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Key Words
IAT-indirect antihuman globulin test, DAT-direct anti human globulin Test, CDC-center for disease control, LIS- laboratory information system, HIS-hospital information system. QNS-quantity Not Sufficient, RICU -recovery intensive care unit

Corresponding Author
Melvin Mathew,
Department of IHBT DY Patil Medical College, Navi Mumbai
melvinmathew1393@gmail.com

Author Designation
[1]Associate Professor
[2]Professor and HOD
[3-5]Junior Resident
[6]Professor

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A Retrospective Analysis of Rejection of Blood Samples and Its Impact on Blood Transfusion Services as a Part of Haemovigilance Programme in a Tertiary Health Care Centre

[1]Prasad P. Kulkarni, [2]Seema A. Gupta, [3]Gaurav Kumar, [4]Melvin Mathew, [5]Masum Reza and [6]Vaishali Thakare
[1,2]Department of IHBT Dr DY Patil Medical College, Navi Mumbai
[3,4]Department of IHBT DY Patil Medical College, Navi Mumbai
[5,6]Department of Pharmacology, DY Patil Medical College, Navi Mumbai

Abstract
The integrity of the sample received is very crucial for optimum results in laboratory tests. Dr. D.Y. Patil Hospital Department of Immunohematology and Blood Transfusion receives samples for various tests like compatibility tests and cross matching, ICT, DCT etc. for which, if sample received is not as per acceptance criteria i.e. adequacy, without hemolyzed EDTA and incomplete test requisition forms (CDC sample collection criteria SC00-SC11). We analyzed our data from February 2022 to July 2023 in which 10401 samples were received out of which 211 (2.02%) were rejected due to compromised integrity and incomplete documentation of Test Requisition Form (TRF). The CDC haemovigilance incident code is classified as SC00 to SC11. The leading causes were Form discrepancy (FD) (38.38%), not labeled other than name samples -SC02(28.43%) and Incorrect labeled sample-SC07(21.80%). The Clinical Departments with high rejection rates were Obstetrics and Gynecology (54/ 211 i.e. 25.59%) Surgery (47/211 i.e. 22.27%) Medicine (35/211 i.e. 16.58%) Pediatrics (27/211 i.e. 12.79%) Orthopedics (27/211 i.e. 12.79%). This led to compromised integrity as well as documentation delay in testing as well as issuing right components for transfusion.

INTRODUCTION

In the context of a tertiary health care center, blood transfusion services are a critical component of patient care. Ensuring safe and efficient transfusion services are paramount for maintaining effective patient blood management. However, even with stringent protocols in place, errors in the collection of blood samples can occur, leading to erroneous results in the blood testing process. These pre-analytic errors might include mislabeling, improper sample handling, or insufficient sample volume[11]. Such deviations can lead to the rejection of blood samples, necessitating repeat in collection and documentation result in significant delays in the transfusion services as well as improper utilization of available logistics.

Furthermore, repeated collection of samples can place an unnecessary loss of blood in patients especially critically ill and pediatric cases where margin of loss is considerable. In critically ill patients there is the possibility of poor venous access due to multiple intravenous lines or in case of shock, sample collection becomes very difficult. More to this anxiety of the patients and relatives about repeat collection requires more counselling as they may question about quality of patient care. Thus, the need for a thorough retrospective analysis of rejection samples becomes apparent.

This analysis seeks to identify the root causes of collection errors in accordance with NHSN Haemovigilance Module incident codes given in CDC guidelines and their broader impact on the efficiency and safety of blood transfusion services[10]. By understanding the underlying issues, healthcare institutions can implement corrective measures, enhance staff training, and improve standard operating procedures, ultimately ensuring the integrity and quality of transfusion services. This study highlights the paramount importance of error analysis in blood transfusion services, with the goal of enhancing patient safety, expediting healthcare delivery and optimizing the allocation of healthcare resources. There is no standard method to set the target rejection rate[1].

Aims of the Study: To analyze the total number of sample rejections with respect to various departments/ wards of hospital.

