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Original Article

External Quality Assessment Scheme in Biochemistry: Four Years Experience as a Participating Laboratory

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Abstract

Background: The attainment of quality services in a laboratory requires a both internal and external quality control material. External quality assessment scheme (EQAS) programs are accepted by laboratories to assess the performance of their testing systems.

Aim: The goal of this study was to review EQAS results from time to time in an effort to improve the performance of the laboratory. It is an observational study done at pronounced NABL accredited hospital in Lucknow, from January 2012 to December 2015.

Materials and Methods: In the current study, we have evaluated EQAS test result of the past 4 years, from 2012 to 2015. We receive prepared masterpool of human serum as per the WHO recommended procedure, dispensing the correct volume into the vials which are stored at 2-8°C in the refrigerator. The lyophilized vials are sealed, well packed in thick envelopes, and distributed to all the participating laboratories. The laboratories are requested to reconstitute the sample, analyze, and enter the results. The test results are analyzed and documented.

Results: If outliers are seen, then the root cause analysis is done for those parameters.

Conclusions: This participation in EQAS over the last 4 years has helped us significantly to improve our laboratory services.

Key words: External quality assessment scheme, Laboratory, NABL

INTRODUCTION

Laboratory quality control (QC) is designed to detect, reduce, and correct deficiencies in a laboratory's internal analytical process before the release of patient results, to improve the quality of the results reported by the laboratory. QC is a measure of precision, or how well the measurement system reproduces the same result over time and under varying operating conditions. Laboratory QC material is usually run at the beginning of each shift, after an instrument is serviced, when reagent lots are changed, after calibration, and whenever patient results seem inappropriate.[1] QC material should approximate the same matrix as patient specimens, taking into account properties such as viscosity, turbidity, composition, and color. It should be simple to use, with the minimal vial to vial variability because variability could be misinterpreted as systematic error in the method or instrument. It should be stable for long periods of time and available in large enough quantities for a single batch to last at least 1 year. Liquid controls are more convenient than lyophilized controls because they do not have to be reconstituted minimizing pipetting error.[1]

Interpretation of QC data involves both graphical and statistical methods. QC data are most easily visualized using a Levey-Jennings chart.[2]

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MATERIALS AND METHODS

External quality assessment scheme (EQAS) samples from the Christian Medical College, Vellore, are received and processed at our laboratory.

For each year, every month's sample was shipped to our center for specific tests as recommended by the organizing laboratory. Each time, unknown samples packed with coolant were received within 3 days of dispatch. 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 are performed (Table 1) and mailed to the organizing laboratory within 1st week of the month.

Every year, a total of 12 samples for biochemistry are received. All tests were performed by dedicated staff using the conventional technique available in the department.

RESULTS

Our study reviewed EQAS result from a pronounced NABL accredited laboratory in Lucknow. The outliers seen month wise in 4 years are mentioned in Table 2.

As seen in Table 2 and Figure 1, most number of outliers were seen in the year 2014, i.e., 67 outliers and in the month of June, i.e., 11 outliers. The next most common year was 2015 with 53 outliers, then came 2013 with 40 outliers. Least number of cases was seen in the year 2012 with 38 outliers.

Outliers seen in the year 2012 are shown in Table 3. Alkaline phosphatase was seen to be most common parameter showing outliers, i.e., 9 times, then comes high-density lipoprotein (HDL) showing outlier 5 times. Next comes total protein, potassium, uric acid, and sodium, all showing outliers 3 times. Total bilirubin, creatinine, serum glutamic pyruvic transferase (SGPT), serum glutamic oxaloacetic transaminase (SGOT), calcium, and urea showed outlier 2 times.

Outliers seen in the year 2013 are shown in Table 4. In the year 2013, most number of outliers were seen in uric acid, i.e., 8. Then, comes total bilirubin showing 7 times outlier; next comes HDL showing 5 times outlier, sodium showed 4 times outlier. SGPT, glucose, alkaline phosphatase, SGOT, and triglyceride (TG) showed 2 times outlier. Total protein, urea, calcium, and cholesterol showed one time outlier.

Outliers seen in the year 2014 are shown in Table 5. In the year 2014, 9 times outliers were seen in HDL. Alkaline phosphatase, calcium, and uric acid showed 6 times outlier. Next comes total bilirubin and glucose which show 5 times outlier. SGPT, urea, and TG showed 4 times outlier. Next come sodium, potassium, SGOT, and albumin which show 3 times outlier. The least common outlier was seen in creatinine, i.e., 2.

