Classifying Pre-Analytical Failure Mode Events in Clinical Laboratory: A Systematic Review and Meta-Analysis

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Introduction

•Risk management is the process of identifying, assessing, and controlling risks. It is defined as systematic policies, procedures, and practices to analyze, evaluate, and manage risks.

•In the healthcare industry, risk management is directly associated with patient safety, which is the prevention of patients from errors and adverse events in a healthcare setting.

•The Joint Commission International (JCI) in their standards on Facility Management and Safety (FMS2) and standard FMS 1a of the NABH focuses on hazard identification and risk analysis exercises making them mandatory for hospitals.

• Contemporarily, many approaches like Plan Do Check Act model(PDCA), Root Cause Analysis (RCA), Failure Mode and Effects Analysis(FMEA) and Lean Six Sigma in healthcare are used to asses, improve, measure, monitor, and evaluate different hospital processes for risks and errors.

• Failure mode and effects analysis (FMEA) is a proactive risk management tool for identifying possible errors in a system, process, product or service, analyzing the causes and effects of these errors and eliminating or reducing the most significant ones by proposing risk mitigation actions.

•According to JCAHO FMEA in healthcare should conducted under the following steps

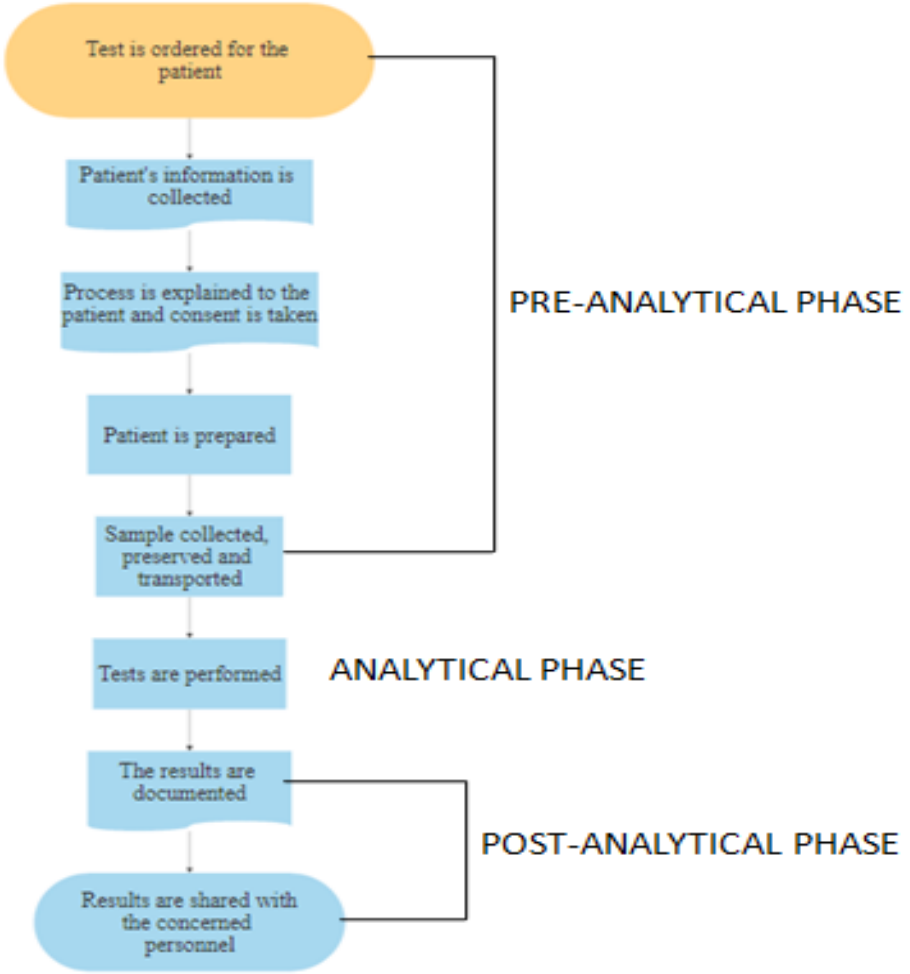
•Forming a flow chart of the process to be studied for errors and description of the effect for each failure mode

•Description of causes for each failure mode using a fishbone diagram

•A numeric value for each failure mode event according to the severity, probability of occurrence and detection capabilities and inferring the risk priority number from these values

•A proposal and implementation of mitigation for causes of the failure modes

Laboratory Medicine Work Flow



Rationale

•Classification of data has always helped in making the information simple, brief, comparable and easy to understand

• Classifying failure mode events identified by FMEA of clinical laboratory can help the management to narrow down their improvement plan to a particular part of the process associated with the most number of failure mode events, making the utilization of resources more effective and efficient

• Classifying the risks has made the mitigation more focused and precise in clinical laboratories improving the quality, reliability and safety of the process.

