

## Original Research Article

# Quality indicators in a hematology laboratory- a retrospective analysis

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## ABSTRACT

**Background:** Quality indicators are objective parameters which help to assess the effectiveness of the working system in any laboratory. Aim and objective were to study 7 common quality indicators in the hematology laboratory of a tertiary care centre.

**Methods:** It was a retrospective analysis over a period of two and a half years (Jul 2017- Dec 2019). The following 7 QIs were analysed- sample rejection rates, sample redo rates, routine turnaround time (TAT), critical reports and their TAT, corrected reports, staining quality assessment and concordance in EQAS programme. The QI rates were calculated on monthly (or as specified) basis and trends were analysed. P value <0.05 was considered significant.

**Results:** The final result showed average routine, urgent and critical turnaround time to be 6.5 hrs, 1.1 hrs and 3.4 hrs respectively. The other QIs were as follows - sample redo rates (3.8%), sample rejection rates (3.2%), corrected report rates (before validation- 8.5%, after validation- 1.2%) staining quality (unsatisfactory days rate- 4.5%), 98% concordant performance in EQAS. Over the study period, a significant downward trend was noticed in TAT and sample rejection rates (p value=0.001 and 0.007 respectively). Number of monthly critical alerts showed an upward trend (p value=0.045) which could be attributed to increased awareness amongst lab staff. Redo rates showed no significant change in trend over study period.

**Conclusions:** Quality indicators help in self-assessment and self-improvement. Their continuous monitoring is mandatory to have a tight quality check system and better clientele satisfaction.

**Keywords:** Quality indicators, Sample rejection, Redo, Turnaround time, Critical tests

## INTRODUCTION

Quality health care is defined by institute of medicine (IOM) as “the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge”.<sup>1</sup> Since, laboratory testing forms an integral and essential part of this system, quality of laboratory reports have a significant impact on the overall quality of any health delivery system.<sup>2</sup>

Each laboratory endeavors to deliver reports of highest quality within a reasonable time by putting some checks

and balances in their work system. To assess the effectiveness of the final working system, some objective indicators- quality indicators (QI) which can be followed up for comparison or self-improvement are required.<sup>3,4</sup> To define a quality indicator- “It is a parameter which evaluates critical component (eg patient safety, effectiveness, equity, patient-centeredness, timeliness, and efficiency) of health care system, can be objectively assessed based on evidence and can be implemented in a consistent and comparable manner across settings and over time.”<sup>5</sup> A comprehensive approach to quality testing would address all the above stages of the testing process with a focus on the areas which are most likely to have

significant consequences on patient care and health outcomes.<sup>5</sup>

The authors decided to analyse some common quality indicators of the laboratory covering all phases of testing (preanalytical-analytical-postanalytical) which could be assessed objectively. Till date, there have been only few studies on the quality indicators and to the best of authors knowledge, this is the first Indian study analysing the same in a diagnostic hematology laboratory.

## METHODS

This study included retrospective analysis of the recorded data for a period of two and a half years (July 2017-

December 2019). The hematology laboratory of our institute (command hospital airforce bangalore) is a part of a large laboratory (receiving >500 samples per day) catering to a tertiary multi superspeciality care setting. The tests received in this section include complete blood counts, erythrocyte sedimentation rate, reticulocyte counts, coagulation screen (PT APTT INR), DIC screen, peripheral smears, bone marrow aspirates, malaria rapid test, G6PD screens, sickling tests, Osmotic fragility tests etc. These demands are a mix of routine, urgent as well as critical nature which require the laboratory to maintain a fine balance of quantity as well as quality in the delivery system. Hence, the quality indicators selected were not only practically useful and easily recordable but the targets set were also realistic and clinically relevant.