Outliers seen in the year 2015 are shown in Table 6. In the year 2015, maximum number of an outlier was seen in total bilirubin, i.e., 8 times, then comes calcium showing 6 times outlier. 5 times outliers were seen in alkaline phosphatase, potassium, and glucose. 4 were seen in urea and uric acid.

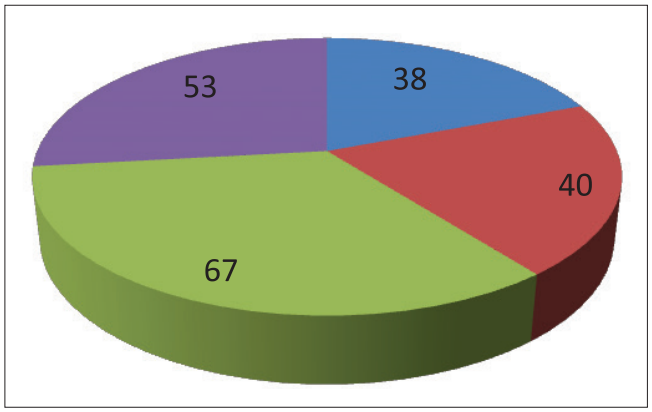

Figure 1: Outliers seen in 4 years

Table 1: Tests with their methords

S No.	Analyte	Method
1.	Glucose	God-pod
2.	Urea	Ned dye
3.	Creatinine	Jaffe's kinetic
4.	T.Bilirubin	Jendrassik
5.	T-protein	Biuret
6.	Albumin	Bcg
7.	Calcium	Arsenazo
8.	Uric acid	Enzymatic
9.	Cholesterol	Chod-pap
10.	Triglyceride	Enzymatic
11.	Hdl cho	Direct method
12.	Sodium	ISE
13.	Potassium	ISE
14.	AST	UV kinetic
15.	ALT	UV kinetic
16.	ALP	PNP AMP kinetic

Table 2 : Outliers seen in 4 years

Month	2012	2013	2014	2015
Jan	3	5	6	7
Feb	3	3	2	4
March	5	5	4	4
April	3	1	6	9
May	1	4	5	3
June	3	1	11	4
July	5	3	3	3
August	No entry	3	6	3
Sept	2	1	7	2
Oct	2	4	7	5
Nov	5	6	6	4
Dec	6	4	4	5

Then, comes HDL and sodium with 3 times outlier. 2 times outliers were seen in albumin, SGOT, TG, and creatinine.

Root cause analysis was done to rule out the cause of outliers. Inter laboratory comparison was done with two other NABL labs. Root cause analysis was done following these few points:

- Temperature and reagents were checked
- QC was checked for whole week
- If outlier was seen then, QC was rerun and machine calibrated
- Engineer was called, and the machine was maintained if required.

DISCUSSION

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. The program provides an opportunity to the participating organizations to compare activities and modify their own practices, based on what they learn.[3,4] 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 standard operating procedures and manufacturer's instruction, considering each lot as routine working samples.

CONCLUSION

An EQAS program plays an important role in improving the efficiency of a laboratory service and thereby optimizes the overall quality of a health care system. In the last 4 years, we could significantly improve our laboratory services in terms of performance evaluation, patient care and overall

Table 3: Outliers seen in year 2012

Month	Outlier	VIS
Jan	Total bilirubin	239
	Sodium	274
	Alkaline phosphatase	223
Feb	Creatinine	231
	Alkaline phosphatase	209
	HDL	381
March	Total protein	213
	HDL	400
	Sodium	226
	Potassium	323
	Alkaline phosphatase	400
April	Total protein	320
	SGPT	235
	Alkaline phosphatase	252
May	Alkaline phosphatase	400
June	Calcium	344
	Potassium	211
	Alkaline phosphatase	400
July	Urea	400
	HDL	400
	Alkaline phosphatase	337
	SGOT	273
	Potassium	261
August	No result was sent	
Sept	Alkaline phosphatase	312
	HDL	393
Oct	Urea	257
	Uric acid	325
Nov	Total bilirubin	263
	Uric acid	371
	HDL	309
	Alkaline phosphatase	216
	SGOT	204
Dec	Creatinine	286
	Total protein	298
	Calcium	336
	Uric acid	400
	SGPT	205
	Sodium	354

