VOLUME - 12, ISSUE - 09, SEPTEMBER - 2023 • PRINT ISSN No. 2277 - 8160 • DOI : 10.36106/gjra

Original Research Paper

Hematology

EVALUATING QUALITY INDICATORS IN HAEMATOLOGY LABORATORY OF A TERTIARY CARE HOSPITAL OF WESTERN INDIA

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ABSTRACT

Background: Laboratory reports play a vital role in diagnosis and monitoring patient outcome. It is of crucial importance to monitor total testing processes (TTP), which includes pre-analytical phase, analytical phase and post-analytical phase by evaluation and monitoring of quality indicators (QI), performance in Proficiency testing/external quality assurance (EQA) programs and reports of external audits by accreditation.

Aims:

(1) To evaluate and monitor Quality Indicators in Haematology laboratory
(2) To analyze the result and implement corrective actions and preventive actions (CAPA) where shifts/trends are noted
(3) To assess whether standardization of use of QI within laboratories is possible

Settings & Design: This record based observational longitudinal study was conducted in Haematology laboratory. 16 QI's were monitored for period of 9 months. The data was analysed 3 monthly. Corrective and preventive actions were taken for deviations and errors. **Result:** Pre analytical phase accounted for the highest incidence of errors (87.44%) followed by post analytical phase (10.48%), and analytical phase (2.08%). The most common pre analytical error was misidentified requests (15.55%). Feedback forms for satisfaction for outpatient specimen collection recorded > 70% satisfaction rate in all parameters evaluated over score of 5. Statistically significant decrement was observed in pre-analytical QIs over period of 9 months. (p value 0.036) **Conclusion:** About 60-70% of clinical decisions are based on laboratory results and so it is mandatory for laboratories to ensure accuracy of results. Each laboratory should establish, analyze and monitor QIs covering the total testing process. A need for standardizing the definition of QI and for setting benchmarks for parameters wherever applicable is felt.

KEYWORDS : Total testing processes (TTI), Quality Indicators (QI), External Quality Assurance Scheme (EQAS), Corrective and preventive action (CAPA)

INTRODUCTION

Quality health care as defined by Institute of Medicine (IOM) is "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".[1]

Quality in laboratory medicine begins from the time the test is decided during patient evaluation to the time when the test is performed and interpreted to derive a clinical conclusion.[2]

Quality objectives should be relevant for specific functions within the laboratory and should be measurable.[3]

QMS should be established, documented, implemented, evaluated and improved in accordance with International Standard.[3] The laboratory should establish quality indicators (QI) to monitor and evaluate performance at the critical stages of pre- examination, examination and post-examination processes. Every laboratory should monitor trends and changes, to ascertain whether laboratory services continue to meet performance expectations

Thresholds set for QI should be realistic and can be changed as part of quality improvement program to reduce and prevent errors.

MATERIALS AND METHODS

This prospective study was conducted in Hematology laboratory of the Institute after seeking approval from Institutional Human Ethics Committee (IHEC) and involved analysis of the recorded data for a period of 9 months from November 2021 to July 2022.

16 quality indicators- 8 in pre-analytical phase, 3 in analytical phase and 4 in post-analytical phase and one Q- Track (QT7: Satisfaction with outpatient specimen collection) in Hematology Laboratory were selected for evaluation and monitoring (Table 19).[04] Assessment of satisfaction with outpatient specimen collection was done on basis of information sheet, consent form and feedback forms filled by OPD patients [Annexure I, II, III]

The data was analyzed 3 monthly. Corrective actions and preventive actions were taken for deviations and errors.

Inclusion Criteria

(1) Samples received from OPDs, indoor admissions, EQAS cycles for hematological investigations
(2) Request forms received from all indoor admissions
(3) Feedback forms filled by OPD patients

Exclusion Criteria

(1) Feedback from indoor admissions (wards, ICUs, casualty, labour room)
(2) Patient's refusing to fill feedback form

Only request forms received from IPD were included in the study because test requests from OPD are mentioned on case paper itself and no request forms are received for the same.