Research Aim

•This study aims to identify the phase in clinical laboratory with the maximum number of recorded failure mode events and further classify those events into subcategories

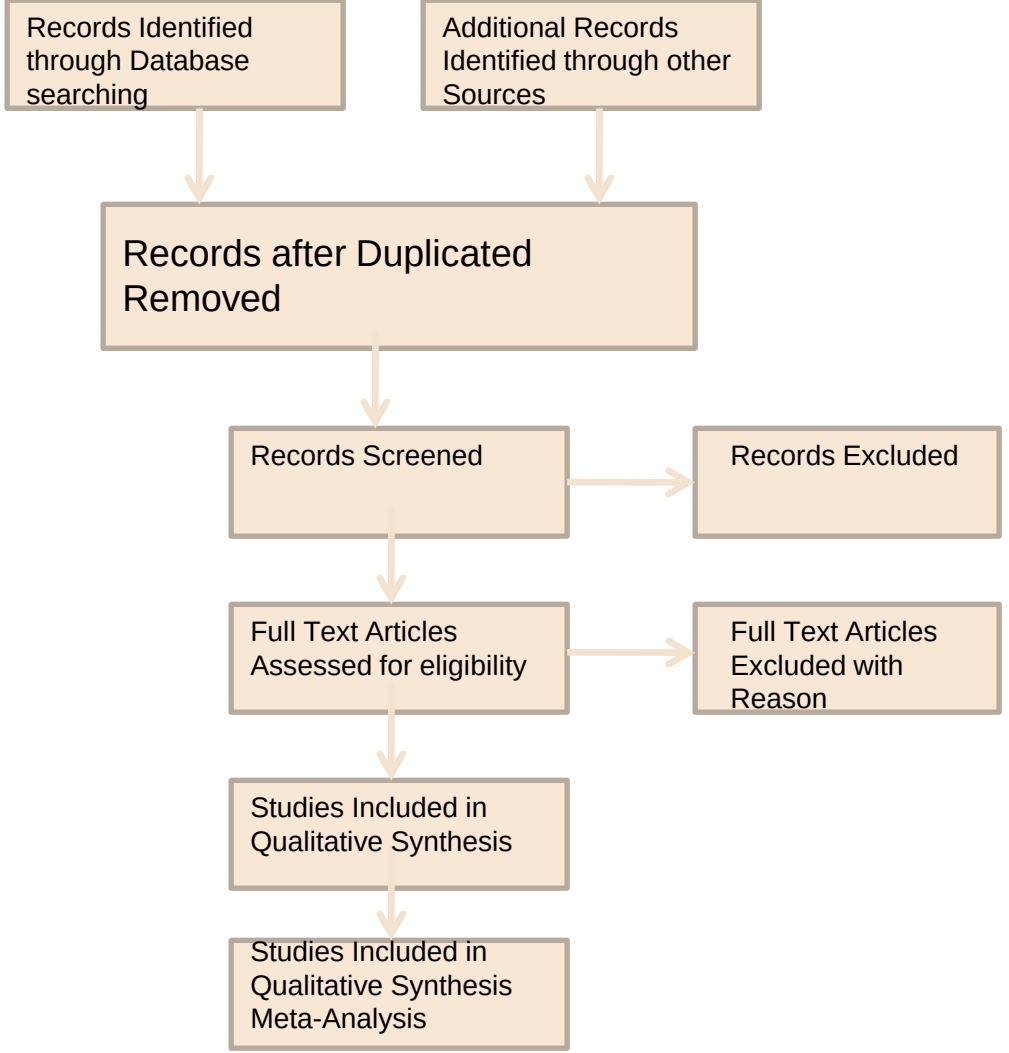
• The study aims to understand the causes of different failure mode events and arrange them scientifically, to ensure easy and systematic planning of improvement.

