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RESEARCH ARTICLE
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A STUDY ON BLOOD SAMPLE REJECTION AS A QUALITY INDICATOR FOR CONTINUAL IMPROVEMENT OF LABORATORY SERVICES IN A TERTIARY CARE TEACHING HOSPITAL IN BANGALORE.

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Abstract :
Background : In a diagnostic laboratory, there are 3 phases of analysis : Pre-analytical, Analytical and Post-analytical. Any Error in these phases can lead to erroneous results and it will compromise the patient management . To ensure that samples are suitable for testing sample rejection criterias are used as a quality indicator for prevention of invalid wrong results. In all the labs, precision, accuracy, and short turnaround time (TAT) are important in effective emergency laboratory services. Laboratory test results where pre analytical errors are there will cause repeat collections in patients and will delay the major clinical decisions. Identification of problem areas and continuous training of phlebotomy staff and ward nurses are important tools in reducing these errors.

Materials and method : Details of all rejected blood samples were recorded using the data sheets for each rejected samples from the Hematology, Biochemistry and Microbiology sections in the laboratory. Our lab has a defined policy for sample rejection based on a list of criteria identified by the lab for rejection.

Objective: 1. This study is done in order to analyse the sample rejection rates from each section of the laboratory including Hematology, Biochemistry and Microbiology according to the types of pre analytical errors.
2. To monitor the Sample Rejections rate as a Quality Indicator for Continual improvement of the Laboratory.
Result: Total of 230 Rejected Blood Samples were included in the study which were rejected during the period from 01/01/24 to 31/07/24 out of Total 58631 blood samples received. Clotted samples was most frequently rejected sample in hematology section (34%) followed by insufficient volume (6.5%) and hemolysed samples(3.9%). In Microbiology lab, most frequent rejection was due

to hemolysed sample(7.8%) followed by volume insufficiency in serology(3.4%) followed by leakage samples (0.8%). In Biochemical tests the most frequent rejection reasons were hemolysed samples (28%) and inadequate volume (9%).
Conclusion : The knowledge of nurses and technicians regarding sample collection in some aspects are needed. Continuing education and training programmes for the technicians and nurses to enhance the quality of blood sample collection and evaluation for the effectiveness is emphasized.
Taking preventive & corrective actions to reduce the sample rejection rate in daily practice definitely improves the quality of the laboratory results and is a quality indicator for continual improvement of the laboratory.

Keywords: Rejection rate, Pre analytical error, Hematology, Blood sample, Sample collection, Quality indicator.

Introduction :
It has been demonstrated by the specialists in laboratory that 70% of errors occur in the pre analytical phase which is an important component of laboratory medicine. The International Organization for Standardization (ISO) 15189:2022 standard for laboratory accreditation defines the pre analytical phase as **"**processes that start, in chronological order, from the clinician's request and include the examination request, preparation and identification of the patient, collection of the primary sample(s), and transportation to and within the laboratory, and end when the analytical examination begins" In our Central Diagnostic laboratory, we receive samples from Emergency departments (EDs), Inpatient services and Intensive care units (ICUs)and Various wards.

Materials and methods: This is a retrospective observational study done among all the blood samples presenting to our Central diagnostic lab, The Oxford medical college hospital and research centre, Bangalore**.** We routinely determine the common causes of sample rejections, conduct a root cause analysis to identify the problem areas and undertake corrective action in the form of training of relevant staff to minimize errors. This study was done from the period 1st January 2024 to 31st July 2024. During the study we analyzed the problem areas, namely wards from where rejections were more common compared to others and also the common causes of sample rejection. We receive samples from emergency departments (EDs), inpatient services, intensive care units (ICUs) and various wards. The root cause analysis was done and training sessions for the phlebotomy staff including nursing staff in the form of lectures are done on a regular basis. We also started sharing the ward wise analyzed data for sample rejection with the nurses during the training modules, helping the nurses better understand the problem areas for their wards and diligently act upon them. It also brought about a spirit of competition among the nurses to reduce the errors from their respective areas. The trainee pool consisted of mainly regular nursing staff; however, a part of the group was newly inducted nurses as and when required by the organization. The assessment is continued every year with the aim of reducing the errors.

