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RESEARCH ARTICLE

Five years experience as a participating laboratory in External quality assessment scheme – NABH Accredited blood bank from rural area

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Abstract

We participated in External Quality Assessment Scheme (EQAS) during the year 2008 to 2013 as per recommendation by National Accreditation Board for Hospitals & Healthcare Providers (NABH). We present our five years' experience. Analyses of results have helped us to significantly improve our transfusion service.

INTRODUCTION: Quality assurance in blood bank includes active participation in EQAS. Such programme offers valuable benefits in terms of performance evaluation, improvement in patient care and safety and overall quality of blood bank practices.

METHOD AND MATERIALS: For EQAS, we receive blood sample from Jaipur for ABO grouping, Du typing, direct and indirect Coomb's test and transfusion transmitted disease(TTI) six monthly and from Indian red cross society, Bombay for TTIs six monthly. We analysed the results of EQAS from 2008 to 2013.

RESULT: We observed 100% correlation in ABO grouping, Du typing, direct and indirect Coomb's test and HBsAg. Discordant results were observed in HIV ½, anti-HCV and VDRL once. In root cause analysis we found that false positive results in HIV 1/2 were due to random error and ELISA washer machine break down. Manual washing was done. The false negative result in anti-HCV was due to sample integrity. VDRL was done by RPR card test method, which has low sensitivity than treponema pallidum hemagglutination method.

CONCLUSION: We believe that participation in EQAS program will definitely improve quality of 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.

Introduction

Quality system essentials (QSE), the guiding principles to any laboratory quality program, were established by the Clinical Laboratory Standards Institute (CLSI) in 1991[1] As many as ten or more major laboratory activities were developed under these essentials to ensure accurate laboratory practices that would serve the needs of patients as well as clinicians. Quality control and assurance is an important component of QSE that not only helps to carry out a laboratory quality program systematically, but also dictates active participation in external quality assessment (EQA) or proficiency testing (PT).[2]

External Quality Assurance aims at ensuring that the data provided are relevant and reliable, thus improving trust and performance of Blood Banking and Immuno-hematology services offered by Blood Banks.

Continual improvement of blood bank laboratories performance can be achieved by internal quality control and external proficiency scheme. Because of the improving of medical laboratory technology and instrumentation as well as the standardization of blood banks testing protocols, the accuracy and quality of blood bank advanced dramatically worldwide [3-5].

Quality Assurance involves all measures that can be taken to improve Blood bank's efficiency and effectiveness with a view to the maximum benefit to the individuals and the community. Besides implementation of good laboratory practices, Internal and External Quality Assurance are integral parts of Quality Management. We present here our experience with EQAS for the past five years.

Material & Methods:

We participate in three External Quality Assessment Schemes. The results of five years duration 2008 to 2013 are taken into consideration.

1) EQAS blood samples from Blood Bank External Quality Assessment Scheme (BEQAS), Jaipur were received two times in year for test of HIV, HCV, HBsAg, MP, syphilis, Blood group, Cross matching ,coomb's test and Du test.
2) EQAS samples from National AIDS Research Institute, Pune were received two times in year for HIV testing.
3) Eight (8) samples each for HIV, HbsAg, HCV were sent Indian Red Cross, Mumbai throughout the year in biannual cycles.

Each time, unknown samples consisting of red cell suspension or serum or both, all packed with coolant were received from organizing laboratory. All the samples were handled as part of routine work samples and recommended tests were performed by the concerned laboratory technician on duty. The tests were performed on the same day of receipt of the samples and results mailed to the organizing laboratory within a week.

During five year, a total of 20 blood samples for red cell serology and 126 serum samples for TTI were received. The red cell serological tests recommended by the organizing laboratory included ABO grouping and Cross – matching. Tests for TTI included HBsAg, Anti HCV, Malaria Parasite, and test for syphilis and anti-HIV antibody testing. Tests for HIV-1, HIV-2, HCV and Hepatitis-B were performed by the routine conventional sandwich ELISA. ABO grouping and D typing, including D_u testing, were performed by the conventional tube technique (CTT), following the standard operating procedure (SOP) of the department. Antibody screening and identification were done using CTT. Cross-matching were performed by the conventional tube technique both saline and AHG (Anti human globulin method).

Results:

Table 1: External quality assessment scheme test result: Red cell serology (2008-2013)

Test	Total no of tests	Method	Concordance result	Discordance result

Blood grouping	10	Tube Method	10	00
Cross matching	10	Tube Method (Saline and AHG)	10	00

100% Concordance was observed in blood grouping and cross matching.

Table 2: External quality assessment scheme result: Transfusion transmitted infection testing (2008-2013)

Test	Total no of tests	Method	Concordance result	Discordance result
Anti HIV	62	Elisa (3rd generation)	61 (98.38%)	01 (1.61%)
HBsAg	22	Elisa (3rd generation)	22 (100%)	00 (0%)
Anti-HCV	22	Elisa (3rd generation)	21 (95.45%)	01 (4.54%)
Test for syphilis	10	RPR card test	09 (90 %)	01 (10%)
Malaria Parasite	10	Peripheral smear	10 (100%)	00 (0%)

100% concordance was observed in anti-HBsAg, malaria parasite. There were three discordances, one in anti-HIV, anti-HCV and test for syphilis.

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. The program provides an opportunity to the participating organizations to compare activities and modify their own practices based on what they learn.[2,7] In a transfusion service, EQAS evaluates the performance of procedures, equipment, materials, and personnel, and suggests areas for improvement.

Root cause analysis of each discordant result was performed and followed by appropriate corrective action. False positive result was noted in anti-HIV. ELISA washer was not working and repeated breakdown of machine. For this manual washing was done. The controls were proper and cut-off value was within -2SD and +2SD. It was due to random error. Corrective action: Because of Manual washing this was discordance. This reinforces the importance of routine quality control of equipments and reagents.

False negative result was observed in anti-HCV. In duplicate run, the result remained same. Controls and equipment were proper and no inter-observer variability was found. So sample integrity appeared only possibility of non-conformance.

False negative result was observed in test for syphilis. As the sample was not available, repeat testing could not be possible. Sample should be preserved till the result comes. The test was done by RPR card method, which has low sensitivity as compared to treponemal tests (TPHA)

Conclusion:

External Quality Assessment Scheme offer a valuable management tool because they enable laboratory personnel to compare their laboratory results with those obtained in other laboratories when the same material is examined. In addition, EQAS program can help participants to detect their potential problems. The information collected in the long term surveillance, EQAS, is an essential reference for the design of good training courses and continuing education of the quality
Improvement. [6,7] No health care facility can be totally self-reliant and there is always predisposition for improvement and development in a system.

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