates in EQAS organized by Instand eV, Dusseldorf, Germany, since 2011. We analyze results of EQA after every survey. Institute for accreditation of the Republic of North Macedonia is NAB. As accredited laboratory, BAL has an obligation to fulfill two documents: plan for participation in EQAS/PT/ILC and review of participation (documents OB 05-18-2 and OB 05-18) and to present them to the lead assessor and technical assessor on annual basis during the on-site assessment of the laboratory.
Results: Our laboratory participates in surveys for: haematology (differential blood count) and clinical chemistry (conventional analyses). Performance in the last 8 years varied by panel.
Testing samples from each panel are sent to the BAL 3-4 times/year. There is variation in performance, with a best annual average performance in 2016 and 2017. Acceptancce criteria is +/- 2SD.
Except for haematology, annual performances for enrolled panels varied from year to year, indicating some difficulty in maintaining consistency in quality.
The main challenges of the EQAS program observed between 2011 to 2019 were funding, sourcing, and safe transportation of quality panels to our laboratory. All these failures in the last years have helped us to significantly improve our overall quality of laboratory practices. Corrective and preventive actions are issued for outlying EQA results. By directing corrective measures at root causes, we had realized that the likelihood of problem recurrence was minimized.
Key benefit of participation in EQAS is improvement of the laboratory performance through: discovering of sources of error; systematic errors; demonstration of effectiveness of changes; common understanding of method differences; discovery of method sensitivities, etc.
Conclusions: We therefore recommend all laboratories to participate in the EQAS program. Successful performance in an EQA programme reflects the effectiveness of the laboratory's quality management. EQA is important for improvement of the laboratory quality management system, as it is a measure of laboratory performance.
Keywords: accreditation, ISO 15189, medical laboratories, EQAS

1. INTRODUCTION

One of the main aspects of laboratory quality improvement is participation in external quality assessment schemes (EQAS), proficiency testing (PT)[9] or interlaboratory comparisons (ILC)[10].
External Quality Assessment (EQA) is an objective assessment of laboratory's performance by an external facility, agency or personnel.[11]
EQA helps to assure customers, like physicians, patients, and health regulatory authorities in quality of laboratory's performance.[12] In terms of lab tests it means that laboratory results are accurate and reliable.[13] Medical laboratories

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should use EQA to identify issues in laboratory's everyday practices, allowing for applicable corrective action. EQA participation will help to evaluate reliability of methods, materials, and equipment, and to evaluate and monitor competency and training of the personnel. EQA can help to assure that results from different laboratories are comparable. Samples received for EQA testing, as well as the information shared by the EQA provider, are useful for conducting continued education activities.

When participating in EQA programs, the laboratory needs to develop a procedure for the management of the process. A primary objective is to assure that all EQA samples are treated in the same manner as other samples tested. [14]

Management has to assign responsibility for each staff member. Each member should be informed who is the organizer of the EQAS, when are the terms for assessment, types of materials, test that should be assessed and methods for their detection.

Management should monitor and maintain records for test performance, internal quality control (IQC) and EQC.

Standard operational procedures must be developed for preexamination, examination and postexamination phase of the total testing process (TTP).[15]

Staff members have to be competent and trained in:

- Handling of samples
- Analyses of samples
- Record keeping
- Laboratory Quality Management System
- Process control (IQC and EQC)
- Requirements of the Standard EN ISO 5189:2012.

When EQAS results are received and analyzed, management should identify problem (root cause analyses) and corrective actions must be implemented. Effectiveness of implemented corrective measures must be monitored.

Communication of outcomes to all laboratory staff and to management is essential for quality improvement.

2. MATERIAL AND METHODS

Biochemical Analyses Laboratory (BAL), within the Institute of Medical and Experimental Biochemistry, Medical Faculty-Skopje, is a medical laboratory accredited according to the International Standard MKC ISO EN 15189:2013.[16] Participation in EQA programs is not regulated by the law, but it is a requirement of a standard EN ISO 15189:2013 and national accrediting body (NAB), Institute of accreditation of Republic of North Macedonia.

BAL participates in EQAS organized by Instand eV, Dusseldorf, Germany, since 2011. To be successful, EQAS instructions must be followed carefully, all paper work completed accurately, and results submission deadlines met. A laboratory must develop a plan to demonstrate covering of the test methods on its scope of accreditation over a 4-year period. It is mandatory to demonstrate successful participation in EQAS. Acceptancce criteria is +/- 2SD.[17]As accredited laboratory, BAL has an obligation to fulfill two documents: plan for participation in EQAS/PT/ILC (document OB 05-18-2) and review of participation (document OB 05-18) and to present them to the lead assessor and technical assessor on annual basis during the on-site assessment of the laboratory.

