External quality assessment of clinical biochemical assays in a medium non-academic, non-research hospital laboratory

Subhash C. Arya, *MBBS, PhD,*
Nirmala Agarwal, *MBBS, FRCOG,*
Shekhar Agarwal, *MBBS, MCh (Orth),*
Beena Michael, *DMLT.*

Accurate biochemistry results guide the clinicians to apply appropriate preventive, diagnostic, curative, and rehabilitative measures. Accuracy of such results depends on the internal quality control and external quality assessment of the data generated by the laboratory. The external quality assessment (EQA) in medical laboratories would ensure good laboratory performance, including evaluation of methods, post-market vigilance, and training.[1] The program provides an opportunity to the participating organizations to compare activities, and modify their own practices based on what they learn.[2] Such a program offers valuable benefits to participating laboratory in terms of performance evaluation, improvement in patient care and safety, and the overall quality of laboratory practices.[3] This idea was implemented with an affirmative consequence in a non-academic, non-research, privately owned Sant Parmanand Hospital, New Delhi, India from April 2007 to December 2009 (a period of 33 months) in participation with Randox International Quality Assessment (RIQAS [Randox Laboratories, Crumlin, United Kingdom]) Program. The aim of the study was to watch the performance of every biochemical investigation carried out in the laboratory. The RIQAS participation was approved by the hospital management.

At the start of April 2007, the results obtained for 28 biochemical parameters (albumin, alkaline phosphatase, serum glutamate pyruvate transaminase (SGPT), total amylase, serum glutamate oxaloacetate transaminase (SGOT), bilirubin direct and total, calcium ionized and total, cholesterol, creatinine kinase (CK) total, gamma-glutamyltranserase (GGTP), glucose, HDL cholesterol, iron, inorganic phosphate, potassium, total protein, prostate specific antigen (PSA) total, sodium, triidothyroxine (T3), thyroxin (T4), total iron binding capacity (TIBC), triglycerides, thyroid stimulating hormone (TSH), urea and uric acid) continued to be assessed at our hospital through RIQAS for clinical biochemistry. The RIQAS included an average of 1381 participants for an analyte: minimum of 106 for free T3, and a maximum of 2125 for glucose. Samples for local analysis from Randox were received annually but analyzed monthly. Lyophilized 5 ml samples were reconstituted with 5 ml of freshly distilled water at room temperature. The reconstituted vials were stored for 60 minutes in the dark before being run on the analyzers. Reconstituted materials were loaded in the respective analyzers. Appropriate commands were given for the analysis of individual analyte. The reagents employed were in accordance with the manufacturers' directives. Results generated were returned to RIQAS by the internet. No patient samples were involved in the study. The RIQAS scrutinized individual laboratory results and communicated to all participants the cumulative mean, standard deviation, and the percent coefficient of the variations derived. No statistical testing was involved locally.

Upon receipt of RIQAS reports, our laboratory drew on the standard deviation index (SDI), the expression representing the difference in terms of the number of standard deviations from the overall mean, to categorize our internal performance with individual analytes. The result for a parameter could be either "satisfactory" with SDI ≤1.0, or "acceptable but borderline" with SDI 1-2, or requiring "review of techniques and check on calibrations" with SDI 2-3, or "requires urgent intervention" with SDI >3.4 With every SDI value exceeding 2.0, the reagents used during laboratory assays were scrutinized for any exposure to harsh environment during shipment from the manufacturer, or in the hospital storage. During the 33 months interval, RIQAS scores for 19 analytes were unsatisfactory with an SDI>3.0, both with the automatic or semi-automatic analyzers. Scores were unsatisfactory for more than one occasion with alkaline phosphatase, CK-total free T4, iron, inorganic phosphate, cholesterol, bilirubin, albumin, total protein, and potassium (**Table 1**). With every unsatisfactory score, the calibration records and internal quality control data with the analyzer used were appraised again. Poor scores were frequently recorded when several personnel went on leave, or left the job at short notice. The quality of deionized water employed was sub-standard on one occasion. Poor performances with ABL 555 (**Table 1**) were tracked by instant replacement of electrodes and re-calibration by the supplier. Deficient scores originating from Biolis 24i (Tokyo Boeki Medical System Ltd., Tokyo, Japan) and Access® (Beckman Coulter, Fullerton, CA , USA) (**Table 1**) were tackled by meticulous re-calibration by the respective vendors. Persistently inaccurate scores with Daytona® (Randox Laboratories Ltd., Crumlin, UK), CombisysII (Eschweiler GmbH & Co., Holzkoppelweg, Germany), and Humalyzer 3000 (Human GmbH, Wiesbaden, Germany) (**Table 1**) speeded up their substitution. There was a progressive decline in analytes requiring urgent attention during the 3 successive 11-month intervals from 15 to 9 and 4.

