Broadening Vision to Create Quality—An Analysis of the Participants' Results of an EQAS Conducted by a PT Provider in Western India.

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ABSTRACT

Introduction: Having undergone training by the NRL, Australia, a programme sponsored by the Indo-Australia Council, the IRCS, Blood Centre, Mumbai has been conducting an EQAS programme in TTI for HIV, HBV and HCV since 2002. A retrospective study from 2002 to 2015 was undertaken and the results of all the panels for all three markers i,e HIV, HBV, HCV were analysed. The erroneous results were identified and the commonest cause for these errors are discussed

Material and Methods: A Panel of 8 samples for each parameter in TTI screening viz HIV,HBV,HCV are sent to the participating laboratories. . After the results are received, the data is analysed and a preliminary report followed by a detailed report which highlights the erroneous results and the likely causes for the same is sent out.

Results: It was observed that majority of the errors i.e 72.8%, were due to poor technique, followed by assay related problems (17.46%) . Clerical errors contributed to 7.3 % and systematic errors were to the tune of 7.26 %.This clearly indicates the need for training.

Conclusion: The information obtained from EQAS results is valuable and could be used by the government authorities to apprise them of the quality standards practiced by the laboratories and also the type of assays used, so that cognizance and appropriate action can be taken.

Keywords: EQAS, TTI Screening, Quality management System, Training, Technical errors

INTRODUCTION

In the late 1990sand early 2000s, quality management systems (QMS) hardly existed in the transfusion medicine services of India. Very few centres, (possible a handful) had implemented a QMS. In parallel, participation in an external quality assessment scheme (EQAS) was also very poor, evidence suggests laboratories were not even aware of the existence of such schemes.

In 1999, with the support of the Australian Red Cross through the Australia-India Council, the Indian Red Cross Society, Blood Centre, Mumbai undertook a project for setting up a Quality Management System at its Blood Centre in Mumbai. Following the encouraging results and success of the programme, the Australia-India Council supported another project with the aim to establish the Indian Red Cross Society, Blood Centre as a referral centre for Transfusion Transmitted Infections under the guidance of the National Serology Reference Laboratory, Australia (NRL, Australia). NRL, Australia then trained the IRCS Blood Centre staff to carry out the EQAS for the Laboratories of India (to establish the IRCS as a Proficiency Testing (PT) Provider). In order to build confidence in the participating laboratories the Bombay Red Cross Blood Centre participates in EQAS conducted by NRL, Australia each year.

In 2002 a pilot scheme for HIV was run for 10 laboratories of Mumbai whilst the training was being undertaken. In 2003 HIV panels were sent to 25 laboratories from the Federation of Bombay Blood Banks, and in 2004 the scheme was extended to include hepatitis B and hepatitis C serology markers and presently there are approximately 100 participants in the scheme.

Primary objective - To analyse the most common reasons for erroneous results reported by participants.

Secondary objective - To provide feedback on the testing standards and strategies, the type of assays, the knowledge, the attitude and the practices used by the different blood bank laboratories in India

The overall aim is to determine whether there was sustained improvement in the quality of testing services provided by the participating laboratories for the benefit of the patients.

MATERIAL AND METHODS

The Indian Red Cross Society, Blood Centre, has developed a good repository of samples over a period of many years (the sample bank) as high quality samples are a critical element of any good EQAS.

The samples are well characterised according to a validated testing algorithm using different assays and then stored appropriately frozen at -80 C. Characterisation of the samples is done by testing the samples on 3-4 different assays with different technology including the most frequently used assays by the participants. In the event of conflicting results the samples are also run on those assays which have given conflicting results. An inventory is maintained in the form of a database, which includes the history of the sample and the

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volume of the sample archived. Maintaining the database is an ongoing process as the newer samples are being regularly archived.

Before the participants join the scheme, a detailed questionnaire is sent to them to get information about the assays and testing strategies used by the participants.

