International Journal of Life Sciences, Biotechnology and Pharma Research Vol. 14, No. 5, May 2025 Online ISSN: 2250-3137
Print ISSN: 2977-0122

DOI: 10.69605/ijlbpr_14.5.2025.105

ORIGINAL RESEARCH

A study of extra analytical quality indicators in a clinical pathology laboratory in a tertiary care hospital, in central Gujarat: A retrospective observational study

[1]Dr. Kirty Patel,[2]Dr. Aditi Dholakia,[3]Dr. Yogita Kareliya

[1]MD (Path), Senior Resident, GMERS, Medical College Gotri, Vadodara, Gujarat, India
[2]MD (Path), Associate Professor, GMERS, Medical College Gotri, Vadodara, Gujarat, India
[3]MD (Path), Assistant Professor, Govt. Medical College, Vadodara, Gujarat, India

Corresponding Author
Dr. Aditi Dholakia
MD (Path), Associate Professor, GMERS, Medical College Gotri, Vadodara, Gujarat, India

Received: 10March, 2025 Accepted: 11April, 2025

ABSTRACT

Background: Laboratory testing has become an integral and essential part of health care system, which implies a need of quality assurance in this field. Quality indicators (QI) serve as a matrix for evaluation of quality in laboratory services. Present study has focused on assessment and analysis of QI applicable in extra analytical phase (pre and post analytical) of laboratory sample testing.**Material Method:** The present study conducted for the period of one year (Jan 24 to Dec 24) considering testing parameters which are under NABL scope. Total five QI in pre analytic phase and three QI in post analytic phase were evaluated. Percentage of each QI calculated according to formula set by quality policy of the laboratory.
Results: Out of total 67326 samples received for hematological analysis, sample rejection rate was 2.32%, with clotted samples were the most common cause. Frequency of incomplete TRF was 13.01%.Among post analytical QI, frequency of TAT outlier test report was 0.6%; frequency of critical value reporting was 3.98%; frequency of revised reports was 0%. Sigma score for individual QI was calculated which was ranging from 2.7 to 4.1.**Conclusion:** Extra analytical phase (Pre and post) has impact on overall performance of laboratory services and is as important as analytical phase of sample testing. In present study errors in pre analytical phase were more frequent (15.33%) as compared to post analytical phase (4.58%). Analysis of QIs provides an objective assessment of quality of laboratory testing and provides insight about area of improvement.

Key words:QI, Pre-analytical, Post-analytical, TRF

INTRODUCTION

Laboratory services are increasingly recognized as crucial for reducing diagnostic uncertainty and helping in providing quality patient care[1]. More than 60% of decisions related to patient diagnosis and treatment involves test results given by laboratories[2].The amount of dependence on laboratory services for patient management highlights the need for quality assurance in these services.

Quality assurance is essentially needed in all the three phase of laboratory testing i.e. preanalytical, analytical and post analytical. There is raising awareness about the fact that quality outcome of laboratory services is not only depend on sample analysis but also impacted by extra-analytical performance of the laboratory[1]. The extra-analytical phase includes both preanalytical (test request, collection, handling and transportation of samples) and post analytical (final dispatch of laboratory results and clinician notification regarding the same).

International organization for standardization 15189 and NABL India offer guidelines for setting up quality management system for medical laboratory which helps to bring improvement in all three phases of laboratory testing. Certain determinants are needed for objective evaluation of quality in laboratory functioning. These determinants or metrics are called as quality indicators (QI). QIs help to identify the

DOI: 10.69605/ijlbpr_14.5.2025.105

areas for improvement and help to ensure the reliability of laboratory results.

Present study is conducted in a clinical pathology laboratory in a tertiary care hospital where we are focusing on evaluation of quality indicators (QI) applicable to pre and post analytic phase of laboratory testing.Based on these results six sigma values for parameter calculated and compared with other studies.

MATERIAL & METHODS

A) STUDY DESIGN & SITE

This study was an institution based, observational retrospective cross sectional analytical study.