**Table 1: Important quality indicators in laboratory– their definition, calculation and role in increasing the quality of whole system.**

S. no.	Name of quality indicator	Definition	Calculation	Frequency of data analysis	Phase of testing	Focus area
1	Sample rejection rate	Any sample not meeting the criteria of adequacy / quality to process further	No of sample rejected x100 / total no of samples received in a month	Monthly	Preanalytical	Effectiveness Efficiency Safety
2	Sample Redo rate	Cases where a repeat fresh sample was asked due to delta check/clinical correlation failure	No of redo x100 / total no of samples received in a month	Monthly	Preanalytical/analytical	Effectiveness Timeliness
3	Turnaround time	Time elapsed between sample collection and result entry.	HIS software module	Monthly	All three phases	Timeliness
4	Critical report	Any sample with result values meeting the set critical values	HIS software module	Monthly	Analytical	Effectiveness Timeliness
5	Corrected reports	Reports modified/ amended after entry into HIS	No of modified reportsx100/total no of tests in a month	Monthly	Post analytical	Safety
6	IQC failure rate	% of failure rate per month	No of failed IQC run x 100/total IQC run in a month	Monthly	Analytical	Efficiency Timeliness
7	Performance in EQAS/ ILC	% Concordance with consensus reports in EQAS.	Concordant reports with EQAS x100/total tests received	As per EQAS cycle)	Analytical	Safety Efficiency

The seven QIs assessed over these two years were-sample rejection rates, sample redo rates, turnaround time (TAT), critical reports and their TAT, corrected reports, staining quality assessment and performance in EQAS programme/ interlaboratory comparison (ILC). These

indicators were selected in accordance with IOM aiming to cover 3 conceptual areas: (a) importance, (b) scientific soundness, and (c) feasibility of a measure.<sup>5</sup> The records were fetched from hospital information system (HIS) and other registers as required. The indicators assessed, their

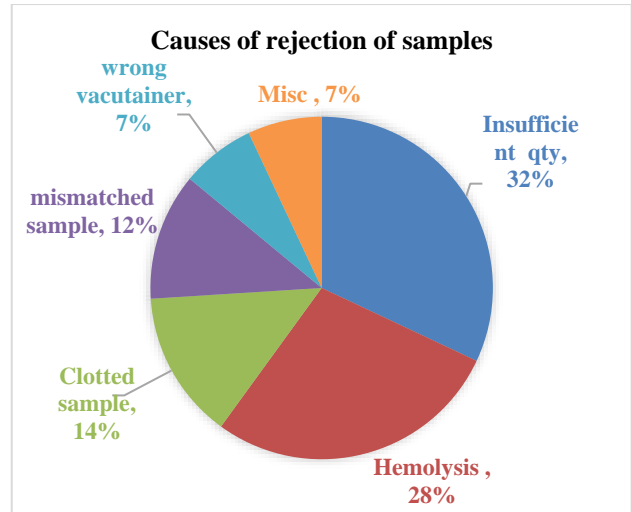
frequency of measurement and area of testing focussed are as per (Table 1). The rates were calculated on monthly (or as specified) basis and were compared with previous recorded results. The data was entered in MS EXCEL spreadsheet and analysis was done using statistical package for social sciences (SPSS) version 21.0. Trend was analysed using regression analysis wherever applicable to assess the process. P value of <0.05 was considered statistically significant. The authors obtained necessary clearance from institute ethics committee for analysing the data from HIS/hospital records.

**RESULTS**

This study was a retrospective analysis of data pertaining to quality indicators spanning a period of two and a half years. The laboratory has a robust hospital information system which stores data for indefinite period. The result was compiled as under.

**Sample rejection**

The samples which did not meet the adequacy/quality criteria for requisite tests were rejected at sample validation stage in laboratory. The most common cause for rejection was insufficient quantity (32%) and the most common sample rejected was PT/INR sample (coagulation study- sodium citrate vial) for incorrect sample volume. Other causes being hemolysis 28%, clotted sample 14%, unlabeled/mismatch sample 12 %, wrong vacutainer 7% and miscellaneous (eg leaking vacutainer, no requisition– 7%) (Figure 1). The ward with most common rejection were chronic wards (55%) and least rejection was from intensive units like ICU/ICCU/JICU (9%). The average rate of rejection was 1.5% over 2.5 years period. On trend analysis the rejection rate showed a significant downward trend over the study period. (p value=0.007) (Table 2).