- To analyze various reasons for rejection of samples
- To assess impact of rejection of sample in patient care
- To recommend policy changes so as to minimize sample rejections and improve blood transfusion services

MATERIAL AND METHODS

A Retrospective study was conducted in Dr. D.Y. Patil Hospital and Research Center Nerul Navi Mumbai, which functions as a tertiary care center. The hospital offers 1260 bedded as well as state of art ICUs and operation theatres. Our Immunohematology department offers serological testing services as well as providing blood components round the clock. We analyzed the samples received in the Immunohematology Department over a period of 18 months i.e. from 1st February 2022 to 31st July 2023 for various serological tests like pre-transfusion compatibility tests, ICT, DCT, Rh titer, extended phenotyping, antibody identification. All data entered in excel sheet format and analyzed. We received ethical clearance from our institutional ethical committee for this study. A total of 10401 samples were received within the study period, out of which 211 samples were rejected. The data was collected from the rejection sample register of our department. The medical lab technician followed specific guidelines according to CDC criteria to accept samples received for testing from different clinical departments. Inclusion criteria: All IPD samples received for various serological tests in the Dept. Exclusion criteria:1. OPD samples 2. Samples received from outside hospitals.

RESULTS AND DISCUSSIONS

As per NHSN Hemovigilance Module incident codes given in CDC guidelines10 SC00 Details not specified, SC01 Sample labeled with incorrect patient name, SC02 Sample not labeled, SC03 Wrong patient sample collected, SC04 Collected in wrong tube type, SC05 Sample QNS, SC06 Hemolyzed Sample, SC07 Label incorrect other than name, SC08 Sample collected in error, SC09 Requisition arrived without samples, SC10 Wrist band incorrect/not available, SC11 Sample Contaminated , FD-Form discrepancy (code for documentation errors in the requisition form termed by our department).

In a study conducted by Kamal *et al.*[1], rejection of blood samples in hematology and transfusion medicine were included. Relevant data from the transfusion medicine department is taken into consideration exclusively for comparison. Even though total number of rejection of samples in present study is more [211] than the those of Kamal *et al.*[2][176], our sample size in relatively more [10401] and overall percentage of rejection is quite less [2.02%]. We could not get any other similar research articles after extensive web search. The benchmark for rejected samples in blood centers is not defined universally. The limit varies in different institutes.

Analysis revealed that sample rejection rate in present study is 2.02% from the data collected from 1stFebruary 2022-31thJuly 2023. One significant observation was the high prevalence of form discrepancy [81 i.e. 38.38%] as a cause for rejection. Not labelled sample SC02 (FD) [60 i.e. 28.43%] and Incorrect label other than name, SC07[46 i.e. 21.80%] were other common reasons for the rejection. This

highlights the critical need for enhanced education and training of healthcare professionals involved in the collection and handling of blood samples.

Not labeled [28.43%] emerged as another prominent cause of rejection. Incomplete labeled samples can lead to wrong identification, compromising the integrity of the entire blood transfusion process. Implementation of bar code systems and electronic data entry may also resolve this issue, reducing the likelihood of errors and authenticity of sample identification process. Implementing Laboratory Information System (LIS)[2] software and Hospital management information system (HIS)[3] significantly mitigates rejected blood samples. This advanced system integrates bar-code technology; automating data entry minimizes human error in sample collection and labeling. Real-time communication between hospital staff and blood transfusion service providers enhances patient identification accuracy, reducing rejection incidents. The LIS serves as a centralized platform for seamless record-keeping, minimizing inadequate labeling. Its analytical capabilities enable trend identification and targeted intervention implementation, ensuring a streamlined, error-resistant blood transfusion process that ultimately improves patient safety and healthcare efficiency.

In a comparative study conducted by Kamal *et al.*[1] observed this13.9 % hemolyzed sample against present study as 2.3%. Hemolysis is defined as the rupture of erythrocytes resulting in the release of its intracellular components in plasma or serum. Azman *et al.*[4] states in vitro hemolysis is a result of per-analytical causes associated with sample collection, jarring transportation, extreme temperatures, improper sample handling, delayed processing and prolonged storage. During phlebotomy it may be caused by incorrect needle size, improper tube mixing and incorrect filling of tubes, excessive suction, prolonged tourniquet and difficult collection. Hemolysis may occur from the point of venipuncture and then continue downstream of the process up to the time of analysis. Another study conducted by Kennedy et al5 observed that hemolysis of blood samples obtained by an i.v. catheter was significantly higher than when blood was obtained through vacutainer venipuncture and there was an inverse correlation between i.v. catheter diameter and the rate of hemolysis Best Practices to prevent Hemolysis6 includes:(a)Use of correct needle size for blood collection [20-22 gauge] (b)Avoid using butterfly needles, unless specifically requested by patient. (c)Warm up the venipuncture site to increase blood flow. (d)Allow disinfectant on venipuncture site to dry completely. (e) Collect blood sample in the correct blood collection tube. (f)Collect the correct volume for the tube size. Use smaller tubes for difficult draws. (g)Centrifuge samples for serum separation within 4 hours of sample collection.(h)If tests are to be performed within 48 hours of collection, transfer serum to a sample tube (cryovial) and store at 4°C.(i)If tests will be performed more than 48 hours after collection, aliquot samples and store at -20°C or lower. Kamal, *et al.*[1] observed that rejected blood samples have tangible consequences for patient care. One of the primary consequences of rejected blood samples is the potential delay in treatments for patients awaiting transfusions. When a blood sample is rejected, it initiates a chain of events that involves the need for recollection, relabeling, transportation and submission to blood transfusion center.