The panel is then designed carefully with a view to assess, whether a particular aspect of testing process is functioning appropriately or not. Usually the samples are selected with specific questions in mind such as whether samples are correctly labelled, whether the results are being transcribed appropriately and also whether the results were reproducible. Once the aims of the panel is designed, the appropriate samples are then selected from the sample bank and tested. The samples are dispensed into micro tubes, packaged carefully with coolants and then dispatched with appropriate paper work which includes the result sheets for laboratories to enter their testing results.

The IRCS Centre sends out panels in sets of eight samples. The programme is carried out twice a year, in the month of January for HIV and in June for HBV and HCV.

When the results are received, the data is then entered into Microsoft Excel for analysis. The tables are produced serially; as per laboratory I.D. as well as assay wise which is arranged alphabetically -this allows for inter-laboratory comparison. All the electronic data generated is verified with the hard copies.

Following the close of the EQAS testing period, a preliminary report is sent out which contains the results of the IRCS Blood Centre viz- provider / reference laboratory along with panel sample status and clinical information. The preliminary report allows the laboratories to compare their results with the Reference Laboratory before the composite / final report was released.

A final report is dispatched within 2 months and it contains details of any aberrant results as well as summaries of all the results in graphic and tabulated format. The report also provides possible reasons for aberrant results, if any, produced by the laboratories and provides solutions so that appropriate corrective action can be taken.

RESULTS

This is a retrospective study carried out on the data from 2002 to 2015.

The errors reported by the laboratories are classified as those due to assay related problems, sample mix up, cross contamination, sample carryover, poor technique, clerical error and/or systematic error. Refer table no.1 and figure no.1 & 2

Errors due to assay related problems are further classified as errors due to insensitive ELISA and/or rapid assays, or due to improper interpretation of the subjectively read assays. This interpretation is based on the results of the peer participants as well as after confirming results that were reported by the provider. The clerical errors are so identified as there were errors during transcription of results.

Systematic errors are classified as those due to poor equipment maintenance and those due to deterioration of the reagents, which could be either due to poor cold chain maintenance during transport or storage. This was interpreted based on the objective values of the results when compared with other participants using same assay and belonging to the same batch.

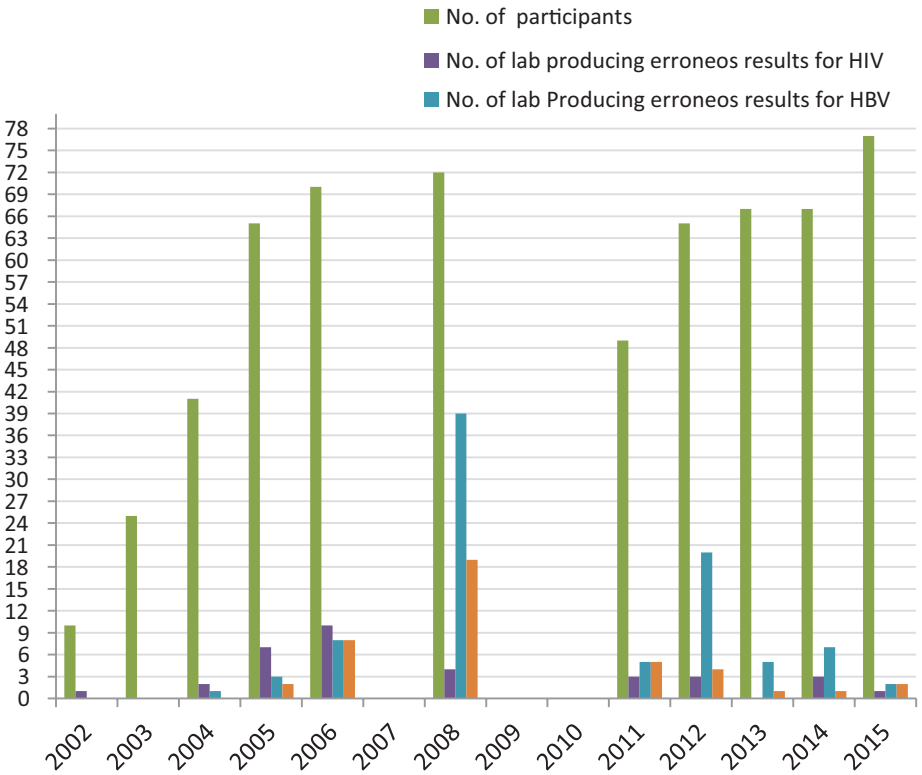

Figure-1:

Infectious marker	Technical error	Assay related problems			Systematic errors			Clerical error
		Total assay related problems	No.of error due to insensitive ELISA	No.of error due to insensitive rapid assays	Total systematic error	Poor equip-ment maintainance	Deterioration of reagent	
HIV	73.52%	8.82%	2.94%	5.88%	11.7%	5.88%	5.88%	5.88%
HBV	73.23%	26.66%	7.77	18.88%	7.77%	4.44%	3.33%	6.6%
HCV	71.41%	16.66%	7.14%	9.52%	2.4%		2.4%	9.5%

Table-1: Classification of errors as per the causes.

Panel	2 Times error No. (%)	3 Times error No. (%)	4 Times error No. (%)
HIV (N = 72)	5 (6.9%)	-	-
HBV(N = 72)	12 (16.66%)	7 (9.7%)	3(4.16%)
HCV(N = 72)	9 (12.5%)	1 (1.38%)	-
Note:This indicates that there is no policy for reviewing the reports and carrying out RCA.			

Table-2: Number of times errors reported by the same laboratories.

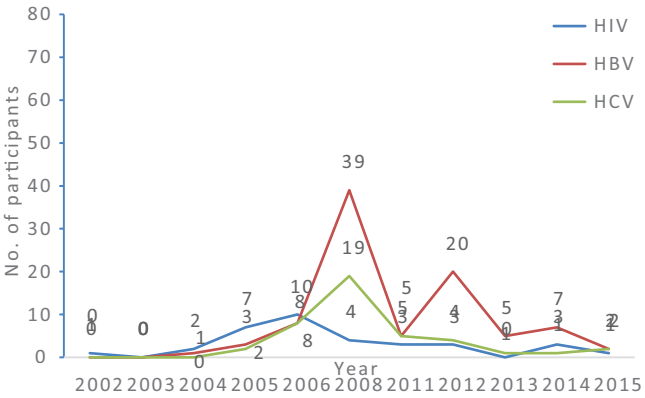

Figure-2: No. of laboratories Producing Erroneous Results for HIV, HBV, HCV

The decision to label an error as a technical error was based on the peer results of the same sample. IRCS decided to group sample mix up, sample carry over and poor technique together as they were mainly due to poor technique and therefore identified as technical errors.

It was observed that the majority of the errors (72.8 %), were due to poor technique followed by assay related problems, which contributed to 17.46% of the errors. Clerical errors contributed to 7.3 % and the rest (7.26 %) were due to systematic errors.

DISCUSSION

External quality assessment schemes are an integral part of the overall quality assurance system of a laboratory. It is very essential for all the healthcare services to ensure that their quality management system is not only implemented, but also good manufacturing practices are disseminated amongst the staff. Any failure in the performance or breakdown of the quality cycle should be promptly recognised and dealt with to protect patients.[1]

In some countries, participation in an EQAS has become mandatory and acceptable performance is a requirement for laboratory accreditation therefore it is very important to have a good EQA scheme.[2] In India participation in an EQAS is a requirement for accreditation by NABH, but it is not yet mandatory according to the regulatory authorities. The authorities as well as the transfusion service directors-in-charge are not even aware of the important role of a good EQA scheme in assuring quality of results.