QT7 Satisfaction with outpatient specimen collection: On a monthly basis, patients were provided copies of a standardized questionnaire in English and vernacular language to a minimum of 25 outpatients using predetermined data collection criteria. This monitor includes any outpatient undergoing venipuncture. This monitor excludes patients seen in the emergency department, trauma care and inpatient department.

Satisfaction scores and satisfaction rates (% of patients rating 4 or 5) for the following categories: Overall experience, waiting time, patient comfort, courtesy, patient privacy and laboratory hours of operation.

RESULTS

Preanalytical phase: Prevalence of errors were maximum in preanalytical phase and were seen in 6356 samples (13.05%

of total samples received). The most common preanalytical error was misidentified request. Out of 29450 requests received from wards/indoor admissions, 4579 request forms were improperly filled (15.55%). The frequency of other errors comprising of clotted samples, quantity not sufficient, samples not stored properly before analysis, sample not received, test transcription errors, and hemolyzed samples were 586 (1.2%), 141 (0.29%), 191 (0.39%), 156 (0.32%), 44 (0.09%) and 18 (0.04%) samples respectively. Results of quality indicators (QI) in preanalytical phase are shown in Table 1.

Table 1: Results Of Quality Indicators Of Pre-analytical Phase

Sr.No.	Quality Indicators	1-3 months Number (Percentage)	4-6 months Number (Percentage)	7-9 months Number (Percentage)	Total Number (Percentage)
1.	Misidentification errors %				
	a) Misidentified requests (IPD)	1608 (16.83%)	1421 (15.19%)	1550 (14.70%)	4579 (15.55%)
	b) Misidentified samples	03 (0.02%)	00 (0.00%)	00 (0.00%)	03 (0.01%)
	c) Samples with <2 identifiers	00 (0.00%)	00 (0.00%)	00 (0.00%)	00 (0.00%)
	d) Unlabeled samples	00 (0.00%)	00 (0.00%)	00 (0.00%)	00 (0.00%)
2.	Test transcription errors %				
	a) OPD requests with data entry error	00 (0.00%)	00 (0.00%)	00 (0.00%)	00 (0.00%)
	b) IPD requests with data entry error	20 (0.21%)	08 (0.09%)	16 (0.15%)	44 (0.15%)
3.	Incorrect sample type %				
	a) Inappropriate samples	05 (0.03%)	03 (0.02%)	03 (0.02%)	11 (0.02%)
	b) Wrong containers	04 (0.03%)	02 (0.01%)	03 (0.02%)	9 (0.02%)
4.	Incorrect fill level %				
	a) QNS Samples	46 (0.30%)	44 (0.28%)	51 (0.28%)	141 (0.29%)
	b) Samples with inappropriate sample: Anticoagulant ratio	225 (1.46%)	185 (1.20%)	208 (1.16%)	618 (1.27%)
5.	Unsuitable samples for transportation and storage problems				
	a) SNR	76 (0.49%)	37 (0.24%)	43 (0.24%)	156 (0.32%)
	b) Samples not stored properly	77 (0.50%)	60 (0.39%)	54 (0.30%)	191 (0.39%)
	c) Samples damaged during transport	NA	NA	NA	NA
	d) Samples transported at inappropriate temperature	NA	NA	NA	NA
	e) Samples with excess transportation time	NA	NA	NA	NA
6.	Contaminated samples	00 (0.00%)	00 (0.00%)	00 (0.00%)	00 (0.00%)
7.	Samples hemolyzed	13 (0.08%)	01 (0.01%)	04 (0.02%)	18 (0.04%)
8.	Samples clotted	211 (1.37%)	193 (1.25%)	182 (1.02%)	586 (1.20%)

OPD:Outdoor Patient Department, IPD:Indoor Patient Department, QNS:Quantity not sufficient, SNR:sample not received

Analytical phase: Out of 2639 control runs, 151 times the result was out of acceptable coefficient of variation (CV) percentage range.

100% concordance was achieved in 16 EQAS/PT samples received during study period.

