ASIAN JOURNAL OF PHARMACEUTICAL AND CLINICAL RESEARCH

INNOVARE ACADEMIC SCIENCES
Knowledge to Innovation

Vol 17, Issue 6, 2024

Online - 2455-3891
Print - 0974-2441

Research Article

NEED OF EXTERNAL QUALITY ASSESSMENT SCHEME – AN EXPERIENCE IN CENTRAL LABORATORY AT RNTMC, UDAIPUR

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Received: 06 March 2024, Revised and Accepted: 18 April 2024

ABSTRACT

Objectives: The objectives of the study are to periodically assess the quality of the external quality assessment scheme (EQAS) with the aim of enhancing laboratory performances.

Methods: An observational study was done at our central laboratory at RNTMC, Udaipur, after approval from the institutional review board. Our laboratory receives quarterly blood samples and already prepared slides from AIIMS, Delhi, for complete blood count (CBC). In addition, lyophilized blood samples for fibrinogen, prothrombin time/international normalized ratio (PT/INR), and activated partial thromboplastin time (APTT) analysis are received quarterly from CMC, Vellore, through courier package. As for cytopathology, the third package includes already prepared 10 slides of 2 cycles for cytopathology analysis along with a brief clinical history.

Results: CBC, peripheral blood film examination findings, and reticulocyte count results were consistently acceptable, except in August 2021, December 2022, and March 2023 when some parameters of CBC were deemed unacceptable. Results for PT/INR, APTT, and fibrinogen were within consensus at all-time except in March 2022, when they were out within consensus and deemed unacceptable. Similarly, result of EQAS evaluation for cytopathology were in concordance with the result of provider, except for a few occasions where deviation were seen for some diagnosis due to interpretation error.

Conclusion: Engaging in EQAS has facilitated the enhancement of test result accuracy, thereby improving the overall quality of laboratory practices and minimizing erroneous outcomes.

Keywords: Quality control, External quality assessment scheme, Accuracy.

 DOI: http://dx.doi.org/10.22159/ajpcr.2024v17i6.50813. Journal homepage: https://innovareacademics.in/journals/index.php/ajpcr

INTRODUCTION

External quality assessment scheme (EQAS), recognized globally, is widely adopted services in laboratories. It ensures periodic evaluation of laboratory performance, instilling confidence in patient test results[1]. External agencies periodically assess each laboratory's performance using samples of known but undisclosed content distributed to participating laboratories [2]. Subsequently, the results are transmitted to the EQAS provider for analysis, and comparisons are made with outcomes from other peer groups employing similar methodologies, instruments, and reagents. The participating laboratories receive performance-based results and are urged to take corrective and preventive actions in the event of unsatisfactory outcomes. This aims to enhance overall performance and prevent potential errors in laboratories. By quality control, we are able to find percent error (>95%) detection and minimize false rejection (<5%) [3].

Despite implementing precautions for maximum accuracy and precision in laboratories, errors may still occur, and EQAS is utilized to detect and address them. Both external quality control and internal quality control are done to attain the best quality services. EQAS is regarded as a crucial program for comparing processes, methods, and result variations among participating laboratories, aiming to identify the presence of any random errors [4].

In 2017, we registered our laboratory in AIIMS, Delhi, for complete blood count (CBC), peripheral blood film (PBF), and reticulocyte count evaluation, and in CMC, Vellore for prothrombin time and international normalized ratio (PT-INR), activated partial thromboplastin time (APTT), and fibrinogen assessment. In addition, in 2021, we also registered our laboratory for cytopathology analysis at Tata Memorial Hospital, Mumbai. Subsequently, we have been regularly receiving quarterly samples for evaluation.

METHODS

An observational study was done at our central laboratory at RNTMC, Udaipur, after approval from the institutional review board.

Our laboratory receives quarterly blood samples and already prepared slides from AIIMS, Delhi, for CBC. In addition, ethylenediaminetetraacetic, lyophilized blood samples for fibrinogen, PT-INR, and APTT analysis are received quarterly from CMC, Vellore, through courier package.

A courier package includes one ethylenediaminetetraacetic acid blood sample for CBC and two already prepared slides, one for PBF examination and another for reticulocyte count.