• Articles that have used FMEA as a tool for identifying risks in the laboratory process flow are studied and the failure mode events identified in them are classified, to precisely visualize the processes that should be prioritized during improvement planning to ensure maximum benefit

Research Objectives

- To identify the phase of a clinical laboratory with the maximum number of failure mode events
- To classify different failure mode events from the phase into sub-phases
- To calculate the incidence of failure mode events
- To evaluate the severity of failure mode events

PRISMA Flow Diagram for Systematic Review and Meta-Analysis



Literature Review

•The literature available on FMEA in a clinical laboratory suggests that the study of the impact of risks must be made in operational, strategic, and supportive processes

•Majority of publications focused on one or more aspects of operational processes, namely pre-analytical, analytical, and post- analytical processes

• Only a few studies further classified the operational failure mode events

• A systematic segregation of these operational failures under categories may aid in their management

• A detailed literature review for the study in tabular format is given in the proceeding slides

S No.	Title and Author	Study Findings and Conclusions
1	Engineering for Safety: Use of Failure Mode and Effects Analysis in the Laboratory(Woodhouse)	Errors in laboratories are most often a system error which can be prevented by using engineering analytical tool like FMEA
2	Errors in clinical laboratories or laboratory medicine?(Pelbani)	Failure mode events in laboratories mostly occur during pre-analytical phase, further sub-divided into pre- pre-analytical phase (patient request, sample identification, sample collection, handling, and transport), and pre-analytical phase (sample preparation and sorting)
3	Risk analysis by FMEA as an element of analytical validation(Leeuwen et al.)	Recognized 31 possible failure mode events which help experts in deducing policies and plans against these events
4	FMEA: A model for reducing medical errors(Chiozza et al.)	Patient safety and risk management explored as important part of hospital management. A considerable reduction in RPN observed after application of FMEA in clinical chemistry analytics.
5	Practical aspect of the use of FMEA tool in clinical laboratory risk management(Mendes et al.)	FMEA explored as a tool for risk management and public laboratory improvement. Identifying and prioritizing failure mode events by FMEA had an overall positive effect.
6	Measurement of Errors in Clinical Laboratories(Agarwal)	Two ways for risk management in clinical laboratories explored: a reactive approach in which RCA is done once the error has occurred, and proactive approach where FMEA predicts the system error that may occur in a laboratory system.

7	Practical, transparent prospective risk analysis for the clinical laboratory(Janssens)	Prospective Risk Analysis (PRA) developed as an extension of FMEA which purposefully uses a less detailed approach with processes divided into broad steps and a simpler matrix to capture risk scores. Focused on pre-analytical and analytical phases; pre-analytical phase had majority of failure mode events.
8	Specimen rejection in laboratory medicine: Necessary for patient safety?(Dikmen et al.)	Laboratory specialists demonstrated that 70% of errors occur in pre-analytical phase. A total of 4,53,171 samples were studied out of which 27,067 samples were rejected; majority of failure mode events occur in pre-analytical phase.
9	Using the failure mode and effect analysis model to improve parathyroid hormone and renocroticotropic hormone testing(Magnezi et al.)	Identified 19 failure mode events in a laboratory out; 15 were of pre-analytical origin.
10.	Errors of clinical laboratory and its impact on patient safety(Lao et al.)	Identified 90 failure mode events in different phases of clinical laboratory assigning high-risk priority numbers to pre-analytical and post-analytical failure mode events.
11.	Health Safety Management: The Model of FMEA/FMECA in Anatomic Pathology Service(Ianni et al.)	A model was developed to conduct FMEA as part of wider strategy of risk reduction based on measure-analyze-implement-control methodology, to improve the process of a surgical pathology laboratory.
12.	Application of failure mode and effects analysis to minimize quality failures in clinical biochemistry laboratory(Sudhakar et al.).	Identified 14 failure mode events in the laboratory process out of which 8 were associated with the pre-analytical phase

13.	Utilization of a healthcare failure mode and effects analysis to identify error sources in the pre-analytical phase in two tertiary hospital laboratories(Romero et al.).	Compared two laboratories of different hospitals and classified failure mode events.
14.	A study on identifying pre-analytical phase errors leading to biochemistry and hematology sample rejection by using FMEA and pareto's principle (Rachana et al.).	Primarily focused on pre-analytical phase failure mode event, as it has been established from the previous literature that majority of failure mode events are of pre-analytical origin this study identifies and prioritize them
15.	Risk management in clinical laboratory-use of failure modes and effects analysis(Tosheska-Trajkovska).	Classified failure mode events identified in the laboratory medicine under environmental, operator, specimen and analysis according to the cause of the event.