This study was conducted at central pathology laboratory, pathology department at tertiary care health center in central Gujarat, having 750 bed capacity, 81% bed occupancy and approximately more than 1400 outdoor patients daily.

Data was collected over one year period from 01/01/24 to 31/12/24.

This lab is NABL accredited since 2 yrs and all samples are processed according to standard operative procedure.

The lab had established various quality indicators to monitor quality during preanalytical, analytical and post analytical phase.

B) SAMPLE COLLECTION & TRANSPORTATION TO CPL

The study samples were collected from OPD as well as indoor patients in different wards of hospital. Samples were collected in suitable containers and transported to the laboratory at appropriate temperature along with test requisition form.

C) SAMPLE PROCESS

On receiving samples at the lab, lab technicians carefully screen samples and test request forms as per quality policy set by labs for preanalytical indicators (Acceptance and rejection criteria). The rejected samples are documented and clinician is informed regarding same.

Samples are analyzed and results are released according to quality policy set by the lab.

In post-analytical phase monitoring done by various indicators established by the lab e.g.

Number of reports delivered outside the specified TAT, Critical value of test results notified & number of revised reports issued.

Quality indicators used in current study are described below in table.

Table 1: Description of extra-analytical quality indicators (QI)

Indicators	Description
Preanalytical	
Clotted samples	(Number of samples clotted/total number of samples with an anticoagulant) x 100
Insufficient specimen for procedure	(Number of samples with inadequate sample-anticoagulant received/Total number of samples) x 100
Mislabelled specimen	(Number of samples improperly labelled received/Total number of samples) x 100
Not received specimen	(Number of samples lost-not received/Total number of samples) x 100
Incomplete requisition form	(Number of incomplete requisition forms/Total number of requisition forms) x 100
Postanalytical	
TAT (turnaround time)	(Number of samples delivered outside the specified TAT/Total numbers of reports issued) x 100
Critical value notification	(Number of critical values notified/Total number of test requests) x 100
Revised reports	(Number of revised reports issue/Total number of reports issued) x 100

All the blood-test requests under NABL scope received in the lab were included in the study, while tests outside NABL scope were not included. Tests parameters under NABL scope includes: CBC, ESR, MP, PS, AEC and RC.

After getting approval from lab administrators, datas and records were collected and analysed.

CALCULATION OF PREANALYTICAL QUALITY INDICATORS

It is defined as % of samples &/or forms rejected (No. of samples &/or forms rejected/ Total no. of test requests)x100.

Sample rejection criteria defined in quality policy of the laboratory includes:

- Unlabelled specimen.
- Mislabeled (incorrectly labelled)specimen.
- Incorrect container/ preservative.
- Insufficient specimen for procedure.

In case of sample not received, TRF (test requisition form) is registered & remark is given that sample not received in register & software as well as on reports.

POLICY FOR PERIODIC REVIEW OF LAB REQUISITION FORM

Periodic review of requisition form is done 6 monthly. 1% requisition forms are selected randomly from past 6 months requisition forms and checked for completion of all information that includes

- Patient's full name.
- Age.
- Sex.
- Date of sample collected.
- Pateint's location.

DOI: 10.69605/ijlbpr_14.5.2025.105

- MRD/IP no.
- Ward/OPD
- Reffering doctor
- Clinical diagnosis/history/clinical findings/lab investigations.
- Physician's signature.

% of completed and noncompleted data is calculated and documented.

CALCULATION OF POST ANALYTICAL QUALITY INDICATORS

Post analytical phase in the lab is monitored by following post analytical quality indicators:

TAT(turn around time), critical value notification and revised reports issued.

1) TAT outlier-calculated by(Number of samples delivered outside the specified TAT/Total numbers of reports issued) x 100.

TAT for hematology parameters-for routine test turnaround time is 8 hrs and 4 hrs for emergency test.

2) Critical value notification-Lab has defined policy for critical values of parameters. Test results showing critical alerts are notified to clinician on urgent basis. This communication is documented separately.

