EQAS as a tool for evaluating laboratory performance in tertiary care hospital

Running title: Utilizing EQAS for evaluating laboratory performance

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Abstract

Background: Quality control (QC) is a crucial tool in the clinical laboratory for error identification and correction. While The Internal Quality Control (IQC) ensures daily precision and accuracy, the External Quality Assurance Scheme (EQAS) ensures long-term accuracy by providing external verification. The objective of this study was to evaluate our laboratory's performance in the EQAS program and assess the impact of corrective actions on EQAS performance improvement.

Methods: The retrospective observational study was undertaken in the tertiary care hospital. The Biochemistry department of the laboratory participated in the monthly clinical chemistry EQA program administered by CMC Vellore EQAS. Nineteen parameters were assessed using structured approach to analyze deviating EQAS results. Monthly performance was analyzed in terms of the SDI (Standard Deviation Index) and VIS (variance index score) for the period of October 2019 to September 2021.

Results: Among the nineteen parameters assessed in EQAS program, most showed 'excellent' performance between October 2019 and September 2021 based on mean SDI. Some improvement was observed in the SDI values between the two cycles after implementing a structured approach in root cause analysis and indicates an enhanced level of performance in the EQAS program. The VIS analysis revealed that 89.47% of parameters in the October 2019 to September 2020 period and 94.73% in the October 2020 to September 2021 achieved scores classified as 'very good' performance.

Conclusion: Adopting a structured approach to analyze deviating EQAS results enables the evaluation of laboratory performance and offers opportunities for improvement. Consequently, EQAS plays a significant role as a cornerstone in the accreditation process.

Key words: Quality control, EQAS, Accuracy, Precision, Accreditation.

Introduction

In the realm of evidence-based medicine, laboratory healthcare services are widely recognized as the cornerstone. Clinical lab services link physicians and lab staff jointly enabling patient sample analysis. They are pivotal in diagnosing and aiding medical choices. Standardization in lab medicine aims for consistent, accurate results across tests, methods and locations (1). Precise lab measurements ensure proper care and disease management. Standardized practices offer dependable data, aiding healthcare decisions for patient well-being (2, 3, 4). Quality control (QC) is a highly scientific and essential tool utilized in clinical laboratories to identify and rectify errors during the analytical phase (5). Despite the clinical biochemist's profound understanding of QC process in clinical chemistry laboratories, the significance of adhering to QC measures remains a topic that is often overlooked and overshadowed. This pertains particularly to the application of both internal and external QC in the clinical laboratory (1). Therefore, incorporating daily Internal Quality Control (IQC) procedures and actively participating in External Quality Assurance Scheme (EQAS) programs serves as strong indicators of adhering to good clinical laboratory practice (GCLP) and ensuring the delivery of high-quality laboratory services (5). Internal quality control involves the monitoring of results within a single laboratory, ensuring the accuracy and precision of testing processes. On the other hand, EQAS comprises a set of procedures designed to compare the performance of different laboratories, promoting inter-laboratory proficiency assessment and enhancing overall quality assurance (6). IQC self-assesses lab processes in real time using materials with known values (5,7). Alongside IQC, labs should engage in EQAS for enhancing quality standards, fostering improvement and ensuring the provision of reliable results (5). EQAS serves a dual role as an external verification tool for laboratory's results and a self-monitoring mechanism. Its benefits extend directly to the laboratory itself, as well as indirectly to its customers, regulatory bodies and accreditation organizations. EQAS plays a crucial role in ensuring the accuracy and reliability of laboratory testing, which ultimately enhances customer satisfaction, regulatory compliance, and accreditation standards (8, 9). Even with identical methods, different labs often yield varying results from the same samples. This underscores the importance of objective assessment, which is where EQAS comes in. EQAS offers a systematic review of labs, spotting hidden errors causing result differences. By reducing such inconsistencies, EQAS ensures accurate and consistent patient reports (6, 10). EQAS is a vital lab tool. It finds equipment issues, reagent problems, and staff training gaps (11). It also triggers timely corrective actions spanning analytical, pre- and post-analytical stages (12). Achieving complete self-sufficiency in healthcare facilities is a challenging task, as there is always room for improvement and development within any system. Therefore, participating in a global EQAS program holds potential to significantly enhance the quality of hospital services (6, 13). By engaging in EQAS on global scale, healthcare facilities can benefit from external evaluations, benchmarking, and the exchange of best practices, ultimately leading to improved quality and better patient outcome (6, 14, 15).