Results and observation:
Total of 230 rejected blood samples were included in the study which were rejected during the period from 01/01/24 to 31/07/24 out of total 58631 blood samples received. Of the 230 rejected samples, 104, 98, 28 rejected samples were in Hematology, Biochemistry and Microbiology sections . Sample rejection ratios was 0.1% for Biochemistry tests, 0.1% for Hematology tests and 0.04% for Microbiology tests. In Biochemical tests the most frequent rejection reasons were hemolysed samples (28%) and inadequate volume (9%) .Clotted samples was most frequently rejected sample in hematology section (34%) followed by insufficient volume (6.5%) and hemolysed samples(3.9%).
In microbiology lab, most frequent rejection was due to hemolysed sample(7.8%) followed by volume insufficiency in serology(3.4%) and sample leakage(0.8%).

The comparison of sample rejections showed the wards and EMD(emergency department) as the areas contributing most to the sample rejection.
The highest number of rejections in 2024 were for hemolyzed samples (0.2%), followed by clotted samples (0.1%) and insufficient sample (0.04%).

Figure 1 : Total rejected samples and Total number of samples

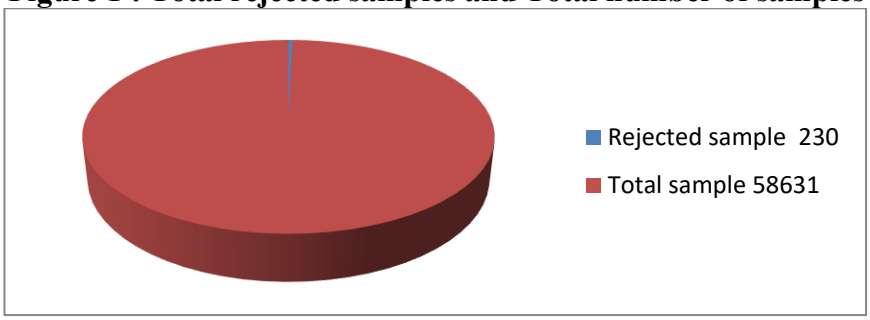


Figure 2 : Rejection from different sections of the hospital

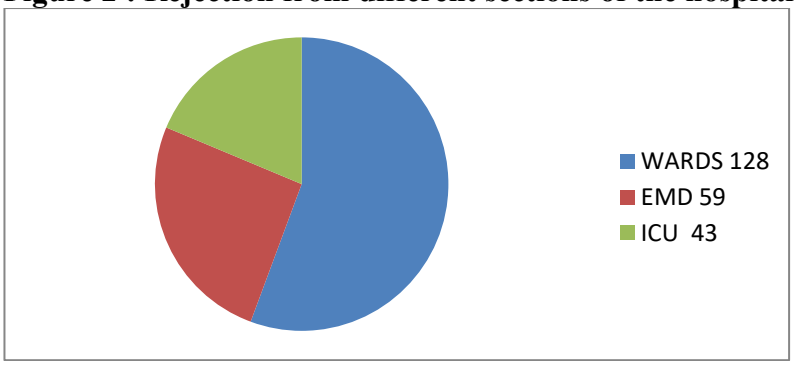


Figure 3: Causes of Sample rejections in the Central Lab

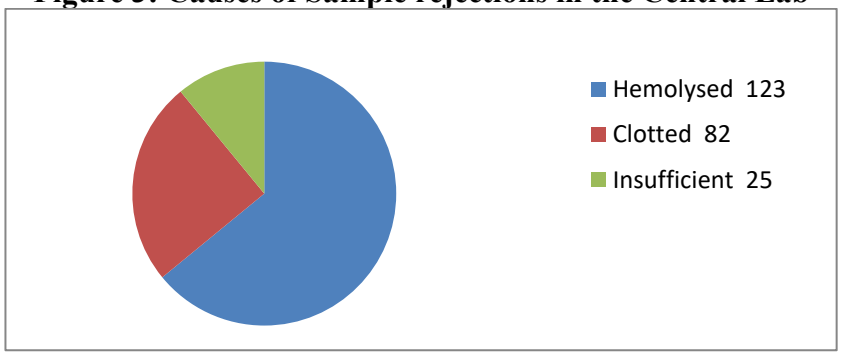


Figure 4: Causes of Sample rejections in Hematology lab