Analysis of EQAS lots with lower, normal, or higher values with several permutations, or combinations for different parameters has been an asset. Similar samples

Table 1 - Frequency distribution of analytes with standard deviation index >3.0.

Analyte	Frequency	Analyzer (frequency)
Alkaline phosphatase	7	Daytona (2), Biolis 24i (5)
Creatine kinase-total	5	Humalyzer 3000
Free thyroxine (T4)	5	Access
Iron	4	Daytona (2), Biolis 24i (2)
Inorganic phosphate	3	Daytone (1), Biolis 24i (2)
Bilirubin	3	Humalyzer 3000(2), Biolis 24i (1)
Albumin	2	Daytona
Potassium	2	CombisysII (1), ABL-555 (1)
Cholesterol	2	Daytona (1), Biolis 24i (1)
Total protein	2	Daytona (1), Biolis 24i (1)
Alanine aminotransferase	1	Daytona
Calcium	1	Daytona
Gamma-glutamyl transpeptidase	1	Daytona
Glucose	1	Daytona
Uric acid	1	Daytona
Triglyceride	1	Daytona
High density lipoprotein cholesterol	1	Biolis 24i
Magnesium	1	Biolis 24i
Free triiodothyronine (T3)	1	Access

of clinical material would not have been available at such frequent intervals. Like instigators at other laboratories,[5] local clinicians were disbeliever on accuracy of free thyroid hormones results. Consistently excellent EQA values for T3 and T4 have been promising. Furthermore, our laboratory personnel with prior experience in calibration of semi- or fully-automated analyzers are now more self-assured while analyzing samples with lower or higher values. There has also been significant improvement in the maintenance of analyzers, regular reagent replenishment, and procurement of spares and accessories in our laboratory. That has been advantageous to administrators, clinicians, and patients. It is certain that every external quality assessment is a retrospective activity as the evaluation reports are available after a gap. Nevertheless, objective and independent EQA from April 2007 covers the period until December 2009, and it has been cost-effective, and has enabled our laboratory to disprove any negative remarks on its reporting. The action is still being carried out.

In general, the EQA performance in a particular month does not interest clinicians. But both the clinicians and patients are satisfied with the accuracy and legitimacy of our internally generated reports. During 2010, EQA has also been set for hematology and coagulation tests. In addition, consistency with satisfactory scores for biochemistry parameters during external assessments will be a strong defense in case of any legal conflict. Therefore, EQA should appeal to all private health care centers in countries with poor laboratory services since consistently excellent EQA scores would be useful to the laboratory, clinicians, and patients.

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From the Laboratory Department (Arya, Michael), and Departments of Gynecology and Obstetrics (Agarwal N), Orthopedics (Agarwal S), Sant Parmanand Hospital, New Delhi, India. Address correspondence and reprints request to: Dr. Subhash C. Arya, Laboratory Department, Sant Parmanand Hospital, 18 Alipore Road, New Delhi110054, India. Tel. +91 (11) 9810642269. Fax. +91 (11) 2394706. E-mail: subhashbhapaji@gmail.com

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