It is calculated by (number of reports with critical values notified/Total numbers of reports issued) x100

3) Revised reports issued-According to quality policy of the lab report can be revised or issued in following conditions:

- To revise identification errors.
- To revise typographical errors.
- To revise originally issued final diagnosis.
- To revise other reported diagnostic information that are significant with respect to patient's management or prognosis.

It is calculated by (Numbers of revised reports issued/ Total numbers of reports issued)x 100

Percentages of errors for each parameter were calculated and results were compared with similar other studies.

Sigma value for each quality indicator included in present study was calculated using sigma calculator available online at http://www.westguard.com/six sigma-table.htm.

The sigma performance evaluation score evaluates quality indicators on the scale of 0-6. According to that minimum acceptable score is more than or equal to 3.Higher the sigma score indicates better performance[3].

Results

Present study was conducted at hematological department at tertiary care center during the year 2024 January to December.

During this period of time total 67326 samples were received for hematological analysis. All the parameters under NABL scope were included in present study. According to quality policy, calculation of quality indicators was done. Out of these quality indicators, indicators applicable in extra analytic phase of laboratory sample processing were included in present study. Analysis, Compilation and review of these QI were done and following observations were made.

PREANALYTICAL PHASE

Table2: Prevalence of total preanalytical errors during study period

Preanalytical indicator	Frequency
Sample rejection	2.32%
Incomplete TRF*	13.01%

*TRF-Test requisition form

During the preanalytical phase, incomplete TRF received in the laboratory was the poorest quality indicator observed (13.01%) which was followed by sample rejection (2.32%)

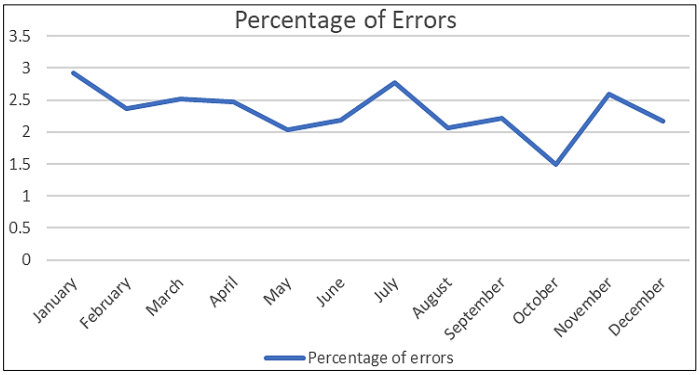

Chart 1: Preanalytical errors (Sample rejection) monthly data

DOI: 10.69605/ijlbpr_14.5.2025.105

Highest preanalytical errors was observed in month of January while least errors observed in month of October.

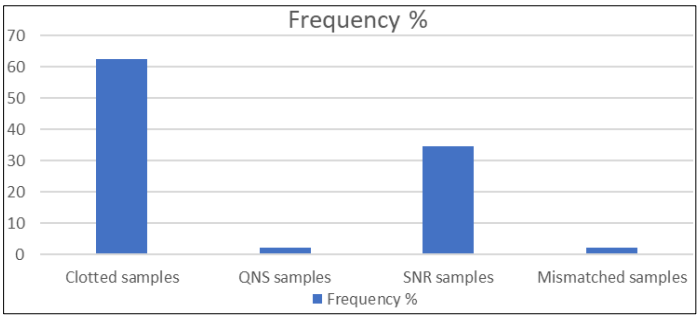

Chart 2: Prevalence of reasons for Sample rejection during 1 year period

The most common cause for sample rejection was clotted samples (62.63%) followed by not received samples (34.76%). Remaining causes were QNS samples (2.18%) & mismatched samples (2.16%).

