ISSN No:-2456-2165

Laboratory Quality Indicators: An Essential Tool of the Quality Management System

Dr.Lakshmi jyothi.T
Additional professor
Department of Microbiology
All India Institute of medical sciences, Bibinagar
Corresponding author

Kamalakar Sarva
Quality manager
Department of Microbiology
All India Institute of medical sciences, Bibinagar

Karthik Kamani
Quality Head
St Theresa Hospital, Hyderabad

Abstract:-

- ***Objective:***

Laboratory quality is defined as the accuracy, reliable and timely issuing of reported results. To measure the quality of the laboratory there are various indicators available, those are called Quality indicators.

- ***Material & method:***

The retrospective study was taken place at St. Teresa hospital, Hyderabad. The following QIs are identified and analyzed over a period of 2 years (January-2019 to December-2020). The following indicators are evaluated Pre analytical: Patient/Specimen identification, Sample rejections, Adherence of Lab safety policy, Analytical: Re do's/Repeat testing, Post analytical: Critical alert information, Turnaround time.

- ***Results:***

Sample rejection was high in 2020 (0.20%), the most prevalent rejected sample was clotted sample for both years, in 2019 n=134(49.6%), in 2020 n=140 (44.8%) followed by hemolyzed samples (36.6%, 31.7%), Insufficient samples (8.8%, 15.5%). 100% of the laboratory staff followed laboratory safety measures. For the analytical process, we evaluated retesting of the primary sample, in 2019 the percentage of retesting was 0.24%, and in 2020 was 0.39%. In the post-analytical process, 0.34% and 0.54% of critical values were not notified in 2019 and 2020 respectively. 1% and 0.63% of laboratory reports were issued after laboratory-defined TAT in 2019 and 2020 respectively.

- ***Conclusion:***

Current study indicates the status of the laboratory quality compared to national and international standards. Based on the evaluated quality indicators the laboratory identifies the lacunae in quality management system and gives the best services to its client or patients

Keywords *- Pre-Analytical Process, Analytical Process, Post-Analytical Process, Quality Indicators.*

I. INTRODUCTION

The outcome of the laboratory diagnostics was to provide a quality report to its patients or clients. Laboratory quality is defined as accuracy, reliable and timely issuing of reported results (1). The testing processes are complex, involve many procedures, and it is difficult to always maintain the desired quality. In this context, laboratory quality needs to be measured and monitored regularly for desirable out come. To measure the quality of the laboratory there are various indicators available, those are called Quality indicators (QI).

Quality indicators (QIs)are measurable, objective, quantitative measures of key system elements performance. They indicate the extent to which a certain system meets the needs and expectations of the customers (2).QIs should cover all three processes of the laboratory; those are pre-analytical, analytical, and post-analytical. QIs which are applied in the pre-analytical process are sample registration errors, patient identification and sample rejections, needle stick injuries etc. Analytical QIs area failure in the internal quality controls and external quality assurance system results (EQAS), Blood culture contamination rate, frequency of calibration failure and equipment breakdown etc., and post-analytical QIs are Turnaround time (TAT) and short turnaround time (STAT), Reporting errors, and critical alert information etc. (3).

Depending on the size of the laboratory, workload, test volume, and mainly laboratory quality objectives the laboratory can decide the number of QIs they measure, however, all three processes should be covered. In the current

ISSN No:-2456-2165

study, we have chosen a few of the QIs for monitoring the quality in our laboratory.

II. MATERIALS AND METHODS

The retrospective study was taken place at 330 bedded super specialist Hospital with NABH & NABL accreditation in Hyderabad. The following QIs are identified and analyzed over a period of 2 years (January-2019 to December-2020)

Table 1: List of quality indicators evaluated.

Pre-analytical	Analytical	Post-analytical
Wrong billings	Re-do's/Repeat testing	Critical alert information
Sample rejections		Turnaround time (TAT)
Lab safety		

❖ *Analysis of QIs:*

➢ *Pre-analytical:*

- *Patient/Specimen identification:*

Number of wrong bills/Total Number of Registrations x 100

- *Sample rejections*

Number of samples rejected/Total number of samples received x 100

- *Adherence to Lab safety policy*

Number of staff adheres to lab safety policy/ Total number of staff x 100

➢ *Analytical*

- *Re-do's/Repeat testing*

Number of re-analyses of the samples/Total number of samples tested x 100

➢ *Post analytical.*

- *Critical alert information*

Number of critical results informed stipulated time (<10min)/number of critical alert values x 100

- *Turnaround time*

The number of samples deviated from lab Turnaround time/ number of investigations performed x 100

For all QIs, benchmarks or thresholds were set up that represented action limits. All the data was collected by the laboratory quality manager and was analyzed every month. If any QI crosses the benchmark, corrective and preventive action (CAPA) was taken accordingly.