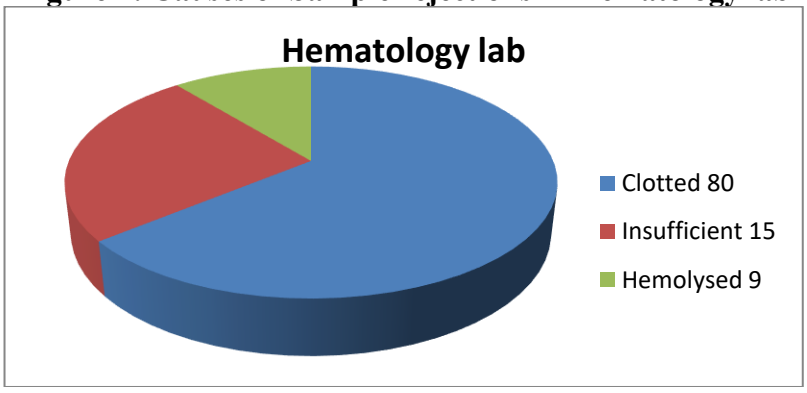


Figure 5 : Causes of Sample rejections in Biochemistry lab

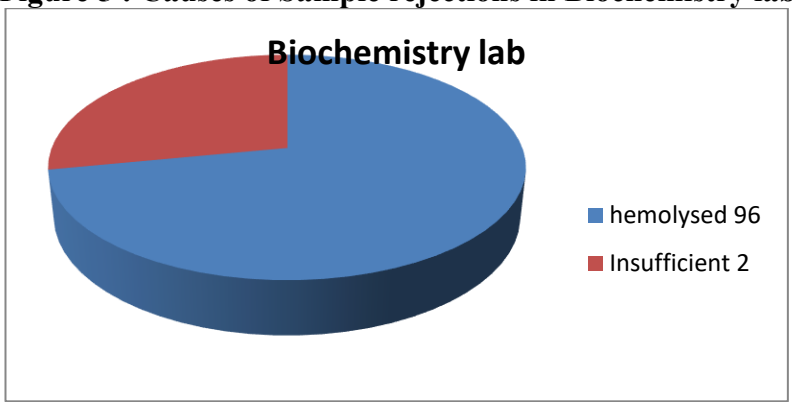
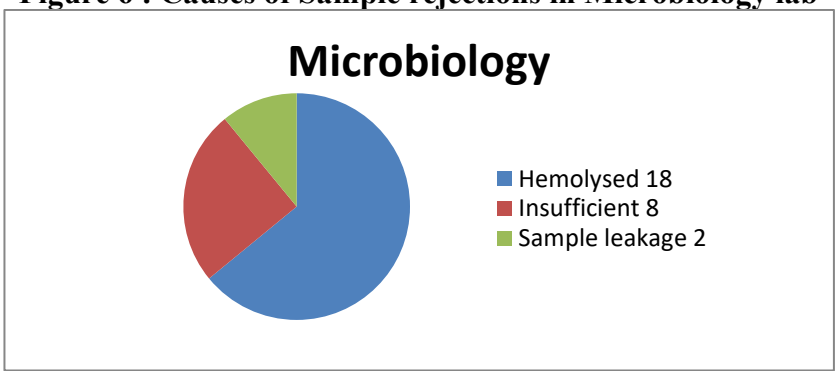


Figure 6 : Causes of Sample rejections in Microbiology lab



Discussion: A key role is played by the laboratory in treating a patient and the clinician's decision in the management of the disease. Pre analytical errors are most frequently caused by the absence of a sample and/or inappropriate understanding of a test request, mislabeling, contamination from the sampling site, hemolysed, clotted, insufficient samples, storage issues, and inappropriate blood to anticoagulant proportion or inappropriate choice of anticoagulant. [1]

In our study, Hemolysis was found to be the most frequent pre-analytical error resulting in 0.2% of the total rejection rates, similar results were reported by H L Vishwanath et al (2021)[2] and Bhutani N et al (2020) [3]

The laboratory has the right to refuse and reject samples that are incompletely, incorrectly labelled because of wrong methods of collection, storage and transportation for the sake of patient safety. Measures in the lab are taken in terms of training and sensitisation of lab personnel, medical and nursing staff and assess its effect on monitoring quality indicators as a part of NABL ISO 15189 criteria. To achieve this goal we assessed the frequency of rejection due to haemolysis/clotting of sample, inappropriateness of vial or insufficient quantity of sample received.

