IOSR Journal of Biotechnology and Biochemistry (IOSR-JBB)
ISSN: 2455-264X, Volume 4, Issue 4 (Jul. – Aug. 2018), PP 16-20
www.iosrjournals.org

External Quality Assurance Scheme (EQAS): Criteria for Evaluating Performance of a Laboratory

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Abstract:
Introduction: *External Quality Assessment Scheme (EQAS) involves evaluation of a number of laboratories by an outside agency on the performance of a number of laboratories based on their analytical performance of tests on samples supplied by the external agency. 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(SDI, VIS) used by the EQAS body.*
Materials and Methods: *EQAS results were evaluated since our participation in the EQAS clinical chemistry monthly programme from BIO- RAD laboratories for the period July 2016 to July 2018 (cycle 15and cycle 16 each cantaining 12 samples) in terms of statistic parameters used by the EQAS body.*
Results: *On analyzing mean Z- Score of each parameter for the study period July 2016 to July 2017(Cycle 15)of the 21 parameters 19 with mean Z-score <1.25, one (Creatine kinase) with 1.25-1.49 and one (Direct Bilirubin) with 1.5-1.9 For the period July 2017 to July 2018, from EQAS cycle 16 of the 21 analytes, 20 with mean Z-Score<1.25 and one(Creatine kinase)with 2.0-3.0 The study revealed excellent scores with 76.2% in cycle15(July 2016-July 2017), 80.9% in cycle 16(July 2017-July 2018) and very good performance score(VIS<100) with 95.2% (cyc15), 90.4%(cyc16) of the total results falling in the category respectively in terms of Variance Index Score (VIS). Study also revealed inconsistencies in the performance of a few parameters especially Creatine kinase(CK), Direct Bilirubin and HDL Cholesterol.*
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/Z-Score*

Date of Submission: 02-07-2018 Date of acceptance: 21-07-2018

I. Introduction

A significant number of measures are undertaken on a daily basis in clinical chemistry laboratories in order to maintain a strict control over the results generated from the laboratory. The constant endeavour to improve the quality of results and to maintain them at those levels constitutes the quality improvement process. The procedures followed to monitor the results in a single laboratory are known as internal quality control (IQC) [1] while the set of procedures followed in order to compare the performance between different laboratories is known as external quality assessment (EQA). Proficiency testing is an integral component of the quality improvement process as it provides an objective assessment of laboratory competence for the consumers, accreditation bodies and regulatory agencies [2].

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[3].

The IQC aims to maintain the daily precision and accuracy of the particular analytical method while EQA is important for maintaining the long term accuracy of the methods. EQA systems had to be introduced to objectively compare the processes followed in different laboratories as the aliquots of same samples analysed in different laboratories even with same methods showed wide variation in the results. The variation in the results of the laboratories may be in part due to the presence of undetected systematic errors in the methods. The use of EQA subsequently resulted in the standardization of procedures and calibrators in the laboratories so that

uniformity could be achieved among the laboratories [4]. Apart from improving the methods and procedures in the participating laboratories, EQA is also an important part of the accreditation process for any clinical chemistry laboratory. The present study was conducted to evaluate our performance as a participating lab in the EQAS programme services.

II. Materials and Methods

The present observational study was undertaken in the NABL accredited laboratory of NRI MEDICAL COLLEGE AND GENERAL HOSPITAL, CHINAKAKANI Since July 2016 to July 2018. The biochemistry section of the laboratory was enrolled in EQA clinical chemistry monthly programme run by BIO-RAD laboratories. A total of 24 Unknown /blind samples (Cycle 15 and Cycle 16 each containing 12 samples) provided by the EQAS body received each month at Department of Clinical Biochemistry were taken for study that needed to be stored reconstituted on scheduled dates and analysed for the parameters for which our laboratory participated as per the guidelines and schedule provided by the organising EQAS body.