Methodology

Research Questions

•What are the different classification categories of pre-analytical failure mode events in a clinical laboratory?

•Which of these pre-analytical phase categories have the maximum and most severe failure mode events?

Research Design

The study design for the study is of descriptive type, the analysis was done on secondary data.

Study Selection

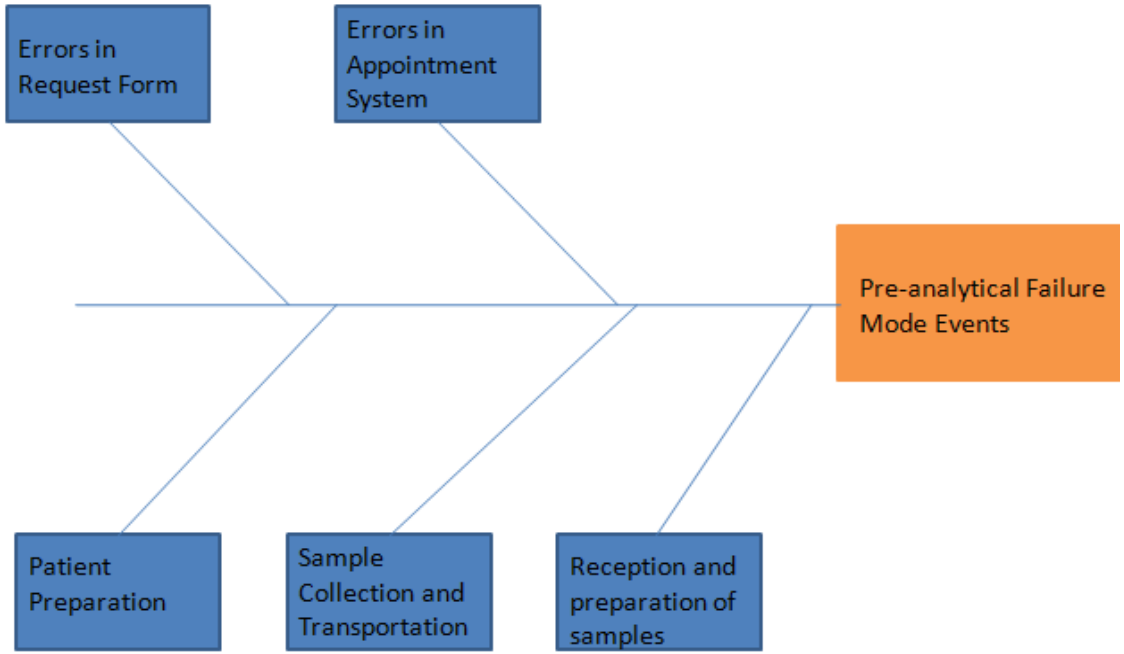
A two-stage screening process was used to identify articles to be included in the meta-analysis.

In the first stage, A search was made through Google Scholar and Pub Med for articles whose title, abstract, or keywords included a reference to FMEA in clinical laboratories or laboratory medicine.

In the second stage, only those publications were included which were based on primary data and have classified the failure mode events operationally into pre-analytical, analytical, and post-analytical phases, or should have at least focused on the pre-analytical phase for failure mode events.

Further, for the meta-analysis only those publications were short listed which have provided the list of failure mode events identified by them during the course of the study.