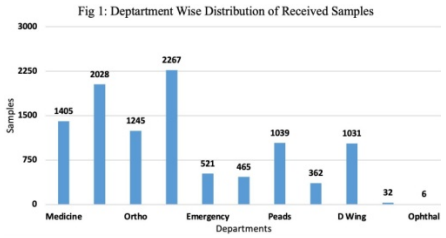

Fig. 1: Samples received from Dept of Obstetrics and Gynecology (2267) are the maximum followed by Surgery (2028) Medicine (1405) Orthopedics (1245)

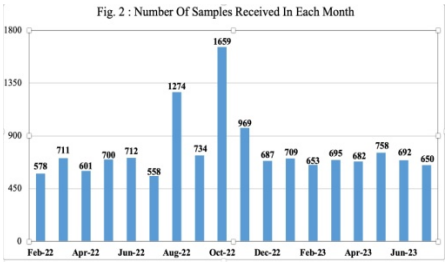

Fig. 2: Total samples received are maximum in October 22 (1659) followed by August 22 (1274), November 22 (969)

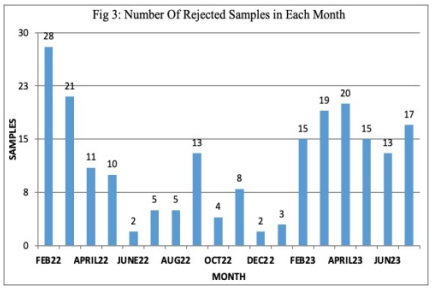

Fig. 3: Total number of rejections is maximum in Feb 22 (28) followed by March 22 (21), April 23(20)

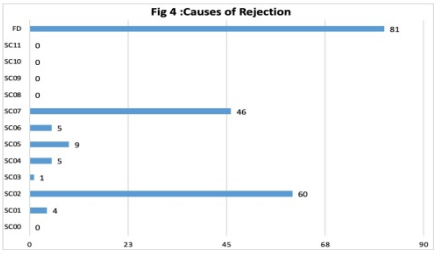

Fig. 4: Most common reason of rejection of sample was Form Discrepancy (FD*)-81 followed by Not labeled- 60 and incorrect label other than name-46

Table. 1: Comparison with other study

Parameters	Criteria	Study of Kamal *et al.*	Present study
1	Duration Of Study	22 Months	18 Months
2	Total samples received	3082	10401
3	Total sample rejected	176	211
4	Leading cause of rejection	Hemolyzed (38)	Not Labelled (65)
5	Overall Percentage of rejection	5.71	2.02
6	Department with highest rejection	Ward	Obstetrics and Gynecology

Table no.2: Overall percentage of rejection 2.02%. Maximum percentage of rejection for individual department received from Medicine (2.49%). The highest individual department rejection ratio was from OBGY (0.25).

CODE/DEPT	MED	SUR	ORTHO	OB/GY	EMG	CVTS	PEDS	D-WING	TOTAL
SC00	0	0	0	0	0	0	0	0	0
SC01	1	1	0	1	0	0	1	0	4
SC02	13	13	8	15	4	3	2	2	60
SC03	0	0	0	0	1	0	0	0	1
SC04	1	1	0	1	1	0	1	0	5
SC05	1	3	0	0	1	0	4	0	9
SC06	3	0	2	0	0	0	0	0	5
SC07	9	7	9	9	2	1	8	1	46
SC08	0	0	0	0	0	0	0	0	0
SC09	0	0	0	0	0	0	0	0	0
SC10	0	0	0	0	0	0	0	0	0
SC11	0	0	0	0	0	0	0	0	0
FD*	7	22	8	28	1	3	11	1	81
% of rejection	2.49	1.96	2.16	2.38	1.9	1.5	2.5	0.38	2.02
Ratio of rejection	0.16	0.22	0.12	0.25	0.04	0.03	0.12	0.01	__
Dept Total Rejected	35	47	27	54	10	7	27	4	211
Total sample Received	1405	2390	1245	2267	521	465	1039	103	10401

