ASSESSING THE MAJOR PRE-ANALYTICAL REJECTION REASONS OF SAMPLES COMING IN LABORATORY AT MEDANTA-THE MEDICITY HOSPITAL, GURUGRAM, INDIA

Dissertation Submitted to

The IIHMR University, Jaipur

for the partial fulfillment for the award of the degree of

Master of Business Administration (MBA)

in

Hospital and Health Management

by

Mahima Pahwa

Under the Supervision and Guidance of

Dr. Seema Mehta

2025

Global Health
Limited

Date: 12.06.2025

TO WHOMSOEVER IT MAY CONCERN

This is to certify that **Dr. Mahima Pahwa (Emp.ID-00063956)** is engaged with **Global Health Ltd (GHL), Medanta - The Medicity** since 17.03.2025 till date. She is working as **Trainee - Medical Administration & Clinical Operations** at the below address:

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CERTIFICATE

This is to certify that dissertation titled "**Assessing the major Pre-analytical rejection reasons of samples coming in laboratory at Medanta- The Medicity Hospital, Gurugram, India**" is a record of the research work undertaken by Dr. Mahima Pahwa in partial fulfillment of the requirements for the award of the degree of MBA Hospital and Health Management from the IIHMR University, Jaipur under my guidance and supervision and her approach to the research study has been sincere, scientific, and analytical.

Dr. Seema Mehta

IIHMR University, Jaipur

Date- 16th June, 2025

Dr. Sanjay Gupta

IIHMR University, Jaipur

Date- 16th June, 2025

DECLARATION BY STUDENT

I hereby declare that this dissertation titled "Assessing the Major Pre-Analytical Rejection Reasons of Samples coming in Laboratory at Medanta-The Medicity Hospital, Gurugram, India" is the bonafide record of my original research work. I declare that it has not been submitted by any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

Mahima

(Signature)

Mahima Pahwa

Date: 16th June, 2025

ASSESSING THE MAJOR PRE-ANALYTICAL REJECTION REASONS OF SAMPLES COMING IN LABORATORY AT MEDANTA-THE MEDICITY HOSPITAL, GURUGRAM, INDIA.

Abstract

Introduction

The quality of laboratory testing is foundational to accurate diagnosis, effective treatment, and overall patient care. Among the three phases of laboratory workflow—pre-analytical, analytical, and post-analytical—the pre-analytical phase is often the most error-prone, accounting for most laboratory-related mistakes. This phase includes critical steps such as test requisition, sample collection, labelling, transport, and storage. Despite having standard operating procedures (SOPs) in place and access to modern infrastructure, pre-analytical errors remain a persistent challenge in high-volume healthcare institution like Medanta Hospital. These errors not only result in sample rejection but also delay diagnosis, increase patient discomfort, raise operational costs, and affect clinical outcomes.

Objective

This study aims to assess the major pre-analytical causes of sample rejection in the laboratory of Medanta over a one-year period (April 2024 to March 2025). The specific objectives include:

1. To identify the primary reasons for sample rejection.
2. To evaluate monthly trends in sample rejection.
3. To compare rejection reasons across patient categories—In-Patient Department (IPD) and Out-Patient Department (OPD).
4. To analyse rejection frequencies within the departments of laboratory.

Methodology

The study is retrospective in nature as it is based on secondary data retrieved from the Laboratory Management Information System (LMIS). Rejection records are analysed by patient class, major reasons for rejection, hospital location, and department to access the frequency and trend patterns.

Key Results

Haemolysis emerges as the leading cause of rejection (32.55%), followed by clotting, incorrect order placement, and duplicate orders. The IPD accounts for the highest rejection rates, especially from specific ICUs and higher floors (11th, 12th, and 14th). Biochemistry reports a continuous rise in haemolysed samples throughout the year, whereas These trends reflect consistent inefficiencies in sample handling and collection practices. In the department of haematology records majorly clotting-related rejections. Common root causes include prolonged tourniquet use, inadequate sample inversion, use of open syringes, lack of adherence to standard operating protocols, transport delays or careless transportation, and incorrect LMIS entries.

Discussion

Pre- analytical errors often stem from practical execution gaps, insufficient retraining, and absence of accountability mechanisms. A root cause analysis using the Ishikawa (fishbone) diagram categorises these factors into domains such as Manpower, Methods, Materials, Measurement, and Environment. Literature supports that such errors are common in high-volume labs and underscores the need for structured quality interventions. The study highlights the absence of real-time dashboards, underutilisation of quality tools like Failure Mode and Effects Analysis (FMEA) and Pareto analysis, and lack of periodic hands-on staff training. A notable spike in haemolysis cases during March 2025 suggests system-level inefficiencies requiring urgent attention.

Conclusion:

Pre-analytical sample rejection remains a major challenge at Medanta- the Medicity hospital, primarily due to modifiable human and operational factors. Implementing structured, department-specific training programs, establishing real-time rejection dashboards, standardising sample collection tools, and improving transport protocols can significantly reduce rejection rates. Creating a culture of non-punitive error reporting and integrating quality tools into routine workflows enhance diagnostic accuracy, operational efficiency, and patient safety. These improvements not only elevate laboratory performance but also contribute to better healthcare delivery across the hospital.

Keywords:

Pre-analytical errors, sample rejection, haemolysis, clotting, laboratory quality, LMIS, diagnostic accuracy, patient safety, quality improvement, healthcare operations.

ACKNOWLEDGEMENT

My sincere thanks go out to Dr. Sanjay Durani, Medical Superintendent, Medanta- the Medicity Hospital, Gurugram, and Dr. Nupur Garg, Deputy Medical Superintendent, Medical Administration and Clinical Operations Department, Medanta- the Medicity Hospital, Gurugram, who gave me all the support and direction I needed to finish my training.

I am indebted to Mr. Sushil Rana, Head of Diagnostics, Medical Administration & Clinical Operations Department, Medanta- the Medicity Hospital, Gurugram, for his unwavering commitment to providing me with comprehensive guidance throughout the execution of my training assignments.

The departments of Laboratory, i.e. Haematology, Biochemistry, Microbiology, Histopathology and Cytopathology, Infection Control Department, Blood Bank, Department of Sample Collection are also acknowledged for their willing assistance, generosity, and cooperation in helping me finish my training.

I am appreciative to the Honourable President Sir, Dr. P.R. Sodani, the Dean, Dr. Sanjay Gupta, Mr. Vinod Tejwani, the Dean of Placement and Alumni Relations, and Dr. Seema Mehta, my university's mentor, for providing me with the opportunity to work in this esteemed hospital and for integrating me into IIHMR University. I sincerely appreciate your encouragement and prompt assistance which have always illuminated my path.

I am incredibly appreciative of my family's cooperation, moral support, and unwavering encouragement in getting this study accomplished.

Place: Medanta- the Medicity Hospital, Gurugram

Date:

Dr. Mahima Pahwa

CONTENT

Abbreviations

SOPs	Standard Operating Procedures
LMIS	Laboratory Management Information System
IPD	In-Patient Department
OPD	Out-Patient Department
ICU	Intensive Care Unit
FMEA	Failure Mode and Effects Analysis
Qmatic	Queue Management Automatic Ticketing System
UHID	Unique Health Identification
IPSG	International Patient Safety Goals
GDA	General Duty Assistant
TAT	Turnaround Time
RCA	Root Cause Analysis
PDCA	Plan-Do-Check-Act
EDTA	Ethylenediaminetetraacetic Acid

List of Figures and Graphs

About Medanta-The Medicity Hospital

After seeing the difficulties experienced by Indian patients who could not afford to travel outside for treatment, Dr Naresh Trehan saw the need for an advanced super-specialty medical institution in India. He understood the significance of offering excellent affordable access to modern technology, healthcare, and a blend of modern and traditional Indian medical techniques. Under the visionary leadership of Dr Naresh Trehan and alongside the unwavering commitment to achieving the purpose, this vision became the foundation for Medanta, which is today India's top private hospital.

Medanta's Mission and Vision:

Mission

Our mission is to deliver world class, patient-centric, integrated, and affordable healthcare through a dynamic institution that focuses on the development of people and knowledge.

Vision & Values

The institute is governed under the guiding principles of providing affordable medical services to patients with care, compassion and commitment.

Core values of Medanta:

- **Patient Centric Care:** Encourage an environment in which everyone is dedicated to providing care for patients and their caregivers.
- **Leadership & Quality:** By performing and behaving outstanding, we pledge to deliver excellence in everything we do.
- **Integrity & Courage:** Respect the highest moral standards by prioritizing the patient and possessing the fortitude to act morally.
- **Collaboration, Learning & Innovation:** Foster a culture of teamwork and collaboration, embrace change and creativity, and foster innovation.

Specialties Offered:

- Institute of Musculoskeletal Disorders and Orthopaedics
- Cancer Institute
    - Breast Cancer
    - Head and Neck Oncology
    - Medical and Haematoma Oncology
    - Radiation Oncology

- Institute of Critical Care and Anaesthesiology
- Institute of Digestive and Hepatobiliary Sciences
    - Gastroenterology
    - GI Surgery, GI Oncology, and Bariatric Surgery
- Institute of Chest Surgery-Chest Onco Surgery and Lung Transplantation
- Heart Hospital
    - Clinical and Preventive Cardiology
    - Cardiac Surgery
    - Electrophysiology and Pacing
    - Interventional Cardiology
- Kidney and Urology Institute
    - Nephrology
    - Urology and Andrology
- Institute of Liver Transplantation and Regenerative Medicine
- Institute of Neurosciences
- Ayurvedic Medicine
- Clinical Immunology and Rheumatology
- Dental Sciences
- Dermatology
- Emergency and Trauma Care
- Endocrinology and Diabetology
- Gynaecology and Gynae Oncology
- Internal Medicine
- ENT, Head & Neck Surgery Hospital
- Department of Pathology and Laboratory Medicine
    - Pathology and Blood Bank
- Ophthalmology
- Paediatrics
- Peripheral Vascular and Endovascular Sciences
- Radiology and Imaging
- Respiratory and Sleep Medicine
- Plastic, Aesthetic and Reconstructive Surgery

Facilities and Services offered:

- Emergency & Trauma Care
- Critical Care Units
- Lab Tests & Diagnostics
- Wards & Rooms
- eCLINIC-Telemedicine Services
- Day Care
- Home Sample Collection
- Patient Support Services
- Homecare Services
- Medicine Delivery

Medanta Labs

At Medanta Labs, there is set standard for precision in diagnostics. It's world-class lab facilities, accredited by the JCI and the NABL, reflect the commitment to excellence, employing state-of-the-art imaging and fully automated systems to deliver real-time, reliable results. It has expansive network brings world-class diagnostic services directly to people, making advanced care accessible wherever the patient is. Highly qualified doctors provide expert interpretations that guide accurate, life-saving diagnosis and personalized treatments. Medanta has 250+ collection centres, across India. With Medanta Labs, where any patient can begin their healthcare journey with confidence, knowing that Medanta's diagnostics are not just comprehensive but correct- "Medanta hai to sahi hai".

