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Monitoring quality indicators in a medium-sized laboratory of South Bengal: moving towards accreditation
Running title: Evaluation of quality indicators

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ABSTRACT:
Introduction: Documenting and monitoring quality indicators are important to improve the quality of a laboratory. The objective of this study was to record the quality indicators of a clinical laboratory and prepare it for accreditation by National Accreditation Board of Laboratories (NABL) as per ISO 15189.
Materials and methods: A total of 9 quality indicators in different phases of sample analyses viz. pre-analytical, analytical and post-analytical were monitored for 21459 samples over a period of one year.
Results: Incomplete requisition forms were the most common outlier (2.5%) in the pre-analytical phase followed by samples not maintaining cold chain during transport (2.1%). Internal non-conformance with quality control was seen in 0.6% of samples in analytical phase. In post analytical phase, turnaround time (TAT) could not be maintained for 8% of the samples.
Conclusion: Monitoring and recording quality indicators give us an idea about the performance of a medical laboratory. Therefore, working with a goal to reduce quality indicator outliers will improve the quality of a laboratory and ultimately enhance patient care. Moreover, it can help comparing different laboratories in a particular area based on performance.

KEY WORDS: accreditation, evaluation, quality indicators

I. INTRODUCTION:

In the delivery of health care, laboratory testing and services play a very significant role as most of the treatment strategies are planned based on the test results.[1] However, gradually reducing laboratory efficiency is a growing cause of concern among common people. In this era of value-based healthcare (VBHC), where improving the ratio of patient outcomes to expenses is important, laboratories need to self-monitor themselves based on certain standard parameters in order to reduce errors.[2] Reduced mistake rates and improved laboratory structure and logistics can both help improve laboratory efficiency.[2] Quality indicators (QI) or performance indicators (PIs) play a significant part in this improvement process because they may be used to assess laboratory performance.[3] Process performance can be quantified using a PI, which is an objective and improvable measure. Using quality indicators or performance measures to assess the quality of laboratory services necessitates a systematic, transparent, and consistent strategy to data collection and analysis.[3] A comprehensive strategy, as per ISO-15189 (2012), would include all stages of the complete testing process in the laboratory, with an emphasis on the areas most likely to have significant implications for patient care and health outcomes.[4] Data on quality indicators should be collected over time to identify, correct, and continuously monitor problems, as well as to improve performance and patient safety by identifying and analyzing the root cause behind these problems/errors.[4-8]

This study was done in one of the stand-alone medium-sized laboratories of South Bengal with the objective of monitoring and recording the performance indicators in order to improve the performance of the laboratory. The laboratory had applied for accreditation from National Accreditation Board of Laboratories (NABL) and the need for accreditation was felt primarily because of two reasons:

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1. To build confidence and trust amongst the public and the clinicians regarding the quality of the reports generated.
2. There was no other accredited stand-alone laboratory in the region.

II. MATERIALS AND METHODS:

The study was done to evaluate the laboratory performance by monitoring the following nine (9) performance indicators (3 each in pre-analytical, analytical and post-analytical phase) over a period of one year from January 2021 to December 2021:

A) Pre-analytical
1. Incomplete test requisition forms
2. Sample rejection
3. Sample transportation time and sample temperature

B) Analytical
1. Machine downtime
2. Internal test non-conformance with quality control
3. EQAS and ILC

C) Post-analytical
1. Reporting/Typing error
2. Turnaround time
3. Complaints from patients/physicians

A total of 21459 samples received during the study period were evaluated retrospectively for the above quality indicators. The different quality indicators monitored for these samples are tabulated below (table 1) with their defined targets.

Table 1 showing the different Quality Indicators with their targets

Area	Quality Objectives	Indicators Name	Target
Pre-analytical	To maintain strict internal quality control and improve quality oftesting.	Incomplete test requisition forms	0 (Zero)
		Sample Rejection in Laboratory	< 20 in a Month
	To preserve sampleintegrity	Sample Transportation Time & Temperature	Time < 2 hours Temp: 2 – 8 °C
Analytical	To maintain strict internal quality control and improve quality oftesting.	Machine down time	< 15 hours in aMonth of each machine
		Internal non-conformance with QC	< 3 in a Month
	Participation in EQA/PT to evaluatetest competency.	EQAS & ILC	EQAS: SDI Score < ± 2SD & ILC: Concordance between the results
Post-analytical	-	Reporting/Typing Error	< 5 in a Month
		Turn Around Time	< 6 Hours
		Complaint ● Testing ● General	< 2 in a Month < 3 in a Month

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III. RESULTS:

A total of 21459 samples were received during the study period between January 2021 to December 2021. The results of these nine QI were calculated monthly for this period and arranged in an organized manner as shown in Table 2 below.