Hence, the primary objective of this study was to assess our performance as a participating laboratory in the EQAS program services and investigate the impact of corrective actions implemented, where necessary, to enhance EQAS performance. By conducting this evaluation, we aimed to gain insights into our laboratory's proficiency in EQAS and identify areas for improvement to further enhance the quality of our services.

Methods

A retrospective observational study was conducted in a tertiary care hospital spanning from October 2019 to September 2021. The study received approval from the institutional ethical committee [Reference number: SKNMC/Ethics/App/2022/879]. The Biochemistry department of the laboratory participated in the monthly clinical chemistry EQAS program administered by CMC Vellore EQAS. This program served as the platform for assessing and monitoring the laboratory's performance in clinical chemistry. In the Department of Clinical Biochemistry, a total of 24 blind samples, provided by the EQAS body, were received in three separate batches. These samples were stored following the guidelines provided by CMC Vellore EQAS. Each month, the corresponding samples were reconstituted and analyzed for the parameters in which our laboratory participated, using standard protocols and following the schedule provided by the EQAS organizing body. The results were then uploaded onto the EQAS website (CMC Vellore EQAS) on the designated dates, and our performance report was downloaded upon completion of each month's analysis. For the purpose of this study, a total of nineteen parameters from the EQAS program, were selected for assessment in our laboratory.

The biochemical parameters included for analysis were glucose, urea, creatinine, total protein, albumin, total bilirubin, AST (Aspartate Transaminase), ALT (Alanine Transaminase), ALP (Alkaline Phosphatase), total cholesterol, HDL cholesterol, triglyceride, uric acid, amylase, calcium, phosphorus, sodium, potassium and chloride. These parameters were analyzed using Dry Chemistry automated analyzer Vitros 5600. Performance evaluation was conducted monthly, employing the SDI (Standard Deviation Index) and VIS (Variance Index Score) as the key metrics, for the period spanning from October 2019 to September 2021.

The SDI was calculated as the difference between the laboratory value and the target value (or designated value, DV) divided by the standard deviation (SD) of the mean for the comparison group. The interpretation of SDI was as follows: SDI between -1.00 and +1.00 indicated 'excellent' performance, between ± 1.01 and ± 2.00 indicated 'good' performance, between ± 2.01 and ± 2.99 indicated 'accept with caution (warning signal)' performance and beyond ± 3.0 indicated 'unacceptable' performance and triggered an 'action signal'. The EQAS provider assigned the SDI as the statistical tool for the laboratory. SDI served as a measure of relative inaccuracy or relative bias, providing insights into the performance of the laboratory compared to the comparison group (1, 5, 6).

The VIS was calculated as the difference between the participant's results and the group mean, multiplied by 100 and divided by the group mean. The VIS was interpreted as follows: VIS below 100 indicated 'very good' performance, VIS between 100 and 150 indicated 'good' performance, VIS between 150 and 200 indicated 'satisfactory' performance, and VIS above 200 indicated performance that was not acceptable. The VIS provided a measure of the percentage variation of the participant's result compared to the desired coefficient of variation (CV). It allowed for the assessment of the laboratory's performance in terms of the level of variation observed, helping to determine the quality of the results (1, 5, 6).