Chapter 1: Introduction

1.1 Background and Rationale

In the ever-evolving landscape of modern healthcare, the role of diagnostic laboratories is more critical than ever. From routine blood tests to complex molecular diagnostics, laboratories serve as the silent engines that power timely and accurate patient care. With advancements in medicine and increasing demand for evidence-based care, laboratory investigations have become indispensable tools that guide physicians in diagnosing conditions, monitoring therapeutic responses, and making well-informed clinical decisions. Behind every accurate diagnosis lies a crucial, yet often overlooked, phases/steps that takes place in a laboratory: the pre- analytical handling of clinical samples before testing begins, analytical phase where processing of sample takes place and post- analytical where reports are made and decision is taken by the physician based on that report.

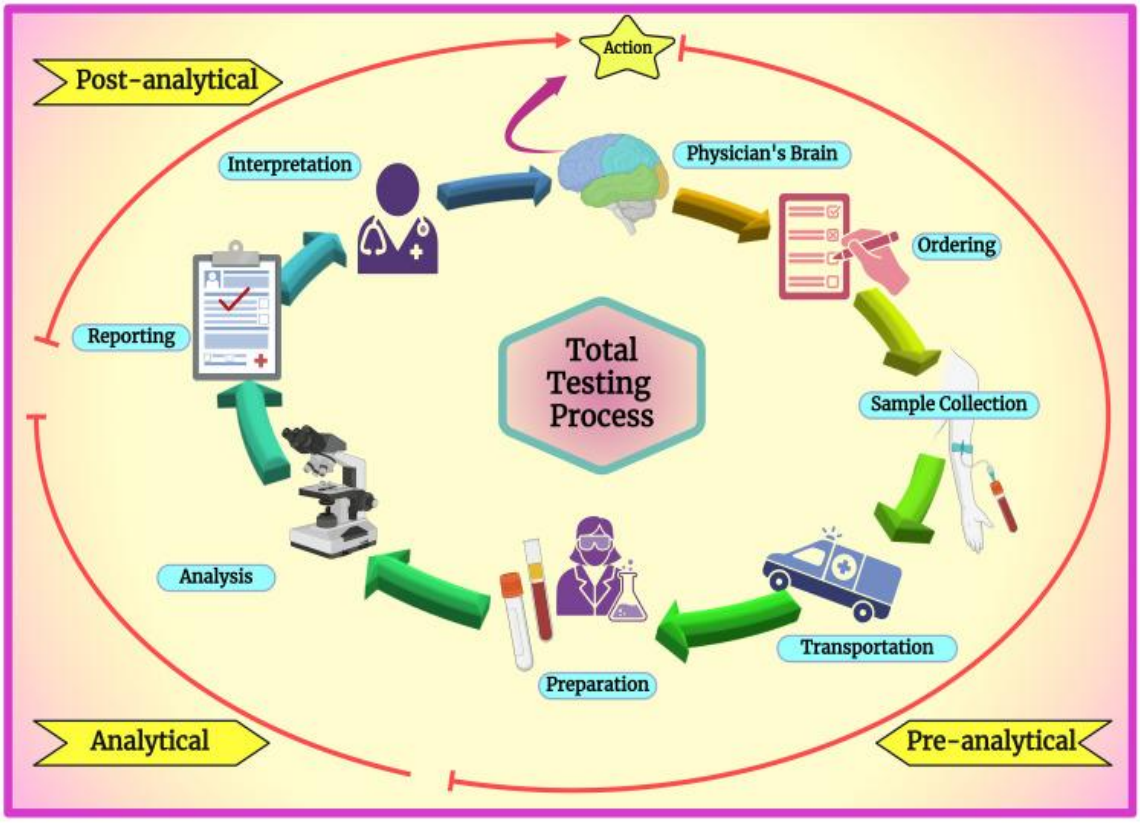


Figure 1.1: Schematic diagram showing the total testing process.
(image source- https://pmc.ncbi.nlm.nih.gov/articles/PMC10981510/)

In present-time healthcare, where speed and precision can determine outcomes, even a minor error in the early stages of laboratory processing can have serious consequences.

The reliability of laboratory test results does not rest solely on the sophistication of testing equipment or the expertise of laboratory personnel. Instead, it is largely influenced by the very first stage of the testing process—the pre-analytical phase that covers a wide range of activities that occur before the actual analysis begins, including test requisition, patient preparation, sample collection, labelling, transportation, and storage, everything from sample collection to its arrival in the lab. This phase is the most vulnerable part of the diagnostic chain and often the most neglected.

At Medanta – The Medicity, one of India's largest and busiest quaternary care super-specialty hospital in Gurugram, over two million diagnostic samples pass through the laboratory annually through its state-of-the-art central laboratory.

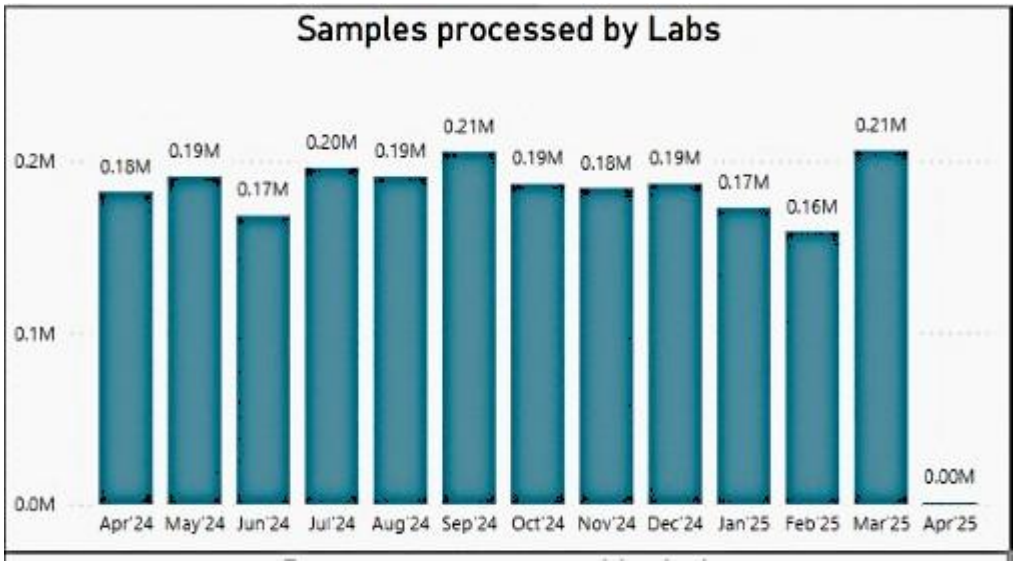


Figure 1.2: Diagram showing the total sample testing done by laboratory in last financial year (image source- Medanta – the Medicity Hospital)

In this high-volume hospital settings with such a massive testing load, the consequences of such errors are amplified that translates into thousands of rejected samples in a year. Each rejected sample signifies a breakdown in the diagnostic workflow—one that may delay treatment, increase the risk of clinical misjudgement, repeat the procedure, additional costs and reduce overall patient safety & satisfaction. These rejections often arise from avoidable errors such as haemolysis, clotting, insufficient volume, or contamination—errors that could be prevented with the right systems and awareness in place.

Globally, studies have shown that majority of lab errors occur during the pre-analytical phase. What makes the pre-analytical phase particularly challenging is its dependence on

multiple stakeholders—including doctors, nurses, phlebotomists, transport staff, and laboratory technicians. These individuals operate across various departments, often under tight timelines and high pressure. This stage involves multiple human touchpoints that's why standardizing it is a challenge.

In a fast-paced hospital like Medanta, where every second matters, reducing these errors is not just a quality improvement—it's a clinical necessity but despite the hospital's focus on quality and efficiency, the complexity of coordinating between various departments, varying levels of staff experience, and the pressure of high patient loads makes the pre-analytical phase particularly vulnerable. These errors are not technical faults within the laboratory itself but stem from systemic issues, often beyond the direct control of laboratory professionals.

Unlike the analytical phase, which is largely automated and standardized, the pre-analytical process involves more manual handling and is, therefore, more vulnerable to variation and human error. The complexity of the pre-analytical process is further magnified by the involvement of multiple departments, varying staff skill levels, time constraints, and occasional non-adherence to standard operating procedures (SOPs). Therefore, it becomes crucial to regularly audit and analyse sample rejection data to uncover patterns, departmental trends, and operational bottlenecks.

This study is driven by the urgent need to understand, quantify, and address these issues at a systemic level. It proposes a comprehensive retrospective study to assess the major pre-analytical reasons for sample rejection at Medanta hospital over a full calendar year (April 2024 to March 2025). The study used the data from the Laboratory Management Information System (LMIS), focusing on major rejection reasons, rejection rate and their monthly trends. The objective is to uncover the most frequently occurring issues, identifying laboratory departments with higher rejection rates, and to examine the specific clinical areas (such as ICU or IPD) contribution to the overall rejection burden.

Reducing mistakes before testing doesn't just help the lab work better—it helps patients get faster, safer, and more accurate care. Doing this first step correctly is very important because it supports the whole treatment process.

1.2 Process of Sample collection and Transportation

The sample collection process begins in sample collection area at Medanta- the Medicity, Gurugram, having a proper Qmatic system (Queue Management Automatic Ticketing System) in place where sequence number for the patient is generated first then the patient

goes to registration desk (Figure 1.3) where the patient pays the bill then a ticket is generated and parked in system of his name and UHID (Unique Health Identification). LED displays showing the sequence of Qmatic number is also present along with the name- calling of patient whenever his/her number for sample collection comes. All of this is done to reduce the waiting time of patient (which on an average is around 10 min. according to the information available on the system).