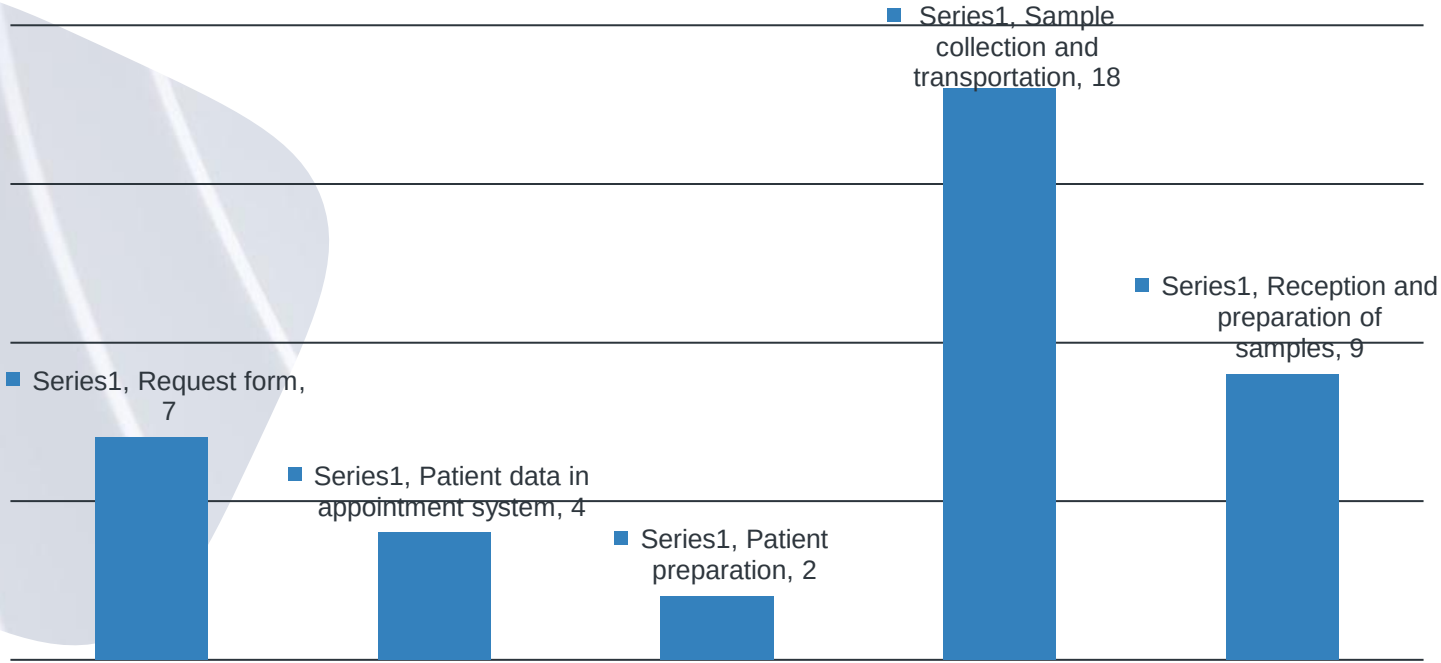
Results



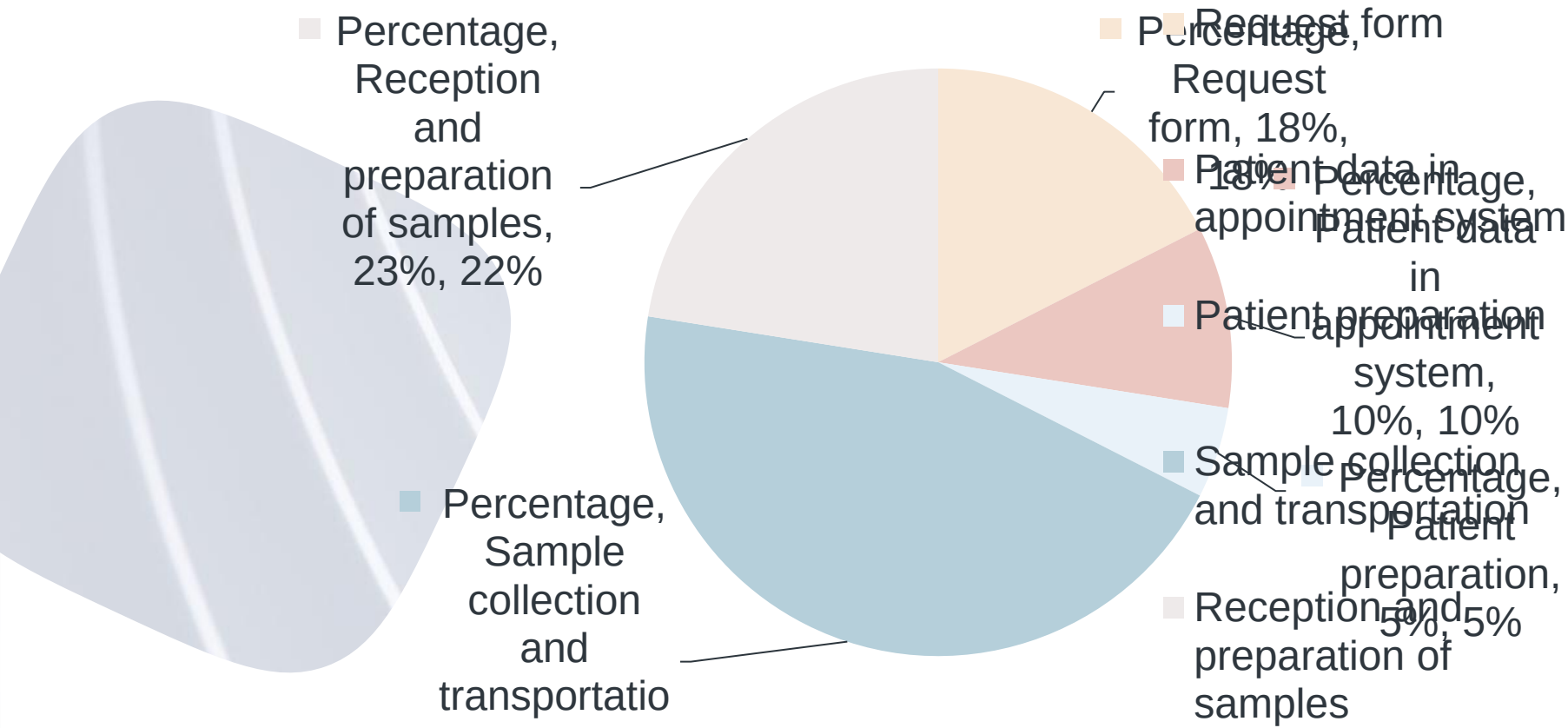
Fishbone diagram depicting the reasons for pre-analytical failure mode events in clinical laboratories which forms the bases for classification of the sub-phases.

Sno.	Failure Mode Event
Sub-phase: Request form	
1	Incompletely Labeled Sample/Request Form
2	Wrong Test Order
3	Double ID Verification Mistake
4	Wrong Patient Identification
5	Request not legible
6	Mistake in patient's Demographic Data
7	Delay in Scanning Paper Forms
Sub-phase: Appointment system	
8	Wrong Entry of Patient Records
9	No Activation of Patient's Request Form
10	Lack of Patient Information
11	Delay in documentation
Sub-phase: Patient preparation	
12	Lack of Knowledge
13	Misinformation to the Patients (fasting time, medication etc.)

Sub-phase: Sample collection and transportation	
14	Samples Taken in Wrong Tube
15	Sample Misplaced
16	Hemolysed sample
17	Refrigerator Failure/Sample not Refrigerated
18	Incorrect Sample Collecting Technique
19	Using Unsterile Containers for Sample Collection
20	Difficulty in Drawing Blood
21	Not Immediately Placing into the Vaculatiners
22	Use of Excessive Physical Force
23	Insufficient Volumes of Blood Taken
24	Delay in Sample collection and transportation to the laboratory
25	Delivery at Wrong Destination
26	Courier does not Arrive on Time
27	Tubes Left on Receiving Table
28	Courier was not Ordered
29	Loss of Sample
30	Clotted sample
31	Error in sample identification
Sub-phase: Reception and preparation of samples	
32	Malfunctioning of Reagent/Improper Reagent Mixing Technique
33	Malfunctioning of calibrator
34	Error in Sample Preparation
35	Double Utilization of Sample Labels
36	Improper Centrifugation
37	No one to Receive the Sample
38	Incorrect storage of samples
39	Contamination of sample
40	Mix up in patient's samples



Graphical representation of the number of pre-analytical failure mode events classified and different sub-phases. Sample collection and transportation have the highest frequency of failure mode events.