Table 2: Results Of Quality Indicators Of Analytical Phase

Sr. No.	Quality Indicators	1-3 months Number (Percentage)	4-6 months Number (Percentage)	7-9 months Number (Percentage)	Total Number (Percentage)
1.	Test with inappropriate IQC performances	81 (7.83%)	17 (1.97%)	53 (7.14%)	151 (5.72%)
2.	Unacceptable performances in EQA-PT schemes	00%	00%	00%	00%
3.	Concordance of alternative approach for tests uncovered by an EQA-PT Control	100%	100%	100%	100%

IQC, Internal Quality Control; EQA-PT, External Quality Assurance Scheme- Proficiency Testing

Post-analytical phase: Errors in post-analytical phase were seen in 762 (1.56%) reports. In the post analytical phase, manual transcription was required in 7409 reports, out of which errors were seen in 330 (4.45%) reports. Only 2 (0.004%) of 48726 reports did not meet the turn around time (TAT)

Out of 1879 reports falling under critical range, 1449 (77.12%) reports were informed to the concerned clinician/ treating doctor. No incorrect report was issued during entire study period. Table 3 shows results of quality indicators of post analytical phase of the present study.

Table 3: Results Of Quality Indicators Of Post Analytical Phase

Sr. No.	Quality Indicators	1-3 months Number (Percentage)	4-6 months Number (Percentage)	7-9 months Number (Percentage)	Total Number (Percentage)
1.	Data transcription errors				

	(a) Errorsin manual transcription	110 (4.77%)	102 (4.69%)	118 (4.03%)	330 (4.45%)
	(b) Information System problem	00 (0.00%)	00 (0.00%)	00 (0.00%)	00 (0.00%)
2.	Inappropriate TAT	02 (1.30%)	00 (0.00%)	00 (0.00%)	02 (0.004%)
3.	Incorrect laboratory reports	00 (0.00%)	00 (0.00%)	00 (0.00%)	00 (0.00%)
4.	Notification of critical values	560 (76.71%)	432 (77.84%)	457 (76.94%)	1449 (77.12%)

TAT, Turnaround time

Feedback forms for satisfaction with outpatient specimen collection recorded >70% satisfaction rate in all parameters on evaluation over a scale of 5.

DISCUSSION

Pre- Analytical Phase

Misidentified errors accounted for majority of pre-analytical errors (72.04%). This error was recorded in 15.55% of all IPD request forms studied, which is more than result reported by Addis Z et al.[05] (8.7%) but less than studies by Manoharan K et al.[06] (99.9%) and Kipkulei JC et al.[07] (98.96%). Majority of misidentified requests were from the Department of Medicine [1045 (22.82%)] followed by casualty [874 (19.09%)] and Obstetrics and Gynecology (OB/GYN) [784 (17.12%)]

Prevalence of misidentified requests declined from 16.83% in first three months (November - January) to 14.70% in last three months (May-July) of study. This can be attributed to repeated instructions issued to the hospital health care workers on the importance of proper documentation.

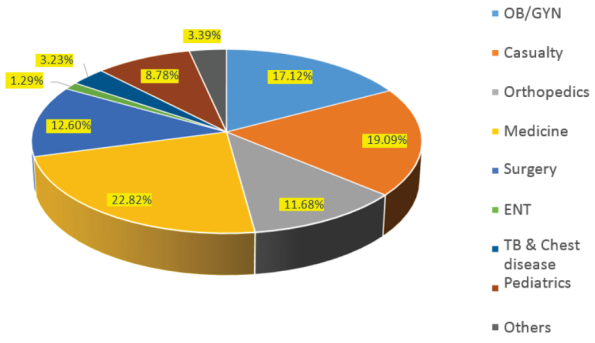

Figure 1 : Proportion Of Misidentified Request Forms Received From Clinical Departments

Table 4: Comparison Of Quality Indicators Of Pre-analytical Phase With Various Studies (I)