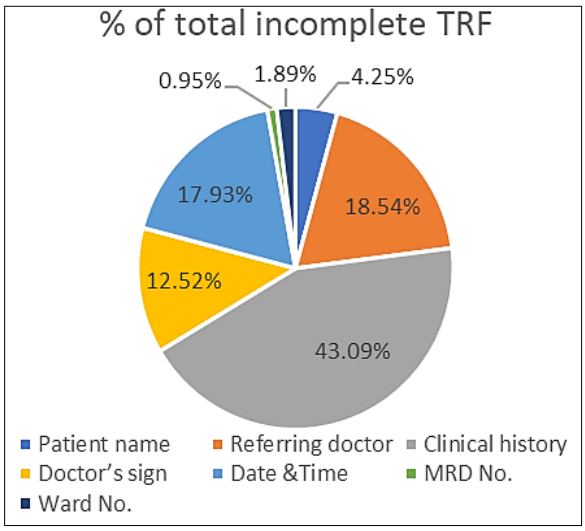

Chart 3: Prevalence of various deficit for incomplete TRF during 1 year period

Parameters observed in TRF analysis were Patient's name, age & sex, MRD no, location, test date and time, clinical history, referring doctor name & signature. Among incomplete TRF, most common cause was absent/irrelevant/incomplete clinical history (43.09%).

POST ANALYTICAL PHASE

Total 3 QI were included in post analytical phase that include TAT outlier, critical value notification and revised reports issued.

Monthly data calculation for these QI gave following results.

Table3: Prevalence of postanalytical QI during 1 year period

QI	Frequency (%)
TAT outlier	0.60
Critical value	3.98
Revised reports	0

DOI: 10.69605/ijlbpr_14.5.2025.105

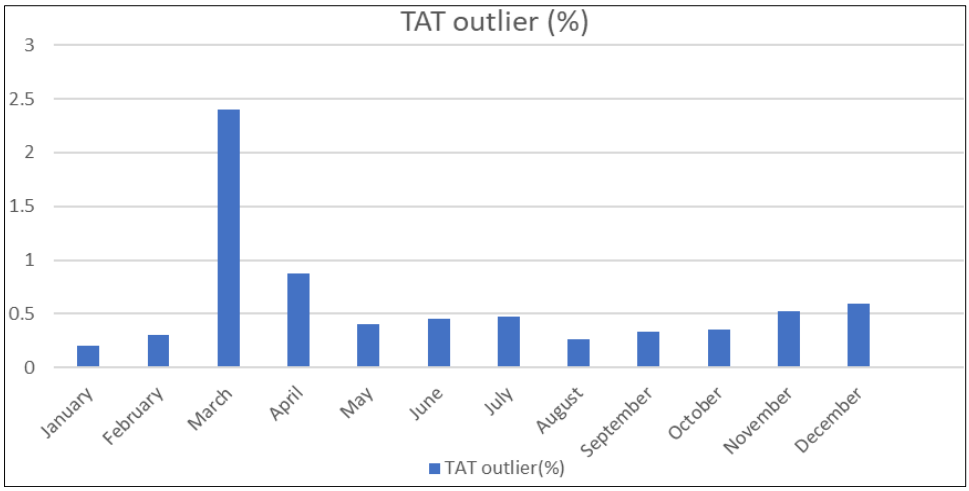

Chart 4: TAT outlier monthly data

TAT outlier of reports of the year was 392(0.60%). Sampleturnaround time was observedhighest in March (2.403%).This was because of operatory mistake in software operation for a single day.