Table 3: Calculations:

	Formula for calculations
Overall Percentage of rejection	Total no. of rejected samples x 100/Total no. of samples received
Percentage of rejection for individual department	Total no. of rejected samples from the department x 100/Total no. of samples received from that department
Individual department rejection ratio	Total no. of rejected samples from the department/Total no. of

This delay can be critical for patients with conditions requiring immediate transfusions, such as those undergoing surgery, trauma victims, or individuals with severe anemia. The time-sensitive nature of medical interventions means that any delay in providing compatible blood products may result in adverse outcomes for patients. With reference to the impact on pediatric patients[7] i.e. newborns and infants have a smaller blood volume compared to adults, making each blood sample crucial for pre-transfusion testing. Rejected samples can potentially lead to increased stress and discomfort for pediatric patients, causing anxiety in parents and relatives. It is a difficult task for hospital staff to counsel the patients and relatives at time of blood collection for various lab tests. Critically ill Patients[8] admitted in ICU or undergoing emergency surgeries, may require immediate access to blood products. Rejected samples can cause delays, potentially impacting on the timely availability of compatible blood and increasing the risk of complications in critically ill individuals. This delay may lead to clinical deterioration, complicating the overall management of the patient and potentially affecting their long-term prognosis due to difficult venous access that could lead to hypovolemic shock and repeat phlebotomy causing pain and other complications.

When a blood sample collection results in a QNS, it can significantly impact patient care. This occurrence may lead to delayed diagnosis, treatment, or monitoring due to the inability to perform necessary tests accurately. In a study conducted by Lippi *et al.*[9] 11% of their rejected sample were due to insufficient volume whereas our study encountered 4.2%. The sufficiency of the sample is decided by the requirement of the number of tests and units required. However, in case of newborn transfusions and critically ill patients it is difficult to withdraw even smaller volumes. Insufficient sample volume may require repeat collection. Improved techniques and proper training can mitigate QNS issues. Beyond the pain due to needle puncture, the rejection of blood samples may induce anxiety and stress, particularly if the patient is already suffering with a serious medical condition. Patients may perceive rejection as a barrier to receiving timely and necessary treatments, leading to more emotional distress. Reducing the rejection rate not only improves patient care but also contributes to the quality of the health care system. Furthermore, the financial implications of sample rejection should be considered. The resources invested in recollection result in additional burden for the organization as well as biomedical waste would be more although not very significant. Addressing the root causes of rejection not only enhances patient care but also optimizes resource utilization and simplifies blood center operations. As per (fig. 3) in the present study for initial phase i.e. February 22 the highest number of rejected samples observed followed by decline for some period however this trend is not continued and there are more rejections in the latter part study period. A meticulous

training program for healthcare professionals involved in phlebotomy is imperative for ensuring optimum quality of blood collection and the efficiency of the blood transfusion services. By addressing the issues of sample collection, emphasizing best practices in labeling and fostering interdisciplinary collaboration, this initiative aims to significantly reduce errors. Through interactive workshops, continuous education and regular assessments to the staff nurses, lab technicians, interns and resident doctors at periodical interval scan acquire the necessary skills to uphold the highest standards in blood collection. As ours is a teaching institute associated multi-specialty hospital, there are new appointments for healthcare staff so training sessions dedicated to sample collection and its importance to avoid pre analytical errors should be included in induction program.

CONCLUSION

- Identifying the root causes of rejection of samples is important in improving blood transfusion services
- Root cause analysis of each incidence followed by corrective and preventive actions should be a continuous process to curtail sample rejection
- Continuous training for best practices of blood collection should be a part of the training programme
- Implementation of laboratory system and hospital information system is way out to avoid documentation errors
- Communication between clinical departments availing transfusion services and blood center staff is of utmost importance to avoid errors in urgent and timely issue of blood

Conflict of Interest: No conflict of interests.

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