External quality assessment scheme (EQAS): Our experience as a participating laboratory

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ABSTRACT

Background: EQAS performance has been shown to reflect the quality of patient specimen testing in a clinical laboratory.

Aim: To evaluate our performance in terms of the performance indicators used by the EQAS body.

Methods: EQAS results were evaluated since our participation in the EQAS programme from Jan 2011 to April 2013 in terms of statistic parameters used by the EQAS body.

Results: The study revealed very good scores with 76.7%, 73.4% and 76.7% of the total results falling in the very good performance score category in the years 2011, 2012 and 2013 respectively in terms of Variation Index Score (VIS). Study also revealed inconsistencies in the performance of a few parameters especially calcium.

Conclusion: Inconsistencies in our performances helped us to significantly improve the quality of our laboratory practices along with good performances providing confidence in furnishing accurate test reports to the patients.

Key words: EQAS, VIS, SDI

INTRODUCTION

Quality control in the settings of a clinical laboratory refers to the procedures designed to monitor the routine performance of testing processes in order to detect possible errors, reduce and correct deficiencies before the test results are reported.[1] In particular, internal quality control (IQC) and external quality assessment (EQA) programs are used to evaluate and continuously improve analytical quality. IQC involves in-house procedures for the continuous and immediate monitoring of the lab work and the emergent results in order to decide whether the results are reliable enough to be released to the physician. On the other hand, EQA is meant for periodic and retrospective monitoring of lab results by an independent external agency to indicate to the lab and its staff, the accuracy or bias in their systems and methods. Above all, it should be clear that while the IQC is necessary for the daily monitoring of the precision and accuracy of the analytical method whereas EQA being important for maintaining the long term accuracy of the analytical methods. Nevertheless EQA supplements IQC and never a substitute for IQC.

External Quality Assessment scheme (EQAS) is an essential aspect of any laboratory operation. EQAS provides a means of assessing the analytical performance of a laboratory compared to other laboratories utilising the same methods and instruments. EQAS measures a laboratory's accuracy using 'blind' samples that are analysed as if they were patient samples. Results are returned to the scheme organiser for statistical analysis. Laboratories receive a report comparing their individual performance against other participants in the programme. The present study was conducted to evaluate our performance as a participating lab in the EQAS programme services.

MATERIALS AND METHODS

Since January 2011 to April 2013, EQAS samples received at Department of Clinical Biochemistry, Vardhmann Mahavir Medical College and Safdarjung Hospital, New Delhi, India were taken for study. Three lyophilized samples were received on a quarterly basis that needed to be stored,

reconstituted and analysed as per the guidelines and schedule provided by the organising EQAS body. For each month unknown/blind sample provided by the EQAS body, CMC Vellore, were reconstituted on scheduled dates and analysed for the parameters for which our laboratory participated. The results were uploaded on the EQAS website on the scheduled dates and our performance score was downloaded after completion of each month. The tests were performed on our clinical chemistry automated analysers: Hitachi 902, 911 and 912 as well as Beckmann Coulter CX5 pro.

Eleven parameters from our lab were chosen for assessment in EQAS programme. These were blood glucose, urea, creatinine, total bilirubin, total proteins, albumin, calcium, uric acid, cholesterol, AST and ALT. Performance was analysed in terms of the VIS (variation index score)and SDI of each month from the period of January 2011 to April 2013.

VIS is calculated as :

$$\% \text{ variation } (\%V) = \frac{\text{Diff b/w participant's result and desig value} \times 100}{\text{Designated value}}$$

Where, designated value for a particular test is the value obtained after excluding results, from labs with same method which are >3SD of the method mean and recalculating the mean after eliminating the outliers. The VIS interpreted as**,** <100- very good; 100-150- good; 150-200-satisfactory and >200-not acceptable.

VIS values for each parameter every month was checked and similarly overall mean of VIS (OMVIS) was checked on monthly basis. OMVIS < 100 indicates that results are very close to the designated value (DV) and is very good. OMVIS in the range of 150-200 indicates need to take care of those parameters for which the reported values are very different from the DV for that particular method. OMVIS >250 indicates reporting many wrong results and urgent steps to locate the problem must be taken followed by suitable corrective measures. If VIS is more than 200 on two or more occasions for the same analyte, then standardization procedures need to be checked.[2] Another statistical tool assigned to the lab by the EQAS provider is EQAS cycle is Standard Deviation Index (SDI). It is a measure of relative inaccuracy/ relative bias.

Standard Deviation Index (SDI): It is calculated as:

$$\text{SDI} = \frac{\text{difference between lab value and target value}}{\text{SD of mean for comparison group}}$$

And interpreted as <1.0 = excellent ;1-1.5 = good;1.5-2.0= accept with caution and >2.0= take action

RESULTS

On analysing monthly VIS of each parameter for the study year 2011- to 2013 this score, it is observed that performance is excellent (i.e. VIS<50) in 49.2% of total test results in the year 2011 and 43.9% of total test results in the year 2012. As far as the VIS of the year 2013 is concerned, the score value did not go beyond 200 in any of the test results till April 2013. Performance of a few of the parameters fared exceptionally excellent in terms of VIS with 75% of the test result values falling under 50 score category. These were cholesterol in the year 2011, glucose in the year 2012 and both T. bilirubin and cholesterol in the year 2013.

Table.1. Test results falling in different score categories of VIS, since participation in the EQAS programme.