Our performance was evaluated for two consecutive years, from October 2019 to September 2020 and from October 2020 to September 2021. At the conclusion of the first cycle in September 2020, we introduced a root cause analysis for parameters that fell outside the acceptable range, if any, as well as for improving the performance. This analysis aimed to identify the underlying reasons for these deviations and implement corrective measures. The root cause analysis was carried forward into the subsequent cycle, allowing for ongoing evaluation and improvement of our performance.

Results

During the study period from October 2019 to September 2021, we analyzed the mean SDI of each parameter in the EQAS program for Biochemistry on a monthly basis. In the first cycle (October 2019 to September 2020), out of the 19 parameters, 17 parameters had a mean SDI within the range of -1 to +1, which indicated the ‘excellent’ performance. Two parameters, total protein (-1.71) and amylase (-1.33) fell within the range of mean SDI ± 1.01 and ± 2.00, which indicated the ‘good’ performance. In the subsequent cycle (October 2020 to September 2021), out of the 19 parameters, 18 parameters had a mean SDI within the range of -1 to +1, indicating the ‘excellent’ performance. Only one parameter, amylase (-1.14), fell within the range of mean SDI ± 1.01 and ± 2.00 which indicated the ‘good’ performance. Overall, the SDI showed improvement compared to the previous cycle (Figure 1).

These findings suggests that the majority of parameters consistently performed within the ‘excellent’ category, indicating the accurate and precise results. The slight improvement observed in the SDI values between the two cycles indicates an enhanced level of performance in the EQAS program.

Table 1 displays the parameters included in the study, along with their respective mean SDI values and SDI ranges. Notably, none of the 19 parameters exhibited a ‘warning signal’ or ‘unacceptable’ performance. This indicates that all parameters fell within the acceptable range, demonstrating consistent and satisfactory performance in the EQAS program.

The monthly analysis of the VIS for each parameter in our study yielded interesting results. In the cycle from October 2019 to September 2020, out of the 19 parameters, 17 parameters (89.47%) achieved scores classified as ‘very good’ performance (VIS<100). Similarly, in the cycle from October 2020 to September 2021, 18 parameters (94.73%) attained scores classified as ‘very good’ performance.

In the October 2019 to September 2020 cycle, two parameters, total protein and amylase received scores classified as ‘good’ performance (VIS within 100-150). In the subsequent cycle (October 2020 to September 2021), one parameter, amylase, also received score classified as ‘good’ performance. Notably, none of the parameters fell into the ‘satisfactory’ or ‘not acceptable’ performance limits, indicating a consistently high level of performance across the assessed parameters (Table 2).

These findings demonstrate that the majority of parameters achieved ‘excellent’ scores, indicating high precision and accuracy in the EQAS program. The presence of only a few parameters with ‘good’ scores suggests room for further improvement, which can be addressed through targeted approach, but overall, the performance was commendable.

Discussion

Quality control is an integral part of quality assurance in clinical laboratories. It involves planned and systematic activities to ensure that the reported results are reliable, accurate and precise (8). Effective management of quality in health laboratories is essential to generate trustworthy test results that healthcare professionals can rely on for emergency situations and disease management. Laboratory quality, characterized by the accuracy, reliability, and timeliness of reported test results, is crucial in avoiding unnecessary treatments, investigations, complications and diagnostic delays Failure to achieve accurate results can lead to increased costs, longer turnaround times and poor patient outcomes (16). Assessments play a critical role in evaluating the effectiveness of laboratory’s quality management system. They involve systematic examination through internal and external audits of the laboratory’s quality management system to ensure compliance with regulatory, accreditation, and customer requirements. EQAS is an important component of assessments providing valuable data and information for monitoring and documenting analytical quality, detecting errors, and initiating corrective actions. By participating in EQAS programs, laboratories can provide objective evidence of testing quality, instilling confidence in customers such as physicians, patients, and health authorities (1, 17). EQAS is the quality control which is performed periodically by the laboratory person with the contribution of an external source like referral laboratory or diagnostic industry (18). Niraula A. et al. demonstrated that the efficient and high-quality laboratory operation critically requires EQAS (1).