III. RESULTS

The quality indicators are analysed into 3 phases: pre-analytical, analytical, and post-analytical. In pre-analytical we monitor the number of wrong bills done in the billing section and a few samples which were rejected. The various pre-analytical quality indicators and their evaluation are represented in Table 1. Sample rejections were high in 2020 (0.20%), the most prevalent rejected sample was clotted samples for both years, in 2019 n=134(49.6%), in 2020 n=140 (44.8%) followed by hemolyzed samples (36.6%, 31.7%), Insufficient samples (8.8%, 15.5%) (Fig1). 100% of the laboratory staff followed laboratory safety measures (Table 2).

In the Analytical process, we evaluated retesting of primary samples, in 2019 the percentage of retesting was 0.24% and it increased in 2020 (0.39%) (Table 3).

In the post-analytical process, we considered the number of critical values unreported by the laboratory and Tern around time (TAT).0.34% and 0.54% of critical values were un-notified in 2019 and 2020 respectively. 1% and 0.63% of laboratory reports were issued after laboratory-defined TAT in 2019 and 2020 respectively (Table 4 & 5)

Table 2: Pre-analytical quality indicators (The number of samples rejected)

Wrong billing		
	2019	**2020**
Number of bills	60878	50826
Number of wrong bills	114	147
% of wrong bills	**0.19%**	**0.29%**
No. Samples Rejection		
	2019	**2020**
Number of samples received	236340	155940
Number of samples rejected	270	312
Percentage of (%) of sample rejections	0.12%	0.20%

ISSN No:-2456-2165

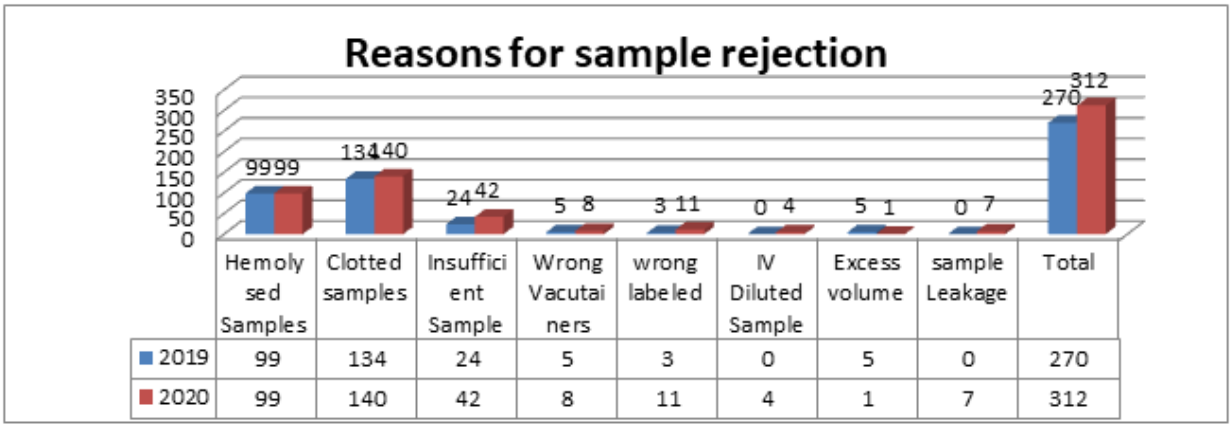

Fig 1: Reasons for sample rejection

Table 3: Analytical indicators (Number of Reanalysis of the samples)

	2019	2020
Number of re-dos	568	610
Number of investigations performed	236340	155940
Percentage of (%) of re-dos	**0.24%**	**0.39%**

Table 4: Post-Analytical indicators (Number of critical values reported)

	2019	2020
Number of critical values reported and notified	4081	2005
Number of critical values un-notified	14	11
Percentage %	0.34	0.54

Table 5: Post-Analytical indicators (Turnaround time(TAT))

	2019	2020
Number of samples with lab-defined TAT	236340	155940
Number of samples out of the TAT	2338	983
Percentage (%)	1	0.63

IV. DISCUSSION

From the writing of the request form to delivering the report to the person requested there are multiple complex steps involved in the process. The laboratory required addressing all the steps and making the necessary corrective actions to ensure the quality of the laboratory is maintained. Quality indicators (QI) were important tools for monitoring the entire process. In the current study,0.48% of the samples were rejected in two years. There is no acceptable threshold for the number of samples the laboratory can reject, however as per the literature 0.3 to 0.8% (3,4) of the samples were rejected in various institutions by different authors. The reason for the sample rejection was clotting in the samples primarily due to uneven mixing of the samples, followed by hemolysis. To address these issues the laboratory initiates training programs frequently and developed a standard operating procedure and circulated in all the wards in the hospital. Reanalysis or repeat testing, the rationale of the retesting is that the first test results may represent a clinically significant analytical error, which is revealed by re-testing (5). In the current study, 0.63% of the samples were retested. The reason for the repeat testing was obtained critical values in the first testing. All the critical values need not be repeated, as per the CAP/CLSI only samples which exceeded the 'allowable error limits' for that parameter required repeat testing (6,7). The laboratory implemented this guideline suggested by CLSI and reduced the number of repeat tests.

