

Original Research Article

ASSESSING QUALITY INDICATORS IN THE HEMATOLOGY LABORATORY

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ABSTRACT

Background: The Institute of Medicine defines quality health care as “the degree to which health care services for individuals and population increase the likelihood of desired health outcomes and are consistent with current medical knowledge”. A quality indicator is a measure that assesses essential elements of the healthcare system, capable of being uniformly applied and compared across different environments and periods. Patient’s treatments are directly affected by the reports from the laboratory, so reducing errors and adopting a quality control system are a priority in laboratories. Quality assurance of laboratory testing in three phases has continuously gained attention among healthcare professionals. Within the hematology laboratory context, these quality indicators are crucial in overseeing laboratory performance, underscoring the necessity of regular evaluations to gauge the laboratory’s effectiveness. **Aim:** To study quality indicators in a hematology laboratory in three phases of testing to improve the quality of health care services.

Material and Methods: 50000 consecutive samples received for hematological investigations in the central laboratory at a tertiary care hospital were taken into study. Seven quality indicators such as sample rejection rate, sample redo rate, turnaround time, critical values, corrected reports rate, internal quality check rate and concordance in EQAS were assessed in three phases of testing - pre-analytical, analytical and post-analytical.

Results: Out of 50000 samples processed in hematology laboratory, sample rejection rate was 1.3%, sample redo rate was 1.24%, corrected report rate was 10.9% & 2.6% before and after validation respectively. The turnaround time for routine, critical and urgent samples were 6hrs, 1.5hrs and 2.5hrs respectively. The IQC failure rate was 2.5% and values of EQAS were within consensus. In 94.3% cases, clinicians were informed about critical values. Regular quality checks were done to improve quality of laboratory services by implementing corrective action and preventive action (CAPA) whenever necessary.

Conclusion: Laboratory testing forms the integral and essential part of health delivery system. Therefore, it is necessary to have regular quality checks to improve the quality of laboratory services.

Keywords: Quality indicators, hematology, quality control.

INTRODUCTION

Quality health care is defined by the Institute of Medicine (IOM) as “the degree to which health care services for individuals and population increase the likelihood of desired health outcomes and are

consistent with current medical knowledge”.^[1] A quality indicator (QI) is a metric that evaluates key aspects of the healthcare system, allowing for uniform application and comparison across different settings and periods.^[2] Patient’s treatments are directly affected by the reports from the laboratory,

so reducing errors and adopting a quality control system are a priority in laboratories.^[5] The data of quality indicators should be collected over time to identify, correct and continuously monitor problems and improve performance and patient safety by identifying and implementing effective interventions. Therefore, these quality indicators assume a crucial role in overseeing laboratory performance, underscoring the necessity of regular evaluations to gauge the laboratory's effectiveness. This study was conducted study quality indicators in a hematology laboratory in three phases of testing to improve the quality of health care services.

MATERIAL AND METHODS

The study involves retrospective analysis of all the recorded data at hematology section of central laboratory at a tertiary care hospital. The scope of hematology laboratory included were Complete blood count, erythrocyte sedimentation rate, reticulocyte count, peripheral smear study, coagulation studies, hemolytic work up. All the samples received were checked for the correctly filled test requisition forms and quality. The quality of sample (appropriate quantity, hemolysed, clotted) were checked by the laboratory technician and were categorized as "sample accepted" or "rejected". The tests were carried out at different levels by well trained staff who undergo external as well as internal competency assessment regularly. Any deviation from already set standards were noted in registers (sample rejection register, sample redo register etc) and entered in hospital information system.

RESULTS

A total of 50000 consecutive samples were analysed. The laboratory has HIS software which stores data for indefinite period. The results were compiled as follows.

Sample rejection rate

The inadequate sample/improper samples were rejected at initial stage of inspection by lab technician. Out of 50000 samples, 650(1.3%) were rejected due to different causes listed in fig 1. Most common cause for rejection was clotted sample.

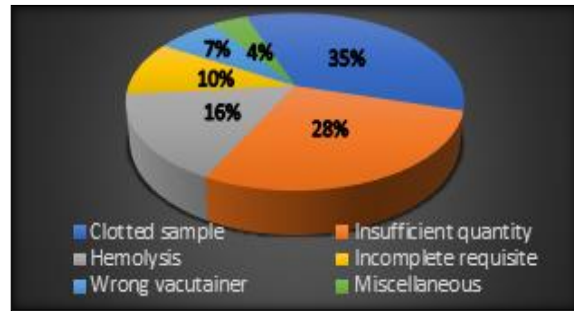


Figure 1: Causes of Sample Rejection

Turnaround time

Time elapsed between receiving time of sample at lab to the time of reporting the result. The time period was calculated using HIS software. The maximum time permissible for routine tests, urgent tests are 8 hrs and 2 hrs respectively. Among 50000 samples 3702 routine samples had been reported out of stipulated time. None of the urgent reports were delayed beyond the mentioned time.