Our laboratory has been actively participating in EQAS program since 2014. We strictly adhere to standard operating procedures (SOP) and manufacturer's instructions for all investigations as part of our participation. The impact of EQAS extends beyond the analytical process and can also influence the post-analytical phase, including use of proper unit of measurement, rounding-off and accurate reporting (6). Bhatt RD et al. interpreted that good laboratory practices can be ensured by participation and periodic evaluation of EQAS indicators along with IQC (5).

The EQAS program assesses performance using indicators such as the SDI and VIS. SDI measures relative inaccuracy or bias by calculating the difference between laboratory mean and target mean divided by the standard deviation. VIS, on the other hand, quantifies the deviations from the target value as a percentage. Deviations from expected results prompt laboratories to take corrective actions, such as changing reagents, kits or instrument calibrations and providing skill training to personnel for proper sample reconstitution and storage (6).

In our study, we observed that the majority of parameters achieved excellent SDI scores, with some improvement seen after implementing a structured approach in root cause analysis. Our findings align with previous research that highlights the potential for improving hospital service quality through global participation in EQAS programs (6, 19).

We developed a systematic approach for handling deviated EQAS results, including troubleshooting, and documentation of analysis. The analysis of EQAS results for deviated parameters was done considering following points: 1. Identification of deviated parameters. 2. Comparison of the expected and reported results for each deviated parameter. 3. Assessment of the expected SDI range and SDI mean value for each parameter.4. Examination of equipment operation during the EQAS run to identify any issues. 5. Evaluation of reagent/test performance related to the deviated parameters. 6. Verification of the IQC sample to ensure it was within the acceptable limits on the day of EQAS run. 7. Confirmation that the appropriate EQAS sample was used/run for the deviated parameters. 8. Investigation of any errors in the reconstitution or storage of the EQAS samples. 9. Analyzing the potential causes of EQAS deviation, including clerical errors in reporting test results to the EQAS organization, mixing up test results, reporting results with the wrong unit, using the wrong method or equipment, or other relevant factors.10. Recording the results of repeat analysis using the stored EQAS material for further analysis. This structured approach was utilized to gain insights into the reasons behind deviated EQAS results and helped us identify potential sources of systematic errors and take appropriate corrective actions, preventive actions and perform root cause analysis as part of our laboratory's quality control system. According to Hastings RJ et al. (20), EQAS schemes serves as a surveillance mechanism that effectively detects laboratory errors. By doing so, they play a crucial role in improving the overall quality of diagnostic services provided to patients (20, 21).

In the first cycle of our laboratory, two parameters fell within the mean SDI range of ± 1.01 to ± 2.0. In the subsequent cycle, one parameter also fell within this range. Notably, there was an improvement in the performance of various parameters, including glucose, amylase, total bilirubin, total protein, calcium, uric acid, cholesterol, triglyceride, sodium, potassium and ALT, compared to the previous cycle. This approach aligns with the ISO 15189 guidelines, which emphasize the importance of laboratory participation in EQAS, monitoring and documenting EQAS results, and implementing corrective actions when predetermined criteria are not met (22, 23). While many laboratories run EQAS samples as part of their routine, the critical aspect lies in the analysis of EQAS results and the subsequent implementation of corrective actions. Our laboratory followed a structured approach to refine the outcomes and ensure the quality of testing, in line with the insights provided by Kristensen GB et al. on handling unacceptable EQAS results and the necessary corrective actions to be taken (19).

Accreditation is another crucial aspect, as it provides formal recognition of an organization's competency in specific tasks. ISO 15189: 2012 and ISO 15189: 2022 standards define the criteria for maintaining quality management in medical laboratories (22, 23). Participation in EQAS is a prerequisite for ISO15189: 2012 (now ISO 15189:2012) accreditation, emphasizing the importance of laboratory personnel's awareness, competence, and continuous improvement through structured root cause analysis and corrective actions (24).