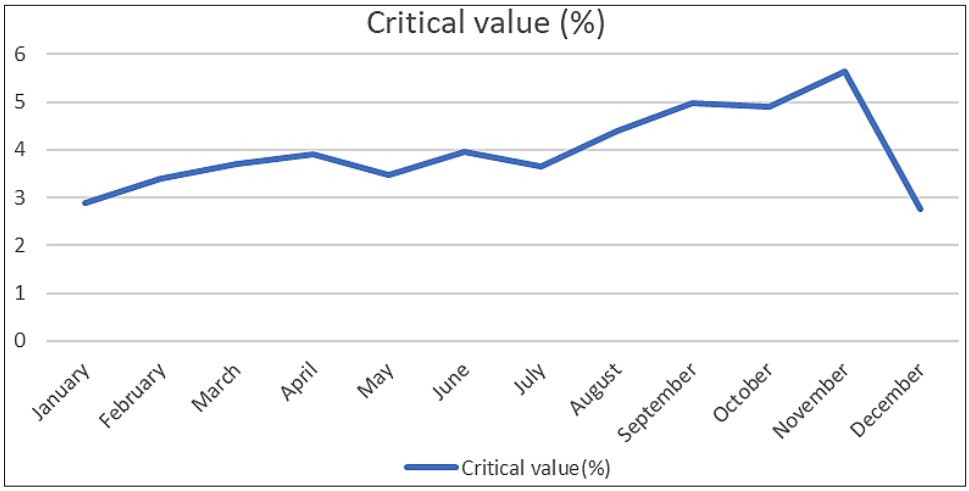

Chart 5: Critical value monthly data

Overall critical values of the year were 2683 (3.98%). Highest numbers of critical values were reported in November (5.63%)
Frequency of revised reports issued was 0%.
Total 19.91% errors were recorded from extra analytical (pre and post analytical) phase in the year. Out of them preanalytical phase errors are most common with 15.33% followed by post analytical phase 4.58%.

Table 4: Calculated sigma value of individual QI

QI	Sigma value	Performance level
Sample rejection	3.5	Acceptable
Incomplete TRF	2.7	Unacceptable
TAT outlier	4.1	Good
Critical value	3.3	Acceptable
Revised reports	Undefined	-

DISCUSSION

In present study, total 19.91% of extra analytical errors reported. Out of these total errors, preanalytical errors were 77% which is comparable to study done by Berta DM*et al*., Tola *et al*.,& Tedesse *et al*., (74.8,71.8 &75.5%respectively) while post analytical errors were 23% which is also comparableto study done by Berta DM*et al*., Tola *et al*.,& Tedesse *et al*.,(22.3,20.6& 22% respectively)[4-6].
Sample rejection rate in different studies have been reported between 0.1to 4.6%[7-9].In present study, sample rejection rate was 2.32% out of the total of 67326 samples received over a period of 1 year. This data was comparable to study done by Elham *et*

DOI: 10.69605/ijlbpr_14.5.2025.105

al.,and by Soloman *et al*.,where sample rejection rates were 2.21% and 1.99%[10, 11].

Most common cause for sample rejection was clotted sample (62.63%) which is comparable to study done by SiniciLay *et al*., (55.8%). Study done by Pinal *et al*., shows 82.8% of clotted samples among total sample rejected, while study done by Alshaghdali K*et al*., Soloman *et al*., and Elham *et al*., shows values of 38.6, 32.23 & 32.31% respectively[9-13].

In present study second most common cause of sample rejection was SNR sample 34.76%. Thisresult was comparable to Alshaghdali K*et al*., study which has 38% of SNR samples[13].

Less common causes of sample rejection included QNS samples (2.18%) and mismatched samples (2.15%) which was lesser than the study done by Pinal *et al*., Soloman *et al*.,and Elham *et al*.,[10-12].

Frequency of sample rejection in a clinical pathology laboratory can be improved by proper sensitization and regular training of staff allotted for sample collection in wards and OPDs.

Present study reports frequency of incomplete TRF (test requisition form) to be 13%. Results from various studies indicate that incompleteness on lab request range from 10-98%[14, 15].Chillar N *et al*.,and Gyawali P *et al*.,observed frequency of incompletely filled test request form 17.3% and 37%respectively which are higher thanpresent study[16, 17].