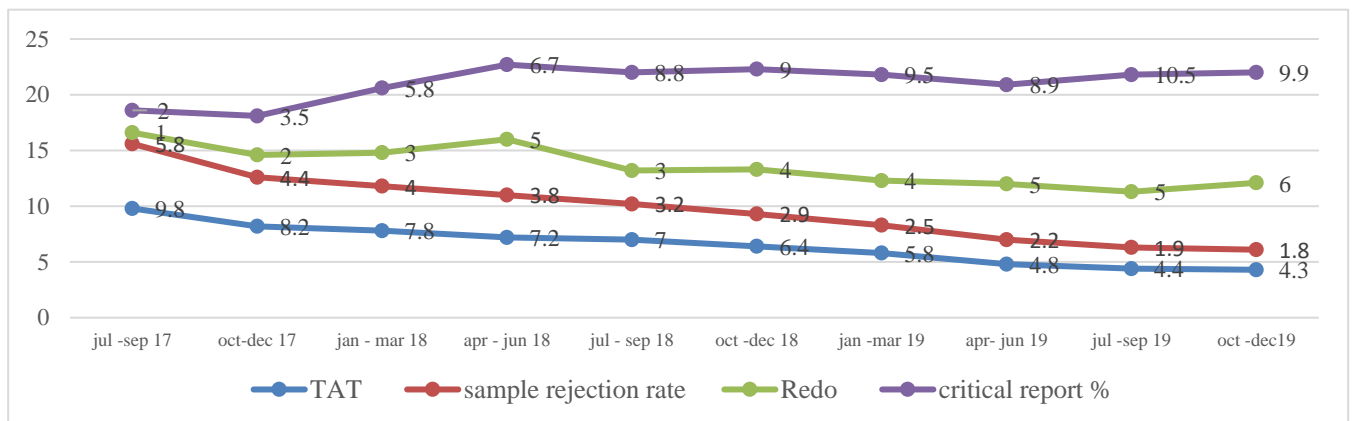


**Figure 1: Causes of rejection of samples.**

**Turnaround time**

Turnaround time (TAT) was defined as time elapsed from sample collection to time of reporting of results. This period was calculated as part of HIS software from the time the sample is validated to the time the report is available on HIS. The maximum permissible TAT set was 8 hours for routine tests and 2 hours for sample marked urgent (excluding Bone marrow reports). The average TAT as recorded by HIS for routine samples was 6.5 hours during study period. And for samples marked urgent was 1.1 hours. On trend analysis the TAT showed a significant downward trend during the study period (p=0.001) (Table 2).

Figure 2 trend analysis of average quarterly values of various quality indicators (TAT in hours, sample rejection and sample redo rates in %, critical reports- % of total tests in a month) Significant downward trend noted for TAT (p=0.001) and sample rejection rate (p=0.007). while significant upward trend noted for % of critical alerts (p=0.045). No significant trend noted for sample redo rates (p=0.15).



**Figure 1: Trend analysis of average quarterly values of various quality indicators.**

### Sample Re do rates

A redo was defined in the study as the case where the results did not match either with the previous value (failed delta checks) or with slides or with given clinical picture and hence a fresh sample was asked for confirmation and rechecking of the value. The average redo rates were 3.8 % which showed no significant down/upward trend over the study period ( $p=0.15$ ) (Figure 2). The commonest cause of redo was mismatch with previous values. Common causes leading to redo were- wrong sample, preanalytical error in collection of blood, wrong history provided, technical issues, wrong entry.

### Critical alerts/reports

Critical reports are those samples for which reporting delays can result in serious adverse outcomes for patients. Our laboratory defined critical values for various parameter as per (Table 3). The % of critical reports/alerts was calculated monthly and the trend analysis showed an increase in critical alerts over study duration ( $p=0.045$ ) (Figure 2) The two most commonly reported critical values were low platelet counts (42%) and abnormal PT INR (28%). The average % of critical report in a month were 7.4% and average TAT for the same was 3.4 hours.

**Table 3: Critical alerts as set by our laboratory.**

S. no.	Parameter	Critical Alert
1	Hemoglobin	<6 Gm/dl
2	TLC	>25000/cumm
3	ANC	<1000/cumm
4	Platelet count	<50,000/cumm
5	PBS	Blasts present/active hemolysis/hemoparasite
6	Malaria /sickle /G6PD	Positive
7	ESR	>100 mm in 1 <sup>st</sup> hour
8	INR	>5
9	APTT	>60 sec/No coagulation
10	D Dimer	>200 mg/dl
11	Fibrinogen	<100 mg/l

### Internal quality check (IQC) failure rate

Internal quality checks were done daily for all analysers (cell counters and coagulation) with recommended QC materials. The rates of IQC failures were calculated on monthly basis. The average rate of IQC failure for cell counter was 2% and coagulation analyser was 3.5%. For analytical procedures like staining quality a subjective assessment was recorded daily as satisfactory and unsatisfactory (rate of unsatisfactory stain-4.5%).