The results were uploaded on the EQAS website (BIO-RAD QC NET) on the scheduled dates and our performance report was downloaded after completion of each month. 21 parameters from our lab were chosen for assessment in EQAS programme. The tests were performed on our clinical chemistry automated analysers Siemens DADE dimension RXL(Blood glucose, Urea, Creatinine, Total protein, Albumin, Total bilirubin, Direct bilirubin, AST, ALT, ALP, Total cholesterol, HDL cholesterol, Triglycerides, Uric acid), RANDOX IMOLA(Amylase, Creatine kinase, Iron, Phosphorous), ROCHE AVL Electolyte anlyser (Sodium, Potassium, Chloride). Performance was analysed in terms of the SDI(Standard Deviation Index/Z-Score),VIS (variance index score), and OMVIS (OVERALL MEAN VIS) each month for the period of July 2016 to July 2018.

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

0.0 = perfect comparison with consensus group
<1.25 = acceptable
1.25 -1.49 = acceptable to marginal performance (some investigation of the test system may be required)
1.5 – 1.99 = marginal performance
2.0 – 3.0 = warning signal. (investigation of test system is recommended)
> 3.0 = unacceptable performance. (action signal)

Statistical tool assigned to the lab by the EQAS provider is Z-Score/Standard Deviation Index (SDI). It is a measure of relative inaccuracy/relative bias. If Z-Score >3 is more than two or more occasions for the same analyte, then 2 standardization procedures need to be checked.

VARIANCE INDEX SCORE (VIS) : It is calculated as

$$\%\,\text{VARIATION} = \frac{\text{Difference between participant's result and Group mean}}{\text{Group mean}} \times 100$$

$$\text{VARIANCE INDEX SCORE(VIS)} = \frac{\%\,\text{VARIATION}}{\text{Desired CV}} \times 100$$

The VIS interpreted as**,**

<100 - very good;
100-150 - good;
150-200 - satisfactory
> 200 - not acceptable.

VIS values for each parameter every month and similarly overall mean of VIS (OMVIS) were calculated on monthly basis. OMVIS < 100 indicates that results are very close to the target value 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 target value 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.

III. Results

On analyzing mean Z- Score of each parameter in clinical chemistry monthly programme for the study period July 2016 to July 2017, of the 21 parameters from the EQAS Cycle-15 nineteen with mean Z-score <1.25, one (Creatine kinase) with 1.25-1.49 and one (Direct Bilirubin) with 1.5-1.9. For the period July2017 to July2018, from EQAS cyc16 of the 21 analytes, twenty with mean Z-Score <1.25 and one (Creatine kinase) with 2.0-3.0

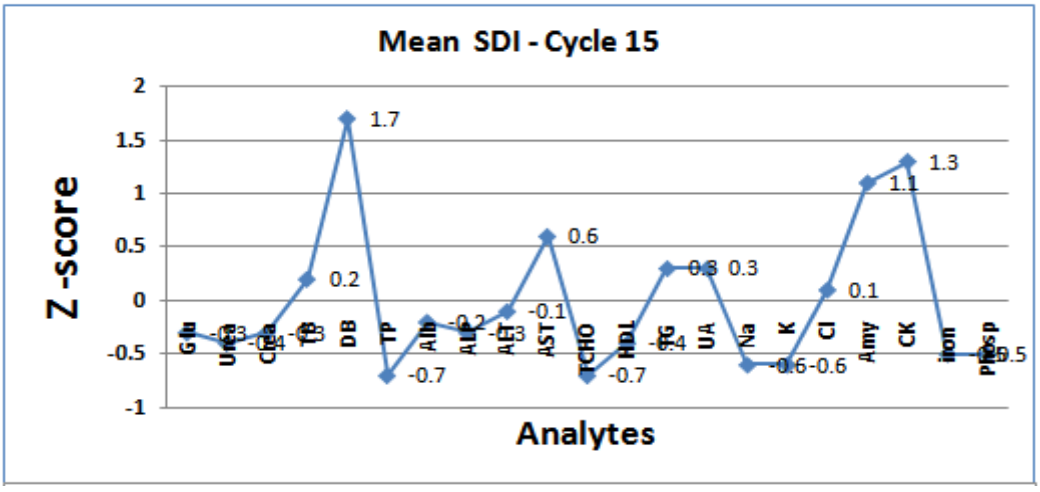
On analysing monthly VIS of each parameter, study revealed of the 21 parameters, 16 (76.2%) in cycle15(July2016-July2017), 17analytes(80.9%) in cycle 16(July2017-July2018) with excellent scores (VIS<50) and very good performance score(VIS<100) with 95.2% (cycle15), 90.4%(cycle16) of the total results falling in the category respectively in terms of Overall Mean Variance Index Score (OMVIS).

