ORIGINAL RESEARCH ARTICLE

Auditing Internal Quality Control Practices in a Large Size Clinical Biochemistry Laboratory

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Abstract

Background: Auditing quality control practices is crucial for ensuring adherence to and compliance with the standard operating procedures of quality assurance. This study examines the internal quality control (IQC) practices in clinical biochemistry laboratories, focusing on their effectiveness in ensuring accurate and reliable test results.

Materials and methods: A comprehensive audit was conducted every month, and records were reviewed periodically in a high-volume clinical biochemistry lab, assessing compliance with established IQC protocols and identifying areas for improvement. Chi-square test was used to assess any significant deviations in the practices from the established protocols.

Results: Overall compliance with IQC practices was 98.8%. The compliance rates of 100% were observed for LJ Chart, Monthly CV%, measurement uncertainty, mean SD calculation, IQC lot verification, accuracy testing records, and kit verification records. Lower compliance rates were noted for patient moving average records at 95.8%. Out-of-control events occurred in 0.12% of the IQC tests. The overall average audit score for six months stands at 94.3%.

Conclusion: The findings reveal very minimal variations in IQC implementation as compared to standard operating procedures and provide recommendations for enhancing quality control processes.

Keywords: Audit, Clinical biochemistry, Competency assessment, Immunoassay, Internal quality control, Risk, Therapeutic drug.

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Introduction

Background

Clinical biochemistry laboratories play a crucial role in healthcare by providing essential diagnostic information. Ensuring the accuracy and reliability of laboratory results is paramount, as these results guide clinical decisions. Internal quality control (IQC) practices are vital components of the laboratory quality management system, designed to monitor and control the analytical processes, detect errors, and ensure test results' consistency and reliability.

Auditing quality control practices are crucial for ensuring the adherence and compliance to the standard operating procedure of quality assurance. Such practices involve procedures and standards that ensure that the quality of audit processes is high and maintain stakeholder trust, regulatory compliance, and audit quality standards. Auditing in quality control practices ensure that practices are performed according to professional standards; therefore, they improve the quality of the audit. Audit of quality control practices help to identify and reduce risk involved in quality control practices and which would get transfer to patients if not mitigated on time.

Importance of IQC

Internal quality control involves regular testing of control materials alongside patient samples, allowing laboratories to detect analytical errors and take corrective actions before reporting results. Proper implementation of IQC practices is essential to maintain high standards of laboratory performance and patient safety.[1]

Previous Research

Previous studies have highlighted the importance of robust IQC systems in clinical laboratories.[2,3] However, there is a need for continuous evaluation and auditing of these practices to adapt to evolving standards and technologies. This study aims to fill this gap by conducting a detailed audit of IQC practices in a clinical biochemistry laboratory.

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Aims and Objectives

Aim

To audit and evaluate the internal quality control practices in a clinical biochemistry laboratory to ensure compliance with established standards and identify areas for improvement.

Objectives

- Assess the compliance of the laboratory's IQC practices with international and national guidelines.
- Review of IQC records in conformance with the requirements.
- Identify gaps and inconsistencies in the implementation of IQC practices.
- Provide recommendations for enhancing IQC processes based on audit findings.

Table 1: Audit checklist and plan

S. No.	*Check point*	*Policy/Process/Procedure/Document/Records*	*Frequency*
1.	Monthly audit	Policy/Process/Procedure/Document/Records	Daily/Monthly
2.	Previous audit follow-up	Policy/Process/Procedure/Document/Records	Monthly
3.	Analytical systems in use	Document	Monthly
4.	Quality control material	Policy	Monthly
5.	Quality control material storage	Procedure and records	Daily
6.	Procedure for internal quality control	Procedure	Monthly
7.	IQC plan	Document	Monthly
8.	IQC testing	Policy and procedure	Daily
9.	Conformance with IQC plan	Procedure and records	Monthly
10.	Lab mean and SD	Procedure and records	Monthly
11.	Review of IQC results	Procedure and records	Daily
12.	Control charting and data analysis	Procedure and records	Daily/Monthly
13.	Troubleshooting of outliers	Procedure and records	Daily
14.	Risk mitigation for outliers	Procedure and records	Daily
15.	Review of IQC data	Procedure and records	Monthly
16.	Trend analysis	Procedure and records	Monthly
17.	Review of summary	Procedure and records	Monthly
18.	Number of outliers	Procedure and records	Daily/Monthly
19.	Review of IQC records	Procedure and records	Monthly
20.	Control of records	Procedure and records	Monthly
21.	Staff training	Procedure and records	Monthly
22.	Competency assessment	Procedure and records	Monthly
23.	Review of non conformances	Procedure and records	Monthly
24.	Total IQC tests	Records	Monthly
25.	Reruns	Records	Monthly
26.	Additional quality control activities	Procedure and records	Monthly

Materials and Methods

Study Design

This study employed a cross-sectional audit design. The monthly QC audits were conducted on the first Saturday of every month over 6 months in a high-volume clinical biochemistry laboratory, apart from reviewing other records periodically as per the plan given in Table 1.