### Corrected reports

This indicator may be used to determine causes of the corrections so that preventive actions can reduce the release of incorrect reports. The average rate of correction/modification of provisional report (before final validation) was 8.5% and correction of validated report (after final validation) was 1.2%. The most common value corrected on provisional report was platelet count after slide validation. The common cause for correction after validation included a wrong selection of positive/negative result from dropdown menu/ clerical error while entering results.

### Performance in external quality checks

Concordance was checked in external quality assurance program and inter laboratory comparisons. It was 99% in CBC and PBS morphology (AIIMS ISHTM EQAP programme) and 97% in coagulation parameters (BIORAD EQAP). Overall concordance of laboratory in various EQAS program was 98%.

### DISCUSSION

A single error at any step during the test process from sample collection, to transport & analysis of sample to the reporting of test results invalidates the quality. To ensure a tight quality system, the process of identifying the errors, their correction and future prevention should be integrated into the system.<sup>6,7</sup> It also needs stringent implementation of quality indicators at ground levels and their continuous assessment for self-improvement.

Sample rejection rate is an indicator of skill testing at all levels of the preanalytical analysis. A low rate indicates an efficient system for eg samples from ICU were least rejected probably due to more experienced staff. Overall rate below 2% is considered to be an efficient system with acceptable rejection.<sup>8</sup> The decrease in rate over study period may be attributed to the increase awareness and more compliance by nursing staff. However, it still needs some improvement. TAT was defined as the time elapsed between sample validation at laboratory to the time the report was available online.<sup>9</sup> The time elapsed between collection of samples at bedside and sample validation at laboratory is highly variable, difficult to calculate and hence was not included. The TAT for routine test need not compete with critical/urgent test as it does not add any useful information to patient management but add unnecessary burden to the laboratory system.<sup>5,10</sup> Also, exceptions to the routine will always be there where a clinical correlation or additional tests may increase the TAT beyond average. The laboratory average TAT for routine, urgent and critical tests fell within the maximum permissible TAT set as a target.

Sample redo rates are indicator of robust delta check being actively followed in the laboratory.<sup>5</sup> Over the two

and a half years - redo rates in our study did not show any significant Upward or downward trend ( $p=0.15$ ). Critical alert reporting is considered an important laboratory process because it can impact clinical decision making, patient safety, and operational efficiency. In a survey of nursing supervisors and physicians, the majority of medical staff interviews (63%) and reviews of medical records (65%) indicated that critical values resulted in a change in therapy, and 95% of surveyed physicians indicated that critical laboratory results were valuable for patient care.<sup>11</sup> The increase in critical alerts ( $p=0.045$ ) over study period may be attributed to the increase awareness and more compliance and stringent documentation by laboratory staff.

Correction or modification of reports (before or after validation) gives a doubt in the minds of users about the correctness of reports, hence this parameter should be kept at lowest possible level. Unnecessary changes (clinically irrelevant) of platelet counts after slide validation should be restricted to minimum. If any correction or significant revision to any validated report is made it should be clearly indicated as revised report, date of revision, reason of revision and a rider stating invalidment of old report should be included for better future reference. Performance in Internal and external quality checks are good indicator of efficiency and accuracy of our machines and reporting system.<sup>12</sup> These parameters are easily analysed objectively overtime hence make a robust quality indicator for any laboratory.<sup>13</sup>

### Limitations

There seems to be a dearth of data from any retrospective or observational studies which can scientifically validate many of these indicators. Such indicators are based primarily on self-reported surveys rather than on scientific study designs and/ or adequately specified, standardized, and consistently implemented data collection methods. Laboratory may design their own quality indicators and set up their own goals as per their intended requirements.

### CONCLUSION

Quality indicators help not only in objective assessment of any laboratory by external agencies but also in self-assessment and self-improvement. Their continuous monitoring is mandatory to have a tight quality check system and better clientele satisfaction.

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