Figure 1.3: Image showing the sample collection area
(image source- Medanta – the Medicity Hospital)

Then after coming inside the Sample collection area the patient goes through the different sequential steps of sample collection that are depicted in the figure below-

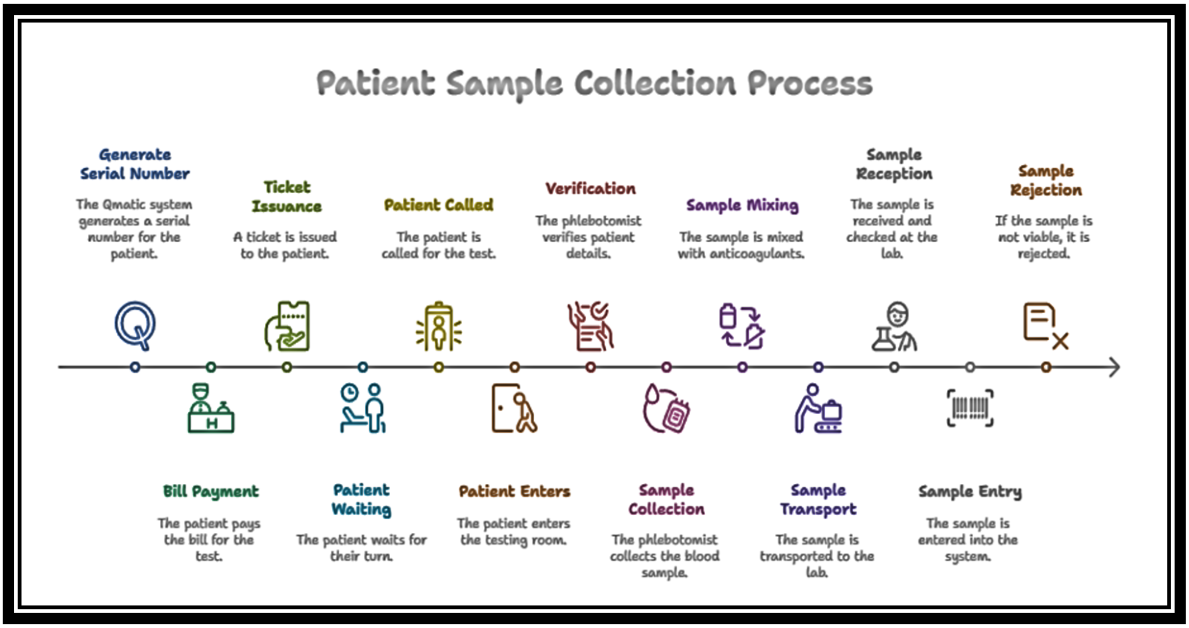


Figure 1.4: Schematic diagram showing the sample collection process
(image source- Medanta – the Medicity Hospital)

Here, in the sample collection area, phlebotomists mostly caters the OPD and Walk-in (or Retail) patients, however, in case of unavailability of nurse on the floor, sometimes the phlebotomists are called digitally by placing a order of sample collection in the system and of which type it is along with timing that whether it is Stat (required to be taken within 30 minutes), Urgent (required to be taken within 2 hours) or Routine (required to be taken within 4 hours) sample. Accordingly, the phlebotomist goes there, matches the UHID (Unique Health Identification) of patient along with his/her name to prevent violation of IPSG- 1 (International Patient Safety Goals). After that Bar-code is placed on the Evacuation tube of patient having his UHID and name, the sample is collected after wiping the area of venipuncture with alcohol swab in circular motion from inside to outside then Torniquet band is placed 2-3 inches away from torniquet band, it should be not too tight otherwise haemolysis or breakdown of blood components in the sample might come having high Potassium and Calcium in the collected blood samples that can stuck in the needle or can cause blood clotting. Also, Torniquet should not be placed more than one minute.

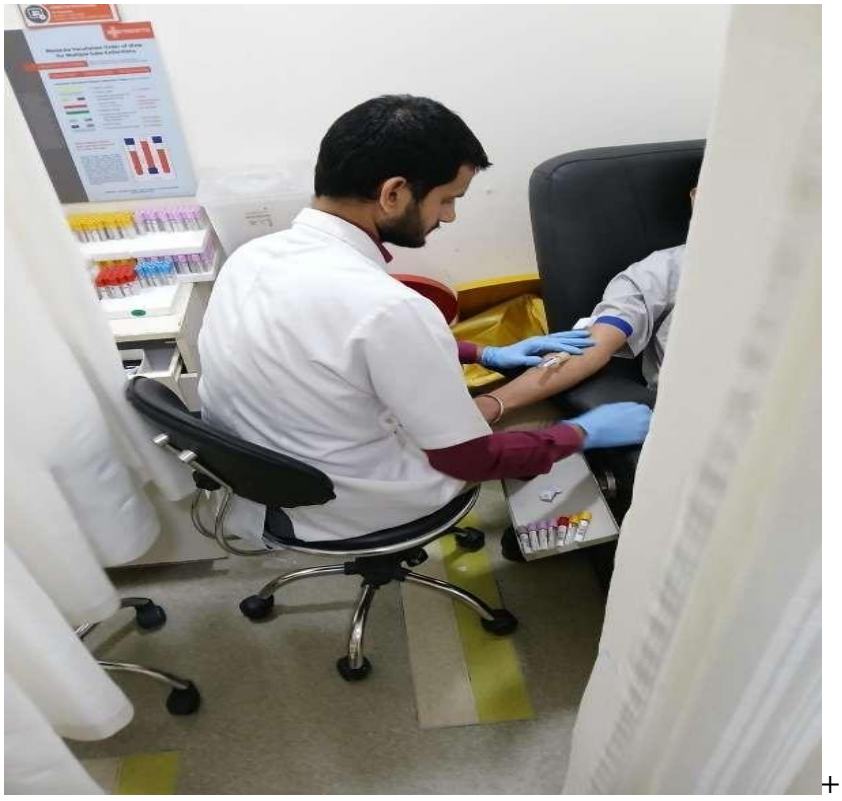


Figure 1.5: Image showing the sample collection by the phlebotomist in sample collection department. Here one can observe that Universal Precautions (gloves, apron) are followed.
(image source- Medanta – the Medicity Hospital)

After the sample collection, it is essential to invert (not shaking) the tube 8 to 10 times depending upon the type of sample, the inversion should be non-vigorous and after that it should be kept straight (not flat) for 10 to 15 minutes. Then General Duty Assistance (GDA) collects the sample, or it is sent through pneumatic shoot in the sample receiving area. Sample transportation time varies from department to department.

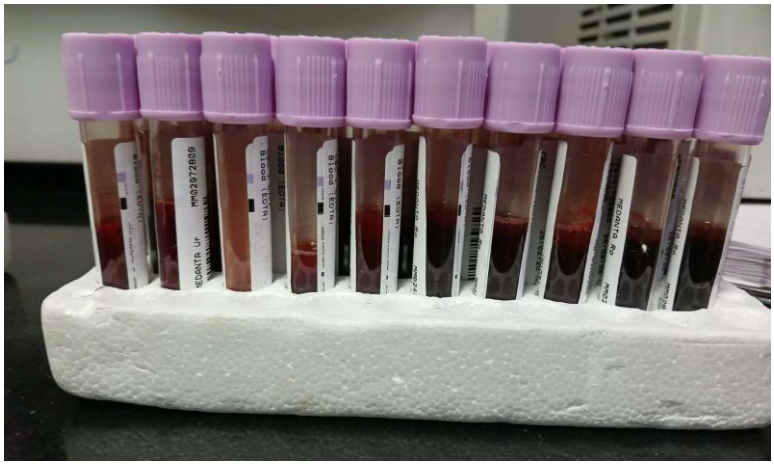


Figure 1.6: Image showing the Evacuation tubes (EDTA), right side tubes having adequate sample whereas left side tubes having inadequate quantity and quality of sample.
(image source- Medanta – the Medicity Hospital)

When the GDA arrives to give the sample in Sample receiving area (SRA), checking of the sample manually takes place for quality and quantity then its entry takes place in the system generating a number to know in which department its processing needs to be done. Also, the entry of sample is done in the system by scanning the bar-code after receiving the sample to close the dispatch of sample raised by the department sending it and side by side signature with time is done in the register brought by GDA having patient's detail whose sample is brought by him/her. All of this is done by judiciously following IPSG-1 from scanning the bar-code of evacuation tube to doing the entry of sample in system. The rejection of samples by separate departments of laboratory are made by the machinery (not manually) when they get received from the SRA after centrifugation. For samples received in pneumatic shoot, same process is followed except signing in the GDA's register.

Separate entry of sample takes place in the LMIS (Laboratory Management Information system) if the sample got rejected with its reason of rejection, date and from which location it came. This information gets displayed in the system of that respective department so that they can repeat the sample collection and send it back.

After the sample is sent to respective labs, the analytical phase begins where they also check the sample first, do their entry in system through scanning of bar-code and then the actual processing of sample takes place by putting the samples in machinery that also do the checking of samples first and rejects those that are not suitable for processing. These samples are dispatched back to the respective department in the same manner as sent back by the SRA. Then the processing of samples is done by the machinery that autogenerates the result. Then reports are sent to the doctor. Two- level report checking is done, one by the staff of lab itself and second by the doctor of lab to ensure that there is no discrepancy in result.

Then in the Post-analytical phase, reports are released. In cases where patient is admitted, the reports are sent directly to the treating doctor's system and in case of OPD or Retail patient, the reports are sent to report dispatch counter from where the patient can collect those reports. The TAT (turnaround time) for reports generation is different for different tests. After that decision for further treatment course is made by the treating physician based on the received reports.

1.3 Problem Statement

Despite the presence of SOPs and modern infrastructure, pre-analytical sample rejection remains a persistent issue at Medanta hospital. Rejected samples result in repeat procedures, treatment delays, patient discomfort, increased cost burden, and possible clinical risks. Without clearly knowing the major reasons behind this, it is difficult to implement targeted solutions to minimize the errors.

1.4 Scope

Scope: At Medanta the Medicity, thousands of samples move through the lab every day, yet pre-analytical errors remain a silent disruptor—leading to unnecessary sample rejections, delayed treatments, and operational inefficiencies. This study dives into "why" these errors occur, uncovering patterns in haemolysis, clotting, contamination, and insufficient volume. By analysing monthly trends and department-wise rejection rates, it sheds light on the most vulnerable points in the pre-analytical phase. With a data-driven approach, this research provides a detailed picture of the major causes of sample rejection within a high-volume hospital setting, paving the way for operational refinement and improved diagnostic accuracy.

1.5 Limitations

- **Retrospective Design Limits Control**
  As a retrospective observational study, there was no control over how data was originally recorded. This may affect consistency, limit validation of missing data, and restrict the ability to investigate variables not captured in LMIS logs**.**
- **Single-Centre Study**
  The study is confined to one hospital—Medanta – The Medicity hospital, Gurugram. While the hospital has a high sample volume, findings may not be directly applicable to other healthcare settings with different processes, staffing, or patient loads.
- **Possible Data Incompleteness or Inaccuracy**
  The study relies on LMIS-generated logs, which may have errors due to incorrect data entry, misclassification, or failure to document reasons for rejection accurately. Incomplete rejection categorization may limit depth of analysis.
- **Unaccounted Changes in Hospital Operations**
  Operational changes during the year (e.g., staff turnover, SOP revisions, or system upgrades) could affect sample handling and rejection patterns. These dynamic variables are not captured in the study.
- **Rejection Classification May Be Overgeneralized**
  Some rejection types (e.g., “clotted” or “insufficient volume”) might be used as broad categories in the LMIS. Without deeper breakdowns, important distinctions within error types (such as whether clots occurred during transport or collection) may be lost.
- **Lack of Intervention Testing**
  Although recommendations are made, the study does not implement or test proposed solutions (e.g., training or SOP redesign), which limits its ability to measure the actual effectiveness of those interventions.