VIS	2011	2012	2013
Excellent(<50)	49.2%	43.9%	33%
Very Good(50-100)	27.5%	29.5%	43.7%
Good (101-150)	10.6%	11.3%	6.25%
Satisfactory(151-200)	3%	4.5%	8.33%

The overall performance of our lab in terms of OMVIS for the years 2011, 2012 and 2013 was very good with 100% of the values falling in the <100 score category in the year 2011 and 2013 and 83.3% of the score values falling under 100 in the year 2012. Moreover none of the OMVIS values had crossed >200 ever since we participated in EQAS programme. However the VIS for calcium crossed the mark of >200 in the months of January and May in 2011. The possible reasons could be inconsistencies in the maintenance of water pH.

Considering the other parameter of performance accepted by EQAS body, the SDI for each variety of samples was calculated on month-wise basis for the study years. Majority of the results were observed to be in the range of excellent to good in all years of the study period. However uric acid test was not performed in few months due to delay in the supply of reagents.

DISCUSSION

EQAS is an important tool to monitor and maintain the laboratory performance output. VIS of various biochemical parameters indicate the deviations from the target/expected result. In significant deviations, a laboratory has to take corrective measures ranging from kits to instruments including deployment of trained skilled manpower.

The overall performance of our lab as far as the OMVIS for the years 2011, 2012 and 2013 is concerned, was very good (100% of the score values falling in the <100 score category) in the year 2011 and 2013 and 83.3% of the score values falling under 100 in the year 2012. However, the VIS for calcium crossed the mark of >200 in the months of January and May in 2011. The possible reasons could be inconsistencies in the maintenance of water pH.

The results in the month of June 2012 were not at par with other months. There was a major inconsistency in the sample which was sent to us. After reconstitution of the sample, it was found to be turbid and non-homogenous. The EQAS body had also received the same feedback from some other participating labs. Literature have described the instability of the biological compounds in lyophilised and liquid serum stored at various temperatures.[3,4] Therefore, maintenance of temperature during shipping of EQAS sample to the participating labs should also be an area of concern. Apart from these, there has been some inconsistencies in the test results of uric acid and creatinine. Possible reasons could be in method that have been used(Jaffe kinetic method) and influence of temperature; consequently, temperature control is an important component of assay reproducibility. A study survey reports that systematic differences in the calibration of plasma creatinine assays account for 85% of the observed differences between laboratories.[5] Proficiency studies demonstrate that although between-laboratory coefficients of variation (CVs) of <3% are achievable within method groups, overall between-laboratory agreement across methods is much poorer.[6,7] Systematic variation between laboratories of 0.2 to 0.4mg/dl is common.[8]

EQAS program provides an opportunity to the participating organizations to compare activities and modify their own practices based on what they learn.[9,10] Quality management guidelines and practices keep evolving in the clinical laboratory.The analytical quality still remains however the primary issue, because none of the other laboratory quality characteristics matter unless analytical quality is achieved.[1]

For medical laboratories, EQAS have been found useful, in that it initiates a “peer-review” process towards solving technical and methodological problems to improve the quality of service for each individual laboratory as well as to achieve comparability of results among different laboratories.[11]

CONCLUSION

EQAS is an important tool to monitor and maintain the laboratory performance output. The participating labs in order to obtain quality test results and to get confidence in generating a reliable report, the participating lab should ensure the best performance of instrument, use only good quality kits and store suitably and the staff involved in conducting tests must be qualified and updated.

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REFERENCES

1. Westgard JO. Internal quality control: planning and implementation strategies.*Ann Clin Biochem*. 2003 Nov;40(Pt 6):593-611.
2. Chawla R. Quality Control in Clinical Biochemistry. In: Chawla R, editor. Practical Clinical Biochemistry: Methods and Interpretations. 3rd ed. New Delhi: Jaypee Brothers.
3. Boyanton BL Jr, Blick KE. Stability studies of twenty-four analytes in human plasma and serum. *Clin Chem*. 2002 Dec;48(12):2242-7.
4. Marjani A. Effect of storage time and temperature on serum analytes. *Am J Appl Sci*. 2008;5(8):1047–51.
5. Ross JW, Miller WG, Mayers GL, Praestgaard J. The accuracy of laboratory measurements in clinical chemistry: a study of 11 routine chemistry analytes in the college of American Pathologists Chemistry Survey with fresh frozen serum, definitive methods, and reference methods. *Arch Pathol Lab Med*. 1998;122:587-608.
6. Carobene A, Ferrero C, Ceriotti F, Modenese A, Besozzi M et al. Creatinine measurement proficiency testing: assignment of matrix-adjusted ID GC-MS target values. *ClinChem*. 1997;43:1342-7.
7. Lawson N, Lang T, Broughton A, Prinsloo P, Turner C, Marenah C. Creatinine assays: time for action? *Ann Clin Biochem*. 2002 Nov;39(Pt 6):599-602.
8. Hsu CY, Chertow GM, Curhan GC. Methodological issues in studying the epidemiology of mild to moderate chronic renal insufficiency. *Kidney Int*. 2002;61:1567-76.
9. Olson JD, Preston FE, Nichols WL. External quality assurance in thrombosis andhemostasis: an international perspective. *Semin Thromb Hemost*. 2007Apr;33(3):220-5.
10. Bejrachandra S, Saipin J, Nathalang O, Siriboonrit U, Rungroung E, Udee S. External quality assessment scheme in red blood cell serology: A 5-year experience in Thailand. *Immunohematology*. 2006;22:1-5.
11. Jenny RW, Jackson KY. Proficiency test performance as a predictor of accuracy of routine patient testing for theophylline. *Clin Chem*. 11993 Jan;39(1):76-81.