The slides underwent microscopic examination for detailed PBF and reticulocyte count, accompanied by a brief clinical history.

Another package contained a lyophilized blood sample without a clinical history.

As for cytopathology, the third package includes already prepared 10 slides of 2 cycles for cytopathology analysis along with a brief clinical history. On the same day, the recommended tests were conducted according to protocol to prevent errors by our proficient laboratory

technician staff, and the results were sent to their respective websites within 7 days.

In our laboratory, CBC is performed on Sysmex 800i and ADONIS 19 PLU, for PT/INR, APTT and fibrinogen machine used is STA compact max.

RESULTS

The following tests were performed in our central laboratory: CBC parameters, PBF slide, reticulocyte count, PT/INR, APTT, fibrinogen values, and cytopathology evaluation.

Subsequently, the results were sent for evaluation to their respective website through login ID.

Due to the COVID-19 outbreak, EQAS was temporarily suspended for a period.

The results received are as follows:

Hemostasis module report - ISHBT - CMC - EQAS

Month	PT/INR	APTT	Fibrinogen
July 2021	Within consensus	Within consensus	Acceptable
March 2022	Out within consensus	Out within consensus	Not acceptable
July 2022	Within consensus	Within consensus	Acceptable
November 2022	Within consensus	Within consensus	Acceptable
April 2023	Within consensus	Within consensus	Acceptable
July 2023	Within consensus	Within consensus	Acceptable
November 2023	Within consensus	Within consensus	Acceptable

EQAS: External quality assessment scheme, PT/INR: Prothrombin time and international normalized ratio, APTT: Activated partial thromboplastin time

Proficiency testing report- ISHTM- AIIMS - QAP

Month	CBC	PBF	Retic count	Recommendations
June 2017	Result acceptable	Result acceptable	Result acceptable	
March 2018	Result acceptable	Result acceptable	Result acceptable	
June 2018	Result acceptable	Result acceptable	Result acceptable	
June 2019	Result acceptable	Result acceptable	Result acceptable	
September 2019	Result acceptable	Result acceptable	Result acceptable	
December 2019	Result acceptable	Result acceptable	Result acceptable	
September 2020	Result acceptable	Result acceptable	Result acceptable	
February 2021	Result acceptable	Result acceptable	Result acceptable	
August 2021	Result unacceptable	Result acceptable	Result acceptable	Please check calibration/human error
November 2021	Result acceptable	Result acceptable	Result acceptable	
March 2022	Result acceptable	Result acceptable	Result acceptable	
May 2022	Result acceptable	Result acceptable	Result acceptable	
August 2022	Result acceptable	Result acceptable	Result acceptable	
December 2022	Result unacceptable for HB, MCV, MCH	Result acceptable	Result acceptable	Please check calibration/human error
March 2023	Result unacceptable For hemoglobin	Result acceptable	Result acceptable	Please check calibration/human error
June 2023	Result acceptable	Result acceptable	Result acceptable	
September 2023	Result unacceptable For HB and MCH	Result acceptable	Result acceptable	Please check calibration/human error

CBC: Complete blood count, PBF: Peripheral blood film, MCV: Mean corpuscular volume, MCH: Mean corpuscular hemoglobin, HB: Hemoglobin