Chapter 2: Literature Review

2.1 Overview

Pre-analytical errors have been recognized globally as the most common and preventable form of laboratory errors, contributing to nearly 46% to 70% of total laboratory inaccuracies. These errors occur before the sample reaches the analytical stage and include issues such as haemolysis, clotting, insufficient sample volume, labelling mistakes, and contamination. The literature consistently highlights that such errors not only compromise diagnostic accuracy but also lead to treatment delays, increased costs, and reduced patient satisfaction.

Globally, studies like those by Hammerling (2012) and Lippi et al. (2011, 2012) have emphasized that inadequate training, poor sample handling, and lack of standardization are major causes of pre-analytical errors. Their findings support the implementation of automation, staff education, and standard operating procedures (SOPs) to improve compliance and reduce variability in sample processing.

In the Indian and South Asian context, the problem is equally significant. Ali et al. (2023), in a study involving over 250,000 samples, identified haemolysis and clotting as the most frequent causes of rejection and recommended continuous monitoring and retraining. Indian studies by Dhananjay et al. (2019), Alavi et al. (2020), and Patel et al. (2023) reveal similar trends, with clotted, underfilled, and mislabelled samples being prevalent across both urban and rural healthcare setups. Notably, Singh et al. (2020) used FMEA and the Pareto principle to prioritize error types, pointing out that labelling and collection errors were the most impactful.

Despite the depth of insight provided by existing research, most studies are either limited to short-term audits, small sample sizes, or single-department analyses. Few have examined pre-analytical errors across an entire hospital over a significant time frame, and even fewer have translated findings into practical, department-specific interventions. Moreover, studies from high-volume, private quaternary care hospitals in India remain scarce.

2.2 Studies on Pre- Analytic Rejection Rates

Year	Article Name	Author(s)	Sample Size	Study Location	Key Findings / Solutions
2012	Preanalytical Errors in Clinical Laboratory Testing at a Glance.	J.A. Hammerling	Review article	USA	Discusses common pre-analytical errors and stresses education, SOPs, and automation to reduce errors. [1]
2011	Preanalytical Quality Improvement: From Dream to Reality	Lippi G. et al.	Review article	Global	Emphasizes standardization, staff training, adoption of checklists, and system-level interventions to improve lab accuracy. [2]
2012	Reducing Preanalytical Sample Errors through Educational & Technological interventions.	Lippi G. et al.	Not specified	Italy	Shows significant reduction in errors through combined staff education and barcode-based technology use. The study highlights that effective error reduction requires both well-informed personnel and supportive technological infrastructure. [3]

2009	The Detection and Prevention of Errors in Laboratory Medicine	Plebani M.	Review article	Italy	Explores the full lab error spectrum, giving particular attention to the vulnerabilities of the pre-analytical phase and recommends a quality culture across lab phases encouraging proactive error reporting and root cause analysis [4]
2023	Frequency & Types of Pre-analytical Errors in a clinical Laboratory of a Specialized Healthcare Hospital	Ali A. et al.	254,267 samples	Pakistan	Haemolysis and clotting were key causes of pre-analytic rejections; recommends continuous monitoring and retraining. [5]
2019	An Audit of Preanalytical Errors as a Quality measure in central Clinical Laboratory of a Rural Tertiary care Hospital in Eastern Uttar Pradesh	Dhananjay K. et al.	Not specified	India	Most common errors were underfilled and clotted samples; suggests the necessity of routine error audits & regular training to ensure adherence to proper blood collection protocols. [6]

2020	Challenges in pre-analytical phase of laboratory medicine: Rate of Blood Sample Nonconformity in a Tertiary Care Hospital.	Alavi N. et al.	113,817 samples	India	Highlights labelling, clotted, and haemolysed samples as significant causes of sample rejection; implemented continuous audit and staff sensitization. These efforts aimed to increase awareness of proper sample handling practices and reduce the recurrence of preventable errors. [7]
2020	A study on identifying the pre-analytical phase errors leading to biochemistry and haematology sample rejection by using FMEA & Pareto's Principle	Singh P. et al.	Not specified	India	Applied FMEA & Pareto charts to prioritize and identify errors; found labelling and collection issues were top concerns. [8]
2023	Study of Pre-Analytical Errors in Clinical biochemistry laboratory in –	Patel C. et al.	15,189 samples	India	Found 3.75% error rate, mostly haemolysis; emphasized hands-on training and monitoring.

	Dhiraj General Hospital, Piparia.				Additionally, they highlighted the importance of establishing a real-time internal monitoring system to promptly detect and address errors as they occur. [9]
2024	Evaluation of issues pertaining to the pre-analytical phase within the Biochemistry laboratory of the National Hospital of Sri Lanka: A case study.	Chathurika HLS, Nanayakkara R, Priyanka HL.	Not specified	National Hospital of Sri Lanka (NHSL), Colombo	The study identified sample collection and transportation errors as key issues in the pre-analytical phase. Using a nominal group technique, researchers prioritized these problems, and a problem tree analysis helped trace root causes. The proposed solutions included staff training, improved transportation systems, and standardized procedures to enhance efficiency and diagnostic accuracy. [10]

2.3 Research Gaps

1. Lack of Real-Time Error Feedback and Monitoring System

Medanta Hospital has LMIS but is not linked to any dashboard that gives real-time data to monitor or analyse and give immediate information or alert to that department for the pre-analytical errors as they happen. Without such a system, it's difficult to improvise the system (e.g., which department is sending more clotted or haemolyzed samples) and take timely action.

Literature Support:
Ali et al. (2023) and Alavi et al. (2020) highlight that continuous monitoring helps detect recurrent problems early. This allows for timely feedback and intervention before errors become widespread.

2. Limited Emphasis on Hands-On Training and Retraining

Medanta- The Medicity hospital lacks a structured schedule for regular hands-on training, retraining, or competency evaluation for phlebotomists, nurses, and technicians.

Literature Support:
Lippi et al. (2012), Dhananjay et al. (2019), and Patel et al. (2023) found that frequent errors (like underfilled, clotted, or haemolyzed samples) reduced significantly with targeted and repeated training.

Ali et al. (2023) also highlights the importance of identifying which errors are most common per department or over time to implement targeted interventions.

3. Inadequate Use of Quality Tools (FMEA / Pareto Analysis)

There is no use of structured quality improvement tools like Failure Mode and Effects Analysis (FMEA) or Pareto analysis, which help prioritize critical areas contributing to sample rejection in Medanta- The Medicity hospital. Then focusing improvement efforts on those few critical areas will yield maximum impact by analysing which errors happen most often.

Literature Support:
Singh et al. (2020) applied these tools and identified labelling errors and incorrect blood collection techniques as the highest contributors to pre-analytical rejection. These tools helped them prioritize training and corrective actions in a targeted manner, rather than guessing or using trial-and-error approaches.

4. Sample Transport Gaps Not Fully Addressed

Medanta- The Medicity hospital outlines transport methods (such as manual handover or pneumatic chute systems), but it lacks comprehensive guidance on how to handle transport delays, real-time tracking or monitoring of samples in transit, GDA (general duty assistant) sample handling during transit and transport temperature monitoring for critical specimens.

Literature Support:

Chathurika et al. (2024) identified delays and improper transport conditions as major reasons for sample degradation and rejection.

5. No Emphasis on Root Cause Analysis (RCA) or Error Reporting Culture

Medanta- The Medicity hospital lacks any system for conducting root cause analysis when errors are repeated and does not promote a non- punitive error reporting culture, which can suppress honest mistake reporting but there should be a culture of giving rewards to that department which had minimum errors in sample collection and transport.

Literature Support:

Plebani (2009) and Hammerling (2012) stress that building a "culture of quality" requires learning from errors through RCA and encouraging open error reporting without blame.

6. Limited Focus on Double Verification

Medanta describes barcode labelling but does not enforce double verification, such as having a second staff member confirm the patient's identity before sending the sample.

Literature Support:

Alavi et al. (2020) and Singh et al. (2020) found that labelling errors were a top contributor to pre-analytical rejection and suggested stringent double-check protocols.

7. Tourniquet Use and Haemolysis Risk Minimization Not Addressed

Although tourniquet use is practiced at Medanta Hospital, its placement and prolonged application need to be carefully monitored, as they are leading causes of haemolysis.

Literature Support:

Hammerling (2012) and Lippi et al. (2012) recommend limiting tourniquet time to under one minute to reduce haemolysis, especially for tests like potassium or LDH (Lactate Dehydrogenase Test).

8. No Routine Audits for Patient Identification Compliance

While patient identification procedures are described (e.g., using two identifiers), there is no system for random audits (monthly spot audits) to ensure staff are consistently following them.

Literature Support:

Multiple studies underscore the risks of misidentification, which can lead to erroneous results and even wrong treatment decisions.

9. Missing the Voices That Matter

There is lack of use of Nominal Group Techniques- these are structured problem-solving frameworks that help to identify the most frequent, critical, and avoidable errors by involving experts and staff to identify error points that will help in understanding their root causes effectively.

Literature Support:

By learning from Chathurika et al. (2024), it becomes evident that Medanta's sample collection processes would benefit greatly from introducing quality tools that promote team-based accountability, process transparency, and sustainable quality improvement.

Chapter 3: Methodology

Before coming to methodology, it is essential to understand and reduce the instances of pre-analytical sample rejection, and to clearly define the research question along with specific objectives, these are:

3.1 Research Question

What are the predominant pre-analytical reasons for sample rejection coming in laboratory at Medanta- The Medicity Hospital over the last one year (from April 2024 to March 2025), and how can these be minimised?

3.2 Objective

Primary Objective:

- To assess pre-analytical sample rejection trends over the last year, and identifying the key causes, monthly variations, and department -wise patterns of rejection to enhance efficiency.

Secondary Objectives:

- To identify and categorize the major pre-analytical reasons of sample rejection coming in laboratory from hospital over the last year.
- To examine monthly trends in rejection data over the past one year.
- To compare rejection reasons across patient categories—In-Patient Department (IPD) and Out-Patient Department (OPD).
- To analyse the number of sample rejection across different departments.

3.3 Methodology

3.3.1 Study Design

This study adopts a retrospective observational study design, focusing on existing records to assess pre-analytical errors in laboratory sample handling. A retrospective approach is suitable as it allows for the analysis of a large volume of data already available in the Laboratory Management Information System (LMIS), eliminating the need for primary data collection. This non-interventional design enables a review of existing sample rejection logs over a 12-month period, providing a cost-effective and real-time reflection of routine hospital operations. Since no patient-identifiable information is involved, it maintains ethical integrity while offering operational insight.