Critical reports

Critical reports are those whose delay in informing leads to serious adverse outcomes in patients, Predefined critical values for different parameters for our laboratory are as shown in Table no 2. Total number of critical values observed in 50000 samples were 3150(6.3%). Among them 2970 (94.3%) critical values were informed to concerned staff within stipulated time.

Corrected/revised reports

The correction of reports prevents from releasing the wrong reports. The rate of correction before validation is 10.9% and most common cause is platelet count after smear examination. The rate of correction after validation is 2.6% the cause being clerical error while entering results.

Internal Quality Check (IQC) Failure rate

Three level IQC were done twice daily for all the cell counters and one level IQC was done once daily for coagulation analyzer with recommended QC materials. Failure rates are mentioned in Table 3.

Performance in EQAS

In our study, concordance was checked in EQAS and interlaboratory comparison. The values of EQAS for both CBC, peripheral smear and coagulation parameters were within consensus.

Table 1: Different quality indicators were derived using the formulas mentioned

Sl no	Quality indicator	Calculation	Phase of testing
1	Sample rejection rate	Total no of samples rejected x100/Total samples	Preanalytical
2	Sample redo rate	Total no of redo samples x100/Total samples	Analytical
3	Turnaround time	No of reports delivered outside TAT x100/Total no of reports	All three phases
4.	Critical values	No of critical values informed within specified timex100/Total no of reports	Analytical
5.	Corrected report rate	Total no of revised reports x100/Total no of reports	Post analytical
6.	IQC Failure rate	Total no of failed IQC runs x100/Total IQC runs	Analytical
7.	EQAS/ILC performance	No of unacceptable performances in EQASx100/Number of performances in EQAS	Analytical

Table 2: Predefined Critical Values

Sl no	Parameter	Critical Alert
1	Hemoglobin	< 7gm/dl
2	Total Leucocyte count	> 30000/cumm , < 2000/cumm
3	Absolute neutrophil count	< 1000/cumm
4	Platelet Count	< 50000/cumm , > 450000/cumm
5	Peripheral Smear	Presence of blasts/hemolysis
6	Malarial parasite	Positive
7	ESR	> 100mm in 1 st hour
8	INR	> 5
9	APTT	> 60 sec/ No coagulation
10	PT	> 30 sec
11	D Dimer	> 200 mg/dl

Table 3: IQC Failure Rates

	IQC Failure rates
Cell counter	2.54%
Coagulation Analyzer	3.2%
Staining Quality	6%

DISCUSSION

The clinical laboratory plays a very important and highly dependable part in Modern medical practice. Majority of clinical diagnosis are supported by the laboratory values. Hence the information generated by clinical laboratory should be timely accurate and understandable by the end users. To have a check on the values generated by the laboratory there is a need of strong quality management system. Thus evolved are many quality indicators over the time, which help in proper maintenance of laboratory.

We encountered 1.3% of sample rejection rate which was concordant with Khaled et al,^[4] Kashyap et al,^[1] Chawla et al.^[3] The most common cause for sample rejection was found to be clotted sample which was similar to the findings of khalid et al.^[4] Proper training of the staff nurses and phlebotomist will decrease the chances of receiving clotted samples.

Critical value reporting plays a crucial role in patient management. Majority of samples with critical values were informed to the respective clinicians. Sensitization of the laboratory staff regarding the value of reporting critical reports is at most important.

Turn around time (TAT) signifies the quality of laboratory at all the levels. TAT outlier for urgent reports were nil where as for random samples it was found to be 7.3%. Majority of studies had negligible TAT outliers. Surveillance system at all the levels

from preanalytical to post might help in proper maintenance of TAT.

Internal and external quality control runs help significantly in quality functioning of the laboratory. Any outliers help for timely intervention and release of corrected valuable reports.

CONCLUSION

Laboratory testing forms the integral and essential part of health delivery system. Therefore, it is necessary to have regular quality checks not only to improve the quality of laboratory services but also for self-assessment and self-improvement.

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