Setting

The audit was performed in a tertiary care hospital's clinical biochemistry laboratory, which processes approximately 1,500 samples per day.

Sampling

The audit included a review of IQC records for all biochemical tests performed during the study period. Daily IQC data from a total of five analyzers, including 2 pairs of similar analyzers labeled as 'A' and 'B' (AU700 'A', AU700 'B', DXI600 'A', DXI600 'B') was thoroughly analyzed.

Analytical Systems in Use

Beckman Coulter AU700 'A' and 'B', (both clinical chemistry analyzer), DXI600 'A', and 'B' (both immunoassay analyzer), Immage 800 (both nephelometer analyzer).

Number of tests parameters 102.

Data Collection

Data were collected using a standardized audit checklist based on standard operating procedures prepared as per the guidelines from ISO 15189:2022, manufacturers' recommendations, and regulatory authorities. A risk-based approach was used for additional quality control runs and other quality control activities.[4,5] The checklist included checkpoints as per Table 1.

Audit scoring was performed during as per the criteria mentioned in Table 2.

Different auditing methodologies were used, as per Table 3.

Internal quality control plan, which was followed as per standard operating procedure, is as per Table 4.

Westgard rules used to review the daily internal quality control results are given in Table 5.[6]

Additional quality control activities which are used by the laboratory as per the risk-based approach is mentioned in Table 6.

Table 2: Criteria for audit score

S. No.	*Criteria*	*Score*
1.	Non compliance	0
2.	Partial compliance	1
3.	Full compliance	2

Table 3: Method of audit

S. No.	*Criteria*
1.	Staff interviewing
2.	Review of records
3.	Observation
4.	Review of documents

Table 4: IQC plan

S. No.	Quality control	Machine	Timings
1.	Assay chemistry level - 1 and level 2	DXC AU 700 A & B	4:00 a.m.
2.	Assay chemistry level - 1 and level 2	DXC AU 700 A & B	12:00 p.m.
3.	Assay chemistry level - 1 and level 2	DXC AU 700 A & B	8:00 p.m.
7.	Urine chemistry level - 1 and level 2	DXC AU 700	8:00 a.m. 8:00 p.m.
21.	Immuno assay control - L1 and L2	DXI 600 - A & B	8:00 a.m. 4:00 p.m. 12:00 a.m.
30.	Special protein control level and level 3	Immage 800	8:00 a.m. 8:00 p.m.

Table 5: Westgard rules followed

S. No.	Westgard rule	Action	Type of error
1.	12s	Warning	Random/Systematic
2.	22s	Rejection	Systematic
3.	13s	Rejection	Random
4.	R4s	Rejection	Random
5.	10x	Rejection	Systematic

Table 6: Additional quality control activities

S. No.	Additional QC activity	Frequency
1.	Retesting of samples (selected tests as per SOP)	Every 8 hr
2.	Split sample testing (selected tests as per SOP)	Once daily
3.	Retesting of retained samples (selected tests as per SOP)	Once daily
4.	Patients moving average (selected tests as per SOP)	Daily monitoring
5.	Accuracy testing	Monthly once
6.	Kit verification	At reagent lot change

Quality control materials were selected by the laboratory using the criteria's mentioned in Table 7 and all 14 different types of quality control materials were used by the laboratory as mentioned in Table 8.

The laboratory follows standard operating procedures with respect to internal quality control practices including regulatory, accreditation and manufacturing requirements. Troubleshooting was done in cases of outliers as per standard operating procedure.

Data Analysis

The collected data were analyzed using descriptive and inferential statistics. Compliance rates were calculated, and the effectiveness of IQC practices was assessed by analyzing the frequency and resolution of out-of-control events.

Statistics

Statistical Methods

- Descriptive statistics (mean, standard deviation) were used to summarize IQC data.