Table 2: Showing number of monthly outliers for each quality indicator in different phases

	Preanalytical				**Analytical**			**Post analytical**			
2021	**Incomplete test requisition forms**	**Sample Rejection in Laboratory**	**Sample Transportation Time outliers**	**Sample transportation temperature outliers**	**Machine down time**	**Non Conformance with IQC**	**Non conformance with ILC and EQAS**	**Reporting/Typing Error**	**TAT**	**Complaint (Testing)**	**Complaint (General)**
Jan	50	14	29	38	0	9	0	8	144	4	24
Feb	46	16	32	45	0	12	0	9	142	5	25
Mar	36	14	25	32	0	11	0	12	138	6	22
Apr	60	17	29	36	1	8	0	9	152	4	26
May	62	20	22	32	0	15	0	10	160	4	24
June	41	12	28	34	0	12	0	12	210	3	23
July	33	11	30	38	1	13	0	13	142	5	24
Aug	36	16	24	40	1	12	0	10	143	3	22
Sep	52	18	36	48	0	16	0	11	200	3	23
Oct	60	19	27	47	0	7	0	12	110	3	22
Nov	39	8	32	36	0	12	0	9	90	4	24
Dec	21	7	26	26	1	5	0	5	86	4	27
Total	536	172	340	452	4	132	0	120	1717	48	286

Fig 1: Showing total percentage of outliers in different phases during the study peiod

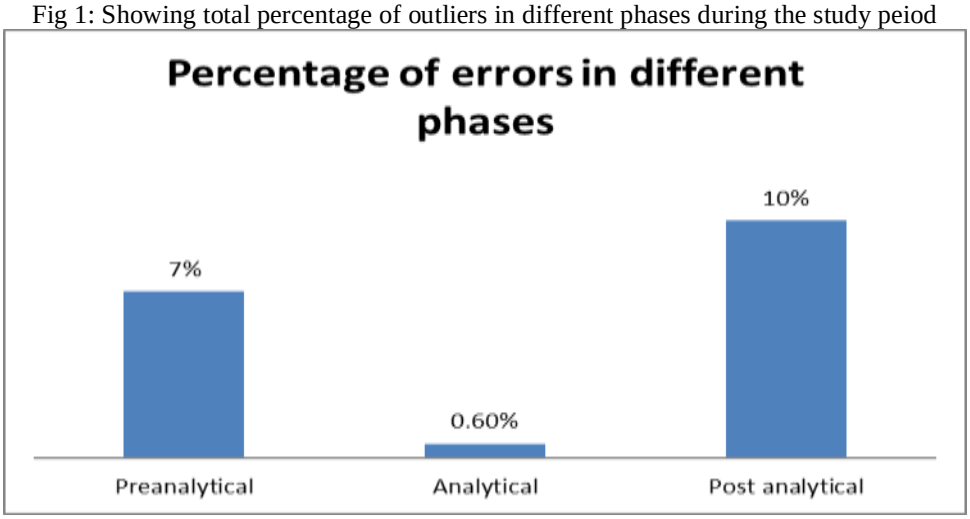

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Table 3: Showing total number of outliers during the study period for each quality indicator in different phases

Area	Quality Objectives	Indicators Name	No of Outliers
Pre-analytical	To maintain strict internal quality control and improve quality oftesting.	Incomplete test requisition forms	536 (2.5%)
		Sample Rejection in Laboratory	172 (0.80%)
	To preserve sampleintegrity	Sample Transportation Time& Temperature	Time < 2 hours: 340 (1.58%) Temp: 2 – 8 °C: 452 (2.1%)
Analytical	To maintain strict internal quality control and improve quality oftesting.	Machine down time	Two machines were down twice for more than 24 hours
		Internal test non-conformance with QC	132 (0.62)
	Participation in EQA/PT to evaluatetest competency.	EQAS & ILC	EQAS: SDI Score < ± 2SD & ILC: No outliers
Post-analytical	-	Reporting/Typing Error	120 (0.56%)
		Turn Around Time	1717 (8%)
		Complaint • Testing • General	48 (0.22%) 286 (1.3%)

IV. DISCUSSION:

It was noted that close monitoring of these performance indicators led to improvement in all steps of the whole testing process, with the preanalytical phase showing the most significant improvement.[7] Although it is a common tendency to concentrate more on the analytical processes, it has been observed that preanalytical errors account for almost 70% of the laboratory mistakes.[7] Most of these errors in laboratory diagnosis are due to human error and may develop because of issues with patient preparation, sample collection, transportation, and processing of samples for storage and analysis.[8,9] In our research, an incompletely filled requisition form was found to be the most encountered error, accounting for 2.5% of all the cases. A root cause analysis revealed that this was occurring mainly because the phlebotomists were overworked and therefore most of the time missed entering the relevant details in the forms. Also, they were not aware of the significance of filling up the required details in the test requisition forms as per ISO-15189 guidelines.[4] To resolve the problem, one trainee phlebotomist

was appointed to help them in writing the forms and also all the phlebotomists responsible for filling up the requisition forms were given extensive training on the importance of doing it completely and appropriately as per ISO-15189 guidelines.[4]