In present study major deficit in requisition form was missing clinical history (43.09%) which was comparable to study done by Tola *et al*.,(43.96%)[5]. Second and third missing parameters in TRF were referring doctor (18.54%) and date and time for collection (17.93%). Data of study done by Tola *et al*.,for these parameters were 50.4% and 17.95% respectively[5]. Higher frequency of poorly filled test request forms might be due to frequent rotation of staff at clinical side and tendency of allotting this clerical work to unexperienced, junior staff. This also can be improved by communication between laboratory staff and clinical person managing patients,inpost-analytical phase, present study critical values reported was 3.98% which was comparable to study done by Pinal *et al*.,(3.3%) and study done by Kouser,S *et al*., (3.7%) while it was lower than study done by Rajeshree K *et al*., (6.3%) & Kashyap *et al*., (7.4%)[12, 18-20].

Laboratory test results released within predefined TAT (turnaround time) proves to be an important quality indicator for the post analytical phase of laboratory testing. In present study 0.6% of all reports dispatched were outside TAT. Frequency of reports dispatched outside TAT in different studies were 0.02% (Alshaghdali K*et al*.,) to 18.3% (Tola *et al*.,)[5, 13]. Rico's and colleagues have suggested that11% is an acceptable fraction of laboratory reports that may exceed the stipulated TAT[21].

In present study, frequency of revised reports was 0%. Percentage of revised reports in other studies ranges from 0% to 1-2%[20, 22].

Less number of revised reports indicates sound communication between laboratory personnel and treating clinician. However, proper SOP formation for issuing revised report and training of laboratory staff regarding documentation of the same should be ensured.

In present study Sigma value for preanalytical indicators was 3.5 for rejected samples and 2.7 for incomplete TRF, which was comparable to study done by Berta DM*et al*., and study done by Queen Mary *et al*.,[4, 23].Understanding the importance of properly filled TRF in maintaining quality of laboratory testing would be helpful in reducing frequency of poorly filled Test request forms.

Sigma value for two post analytical QI i.e.TAT outlier and critical values are 4.1 and 3.3 respectively, which is higher than study done by Berta DM*et al*.,[4]. This shows performance level in report dispatch within prescribed TAT is good. Sigma value for QI critical value shows minimum performance level which indicates more training and sensitization of laboratory staff is needed for critical value notification and its documentation.

Thus, analysis of QI identifies area of improvement and provides direction for utilization of resources for the improvement of laboratory services.

CONCLUSION

The extra analytical phase (pre and post sample analysis) is equally important as analytical phase of sample processing. Right from sample received in laboratory to dispatch of properly signed report requires proper orientation towards laboratory policies and clerical accuracy, which is only possible by proper sensitization and training of laboratory staff. Analysis of QI related to extra analytical phase of sample processing serves as a measure of laboratory functioning in an area other than actual sample processing. It also identifies which aspects need improvement and gives direction for proper utilization of laboratory resources.

REFERENCES

1. Sciacovelli L, Aita A, Plebani M. Extra-analytical quality indicators and laboratory performances. Vol. 50, Clinical Biochemistry. Elsevier Inc.; 2017. p. 632–7.
2. Rohr UP, Binder C, Dieterle T, Giusti F, Messina CGM, Toerien E, *et al*., The value of *in vitro* diagnostic testing in medical practice: A status report. PLoS One. 2016 Mar 1;11(3).
3. van Heerden M, George JA, Khoza S, Heerden VM. African Journal of Laboratory Medicine. 2225;2225–2002. Available from: https://doi.org/10.4102/ajlm.
4. Berta DM, Grima M, Melku M, Adane T, Chane E, Teketelew BB, *et al*., Assessment of hematology laboratory performance in the total testing process using quality indicators and sigma