It is often a case that when a programme is made mandatory by regulatory authorities, participation will increase in number, yet it has also been observed that whenever a programme is made mandatory by a regulatory or accreditation authority, participants who are forced to participate in it will view the programme as a potentially punitive exercise, thereby resulting in the programme not only losing its educational value but also its ability to actually improve quality in the participating laboratories.[3,4,5,6,7]

This was particularly observed in many countries where the grading of laboratory performance was an essential pre-requisite for accreditation or a licensure requirement. Thus, there is a constant dilemma, wherein if the scheme is made mandatory it loses its educational value and at the same time, not making it mandatory reduces participation figures. In this context it is very important that Blood Centres are sensitized on the advantages of participating in such schemes so that it becomes a purely voluntary and educative exercise.[3,4,5,6,7]

EQAS offers an advantage in monitoring the performance of the laboratory continuously over a period of time so as to assure that best quality practices are used for donor serodiagnosis. In case if there is a problem with the laboratory, then they would not only be able to identify their own weaknesses, but the EQAS provider would also be able to identify the source for their problem. The EQAS provider could then accordingly be able to guide a participant to improve performance so that good quality standards are being maintained at all times. This would also help to reassure the participating laboratories of their performance.[8,9]

In order to build confidence in the participating laboratories regarding the quality of EQAS provided by a laboratory, it is critical that the provider also participates in an externally provided EQA scheme. With respect to this statement, the IRCS Blood Centre also participates in the scheme conducted by NRL Australia, a recognised WHO scheme provider.[3,4,5,6,7]

The IRCS Blood Centre programme was introduced as a

pilot study in 2002 and the summary of the EQAS reports from 2002 – 2015 is discussed below. It will be observed from figure no.1 &2 that the HIV, HBV,HCV panels had 34,90 and 42 laboratories, respectively reporting errors and from table no.1 it will be observed that most of the errors were due to poor technique.

The reason for poor technique could be either sample mix up resulting from poor sample handling procedure or improper pipetting of sample / reagent such as whilst pipetting if there is an air bubble it would result in inadequate quantities being dispensed. Inadequate washing or not following procedures are also some of the reasons for technical errors occurring while performing an assay.

Sample carry over/ cross contamination was also one of the commonest technical reasons for the cause of errors, which is likely to be due to problems regarding the maintenance of the ELISA washer in both automated as well as semi-automated equipment. It could happen even during manual dispensing of the reagents if the pipetting is not done properly.

Lack of assay sensitivity contributed to the 9.1 %,26.7% and 16.7% of errors for HIV, HBV, and HCV panels, respectively, but with passage of time we have observed that these errors have reduced as there are better assays available over a period of time. This was particularly seen more often with the results for the rapid tests as compared to ELISA (refer Table no.1), which indicated a great need for developing a well-defined testing algorithm in order to accurately determine status of the sample.

The erroneous results reported with rapid tests were likely due to lack of sensitivity of the assay, not following the manufacturer's instructions for use or incorrect interpretation of the results. Regarding incorrect interpretation of the result, specifically this could be due to lack of training to read rapid tests, as there is an element of subjectivity in their interpretation. Good practice is to establish a system wherein two different individuals independently report all EQAS panel results, whether it is for ELISA or rapid tests, and then the results being finalised by a supervising scientist.

The availability of excellent quality assays does not necessarily mean that laboratories will generate reliable results. There are a number of steps involved in testing of blood, from accepting the samples to reading of test results - at each step anything could go wrong, thus emphasising the great need for a good quality assessment scheme. These schemes not only evaluate the effectiveness of laboratory quality assurance but they also provide an insight into the level of the QA/QC programme of a particular laboratory. Failure of EQAS results would rightly indicate that there may be a problem with QA/QC procedures but at the same time participation in EQAS cannot be considered as a substitute for good QA/QC.[10]

Clerical errors have also significantly contributed to the number of errors (Table no. 1). It is very important that laboratories should devise a system wherein results are reported by one individual, entered in the relevant result sheet by another individual and, finally, checked by technical supervisor.

Lack of cold chain maintenance during transport and the storage of kits has potentially resulted in systematic errors (Table no1). Authorities need to monitor the cold chain as well as need to impress upon the staff the importance of storing test kits appropriately at all the times i.e before, during and after testing.