The limitations of our study include the monitoring of only two EQAS cycles and the exclusion of endocrine parameters. Future longitudinal studies should consider monitoring EQAS in conjunction with internal quality control on large scale in several cycles involving routine and endocrine parameters to comprehensively assess the laboratory performance. This could reveal trends and patterns in laboratory performance, aiding in identifying systematic issues that might otherwise go unnoticed.

Conclusion

EQAS not only helps to monitor the analytical performance but also assess the method performance through inter-laboratory comparison using standardized methods and equipment. This provides the advantage of evaluating the laboratory's accuracy using blind samples, similar to patient samples, followed by generating a report that compares the individual laboratory's performance against other participants in the program. Our study concluded that formulating and implementing a structured approach to handle deviating EQAS results was beneficial for evaluating the performance of procedures, equipment, materials, and personnel, thereby providing opportunities for improvement in these areas. This ultimately leads to the delivery of high-quality laboratory services. EQAS analysis serves as a valuable tool in quality assurance and improvement and ensuring comparability of results among different laboratories. Consequently, EQAS plays a significant role as a cornerstone in the accreditation process. The conclusion of the study provides avenues for future research to develop automated systems that utilize EQAS data to trigger corrective actions and notifications when deviations are identified. This could involve integrating EQAS data into laboratory information management systems for efficient monitoring. Moreover, conducting longitudinal studies that track the impact of corrective actions resulting from EQAS feedback over time would provide valuable insights into the sustainability and effectiveness of the quality improvement measures.

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Ethics approval

The study was approved by institutional ethical committee [Reference number: SKNMC/Ethics/App/2022/879].

Conflict of Interest

The authors declare that they have no competing interests.

Author contributions

All authors contributed in designing the study, analyzing and interpreting data, writing a manuscript and approved the final submission.

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Table 1. Represents SDI Range and SDI Mean for period October 2019 to September 2021

Sr. No.	Analyte	SDI Range	SDI Mean	SDI Range	SDI Mean
		Oct 2019 - Sept 2020		Oct 2020 - Sept 2021	
1	**Glucose ***	- 0.52 − 3.45	0.44	- 1.38 − 3.64	0.30
2	**Urea**	- 1.87 − 1.19	- 0.05	- 2.8 − 2.38	0.08
3	**Creatinine**	- 1.12 − 0.92	- 0.18	- 3.46 − 11.76	0.87
4	**Total Bilirubin ***	- 1.67 − 0.48	- 0.16	- 1.39 − 1.89	0.02
5	**Total Protein ***	- 3.99 − 0.11	- 1.71	- 2.21 − 3.4	0.36
6	**Albumin**	- 2.01 − 1.22	0.25	- 3.87 − 3.31	- 0.95
7	**Calcium ***	- 1.76 − 2.1	- 0.21	- 2.78 − 2.74	- 0.08
8	**Phosphorus**	- 1.76 − 1.89	- 0.19	- 1.09 − 2.36	0.48
9	**Uric acid ***	- 0.58 − 1.48	0.39	- 2.26 − 2.74	- 0.04
10	**Total Cholesterol ***	- 1.1 − 1.38	- 0.35	- 2.06 − 3.06	- 0.16
11	**Triglyceride ***	- 6.39 − 0.9	- 0.93	- 1.79 − 3.33	0.10
12	**HDL-Cholesterol**	- 1.78 − 0.48	- 0.20	- 2.87 − 2.38	- 0.21
13	**Sodium ***	- 1.63 − 1.55	- 0.38	- 3.59 − 6.42	- 0.25
14	**Potassium ***	- 2.6 − 0.58	- 0.41	- 2.97 − 4.71	- 0.10
15	**Chloride**	- 0.39 − 3.77	0.34	- 2.14 − 4.75	0.37
16	**AST***	- 2.4 − 0.84	- 0.25	- 1.07 − 2.4	- 0.04
17	**ALT**	- 2.36 − 1.23	0.22	- 0.96 − 1.61	0.27
18	**ALP**	- 0.9 − 1.43	0.13	- 0.5 − 1.6	0.61
19	**Amylase ***	- 2.61 − 0.01	- 1.33	- 2.92 − 3.06	- 1.14