This observational framework is non-experimental in nature and aims to identify patterns, trends, and associations in sample rejection over a period of one financial year. This makes findings more representative of real-world hospital processes.

3.3.2 Study Area

The study is conducted at Medanta – The Medicity Hospital, a 1,300+ bedded quaternary care facility located in Gurugram, Haryana. The hospital is renowned for its multispecialty services and high-volume diagnostics. The laboratory at Medanta processes more than 2.2 million samples annually, making it a suitable setting for investigating pre-analytical sample rejection in a complex, real-time clinical environment.

3.3.3 Population and Sample

The study population includes all the patient samples received in the laboratory from various departments from April 2024 to March 2025.

- Sample Size**:** Estimated 2.24M total samples that are processed over the last financial year according to LMIS data.
- Target population: All clinical samples from different departments of hospital
- Unit of analysis: Each rejected sample that meets inclusion criteria (5042 samples)

3.3.4 Study Period

- Data analysis from LMIS: April 1, 2024 – March 31, 2025.
- Study duration: March 17, 2025 – June 17, 2025

3.3.5 Inclusion/Exclusion Criteria

- **Inclusion Criteria:**
    - All blood, urine, and other body fluid samples rejected during the pre-analytical phase.
    - Samples collected between April 1, 2024, and March 31, 2025.
- **Exclusion Criteria:**
    - Samples rejected due to analytical (machine/test-related) or post-analytical (reporting, interpretation) errors
    - Samples with incomplete rejection documentation in LMIS

3.3.6 Sampling Technique

This study employs a total enumeration sampling method, where all rejected samples that meet the inclusion criteria will be included in the analysis. This ensures comprehensive and accurate trend identification without bias and gives the review of the full scope of errors, rather than relying on a smaller representative subset.

Also, it involves observing the technique of sample collection by phlebotomists and nurses to know any discrepancy in sample collection methodology and how the sample is received in sample receiving area.

3.3.7 Study Tool/ Data Source

- Laboratory Management Information System (LMIS): The primary data source from which rejection logs will be extracted.

- Supplementary Source: Observation of processes (sample collection and receiving process) during visits to the lab, SRA and Departments.

3.3.8 Variables

Independent Variables:
- Departments (IPD, OPD, ICU, etc.)
- Month of sample collection

Dependent Variables:
- Type of rejection (e.g., haemolysis, clotting, insufficient sample, labelling error)
- Frequency of rejection
- Rejection rate per department and per month

Rationale: These variables allow for comparative and trend-based analysis.
Departmental mapping helps identify error-prone areas, while monthly tracking helps detect operational lapses or training gaps.

3.3.9 Operational Definitions

- Pre-analytical error: Any error occurring during sample collection, labelling, preservation, or transport that results in the sample being rejected before testing begins.
- Sample rejection: The decision by laboratory staff to refuse a sample due to non-compliance with quality or quantity criteria necessary for analysis.

3.3.10 Data Collection Procedure:

Rejection logs will be extracted from the Laboratory Management Information System (LMIS). Each rejected sample will be analysed to identify the predominant reasons for rejection, the departments most frequently sending and receiving rejected samples, and the monthly trends in rejection patterns.

3.3.11 Ethical Considerations

- The study uses anonymized, retrospective data obtained from LMIS, posing no risk to patients.
- No raw data is disclosed.
- Administrative approval obtained from Medanta's laboratory and administration department.

Chapter 4: Data Analysis and Result

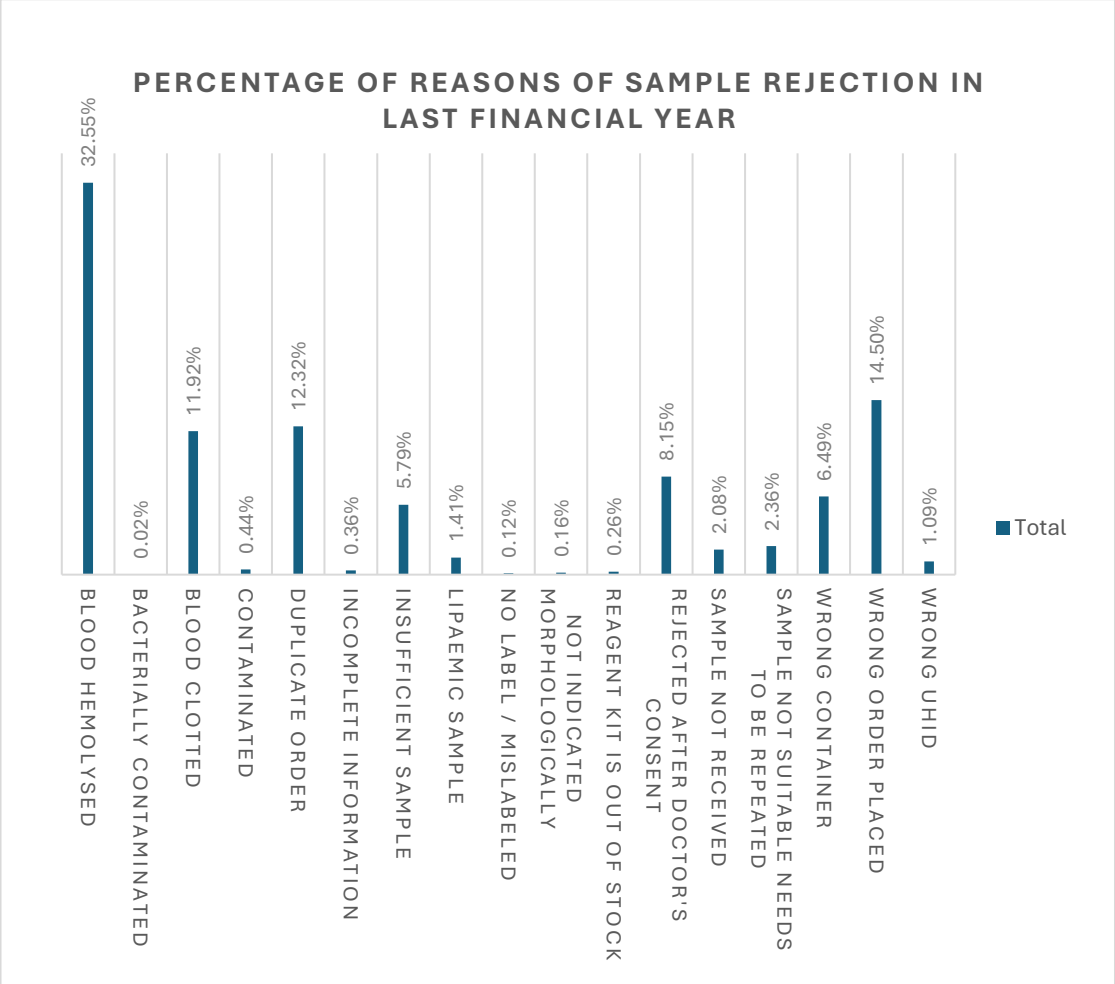
4.1 Analysis Plan

The collected is analysed to achieve the study objectives using:

- **Software Used:** Data analysis is performed using Microsoft Excel.
- **Visualization:** Findings are presented using appropriate visual representations such as bar charts to illustrate key associations and trends.

4.2 Analysis and Result

1. **Percentage of different reasons of rejection in last financial year as per data obtained from LMIS in the hospital**



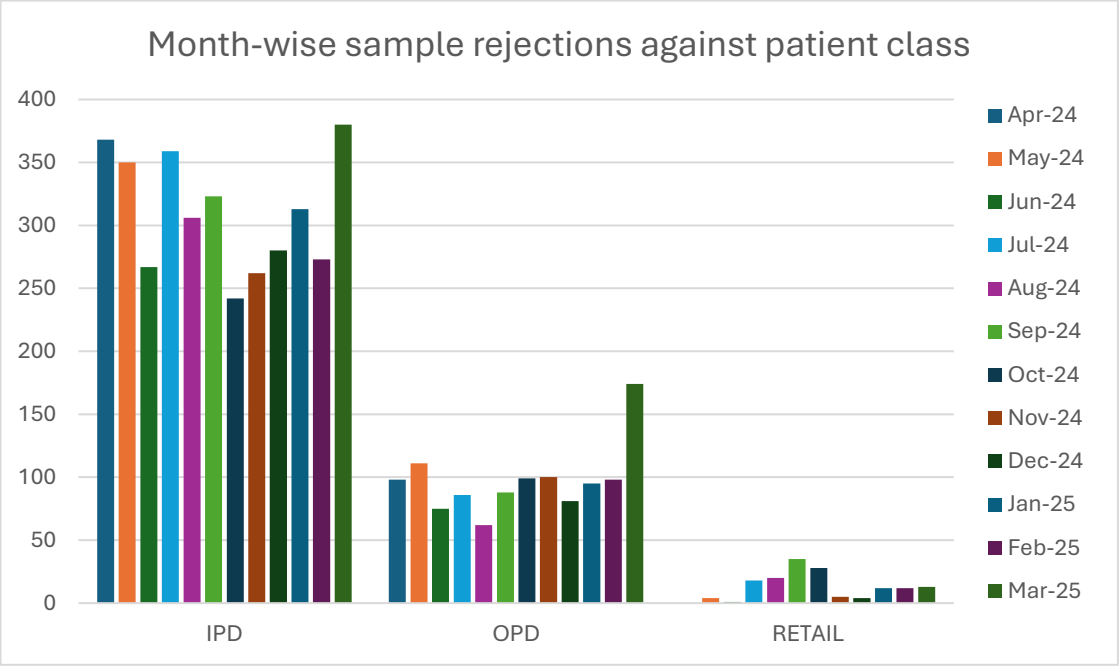
Graph 1: Percentage of reasons of sample rejection in last financial year

According to the graph above, it is depicted that there are various causes of sample rejection that are recorded in LMIS.

One of the leading causes of sample rejection is haemolysis of blood (32.55%) followed by wrong order placed (14.05%) then order duplication and blood

clotting. The least significant reason of rejection is bacterial contamination of sample.