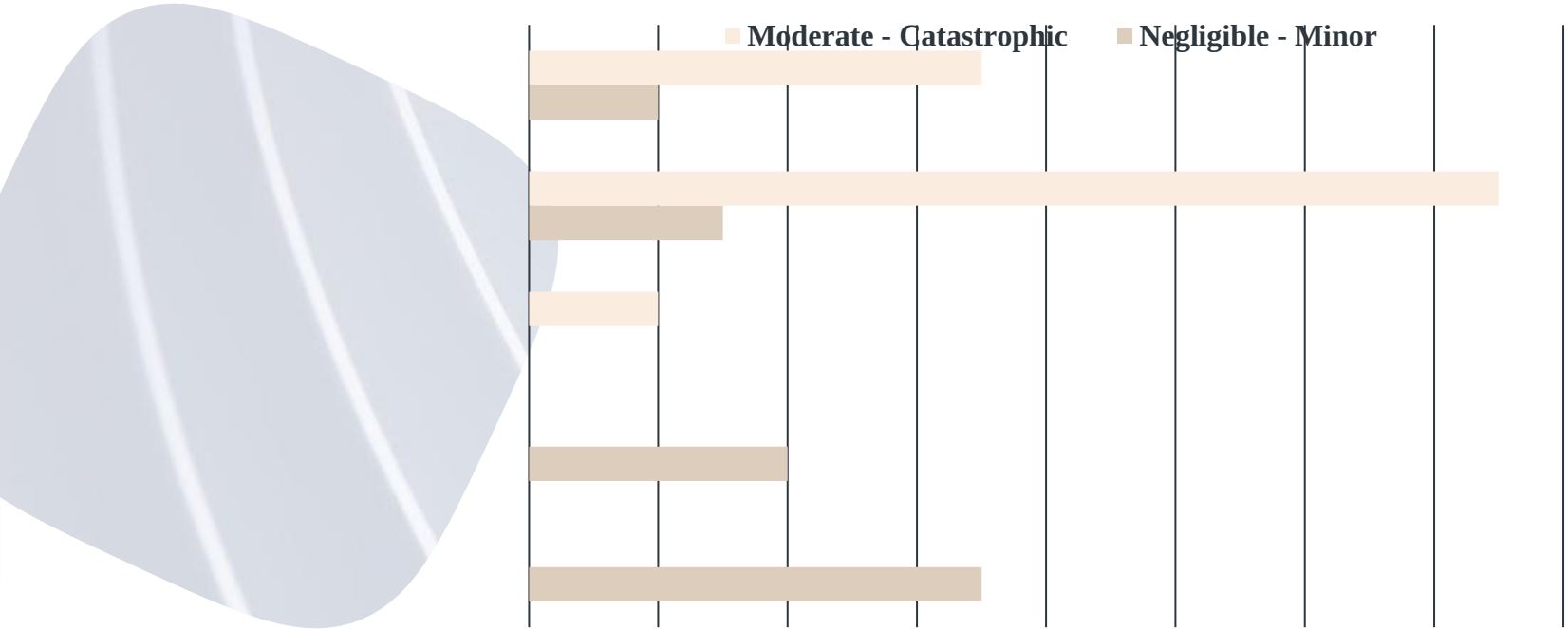
Pie chart showing that 45 per cent of all pre-analytical failure mode events occur due to errors in sampling and transportation.

Severity Index	Failure Mode Event	Sub-phase
5	Incorrect sample collecting technique	Sample collection and transportation
5	Using unsterile containers for sample collection	
4	Lack of knowledge	Patient preparation
4	Misinformation to the patients (e.g., fasting time and medication)	
4	Sample misplaced	Sample collection and transportation
4	Hemolysed sample	
4	Refrigerator failure/sample not refrigerated	
4	Difficulty in drawing blood	
4	Use of excessive physical force	
4	Delay in sample collection and transportation to the laboratory	
4	Loss of sample	
4	Malfunctioning of reagent/improper reagent mixing technique	Reception and preparation of samples
4	Malfunctioning of calibrator	
4	Improper centrifugation	
4	Incorrect storage of samples	
4	Mix up in patient's samples	
3	Not immediately placing into the vaculatiners	Sample collection and transportation
3	Insufficient volumes of blood taken	
3	Delivery at wrong destination	
3	Courier was not ordered	
3	Clotted sample	
3	Error in sample identification	
3	Error in sample preparation	Reception and preparation of samples
3	Contamination of sample	
2	Incompletely labeled sample/request form	Request form
2	Wrong test order	
2	Request not legible	
2	Delay in scanning paper forms	
2	Delay in documentation	Appointment system