In the index study, inadequate sample was the most common cause of sample rejection (0.8 %); hemolysis (0.5 percent) being the second. Ranjana Chawla et al reported a rate of 0.7 percent, making hemolysis the most common reason for sample rejection.[10] Sangeeta Kulkarni et al and Fabio et al both reported a 0.07 percent rate, which is significantly lower.[11,12] A hemolyzed sample interferes with the reporting of electrolytes, enzymes, and prothrombin levels, among other things.[13] Hemolysis is caused mostly by vigorously shaking the tubes, aggressively ejecting blood through a small-bore needle, and centrifuging the material before complete coagulation is achieved.[3] Therefore, a proper sensitization and training of the phlebotomists and the technical staff would significantly reduce such errors in the laboratory.

The sample transportation time and temperature had outliers at a rate of 1.58% and 2.1% respectively. Root cause analyses revealed that these samples were mostly collected from collection centres which were more than 50 kms away from the laboratory. These collection centres were given proper instructions and training regarding packing of samples and the persons responsible for transport of samples were adequately trained so as to maintain the transit time within 2 hours.

During the analytical phase, we discovered that overall non-conformity with internal QC was 0.62 percent. Training on improved technician work practises, better reagent storage, better machine maintenance, timely calibration, and a better understanding of the quality control process were provided to improve concordance with IQC. However, there was no discordance with the EQAS and ILC samples throughout the study period. Kirchner and colleagues presented a cut-off percentage of 0.8 percent for external controls that exceed the desired value.[14] Chawla et al reported 0.1/1000 non-conformity to QC[10], while Aggarwal et al[3] reported 5.07 percent, which is significantly higher.

Due to the lack of a LIS system at our lab, manual reporting was used until recently, and the lab set a TAT of 8 hours for routine haematology, clinical chemistry, and serology tests and 2 hours in cases of emergency or urgent samples. Although no criteria exist for optimum TAT goals, Ricos et al[15] estimate that an acceptable fraction of laboratory results that may exceed specified TAT is 11 percent. TAT was missed for 8% percent of samples in our study. But it can be observed that although it was higher in the initial few months, there was significant improvement later where TAT was maintained for almost 95% of the samples. In their investigation, Sangeeta et al[11] found 1.3 percent of samples with delayed TAT, while Aggarwal et al[3] found 0.025 percent. It is a well-known fact that there is always room for improvement in TAT so that treatment can be initiated at the right time in cases of emergency.

Transcriptional error was another indicator that was monitored in the post analytical phase and was found to be 0.56%. Kale et al reported 1.75% in 2014 which reduced to 0.37% in the year 2016.[1] Sangeeta Kulkarni et al[11] reported 0.15% of transcription error in their study. The main reason behind typing errors was found to be carelessness amongst the technicians who did the report entry and sometimes had to do it in a hurry because of pressure to release the reports on an urgent basis. The introduction of a stringent software for the laboratory and LIS for the laboratory significantly brought down the errors in transcription. Also, introduction of a double check system was introduced where the reports after they were entered by one of the technicians were checked first by the quality manager and approved for release and then finally checked by the consultant pathologist and authorized.

Feedback forms an integral part of the quality management system. When we talk about feedback, we mean gathering feedback from all our stakeholders viz. the clinicians and the patients. In our study, the complaints regarding testing were 0.22% and the general complaints which included staff behavior, cleanliness of laboratory, timing of laboratory etc. was 1.3%. The complaints related to testing was mainly related to TAT which had already been taken care of. Regarding general complaints, training of staff on communication and soft skills and training of housekeeping staff on best sanitation and hygiene practices were provided. However, the request/complaint to increase the laboratory timing to 10 pm could not be complied with for various reasons. It should also be noted that besides these complaints, the laboratory had also received quite a good number of positive feedbacks which boosted the confidence of the staff and motivated them to perform better.

V. CONCLUSION:

Various studies including ours have shown that there is a gradual improvement of performance in all laboratories if the quality

indicators are monitored regularly. However, it must be kept in mind that it is a continuous process.[1-3,7-9] Monitoring of quality indicators not only detects errors but also helps in formulating strategies for continuous quality improvement.[9] Quality improvement helps to motivate and boost the confidence of the staff involved and also enhances the satisfaction of the patients in terms of their services.[10-11]

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