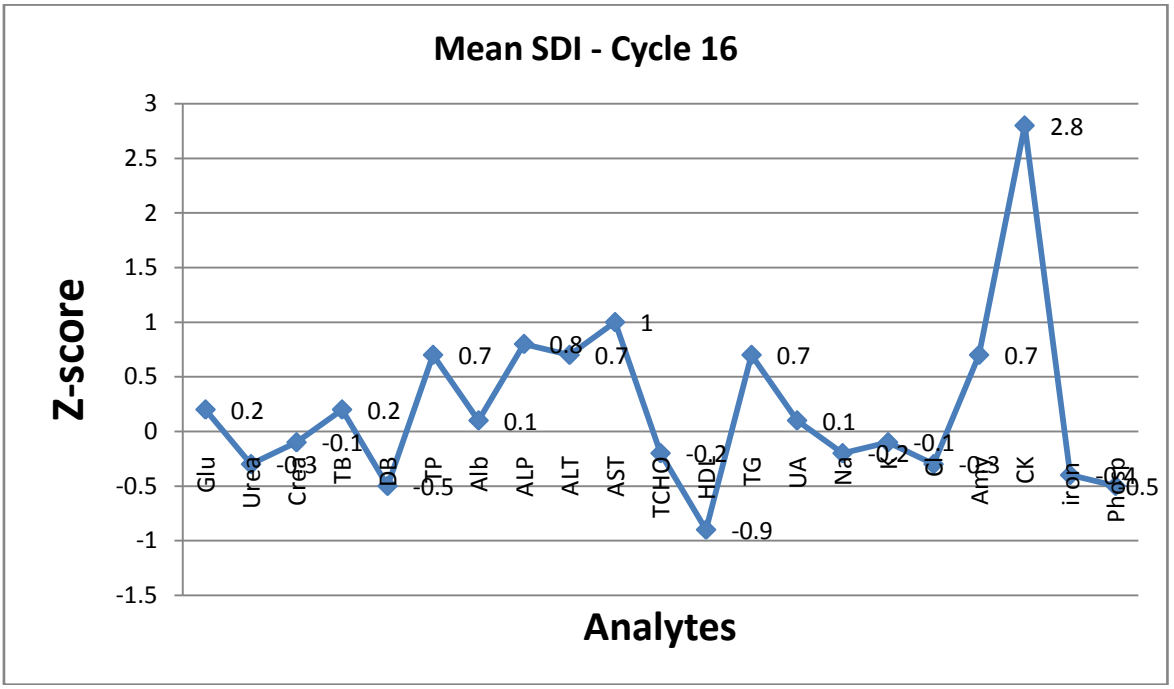
Table 1: SDI(Z-Score) of all parameters for the study period JULY2016-JULY2018

S.No	Analyte	Range of SDI Cycle 15 (July 2016 - July 2017)	Mean SDI (Cycle 15)	Range of SDI Cycle 16 (July 2017 – July 2018)	Mean SDI (Cycle 16)
1	Glucose	-1.83 to 1.09	-0.3	-1.06 to 1.23	0.2
2	Urea	-1.83 to 0.64	-0.4	-2.67 to 1.3	-0.3
3	Creatinine	-1.02 to 0.48	-0.3	-1.34 to 1.2	-0.1
4	Total Bilirubin	-2.48 to 3.11	0.2	-1.52 to 1.76	0.2
5	Direct Bilirubin	-2.5 to 17.9	1.7	-0.98 to 0.7	-0.5
6	Total Protein	-2.58 to 1.79	-0.7	-0.6 to 1.65	0.7
7	Albumin	-1.15 to 2.01	-0.2	-1.08 to 1.43	0.1
8	ALP	-1.58 to 0.87	-0.3	-0.7 to 2.52	0.8
9	ALT	-2.24 to 1.15	-0.1	-0.05 to 1.64	0.7
10	AST	-0.64 to 2.89	0.6	0.08 to 1.65	1.0
11	Total Cholesterol	-2.18 to 0.72	-0.7	-2.1 to 0.59	-0.2
12	HDL Cholesterol	-2.16 to 0.7	-0.4	-2.18 to 0.93	-0.9
13	Triglycerides	-2.56 to 3.34	0.3	-0.4 to 2.88	0.7
14	Uric Acid	-1.07 to 1.68	0.3	-2.01 to 1.41	0.1
15	Sodium	-3.9 to 0.74	-0.6	-2.4 to 2.24	-0.2
16	potassium	-4.87 to 1.48	-0.6	-1.79 to 1.45	-0.1
17	Chloride	-3.44 to 3.31	0.1	-1.57 to 1.1	-0.3
18	Amylase	-0.35 to 1.95	1.1	-1.55 to 1.47	0.7
19	CK	-3.56 to 4.6	1.3	-0.14 to 7.4	2.8
20	iron	-2.36 to 2.04	-0.5	-3.3 to 1.58	-0.4
21	Phosphorous	-1.83 to 1.26	-0.5	-2.7 to 1.83	-0.5