Table 7: Control material selection criteria

S. No.	Factors considered
1.	Use commercially available control materials with known values
2.	3rd party quality control material
3.	Matrix as close as possible to human sera
4.	Clinically relevant challenge
5.	Reacts to the examination method in a manner as close as possible to patient samples

Table 8: Name of QC material used

S. No.	Name of QC materials
1.	Clinical chemistry
2.	Immunoassay
3.	Special immunoassay
4.	Urine chemistry
5.	Special protein
6.	Therapeutic drug monitoring
7.	Maternal first and second trimester screening
8.	Infertility
9.	AMH, Procalcitonin, Ammonia, ADA, Zinc, Copper

Table 9: Number of tests performed for individual internal quality control and additional quality control activity

S. No.	QC activity	No. of testing
1.	Total QC runs	55,080
2.	IQC outlier	66
3.	Retesting of samples	4,860
4.	Split	2,160
5.	Accuracy testing	612
6.	Kit verification	267

- Chi-square tests were employed to assess the association between compliance rates and specific variables (e.g., time of day, type of test).
- Control charts were utilized to visualize IQC performance over time.

Compliance rate = [(Total – Non-compliance)/Total] × 100

Chi-square tests: $\chi^2 = \sum(O_i - E_i)^2 / E_i$

Software

Online calculator was used for Chi-square test[7]
https://www.icalcu.com/stat/chisqtest.html

Results

The audit results were compiled and analyzed using the statistical techniques mentioned above in materials and methods.

Table 9 shows the total number of tests performed for internal quality control and additional quality control-related activity.

Compliance with IQC Guidelines

During the audit, overall average compliance with IQC practices was found to be 98.8%, as shown in Table 10. Compliance rates of 100% were observed for the LJ Chart, monthly CV%, measurement uncertainty, mean SD calculation, IQC lot verification, accuracy

Table 10: Review of records

		Compliance %						
S. No.	*Name of records*	*Nov 23*	*Dec 23*	*Jan 24*	*Feb 24*	*Mar 24*	*Apr 24*	*Average*
1.	Daily IQC record	98	97	99	100	99	98	98.5
2.	LJ chart	100	100	100	100	100	100	100
3.	IQC trouble shooting records	99	98	100	99	98	98	98.7
4.	Monthly CV%	100	100	100	100	100	100	100
5.	Measurement uncertainty	100	100	100	100	100	100	100
6.	Mean SD calculation	100	100	100	100	100	100	100
7.	IQC Lot verification	100	100	100	100	100	100	100
8.	Retesting of samples	95	94	98	99	95	97	96.3
9.	Split sample testing records	98	94	98	96	99	97	97
10.	Accuracy testing records	100	100	100	100	100	100	100
11.	Kit verification records	100	100	100	100	100	100	100
12.	Patient moving average records	97	98	94	95	97	94	95.8
	Overall compliance	98.9	98.4	99	99	99	98.7	98.8

Table 11: Shows the month wise audit score and overall audit score

			Audit score					
S. No.	*Check point*	*Score (0, 1, 2)*	*Nov 23*	*Dec 23*	*Jan 24*	*Feb 24*	*Mar 24*	*Apr 24*
1.	Monthly IQC audit	2	2	2	2	2	2	2
2.	Previous audit follow-up	2	2	2	2	2	2	2
3.	Analytical systems in use	2	2	2	2	2	2	2
4.	Quality control material	2	2	2	2	2	2	2
5.	Quality control material storage	2	2	2	2	2	2	2
6.	Procedure for internal quality control	2	2	2	2	2	2	2
7.	IQC plan	2	2	2	2	2	2	2
8.	IQC testing	2	2	2	2	2	2	2
9.	Conformance with IQC plan	2	2	2	2	2	2	2
10.	Lab mean and SD	2	2	2	2	2	2	2
11.	Review of IQC results	2	2	2	2	2	2	2
12.	Control charting and data analysis	2	2	1	2	2	2	2
13.	Troubleshooting of outliers	2	2	2	2	2	2	2
14.	Risk mitigation for outliers	2	2	1	2	1	1	2
15.	Review of IQC data	2	2	2	1	2	2	1
16.	Trend analysis	2	2	1	2	1	2	1
17.	Review of summary	2	1	2	1	2	2	1
18.	Number of outliers	2	2	2	2	2	2	2
19.	Review of IQC records	2	2	2	2	2	2	2
20.	Control of records	2	1	2	1	2	1	1
21.	Staff training	2	2	2	2	2	2	2
22.	Competency assessment	2	1	2	1	2	1	2
23.	Review of nonconformances	2	2	2	2	2	2	2
24.	Total IQC tests	2	2	2	2	2	2	2
25.	Additional quality control activities	2	2	2	2	2	2	2
	Score	50	47	47	46	48	47	46
	Score in %	100	94	94	92	96	94	96
	Overall %				94.3			

testing records, and kit verification records. Lower compliance rates were noted for patient moving average records of 95.8%.