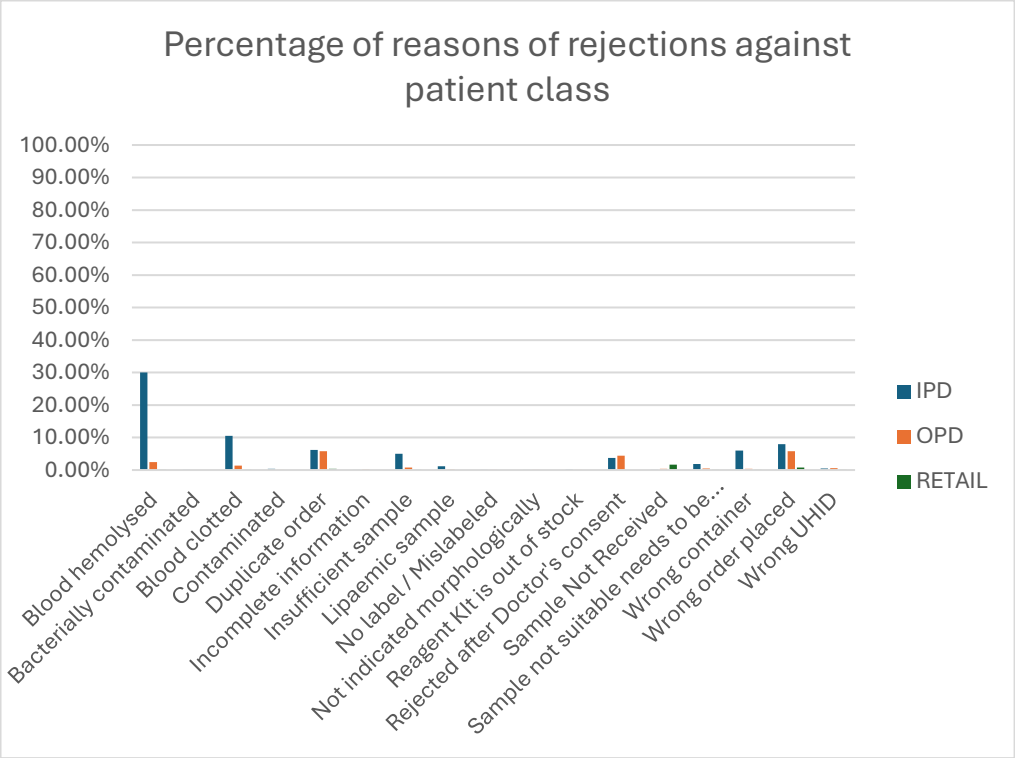
2. **Month-wise distribution of sample rejections against patient class i.e. IPD (that includes samples from floors that is wards and ICUs), OPD and retail patients**



Graph 2: Month-wise sample rejections against patient class

According to the graph shown, IPD (covering all the wards/floors and ICUs) is the major region of focus as it has most of the rejected samples recorded over the last year but in the month of March -2025, sample rejections have shown a significant increase in OPD also (around 175 rejections).

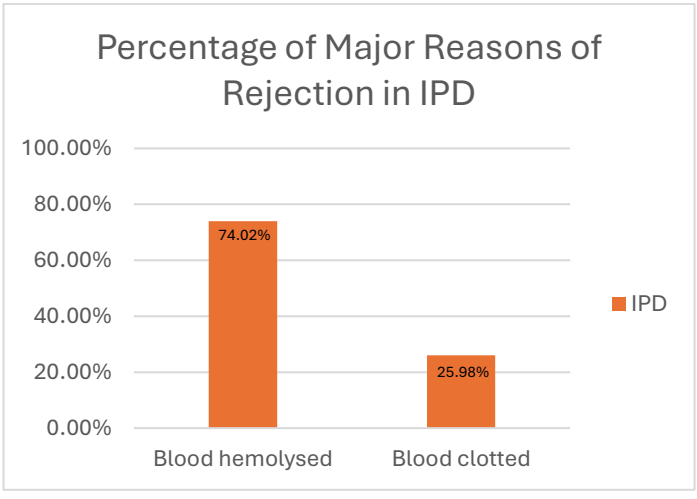
3. **Percentage of reasons of rejection against class of patients**



Graph 3: Percentage of reasons of rejections against patient class

Blood haemolysis and clotting are the two leading causes of sample rejection seen from the graph shown above and majority of the rejections occurred in IPD compared to other departments. Whereas, in case of OPD, the major sample rejection reason includes wrong order placed, duplicate order followed by samples rejected after doctor's consent. However, the frequency of OPD sample rejections are far less than IPD, so our major focus will be on IPD.

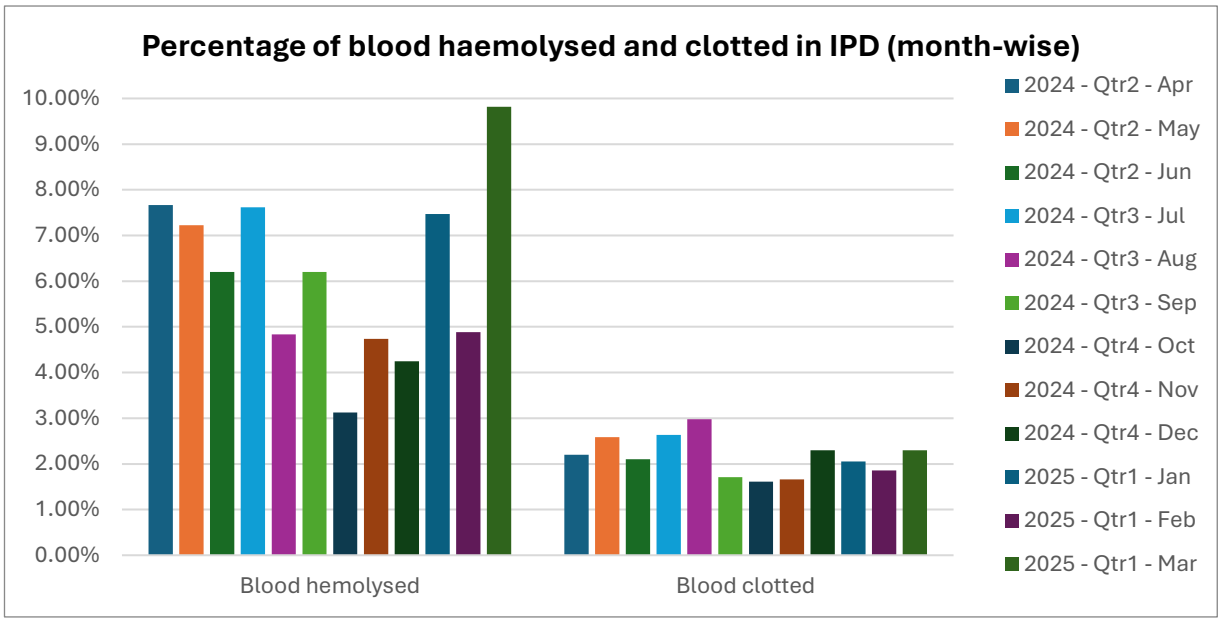
4. **Percentage of major reasons of rejection in IPD (that is, samples from floors that is wards and ICUs)**



Graph 4: Percentage of Major Reasons of Rejection in IPD

As from the previous interpretation of other graphs it was clearly seen that IPD has major rejections and in that the leading causes of rejection are haemolysis of blood (74.02%) and clotting of blood (25.98%) whose percentages are depicted in the graph shown above.

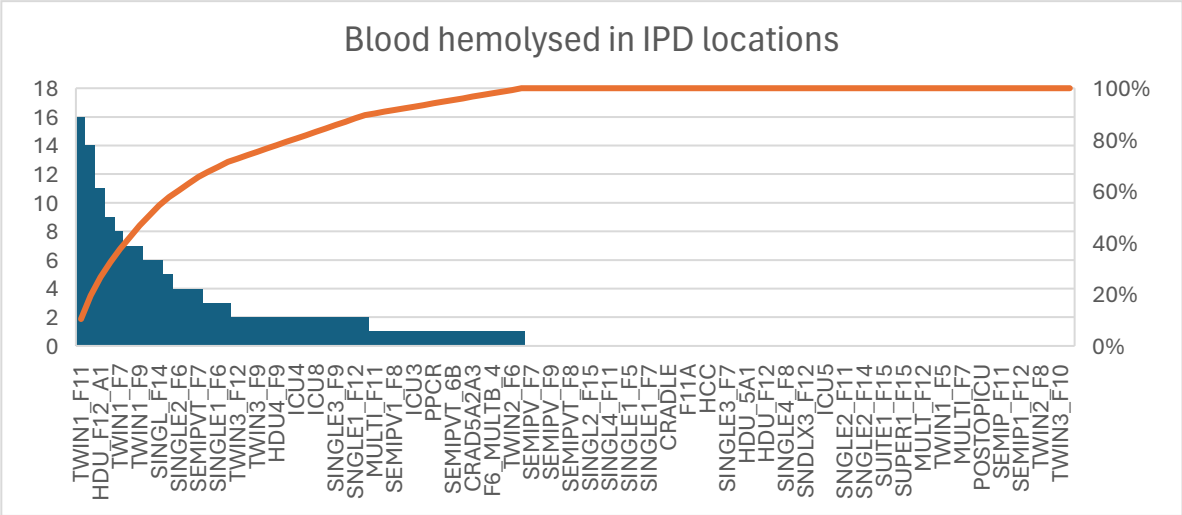
5. Month-wise distribution of Percentage of Major reasons of rejection in IPD



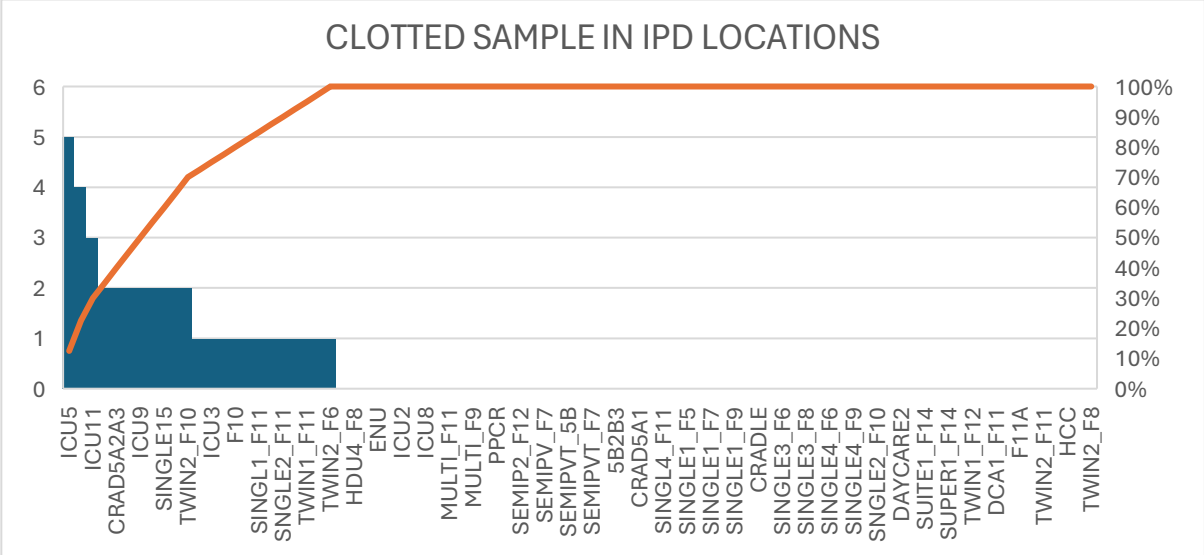
Graph 5: Percentage of blood haemolysed and clotted in IPD (month-wise)

When we see the monthly trends of percentage of blood haemolysis and clotting as reasons of rejections then there is spike in blood haemolysis rejection rate in March-25 after a dip in February-25. It suggests that there is a need to address this issue due to sudden increase in its rejection rate in March-25. However, the rate of blood clotting as reason of rejection remains almost constant with some fluctuations every now and then but it is clearly identifiable that blood haemolysis is the major problematic issue that causes sample rejection.