Table 4: Outliers seen in year 2013

Month	Outlier	VIS
Jan	Total bilirubin	400
	Creatinine	400
	Uric acid	241
	HDL	400
	SGPT	400
Feb	Uric acid	211
	Total protein	290
	Urea	209
March	Glucose	400
	Sodium	400
	Alkaline phosphatase	391
	SGOT	400
	SGPT	400
April	Creatinine	333
May	Uric acid	346
	SGOT	288
	Sodium	228
	Alkaline phosphatase	268
June	Total bilirubin	213
July	Total bilirubin	383
	Triglyceride	400
	HDL	27
August	Total bilirubin	400
	Triglyceride	325
	Uric acid	298
Sept	Uric acid	400
Oct	Total bilirubin	400
	Calcium	400
	Uric acid	400
	HDL	304
Nov	Glucose	329
	Total bilirubin	400
	Uric acid	400
	Cholesterol	286
	HDL	400
	Sodium	346
Dec	Total bilirubin	310
	Uric acid	400
	HDL	272
	Sodium	268

Table 5: Outliers seen in year 2014

Month	Outlier	VIS
Jan	Urea	400
	Total bilirubin	400
	Calcium	336
	Uric acid	208
	Triglyceride	212
	HDL	400
Feb	Total protein	249
	Calcium	383
March	Creatinine	263
	Uric acid	202
	HDL	400
	Potassium	206
April	Total bilirubin	400
	Calcium	206
	HDL	400
	Sodium	349
	Potassium	256
	Alkaline phosphatase	213
May	Calcium	379
	Uric acid	206
	HDL	279
	Sodium	400
	Potassium	400
June	Glucose	400
	Urea	250
	Creatinine	354
	Total bilirubin	400
	Total protein	276
	Albumin	400
	Calcium	400
	HDL	256
	SGOT	400
	SGPT	400
	Alkaline phosphatase	322
July	Total bilirubin	326
	HDL	400
	SGPT	217
August	Glucose	400
	Uric acid	400
	Triglyceride	276
	Sodium	201
	SGOT	400
	Alkaline phosphatase	400
Sept	Glucose	210
	Urea	216
	Albumin	257
	Uric acid	395
	Triglyceride	216
	HDL	368
	SGPT	230
Oct	Glucose	200
	Total bilirubin	273
	Total protein	312
	HDL	400
	SGOT	400
	SGPT	218
	Alkaline phosphatase	400
Nov	Glucose	219
	Urea	387
	Total protein	333
	Albumin	391
	Triglyceride	268
	Alkaline phosphatase	254
Dec	Calcium	284
	Uric acid	400
	HDL	400
	Alkaline phosphatase	381

Table 6: Outliers seen in year 2015

Month	Outlier	VIS
Jan	Urea	222
	Total bilirubin	310
	Albumin	223
	Calcium	213
	Uric acid	400
	SGOT	400
	Alkaline phosphatase	400
Feb	Total bilirubin	400
	Calcium	400
	HDL	350
	Alkaline phosphatase	400
March	Total bilirubin	400
	Calcium	305
	Potassium	268
	Alkaline phosphatase	400
April	Glucose	400
	Urea	400
	Total protein	209
	Albumin	220
	Calcium	400
	Uric acid	400
	Cholesterol	246
	HDL	400
	Alkaline phosphatase	295
May	Glucose	274
	Total bilirubin	400
	Potassium	400
June	Glucose	400
	Urea	400
	Calcium	300
	Uric acid	400
July	Sodium	219
	Potassium	243
August	Glucose	238
	Total bilirubin	400
	Potassium	400
Sept	Total bilirubin	400
	Uric acid	319
	Triglyceride	215
Oct	Glucose	400
	Urea	399
	Creatinine	226
	Sodium	331
	SGOT	400
Nov	Total bilirubin	354
	Calcium	400
	Sodium	328
	Potassium	395
Dec	Creatinine	236
	Total bilirubin	252
	Triglyceride	308
	HDL	211
	Alkaline phosphatase	386

Contd...

quality of laboratory practices.[5,6] 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 a scope for improvement and development in a system.

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