Audit Score

Table 11 shows the month wise audit score as well as overall average audit score calculated quantitatively which stands at 94.3%.

Interpretation of the Chi-square Test

Table 12 shows details of the Chi-square test applied to compliance with various records audited and the total audit score for each month. In both the cases, the *p*-value was greater than 0.01, implying no significant difference in the standard operating

Table 12: Interpretation of Chi-square test applied to record compliance and audit score

S. No.	Statistical attributes	Record compliance	Audit score
1.	Chi-square value	0.146709390801	0.031191019228
2.	Degrees of freedom	11	5
3.	Rows × columns	12 × 2	6 × 2
4.	*p*-value	0.999999998122	0.99999096169
5.	Significance at $p > 0.01$ Y/N	Not significant	Not significant

Table 13: Classification of IQC outliers

S. No.	Causes of IQC outliers	No of outliers attributed	Type of error
1.	17	Incorrect QC material	Random error
2.	9	Insufficient thawing	Systematic error
3.	6	Improper mixing	Systematic error
4.	4	Staff under training	Systematic error
5.	3	Calibration stability	Systematic error
6.	27	Unclassified	Random error

procedure laid down by the laboratory with respect to internal quality control practices and actual implementation.

Gaps and Inconsistencies

Additional quality control activities such as retesting of samples, splitting sample testing records, and reviewing patient moving averages were not adhered on some occasions, resulting in noncompliance. For quality control material testing, thawing and mixing of material were not followed properly, resulting in outliers depicted in Table 13.

Effectiveness of IQC Procedures

Out-of-control events occurred in 0.12% of the IQC tests. Corrective actions were documented for 100% of the out-of-control events, with a resolution rate of 100%.

The root cause identification was done for all the IQC outliers and is stated in Table 13.

Discussion

The auditing of IQC practices in clinical biochemistry laboratories is critical for ensuring the reliability and accuracy of diagnostic results. Our study aimed to evaluate the current IQC practices and identify areas for improvement to enhance overall laboratory performance.

Interpretation of Findings

It is observed that IQC practices covers 24 hours period and supported by additional quality control activities which is as per the standard mentioned by Housley D et al.[8] The lab has also followed assigning mean and standard deviation set by the laboratory. The QC material used by the laboratory is third party quality control material. Westgard multi rules were followed by the laboratory for reviewing the quality control results. The policies followed by the laboratory are in line with suggested by Housley D et al.[8]

The audit revealed that the laboratory generally adhered to IQC guidelines. High compliance with the frequency of testing and documentation indicates a strong commitment to quality. However, the number of quality control materials used by the laboratory is quite high, which may require very careful follow-up and intense staff training on a regular basis. Due to the use of multiple different types quality control materials, the outliers observed in daily of quality control were related to the wrong use of quality control material. The errors of this kind were as high as 17 out of the total 66 outliers over a period of 6 months.

Even though the audit score for training activities is found to be 100%, the audit score for competency assessment is not up to the mark. This is also evidenced by root cause identification for IQC outliers which is mainly attributed to failure to demonstrate on job of competency in IQC procedures as can be seen in Table 13 (Incorrect QC material, Insufficient thawing, Improper Mixing, Staff under training).

Also, the number of quality control tests performed by laboratories is relatively high, which result in the loss of valuable resources that includes quality control materials, reagents and man – hours. The main reason behind the use of multiple quality control tests per day is to satisfy the accreditation requirements.[9]

Lower compliance rates were noted for Patient Moving Average Records of 95.8%. This is attributed to the comparatively newer practices related to additional quality control activities in the clinical biochemistry area.[10]

Recommendations

Selection and use of control materials to cover maximum test parameters, which will reduce the number of types of quality control materials used by the laboratory. This will also help with better compliance and fewer out of the control events.

Implementing a robust training program for staff and focusing on IQC procedures, remains a priority for continual improvement.

Limitations

Even though a complete objectivity and impartiality were maintained during auditing, the only limitation of this study is that data was self-reported by the laboratory, which could introduce bias.

Summary

This study audited the IQC practices in a clinical biochemistry laboratory, revealing high overall compliance but identifying specific areas for improvement. The effectiveness of IQC procedures was generally good, but issues such as appropriate resource management and reducing the number of quality control materials need to be addressed.

Conclusion

Ensuring rigorous IQC practices is essential for maintaining the accuracy and reliability of laboratory results. Continuous auditing and improvement of these practices are crucial for achieving high standards in clinical biochemistry laboratories. Implementing the recommended changes will enhance the laboratory's quality control processes, ultimately improving patient care.

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