Over the period of 7 months from January2024 to July, 2024 0.39 % samples were rejected due to these causes, which was much was similar to (0.3%), Stark et al. [4]

In a similar article by Chavan PD et al, the net sample rejection rate done from 2012 to 2017 was found to be 0.36% [5] The result of any laboratory examination is only as good as the sample received in the laboratory. Some samples are time-dependent. In order for the laboratory departments to process them correctly, specimens must be collected/received within their time constraints to be accepted by the Laboratory. A study done by the American College of Pathologists has observed that the most common reason for errors in the pre analytical setting is human error at about 82.6% and technical errors at only 4.3%.[6]

The challenge for the laboratories is to reduce these errors and deliver quality results. To achieve this, it is imperative to reduce the human part of errors which is possible through training of the individuals involved in the pre analytical processes. It is also important to evaluate the efficacy of these training methods and other corrective measures periodically to assess the subsequent improvement.

Procedure for Laboratory Specimens Rejection followed in our Lab :

The laboratory staff notifies the phlebotomist or technician or the patient's attendants, tell them cause of rejection and request that the specimen is recollected. If necessary, the patient's attendants notify the technician for the need and importance to redraw of blood specimen. The phlebotomist/ lab technician or paramedical staff re-collects the blood specimen. The Laboratory holds the rejected specimen at the appropriate conditions and clearly labels the specimen as "rejected". Specimens may be discarded no sooner than 24 hours after receipt. [7, 8]

Sample rejection prevents sample analysis and leads to new sample request, which prolongs the TAT and cause the delay in diagnosis and treatment of critical patients, leading to adverse patient outcomes [9,10,11]

Unfortunately, it is not easy to standardize all of the pre analytical processes and there are still no universally accepted guidelines for management of unacceptable specimens [12]

Clotting is a major cause of samples rejection in our Hematology laboratory(34%). This result was comparable with a meta-analysis done at identifying the possible reasons of blood specimen rejection in clinical laboratory.

The probably reason might be due to poor mixing after blood collection[13].

Clotting produce low red cell counts (RBC), aberrant red cell indices, low hematocrit, low white cell counts, and platelet count. It also contributed to instrument probe aspiration and clogging, leading to service calls and downtime [14] which prolong TAT of the specimens processing and result reporting. Hemolysis was found to be the most frequent pre-analytical error resulting in 28% of the total rejection in Biochemical tests. Similar results were also found in a study by *Kaur P et al*[15] . The various causes for hemolysis are when venipuncture site is not allowed to dry app), lately (at least 30 sec) after cleaning the site by alcohol, using fine needle syringes, shaking of the vacutainers vigorously and centrifuging the sample specimen before clotting is complete.[16,17]

In Microbiology lab, most frequent rejection was due to hemolysed sample(7.8%) followed by volume insufficiency in serology(3.4%) and sample leakage(0.8%).

The various causes for hemolysis are when venipuncture site is not allowed to dry app), lately (at least 30 sec) after cleaning the site by alcohol, using fine needle syringes, shaking of the vacutainers vigorously and centrifuging the sample specimen before clotting is complete. Any phlebotomist, nurse or doctor should know the proper technique of phlebotomy to prevent hemolysis. Laboratory personnel must ask for new sample when hemolysis is detected.[18]

Training is one of the mainstays of interventions required to reduce errors at preanalytical stage as shown in various studies. [19, 20] The process of quality assurance is a continuous activity in laboratory practice. Continual training of the staff and regular audits are the keys to reducing preanalytical errors.

Conclusion: Common causes of sample rejection in our study were hemolyzed samples, clotted samples, followed by sample insufficiency which reduced considerably post intervention. Intervention in the form targeted training helps reduce errors and improves the quality of the results generated.

Reviewing and redesigning the process of training periodically with the aim of achieving maximum improvement and transfer of knowledge in the trainees would contribute to better clinical outcomes.