Diagnostic cytopathology feedback report - Tata Memorial Hospital

Year	Cytopathology slide	Participant's diagnosis	Concordance/ deviation	Remarks
2021 Cycle no 1	Vaginal cervix	Inflammatory smear. Bethesda grade. NILM	Concordance	
	Pleural effusion	Malignant Effusion- Adenocarcinoma	Concordance	
	Bronchial lavage	Malignant effusion- adenocarcinoma	Major deviation	interpretation error
	Pleural Fluid	Metastatic carcinoma	Major deviation	Interpretation error
	Rt. Cervical Ln. Swelling	Metastatic squamous cell carcinoma	Concordance	
2021 Cycle no 2	Vaginal cervix	Inflammatory smear. Trichomonas seen. Bethesda grade- NILM	Concordance	Trichomonas not seen
	Ascitic fluid	Reactive mesothelial cells. Atypia- favor reactive	Concordance	
	Bronchial lavage	Malignant effusion- adenocarcinoma	Concordance	
	Urine	Atypia- favor reactive	Concordance	
	Liver FNAC	Hepatocellular carcinoma	Minor deviation	Tumor typing error
2022 Cycle no 1	Vaginal cervix	Inflammatory smear. Bethesda grade- NILM		
	Ascitic fluid	Negative for malignant cells	Major deviation	Interpretation error
	Bronchial Lavage	Negative for malignant cells	Concordance	
	Lt. Buccal Mucosa	Benign lesion. Negative for malignancy	Concordance	
	Rt. Parotid	Pleomorphic salivary adenoma	Concordance	
2022 Cycle no 2	Vaginal cervix	Unsatisfactory for evaluation	Minor deviation	Smear satisfactory for evaluation
	Pleural fluid	Positive for malignancy. Metastasis of? Lymphoma? Thymoma	Concordance	Kindly Do not Use Double Diagnosis
	Urine	Negative for malignant cells	Concordance	
	FNAC thyroid	Colloid nodule- Bethesda grade II negative for malignancy	Concordance	
	Lymph node	Metastatic squamous carcinoma	Major deviation	Interpretation error

DISCUSSION

In the present day, EQAS is recognized as a vital tool for assessing the performance of each participating laboratory, significantly contributing to the enhancement of overall test result quality, and benefiting the general population [5]. The tests conducted on provided samples help gauge the accuracy of applied procedures, machinery, and personnel in our labs [6].

The results obtained are as follows:

CBC, PBF examination findings, and reticulocyte count results were consistently acceptable, except in August 2021, December 2022, and March 2023 when some parameters of CBC were deemed unacceptable. It was advised to investigate potential calibration or human errors. Following another assessment, which was inspected for potential calibration errors, the results were subsequently approved.

Similarly, results for PT/INR, APTT, and fibrinogen were within consensus at all-time except in March 2022 when they were out within consensus and deemed unacceptable. The discrepancy was attributed to an error in result profiling, which was promptly corrected. The corrected results were then emailed, leading to their subsequent acceptance.

Similarly, result of EQAS evaluation for cytopathology were in concordance with the result of provider, except for a few occasions where deviation were seen for some diagnosis due to interpretation error.

CONCLUSION

Engaging in EQAS has facilitated the enhancement of test result accuracy, thereby improving the overall quality of laboratory practices and minimizing erroneous outcomes. Over the past 4 years, there has been significant improvement in our laboratory performance. We believe that participating in such a scheme can contribute to the global efficiency of results and gives us confidence in patient's results.

AUTHORS OF INTEREST

All authors have contributed equally to the preparation of this manuscript.

CONFLICT OF INTEREST

None.

AUTHORS FUNDING

None.

REFERENCES

1. Tholen DW, Berte LM, Boone DJ, Cooper WG, Gun-Munro J, Noble MA. Clinical and Laboratory Standards Institute using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline. Vol. 3. Wayne, PA, USA: Clinical Laboratory and Standards Institute; 2022 Oct. p. 221-31.
2. Barbara S, David P, Dacie V. Dacie and Lewis Practical Haematology. Quality Aassurance. Netherlands: Elsevier Health Sciences; 2006. p. 540-1.
3. Miller WG. The role of proficiency testing in achieving standardization and harmonization between laboratories. Clin Biochem. 2009 Mar 1;42(4-5):232-5. doi: 10.1016/j.clinbiochem.2008.09.004, PMID 19863911
4. Desai KN, Vithalani PH, Agnihotri AS, Patel K. Experience of the external quality assessment scheme in haematology at CU shah medical college, Surendranagar. Ann Pathol Lab Med. 2015 Jul-Sep;2(3):98-100.
5. Sciacovelli L, Zardo L, Secchiero S, Plebani M. Quality specifications in EQA schemes: From theory to practice. Clin Chim Acta. 2004 Aug 2;346(1):87-97. doi: 10.1016/j.cccn.2004.02.037, PMID 15234640
6. Thienpont LM, Stöckl D, Friedecký B, Kratochviíla J, Budina M. Trueness verification in European external quality assessment schemes: Time to care about the quality of the samples. Scand J Clin Lab Invest. 2003 Jan 1;63(3):195-201. doi: 10.1080/00365510310000349, PMID 12817905