*** Indicates parameters with improved performance**
SDI: Standard Deviation Index

Table 2. Represents the performance and percentage of parameters as per Mean VIS

Sr. No.	Mean VIS	Performance	Oct 2019 – Sept 2020	Oct 2020 - Sept 2021
1	**< 100**	**Very Good**	89.47 %	94.73 %
2	**100-150**	**Good**	10.52 %	5.26 %
3	**150-200**	**Satisfactory**	Nil	Nil
4	**> 200**	**Not acceptable**	Nil	Nil

VIS: Variance Index Score

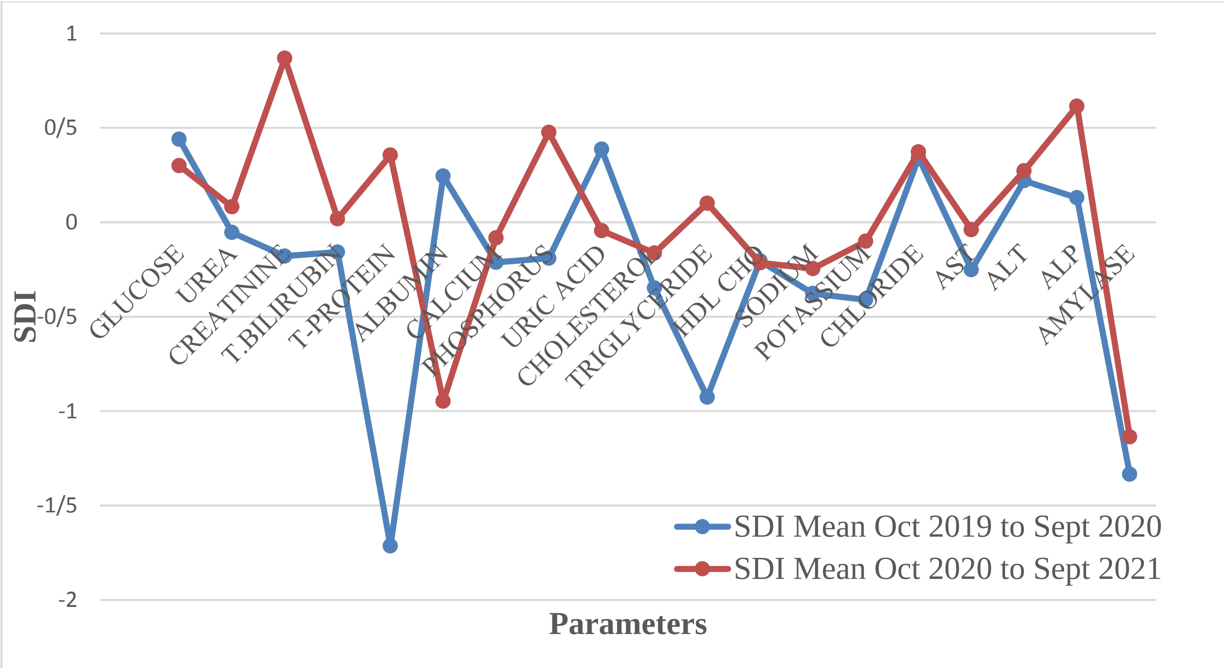

Figure 1: Represents performance of individual parameters as per mean SDI for October 2019 to September 2020 and October 2020 to September 2021 EQAS cycles