References :

1. Noor T, Imran A, Raza H, Umer S, Malik NA, Chughtai AS. An Overview of Complete Blood Count Sample Rejection Rates in a Clinical Hematology Laboratory Due to Various Pre analytical Errors. Cureus. 2023 Jan 31;15(1):e34444. doi: 10.7759/cureus.34444. PMID: 36874705; PMCID: PMC9979861.
2. Vishwanath HL, Vibha C, Krishna M, Sreeja Shanker J, A study of pre-analytical errors in the clinical biochemistry laboratory at Victoria hospital, BMCRI, Bangalore. Inbt J Clin Biochem Res. 2021;8(4):278-280.

3. Bhutani N, Bhutani N. An Analysis of Preanalytical Errors and Turnaround Time in Emergency Biochemistry Laboratory in a Tertiary Care Hospital in New Delhi. Journal of Evolution of Medical and Dental Sciences. 2020 Mar 30;9(13):1065-9.
4. Stark S, Jones BA, Chapman D, Well K, Krajenta R, Meier FA, Zarbo RJ. Clinical laboratory specimen rejection: association with the site of patient care and patients' characteristics. Arch Pathol Lab Med. 1997;121:19–26.
5. Chavan PD Bhat VG, Poladia PP, Tiwari MR, Naresh C. Reduction in sample rejections at the pre analytical phase – Impact of training in a tertiary care oncology center. J Lab Physicians 2019;11: 229-33.
6. Valenstein P, Meier F. Outpatient order accuracy. A collegeof American pathologists Q-probes study of requisition order entry accuracy in 660 institutions. Arch Pathol Lab Med 1999;123:1145-50.
7. Gupta V, Negi G., Harsh M., Chandra H., Agarwal A., Shrivastava V. Utility of sample rejection rate as a quality indicator in developing countries. The Journal of National Accreditation Board for Hospitals & Healthcare Providers. 2015;2(1):30.
8. Gaur K., Puri V., Shukla S., Sharma S., Suman S., Singh R. Finish before the start: analyzing preanalytical sample errors in a tertiary care hematology laboratory. Indian J. Pathol. Microbiol. 2020;63(3):435. [
9. Steindel SJ, Howanitz PJ. Physician satisfaction and emergency department laboratory test turnaround time. Arch Pathol Lab Med. 2001;125:863–71
10. Manor PG. Turnaround time in the laboratory: a review of the literature. Clin Lab Sci. 1999; 12:85–9.
11. Valenstein PN. Pre-analytic delays as a component of test turnaround time. Lab Med. 1990;21:448–51.
12. Simundic AM, Lippi G. Preanalytical phase – a continuous challenge for laboratory professionals. Biochem Med (Zagreb). 2012;22:145–9.
13. A.P. Goswami, S.S. Roy, N.N. Goswami. Evaluation of specimen rejection rate in Haematology Laboratory J Dent Med Sci, 13 (9) (2014), pp. 1-4.
14. N. Baumann QC notes at each phase of the analytical process are explored Adv. Adm. Lab., 20 (2011), pp. 37-41
15. Kaur P et al. Analysis of Rejection rates in a Clinical Biochemistry Laboratory in a Tertiary Care Hospital in Bathinda. APMC Vol. 18 No. 2 April – June 2024
16. Sushma B, Shrikant C. Study on "pre-analytical errors in a clinical biochemistry laboratory": the hidden flaws in total testing. Biochem. Anal. Biochem. 2019;8(374) 2161-1009.
17. Panchbudhe S, Kumar S. Contribution to Lab errors as a healthcare Professional. Journal of Pharmaceutical Research International. 2021 Jul 3;33(34B):242-8.
18. Faghih MM, Sharp MK. Modeling and prediction of flow-induced hemolysis: a review. Biomechanics and modeling in mechanobiology. 2019 Aug 15;18: 845-81.
19. Bhat V, Tiwari M, Chavan P, Kelkar R. Analysis of laboratory sample rejections in the pre-analytical stage at an oncology center. Clin Chim Acta 2012;413:1203-6.
20. Romero A, Cobos A, Gómez J, Muñoz M. Role of training activities for the reduction of pre-analytical errors in laboratory samples from primary care. Clin Chim Acta 2012;413:166-9.