DOI: 10.69605/ijlbpr_14.5.2025.105

metrics in the northwest of Ethiopia: A cross-sectional study. Health Sci Rep. 2024 Jan 1;7(1).
5. Tola EK, Dabi YT, Dano GT. Assessment of Types and Frequency of Errors in Diagnostic Laboratories Among Selected Hospitals in East Wollega Zone, Oromia, Ethiopia. Pathol Lab Med Int. 2022 Mar;Volume 14:1-6.
6. Tadesse H, Desta K, Kinde S, Hassen F, Gize A. Errors in the Hematology Laboratory at St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia. BMC Res Notes. 2018 Jul 3;11(1).
7. Ma Jesus Alsina VANBSB *et al.*, Alsina 2008 publication. Clin Chem Lab Med. 2008 Jun 1;(46):849-54.
8. Goswami AP, Sankar Roy S, Goswami NN. Evaluation of Specimen Rejection rate in Hematology Laboratory [Internet]. Vol. 13, IOSR Journal of Dental and Medical Sciences (IOSR-JDMS) e-ISSN. 2014. Available from: www.iosrjournals.org
9. Incilay Sinici Lay APFA. Turkey sample rejection publication. Journal of Clinical Biochemistry. 2014;47(12):1002.
10. Elham Jafari RMARA. Rates and Reasons of Laboratory Sample Rejection due to Pre analytic Errors in Clinical Settings. Arch Iran Med. 2022 Mar;25(3):166–70.
11. Getawa S, Aynalem M, Melku M, Adane T. Blood specimen rejection rate in clinical laboratory: A systematic review and meta-analysis. Vol. 33, Practical Laboratory Medicine. Elsevier B.V.; 2023.
12. Professor A, Vaghasiya K V. An analysis of quality indicators in hematology laboratory at tertiary care center. Keywords: Quality indicator, pre-analytical phase, analytical phase, post analytical phase. Available from: http://www.iso.
13. Alshaghdali K, Alcantara TY, Rezgui R, Cruz CP, Alshammary MH, Almotairi YA, *et al.*, Detecting Preanalytical Errors Using Quality Indicators in a Hematology Laboratory. Qual Manag Health Care. 2022 Jul 1;31(3):176–83.
14. Toshniwal P, Toshniwal P, Toshniwal S, Jasani J, Shah RM. Test requisition form-A check point in pre-analytical phase for laboratory errors. Toshniwal *et al.*, Asian Pacific Journal of Health Sciences [Internet]. 2017;4(2):175-82. Available from: www.apjhs.com
15. Manoharan K, Manoharan H, Sharma C. Evaluation of laboratory request forms submitted to clinical pathology department in tertiary health care hospital. Int J Res Med Sci. 2019 May 29;7(6):2399.
16. Chhillar N, Khurana S, Agarwal R, Singh NK. Effect of pre-analytical errors on quality of laboratory medicine at a neuropsychiatry institute in north India. Indian Journal of Clinical Biochemistry. 2011 Jan;26(1):46-9.
17. Gyawali P, Shrestha RK, Bhattarai P, Raut BK, Aryal M, Sundar Malla S. Evaluation of pre-analytical errors: Inadequacies in the completion of laboratory requisition forms [Internet]. Available from: https://www.researchgate.net/publication/235327299
18. Kouser S, Abbas FF, Huda NU, Pahore ZA, Khurram S, Qureshi H, *et al.*, Review of Key Performance Indicator in a Hematology Laboratory: A Preventable Source of Error. Journal of the Liaquat University of Medical and Health Sciences. 2023 Jan 1;22(1):44–9.
19. Pruthvi D. Assessing quality indicators in the HAE Matology laboratory. Int J Med Public Health [Internet]. 14. Available from: www.ijmedph.org
20. Kashyap A, Kaur G, Tripathi P, Sen A. Quality indicators in a hematology laboratory- a retrospective analysis. International Journal of Advances in Medicine. 2020 Oct 21;7(11):1682.
21. Ricó C, García-Victoria M, De La Fuente B. Quality indicators and specifications for the extra-analytical phases in clinical laboratory management. Vol. 42, Clin Chem Lab Med. 2004.
22. Sudarshan K, Das S, Hemalatha A, Raju K. Quality Audit of Haematology Laboratory: Challenges and Opportunities. Advances in Human Biology. 2023 May;13(1):S75–9.
23. Mary A Q, Das S, Chaudhary N, Raju K. Analysis of the Six Sigma Principle in Pre-analytical Quality for Hematological Specimens. Cureus. 2023 Jul 25.