In this study it was observed that some of the laboratories continued making similar errors in the subsequent panels, inspite of explaining the potential causes for errors in the final reports of earlier panels (Table no.2).This indicated that the EQAS reports may not have been not read or understood by the participants as there was no evidence of a policy for reviewing results and/or carrying out the root cause analysis. It is very important that laboratory staff should analyse the EQAS report, discuss the results and evaluate possible actions that need to be undertaken to improve laboratory performance. The EQA scheme can only be effective if laboratories take appropriate actions to ensure improvement. Even the best EQAS schemes cannot provide any advantage if laboratories do not use the information provided to them to check and eventually modify internal processes and implement improvement. It is the duty of the laboratory to verify the quality of the service and to also constantly measure quality of service so that best quality services and products are provided to patients.[11,12,13]

EQAS provides a comparison of result obtained on the same sample amongst different laboratories. It also gives comparison of results obtained with different assays and using different equipment, thereby allowing a method to potentially identify systematic, assay related and other problems and allowing these identified issues to be resolved.[10]

In a study carried out in Malaysia on EQAS scheme conducted by their national laboratory for clinical chemistry, it was observed that when laboratories with unsatisfactory performance scores were alerted about their deficiencies, they performed better in subsequent panels. This not only indicated the effectiveness of the remedial action taken by the laboratories, but also the effectiveness of their EQAS. Further, the study also helped the Malaysian NRL get an insight into the knowledge, attitude and practices followed by the laboratories in Malaysia. This information provided laboratories with the necessary feedback to increase effectiveness and benefit of all the QA/QC activities in addition to establishing the need for continuing education, training as well as research in quality improvement. It also helped them to revise the selection of methods and test systems.[2]

In Indonesia, participation in the NEQAS (National External Quality Assessment Scheme) was mandatory for obtaining a laboratory license and the Ministry of Health uses these schemes as one of the means for monitoring and coordinating performance of laboratories throughout Indonesia. The poor-performers are then identified as in need for training.[14]

Based on the experiences of Malaysia and Indonesia, we feel in India too there is a great need for Government to review the performance of laboratories in India from time to time and also hold training programmes regularly.

In Lebanon, the Lebanese EQAS (LEQAS) was established in 2000 with the objective of helping medical laboratories improve the quality and comparability of results. In their study it was observed that the overall performance of laboratories at the start of the scheme was generally unsatisfactory, but as the scheme progressed, participants were educated and their interest also increased and individual performance was also enhanced. The situation in Lebanon reinforces the belief that EQAS are essential components of a quality assurance programme.[15]

In Thailand, the EQAS uses a scoring system to monitor the performance of laboratories and it was observed that this encouraged the participants to improve and maintain their quality standards.[16]

CONCLUSION

EQAS is a method by which the entire testing process, including the quality of results generated by a particular laboratory ,is assessed. EQAS today not only plays an important role in the assessment of each participant but also plays an important role in the assessment of the methods used, and the quality standards practiced, by the laboratories.[10] Sensitisation of the blood bank personnel on the importance of EQAS would increase voluntary participation, which would be an ideal situation as only then will the educative role of EQAS be fulfilled.

In this study it was observed that the potential sources of errors ranged from poor technique, to lack of assay sensitivity, poor cold chain maintenance leading to deterioration of reagents, poor maintenance of equipment and also clerical errors. Of all the sources of error, poor technique was the most commonly observed cause. This clearly highlighted the need for training of staff. This information could be used by authorities to take a step in the right direction, meaning training which would enable sustained improvement in the quality of services provided by the laboratories for the benefit of patients.

The results also highlight the type of assays used by the participants and as a consequence the quality of results produced, thereby providing laboratories with self-appraisal on result quality and the need to improve their performance overall. The scheme also gave information on the testing strategies and the algorithms used by various laboratories so that decisions could be taken to have uniform testing strategies for improving blood safety.

Further, were the Government to support this scheme and use the results to monitor the performance of laboratories, then standards of testing, and as a consequence blood safety, would definitely improve.

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