Individual laboratory report is kept confidential, and is only known by the EQA provider and the participating laboratory.

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3. RESULTS

Our laboratory participates in surveys for: haematology (differential blood count) and clinical chemistry (conventional analyses). Performance in the last 8 years varied by panel.

All the blood samples were processed on Sysmex XS800i hematology analyzer. For clinical chemistry, lyophilized samples were received.

Testing samples for each panel are sent to the BAL 3-4 times/year.

There was variation in performance, with a best annual average performance in 2016 and 2017.

Except for haematology, annual performances for other enrolled panels varied from year to year, indicating some difficulty in maintaining consistency in quality.

The main challenges of the EQAS program observed between 2011 to 2019 were funding, sourcing, and safe transportation of quality panels to our laboratory.

If the laboratory performs poorly on EQA, all aspects of the process have to be checked. We identified failures in three phases of laboratory flow path:

Pre-examination

The sample/specimen was compromised during shipping, or after receipt in the laboratory by improper storage or handling.

The sample was labeled improperly in the laboratory.

Examination

Possible sources of analytical problems include equipment, reagents, applied methods, calibrations, and calculations.

Analytical problems have been investigated for determination whether error was random or systemic.

Competency and training of staff members was evaluated.

Post-examination

Several areas in the post-analytical phase of testing process where potential errors could occur were identified. Sometimes lab personal was confused with the report format; interpretation of results was incorrect or transcription errors (transmission of results) occurred.

Identification of all these failures in the last years has helped us to significantly improve our overall quality of laboratory practices.

Corrective and preventive actions were issued for outlying EQA results. By directing corrective measures at root causes, we had realized that the likelihood of problem recurrence was minimized.

4. DISCUSSION

One of the main purposes of external quality assessment is to maintain a high level of patient safety by improving the quality of examination processes.[18] By participating in EQAS, laboratory is supposed to receive a regular, objective assessment of the validity of its measurements. The results of external quality assessment shall serve as a basis for identifying weaknesses in the laboratory processes and test methods and, consequently, improving its own performance. Furthermore, external quality assessment is a powerful tool for risk mamagement and decision making when procuring new tests.[19]

This study found that the good-participant performance rate increased, and the poor-performance rate decreased with the number of years participating in EQAS. We found out that qualified personnel performed better than non-qualified personnel, and staff performing tests on a daily base performed better than those performing the test less frequently

EQAS is an indicator of performance for lab quality system.[20] In terms of analytical performance it is an indicator for precision and reproducibility.[21] All of the test results performed in a clinical lab are believed to include a little error. The limits of error is called TEa (Allowable Total Error)[22]. In the data collected from IQ some portion of this

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error, sourced from imprecision of the measurement system, can be detected. The rest of the error can be detected by EQAS.[23]

All EQAS results, as well as corrective actions, should be recorded and the records maintained for an appropriate period of time. EQAS is a tool to measure laboratory performance. Therefore, there must be no difference in the treatment of EQAS samples and the patient's sample. EQAS samples must be processed by normal testing method(s) and involve personnel who routinely perform the testing.

Our results showed that the personnel performing internal QC daily performed significantly better than those performing internal QC less frequently.

Analysis of quality errors emphasized the importance of maintenance of equipment. The failure to perform IQC and EQC could be a result of instrumental errors.

The major advantages of the present study were that data from an extensive time period were used, that a large number of surveys was included, that the performance of the laboratory was monitored through the use of the same EQA materials.

It is important to remember that EQAS does have some limitations and it is not appropriate to use EQAS as the only means for evaluating the quality of a laboratory. [24]EQAS will not detect all problems in the laboratory, particularly those that address the pre- and post-examination procedures.[25] A single unacceptable result does not necessarily indicate that a problem exists in the laboratory.

5. CONCLUSIONS

Key benefit of participation in EQAS is improvement of the laboratory performance through: discovering of sources of error; systematic errors; demonstration of effectiveness of changes; common understanding of method differences; discovery of method sensitivities, etc.

EQAS is a tool for maintaining and improving quality in the laboratory. It is a supportive tool for user training and professional skills maintenance.

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