6. Identification of major locations from where the rejection of sample occurred in IPD due to haemolysis and clotting



Graph 6.1: Blood hemolyzed in IPD locations

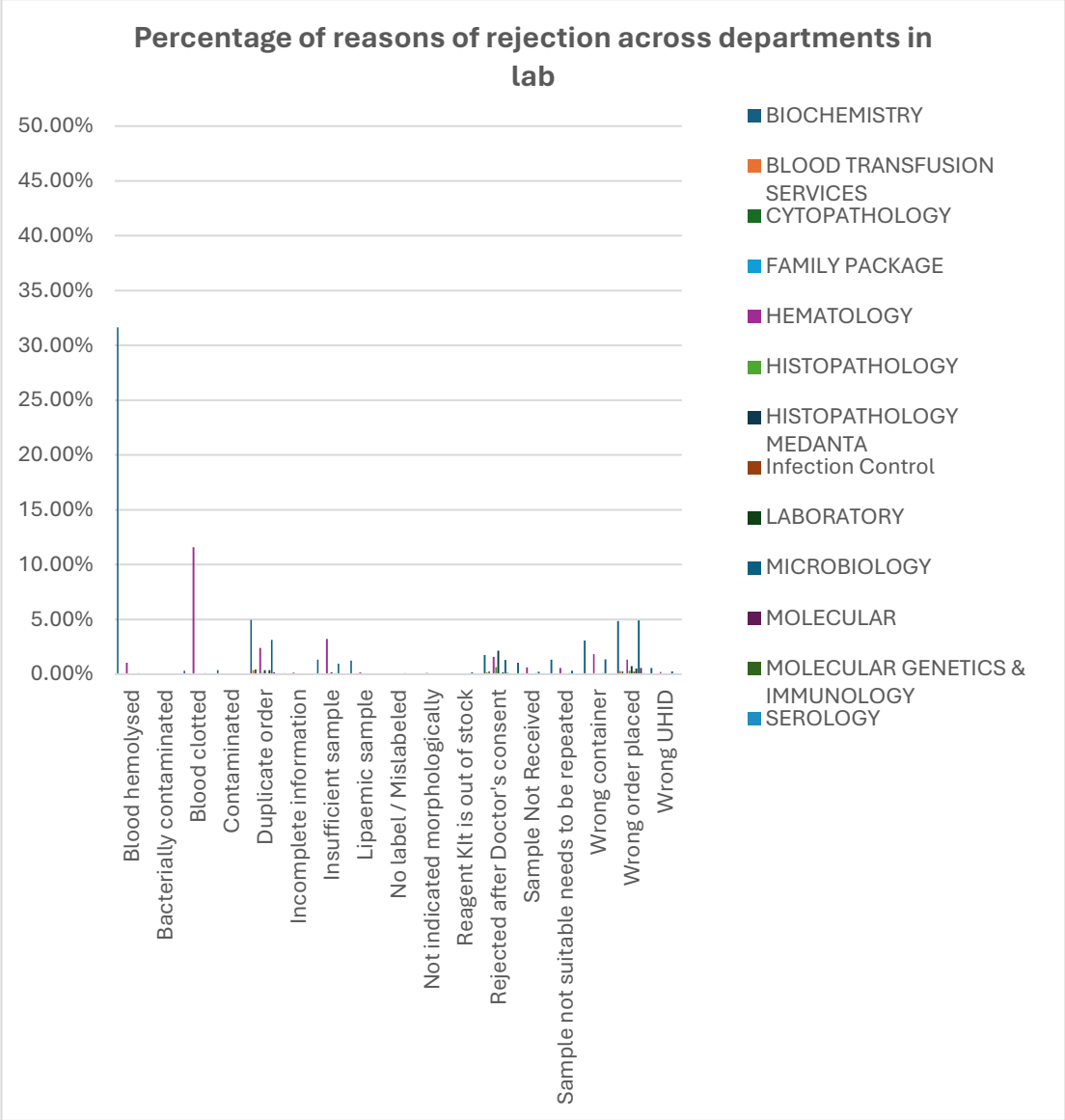


Graph 6.2: Clotted Sample in IPD Locations

It is clearly observed that from around 20% of the locations, majority of sample rejections from haemolysis and clotting of blood comes from. In case of blood haemolysis these locations are 11th floor, 12th floor, 7th floor, 9th floor, 14th floor, and 6th floor. ICU 4 and 8 also contribute to these rejections.

In case of blood clotting, ICU 5 and 11 are the major contributors to rejections followed by 5th floor, ICU 9, 15th floor, 10th floor, ICU 3 and 11th floor.

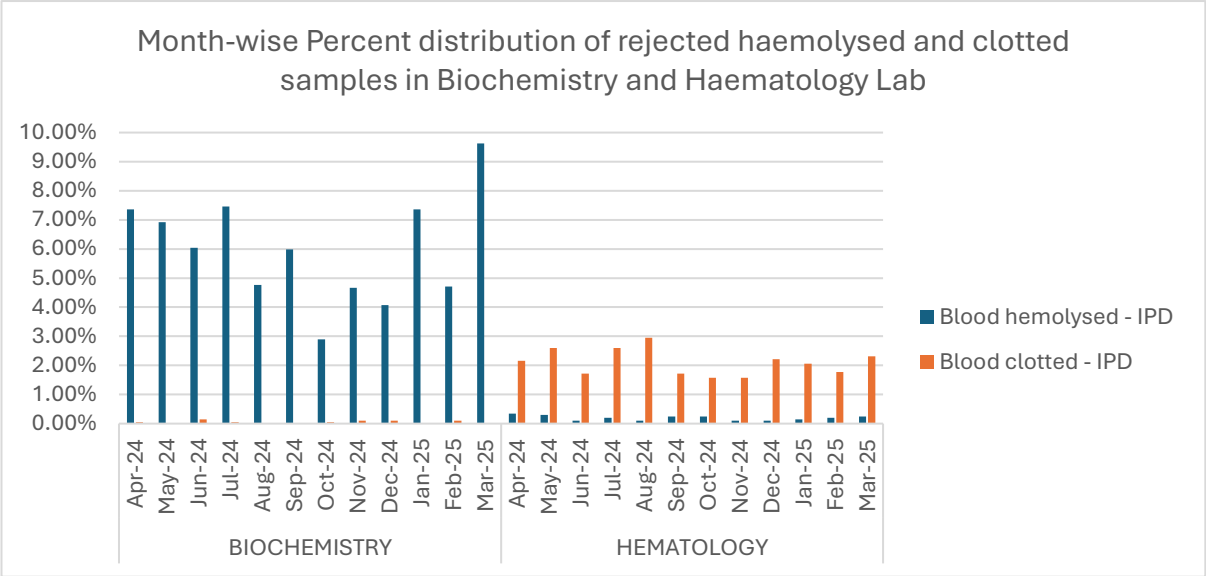
7. Laboratory department-wise percentage of reasons of sample rejection in the last financial year



Graph 7: Percentage of reasons of rejection across departments in lab

According to the above graph, biochemistry lab and Haematology lab receives majority of rejected samples whose major causes are same here also -blood haemolysis and clotting.

8. **Monthly distribution of Percentage of Blood Haemolysis and Clotting as reasons of rejection in Biochemistry and Haematology laboratory**



Graph 8: Month-wise Percent distribution of rejected haemolysed and clotted samples in Biochemistry and Haematology Laboratory

In case of Biochemistry laboratory, major contributor of sending the sample back is blood haemolysis which has increased over the past financial year reaching close to 10% in March-25. On the other hand, Blood clotting is the major reason of sample rejected in the Haematology Laboratory, the trend of its rejection is fluctuating but constant over the year with last recorded data at 2.2% on March-25 which has increased by 0.4% compared to February-25.

4.3 Interpretation

1. **Primary Causes of Sample Rejection**

The LMIS data indicates that blood haemolysis is the most prominent contributor to sample rejection, accounting for roughly one-third of all cases. This is followed by administrative errors such as incorrect order placement and duplicate orders. Blood clotting also being a considerable factor. On the other end, bacterial contamination appears to be relatively rare, suggesting that aseptic precautions are largely effective, though still requiring routine reinforcement.

2. **Patient Category Distribution**

The In-Patient Department (IPD), which includes various wards and ICUs according to LMIS data record, reported the highest volume of sample rejections. This could be due to

the diversity of staff involved in sample collection, new employees that require training, variation in skills/techniques of staff, increased workload, or delay in sample transport that may compromise standard collection practices. In contrast, OPD (around 175 rejections in March-25) and retail areas exhibited fewer rejections, possibly due to more controlled collection environments as there exist phlebotomists for sample collection instead of nurses, also they use close system syringe for sample collection instead of open system.

3. Reasons for Rejection Based on Patient Category

Across all the patient groups, haemolysis and clotting emerged as the most frequent reasons for rejection. A clear majority of these incidents occurred within the IPD, reinforcing the idea that inpatient settings require targeted process improvements of blood collection procedures and transportation.

4. Major Rejection Reasons within IPD

A closer examination of IPD data reveals that haemolysis alone accounts for over 70% of sample rejections, with clotting contributing the remainder. These issues are possibly linked to handling errors—such as prolonged tourniquet time, excessive force during injecting the sample in evacuation tube, or improper mixing of tubes, all these things point to a need for refresher training for clinical staff.

5. Trends Over Time in IPD Rejections

Monthly tracking shows fluctuations in rejection causes, with a notable drop in February-2025, following sudden increase in haemolysis in March 2025. This spike may be due to changes in staffing, increased patient volume, or seasonal pressures on clinical operations. While clotting-related issues remained relatively stable, their persistent presence indicates unresolved process gaps.

6. Frequent Locations for Haemolysis and Clotting

Specific areas within the hospital—such as the 6th, 7th, 9th, 11th, 12th, and 14th floors, as well as ICUs 4 and 8—had a higher frequency of haemolyzed samples. Similarly, ICUs 5, 9, 11, and 3, along with multiple floors, were repeatedly linked to clotting-related rejections. These patterns highlight the need for localized quality improvement efforts and possibly increased oversight in high-risk zones.