Critical or panic values have been described as values where abnormally high or low levels can cause irreversible physical harm unless treated immediately (8,9). In the current study around 0.9% of the critical values were not notified and the critical value reporting frequency of 8.8 per 1000 samples. The reviews of previous literature showed the prevalence of critical value reporting ranging from 1 in 2000 to 1 in 100

samples (10,11) our study was correlated with other studies.1.63% of the reports were issued out of the TAT for two years of the study, due to the failure of the laboratory information system, sometimes additional tests required on primary samples, and consultant unavailability. There are no guidelines for defining ideal TAT targets. However, *Ricosand et al.* have suggested that 11% is an acceptable fraction of laboratory reports that may exceed the regulatory TAT (12).All laboratory personnel follow the safety measures in our laboratory.

V. CONCLUSION

Quality indicators are important for the continual improvement of laboratory quality and for accreditations. The current study indicates the status of the laboratory quality compared to national and international standards. Based on the evaluated quality indicators the laboratory identifies the lacunae in the quality management system and gives the best services to its client or patients

REFERENCES

[1]. ISO 15189 is the international standard that specifies the requirements for quality and competence of medical laboratories. As with ISO/IEC 17025, it covers both technical and management criteria which must be considered.
[2]. Simundic, Ana-Maria & Topic, Elizabeta. (2008). Quality indicators. Biochemia Medica. 18. 311-319. 10.11613/BM.2008.027.
[3]. Shahangian, Shahram, and Susan R Snyder. "Laboratory medicine quality indicators: a review of the literature." *American journal of clinical pathology* vol. 131,3 (2009): 418-31. doi:10.1309/AJCPJF8JI4ZLDQUE
[4]. Ranjna Chawla, Binita Goswami, Bhawna Singh, Aparna Chawla, Vinod Kumar Gupta, Venkatesan Mallika, Evaluating Laboratory Performance With Quality Indicators, *Laboratory Medicine*, Volume 41, Issue 5, May 2010, Pages 297–300, https://doi.org/10.1309/LMS2CBXBA6Y0OWMG
[5]. Dale, Jane C, and David A Novis. "Outpatient phlebotomy success and reasons for specimen rejection." *Archives of pathology & laboratory medicine* vol. 126,4 (2002): 416-9. doi:10.5858/2002-126-0416-OPSARF
[6]. Jones, B A et al. "Complete blood count specimen acceptability. A College of American Pathologists Q-Probes study of 703 laboratories." *Archives of pathology & laboratory medicine* vol. 119,3 (1995): 203-8.
[7]. Rabinovitch, Albert. "Repeat testing of critical laboratory test results." *Archives of pathology & laboratory medicine* vol. 135,11 (2011): 1383; author reply 1383. doi:10.5858/arpa.2011-0207-LE
[8]. Lundberg, George D. "It is time to extend the laboratory critical (panic) value system to include vital values." *Med Gen Med: Med scape general medicine* vol. 9,1 20. 29 Jan. 2007
[9]. Wagar, Elizabeth A et al. "Assessment monitoring of laboratory critical values: a College of American Pathologists Q-Tracks study of 180 institutions." *Archives of pathology & laboratory medicine* vol. 131,1 (2007): 44-9. doi:10.5858/2007-131-44-AMOLCV
[10]. Howanitz, Peter J et al. "Laboratory critical values policies and procedures: a college of American Pathologists Q-Probes Study in 623 institutions." *Archives of pathology & laboratory medicine* vol. 126,6 (2002): 663-9. doi:10.5858/2002-126-0663-LCVPAP
[11]. Kuperman, G J et al. "How promptly are in patients treated for critical laboratory results?." *Journal of the American Medical Informatics Association: JAMIA* vol. 5,1 (1998): 112-9. doi:10.1136/jamia.1998.0050112
[12]. Ricós, Carmen et al. "Quality indicators and specifications for the extra-analytical phases in clinical laboratory management." *Clinical chemistry and laboratory medicine* vol. 42,6 (2004): 578-82. doi:10.1515/CCLM.2004.100