Table 2: Test results falling in different score categories of VIS

S. No	OMVIS (Overall mean VIS)	Cycle - 15 (July 2016-July 2017)	Cycle - 16 (July 2017-July2018)
1	Excellent (< 50)	76.2 %	80.9 %
2	Very good (50 -100)	19 %	9.5 %
3	Good (100 – 150)	nil	4.8 %
4	Satisfactory (151 – 200)	4.8 %	4.8 %
5	Not acceptable (>200)	nil	Nil





IV. Discussion

EQAS is an important tool to monitor and maintain the laboratory performance output. EQAS programmes were introduced as it was observed that when aliquots of the same sample were analysed in different laboratories, it was common to have different results. Then the measurement methods and calibration procedures followed by each centre were different and exclusive, hence the variation in the results. Commutability of the EQAS sample with clinical patient samples is the single most important concept in the design of the EQAS [5-8]. In any EQAS, the participating laboratories are sent aliquots of pooled serum samples and the nominated parameters are performed on the sample and the results submitted to the agency performing the EQAS for the statistical analysis of the results.

As a participant of the proficiency testing program, we performed all the prescribed tests by strictly following the departmental SOP and manufacturer's instructions. The impact of EQAS apart from the standardisation process can also be immense in the post analytical phase steps by using the proper unit of measurement, rounding off and the use of proper decimal points in reporting of the results [9].

The SDI expresses bias as increments of the standard deviation. The target SDI/Z-score is 0.0 which indicates there is no difference between the laboratory mean and target mean. 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 for the study period in terms of mean Z-score of the test results for 21 parameters in cycle 15 is 19 with acceptable, 1 with acceptable (creatine kinase) but requiring investigation of the test system, 1 (Direct bilirubin) with marginal performance. Where as in cycle 16 it is 20 with acceptable, one (creatine kinase) with warning signal and no parameter in both cycles with unacceptable performance. As far as the OMVIS concerned excellent scores (VIS<50) with 76.2% in cycle15(July 2016-July 2017) improved to 80.9% in cycle 16(July 2017-July 2018) .

Literature has described the instability of the biological compounds in lyophilised and liquid serum stored at various [10,11] temperatures. 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 Creatine kinase, HDL cholesterol. Possible reason could be influence of temperature; consequently, temperature control is an important component of assay reproducibility.

Poor performance for Direct Bilirubin could be due to photolysis during the storage and following the reconstitution. Moreover, the performance was inconsistent which could be due to the change in reagents and decrease in number of results being reported. Other causes of inconsistent performance in some analytes could be due to random errors resulted from the volume errors in reconstitution, reagent and sample pipetting. The time and temperature dependent changes in activities of analytes and improper storage of our sample should also be considered.

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 [12,13**]** they learn. 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].

EQAS evaluates the performance of procedures, equipment, materials, personnel and suggests areas for improvement. 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[14].

V. Conclusion

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 terms of performance evaluation, patient care and safety issues, and overall quality of laboratory practices. 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. 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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IOSR Journal of Biotechnology and Biochemistry (IOSR-JBB) is UGC approved Journal with Sl. No. 4033, Journal no. 44202.

Dr.Sowjanya Yerram "External Quality Assurance Scheme (Eqas): Criteria for Evaluating Performance of a Laboratory." IOSR Journal of Biotechnology and Biochemistry (IOSR-JBB) 4.4 (2018): 16-20.