Quality Indicators	Addis Z et al.[05]	Manohar an K et al.[06]	Kipkulei JC et al.[07]	Nutt L et al.[08]	Bhatia K et al.[09]	Jegede et al.[10]	Present Study
Misidentified Requests	8.7%	99.9%	98.96%		100%	99.9%	15.55%
Missing details in requisition form:							
a) Name of Physician	36.4%	99.9%	3.1%	7.4%		9.9%	3.49%
b) Hospital number	2%	4.4%	0.00%	0.3%		1.4%	0.14%
c) Date	19.1%	8.4%	4.5%	3.3%		0.5%	0.79%
d) Ward	9.3%	07%	3.1%	4.9%		0.00%	0.53%
e) Diagnosis	97.7%	90.7%	14.2%	19.1%	58.8%	0.2%	10.58%
Hemolyzed Sample	1.20%						0.04%
QNS	4.1%						0.29%
Clotted Sample	2%						1.20%

QNS, Quantity not sufficient

Table 5: Comparison Of Quality Indicators Of Pre-analytical Phase With Various Studies (II)

Quality Indicators	Olayemi et al.[11]	Agarwal R et al.[14]	Singla Parul et al.[13]	Alshaghdali K et al.[12]	Patel Suchita et al.[15]	Tola Edosa et al.[16]	Present Study
Missing details in requisition form:							
(e) Diagnosis	22.7%					43.96%	10.58%
Misidentified samples		0.05%	07%	0.05%		0.95%	0.01%
Inappropriate Vial		0.023%	07%	0.16%			0.02%
Tests entry Error						2.9%	0.09%
Hemolyzed		0.74%	11%	2.88%	0.03%	0.54%	0.04%
QNS		2.75%	08%	0.46%	0.99%	1.16%	0.29%
Contaminated sample			03%	0.01%			0.00%
Clot				3.6%	3.62%	1.1%	1.20%
SNR			06%	3.54%			0.32%
Inappropriate sample-anticoagulant volume ratio				0.85%			1.27%

QNS, quantity not sufficient; SNR, sample not received

Analytical Phase: In analytical phase, the values were out of range for acceptable CV% (coefficient of variation) in 151 runs (5.72%). Similar incidences were found in other studies such as Tola E et al.[16] (2.6 %); Tadesse H et al.[17] (7.1%) and Kashyap A et al.[1] (2%). Performance in EQAS was 100%, while it was 98% in study by Kashyap A et al.[1]

Table 6: Comparison Of Quality Indicators Of Analytical Phase With Various Studies

Analytical phase					
Quality Indicators	Patel S. et al.[15]	Tola E et al.[16]	Tadesse H et al.[17]	Kashyap A et al.[1]	Present study
IQC failure	0.27%	2.6%	7.1%	2%	5.72%
Performance in EQAS				98%	100%

IQC, Internal Quality Control; EQAS, External Quality Assurance Scheme

Defect with cleaning chamber led to unacceptable values in last three months (7.14%). Chamber valve was replaced as corrective action.

Post Analytical Phase

Among quality indicators of post-analytical phase,

Transcription errors in report printing accounted for 4.45% of errors which was nearly same as that reported by Mays JA et al (3.7%)

Table 7: Comparison Of Quality Indicators Of Post-analytical Phase Between Various Studies

Post analytical phase							
Quality Indicators	Sciacovelli L et al.[19]	Alshaghdali K et al.[12]	Mays JA et al.[18]	Patel Suchita et al. [15]	Tadesse H et al.[17]	Rosita L et al. [20]	Present study
Critical value notification	67.2%				83.02%	100%	77.12%
No. of incorrect reports issued	0.08%						0.00%
No. of reports delivered outside specified time	0.06%	0.02%		1.2%	4.1%		0.004%
Manual transcription error			3.7%		14.8%		4.45%

CONCLUSION

About 60-70% of clinical decisions regarding admission, prescription, and discharge are based on laboratory results and so it is mandatory for laboratories to ensure accuracy of results. Quality Indicators improve laboratory performance. Each laboratory should therefore establish, analyze and monitor QIs covering the total testing process. Pre analytical phase account for the maximum number of errors in laboratory. Corrective action and preventive action can progressively free a laboratory from errors.

In the present study, 16 quality indicators for hematology laboratory from the published literature were selected for evaluation and monitoring. A need for consensus on mandatory QIs globally is deeply felt.

The investigators believe it is pivotal to standardize definition of QI, and set possible for parameters, wherever applicable.

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