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Research Article

The external quality assessment scheme in coagulation: five years' experience as a participating laboratory

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ABSTRACT

Background: The attainment of quality services in a laboratory requires a comprehensive quality assurance programme which includes both internal and external quality control. External Quality Assessment Scheme (EQAS) programmes are accepted around the world as invaluable tools by laboratories to assess the performance of their testing systems. Results are objectively compared to other laboratories, using the same methodologies for every parameter. The goal of this study was to review EQAS results from time to time in an effort to improve the performance of the laboratory.
Methods: Observational study done at Pramukhswami medical college, Shree Krishna hospital, Karamsad from January 2009 to December 2013. In the present study we have evaluated our EQAS test result of the past five years, from 2009 to 2013. We receive two samples in duplicate in lyophilised form, which are stored at 2-8°C in the refrigerator. The samples are reconstituted with 1 ml of distilled water at the time of procedure. The samples are received quarterly in a year. The test results of all the samples are analysed and documented.
Results: Satisfactory results were obtained in all the cycles except four times. Discrepancy was observed in Prothrombin time INR (International Standardized Ratio). Root cause analysis was performed and necessary action taken.
Conclusion: This participation in EQAS over the last five years has helped us significantly to improve our laboratory services in terms of performance evaluation, patient care and overall quality of laboratory practices.

Keywords: External quality assessment scheme, Quality control, Quality assurance

INTRODUCTION

External Quality Assessment (EQA) and Proficiency Testing (PT) are valuable tools in the quality improvement process. They provide objective evidence of laboratory competence for customers, accreditating bodies and regulatory agencies. It is also important to consider that every EQA/PT scheme has some limitations and that it is not appropriate to use EQA/PT as the sole means for evaluating laboratory performance.[1,2] Therefore, there is the need to underline that Internal Quality Control (IQC), EQA/PT and other tools have to be implemented and used to monitor and improve the quality in laboratory diagnostic services. Programmes like this offer valuable benefits to the participating laboratory in terms of performance evaluation, improvement in patient care and overall quality of laboratory practices.[3,4] The organizing laboratory that conducts such an EQAS periodically assesses the registered participating laboratory. Such a registration is not mandatory but absolutely voluntary. Our laboratory services in haemostasis were registered in 2009 with

CMC, Vellore under the haemostasis ISHTM-CMC EQAS programme to develop awareness regarding quality assurance in the laboratory as a part of improving overall patient related diagnostic services. Since 2009 we are participating and have been receiving samples four times a year. Here we share our experience of five years.

METHODS

Samples

EQAS samples are received from the Christian medical college, Vellore under ISHTM-CMC EQAS programme and processed at central diagnostic laboratory, Shree Krishna hospital, Karamsad, Gujarat.

For each year (2009-2013), every three months, samples were received by our centre for specific tests recommended by the organizing laboratory. All the samples were handled as part of routine work samples and the recommended tests were performed by the concerned laboratory technician on duty. The tests were performed and results mailed to the organizing laboratory within the closing date provided by the organizing agency.

Test performed on samples

During each cycle, two samples were received in duplicate, which contained samples in lyophilised form. The samples were reconstituted with distilled water and following tests were performed on each reconstituted vial - Prothrombin Time (PT), activated Partial Thromboplastin Time (aPTT), fibrinogen and factor VIII. All the tests were performed on a semi-automated sysmex coagulation analyser CA-50 in our laboratory.

RESULTS

The following test parameters were tested and documented - PT, aPTT, fibrinogen and factor VIII.

Table 1: Shows the results of five years.

Year	Results
2009	Unsatisfactory in 1 cycle
2010	Unsatisfactory in 1 cycle
2011	Satisfactory
2012	Satisfactory
2013	Unsatisfactory in 2 cycles

Four times discordant results were obtained in PT INR parameter. All the times root cause analysis was done to find the cause of discordance and random error was found to be the issue. In these instances the EQAS result was labelled as ‘unsatisfactory’. The samples were then sent to two NABL accredited laboratories for inter-laboratory comparison and results were found to be satisfactory.

DISCUSSION

The EQAS program is a valuable management tool destined to improve the efficiency and service of a laboratory in particular and a hospital in general.[5] The program provides an opportunity to the participating organizations to compare activities and modify their own practices based on what they learn.[6,7] In a clinical laboratory service, EQAS evaluates the performance of procedures, equipment, materials and personnel and suggests areas for improvement.

As a participant of EQAS, we performed all the prescribed tests by strictly following the departmental SOPs and manufacturer's instruction considering each lot as routine working samples. Four times discordance was obtained in the prothrombin time INR and root cause analysis was performed.

CONCLUSION

An EQAS program plays an important role in improving the efficiency of a laboratory service, thereby optimizing the overall quality of a health care system. In the last five years we could significantly improve our laboratory services in terms of performance evaluation, patient care and overall quality of laboratory practices.[8,9] We believe that global participation in such an EQAS program will definitely improve the quality of a hospital service because no health care facility can be totally self-sufficient and there is always an inclination for improvement and development in a system.

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Ethical approval: The study was approved by the institutional ethics committee

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