7. Laboratory Department-Wise Trends

The data shows that the Biochemistry and Haematology laboratories receive most of the samples that goes into the rejected category later after receiving the sample. Haemolysis was predominantly associated with Biochemistry, whereas clotting was more common in Haematology as reason of rejection. This suggests that each lab is affected by different pre-analytical weaknesses, and each department may benefit from tailored interventions.

8. Monthly Rejection Patterns by Laboratory

In the Biochemistry lab, blood haemolysis rejections gradually increased, peaking in March 2025. This upward trend may reflect procedural inconsistencies. In contrast, clotting in the Haematology lab remained consistent, though it experienced minor month-to-month variations. This consistency, despite fluctuations, implies need for process refinement and continuous monitoring.

Chapter 5: Discussion

5.1 Key Findings

The retrospective analysis of LMIS data at Medanta - The Medicity Hospital revealed that pre-analytical sample rejections are most commonly due to blood haemolysis (32.55%), followed by incorrect order placement and duplicate entries. Clotting was another prominent reason, particularly within the In-Patient Department (IPD) that incorporates data of wards and ICUs. Notably, the IPD contributed the largest proportion of rejected samples, with significant spikes observed in March 2025.

Rejection patterns varied across hospital units, with the 6th, 7th, 9th, 11th, 12th, and 14th floors and ICUs 4 and 8 showing high frequencies of haemolysis. Similarly, ICUs 5, 9, and 11 and the 5th, 10th, and 15th floors had elevated clotting-related rejections. Lab-department-wise, Biochemistry lab experienced rising haemolysed sample rejection trends, while Haematology showed a more consistent but persistent rate of clotting-related rejections.

5.2 Comparison with Literature

The findings align with existing global and regional studies that identified haemolysis and clotting as leading causes of pre-analytical errors (Ali et al., 2023; Lippi et al., 2012). Like the literature, the current study underscores the role of inadequate staff training, improper sample handling, and lack of SOP compliance as possible primary factors. Moreover, studies like those by Singh et al. (2020) and Chathurika et al. (2024) have emphasized the importance of department-level audits and the use of root-cause analysis tools, which this study also supports.

5.4 Root-Cause Analysis using Ishikawa Diagram

According to the observations made during the study duration, Ishikawa diagram is made to know the causes behind sample rejections. the root causes were grouped into categories:

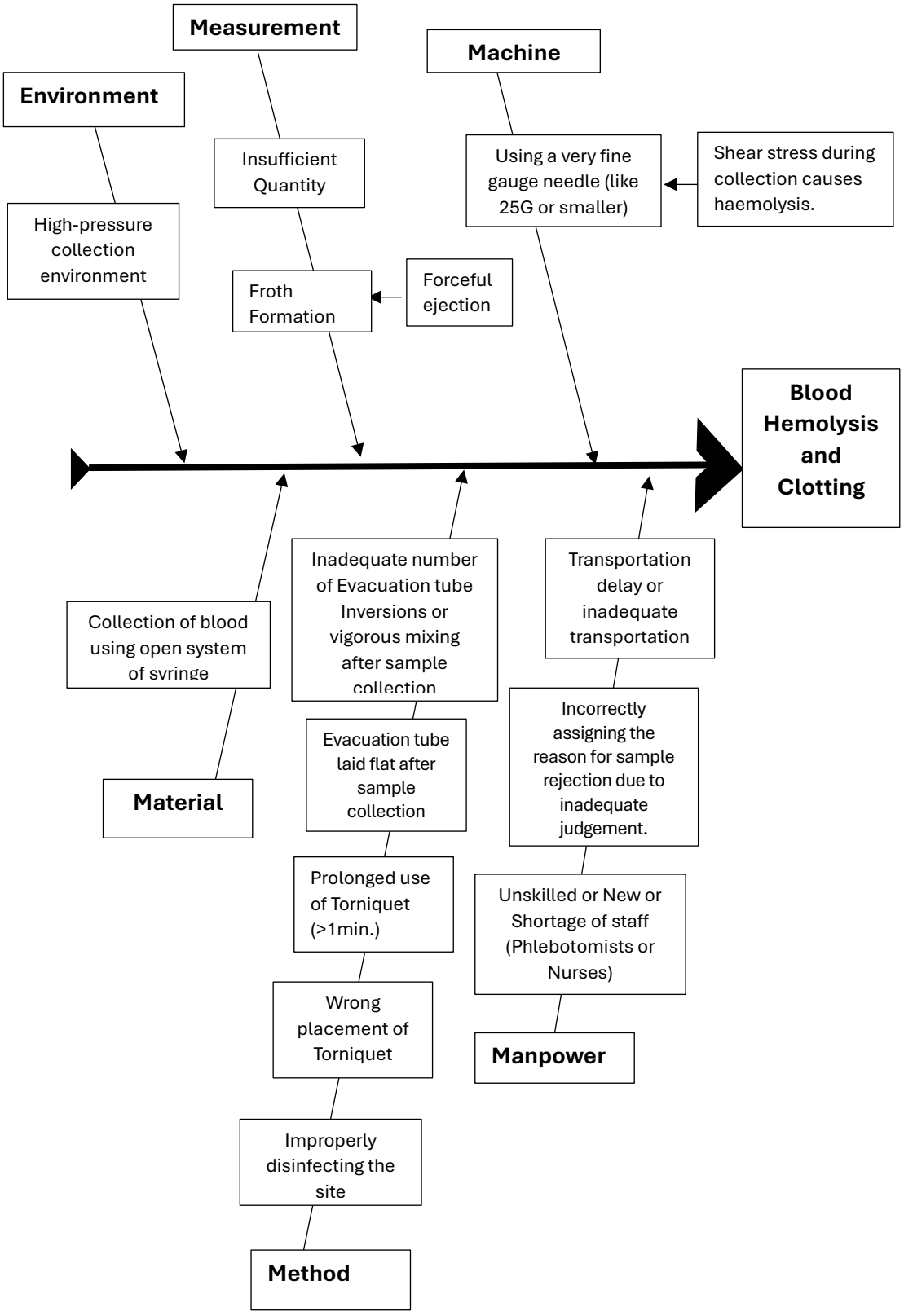


Figure 5.1: Ishikawa (Fishbone) diagram

The diagram helped visualize that haemolysis and clotting are not merely technical issues but outcomes of broader operational inefficiencies and training gaps.

5.3 Implications

These findings point to several operational areas requiring immediate attention. First, IPD sample collection processes need to be streamlined, especially in high-risk locations such as ICUs and general wards. Second, tailored interventions like refresher training programs, better SOP adherence, and implementation of double-check systems are recommended. Third, establishing a culture of real-time departmental feedback could reduce recurring errors.

5.4 Suggestions for Future Research

Future studies should focus on evaluating the impact of corrective actions, such as staff training or automation interventions, on reducing pre-analytical errors. Real-time dashboards and error reporting systems could also be studied for their effectiveness in minimizing sample rejections. Multi-hospital studies would help generalize findings and develop national benchmarks for sample rejection standards.

Chapter 6: Conclusion and Recommendations

6.1 Conclusion

This study conducted at Medanta – The Medicity Hospital focused on identifying and analysing the major pre-analytical causes of sample rejection over a one-year period (April 2024 to March 2025). The findings revealed that, with haemolysis and clotting are the most significant contributors the majority of rejections stemming from the IPD. The problem areas were further traced to specific departments in laboratory, from which it was analysed that major departments receiving rejected samples (mostly haemolysed and clotted samples) are Biochemistry and Haematology. Using a root cause analysis through the Ishikawa diagram, it is identified that issues across manpower, methods, materials, measurement, and environment as key sources of error. These errors, if addressed strategically, can reduce rejection rates, improve operational efficiency, and enhance patient safety. Although the study is limited by its retrospective design and single-institution scope, it provides valuable insights and lays the foundation for practical, department-specific interventions.

6.2 Recommendations

To reduce pre-analytical sample rejections, the following recommendations are made:

1. **Enhance Staff Training and Competence**
    - Implement mandatory, department-specific training for phlebotomists, nurses, and other relevant staff, with periodic competency assessments.
    - Use simulation-based training to practice sample collection, handling, and labelling, with observer-based feedback.
2. **Develop a Real-Time Error Tracking System**
    - Integrate a live feedback dashboard or heatmaps with LMIS to track rejection rates by department and trigger immediate corrective actions.
    - Configure auto-alerts for abnormal rejection rates, prompting departmental interventions.
3. **Conduct Regular Quality Audits and Feedback Sessions**
    - Implement monthly unannounced audits in high-error locations (e.g., ICUs, certain floors) and provide feedback to department heads.

- Use audit results to refine SOPs and implement corrective actions based on recurring trends.

4. **Root Cause Analysis for Recurring Errors**
    - Perform root cause analysis (RCA) when rejection rates exceed predefined thresholds, especially for high-risk departments.
    - Involve cross-functional teams in RCA to address systemic issues and implement sustainable solutions.
5. **Optimize Sample Transportation Protocols**
    - Streamline sample transportation procedures to minimize delays and handling errors.
    - Train transport staff on safe handling and temperature-sensitive sample management.
    - Introduce temperature monitoring devices for cold-chain-sensitive samples.
    - Standardise transport routes and timelines to reduce agitation and delays.
6. **Promote a Non-Punitive Error Reporting Culture**
    - Establish an open, non-punitive error reporting system, with rewards for departments that show significant improvements.
    - Encourage anonymous or open error reporting without fear of penalties.
    - Assign “department champions” to act as communication bridges between clinical units and the lab.
7. I**mplement Quality Improvement Tools (e.g., FMEA, Pareto Analysis)**
    - Encourage departments to adopt Failure Mode and Effects Analysis (FMEA) and Pareto analysis to prioritize high-impact issues and drive targeted interventions.
8. **Standardize Equipment and Sample Collection Kits**
    - Ensure uniform use of closed-system syringes across departments to prevent contamination and clotting.

- Regularly review and update collection kits based on current best practices and operational feedback.

9. **Educational Campaigns and Culture Building**
    - Conduct annual or quarterly awareness drives (like "Zero Rejection Week") to sensitize staff about pre-analytical quality.
    - Share anonymized real incidents where a pre-analytical error delayed diagnosis or affected outcomes—turn errors into learning stories.
10. **Research and Continuous Improvement**
    - Encourage hospital staff or students to conduct internal research on pre-analytical challenges as part of QA initiatives.
    - PDCA Cycles (Plan-Do-Check-Act): Run small-scale pilots to test rejection-reduction strategies and expand based on results.
    - Engage with other hospitals to learn and share best practices in pre-analytical error reduction.

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