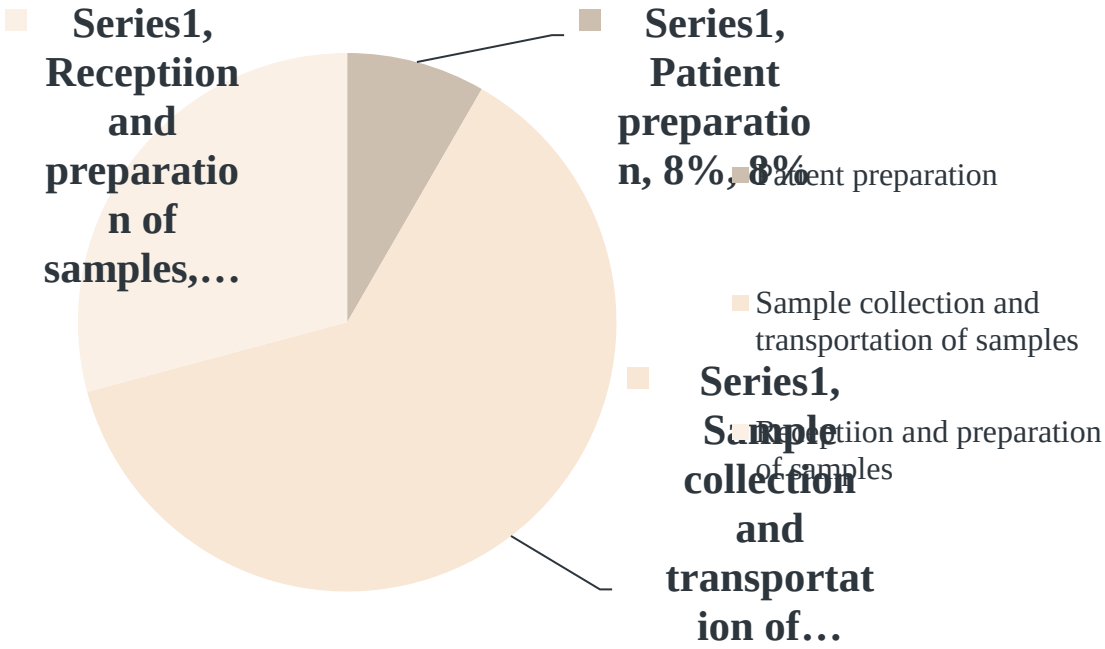
Severity Index	Failure Mode Event	Sub-phase
2	Samples taken in wrong tube	Sample collection and transportation
2	Courier does not arrive on time	
2	Tubes left on receiving table	
2	Double utilization of sample labels	Reception and preparation of samples
2	No one to receive the sample	
1	Double id verification mistake	Request form
1	Wrong patient identification	
1	Mistake in patient's demographic data	
1	Wrong entry of patient records	Appointment system
1	No activation of patient's request form	
1	Lack of patient information	

Criterion	Rating	Description
Severity		
Negligible	1	No adverse clinical outcome: Unchanged patient management
Minor	2	No adverse clinical outcome: Minor change in patient management, e.g., short delay in diagnosis due to delay in reporting of test results
Moderate	3	Minor adverse clinical outcome, e.g., need for an additional venepuncture
Critical	4	Moderate adverse clinical outcome, e.g., on the basis of incorrect blood glucose results the patient was put on hypoglycemic medication
Catastrophic	5	Significant adverse clinical outcome, e.g., significant morbidity or mortality

(Source: Sudhakar et al., 2018)



Severity of failure mode events in different pre-analytical sub-phases. Sample collection and transportation sub-phase has the highest frequency of moderate-to-catastrophic failure mode events.



Sub-phases of pre-analytical phase associated with severity rating of 3 and above.

Discussion

• In clinical laboratories speculation and mitigation of risks is an important aspect of quality.

• Widely applicable norms in medical laboratories (EN ISO 15189: 2012 and EN ISO 9001:2015) are associated with risk management and safety of the patients.

• The empirical literature available on application of FMEA on clinical laboratories provides with evidence that application of FMEA has an overall positive effect on the laboratory process.

• The studies which were scanned for systematic review and meta-analysis showed that the failure mode events in clinical laboratories were by and large classified under three operational phases

• The studies also depict that majority of the failure mode events in clinical laboratories were pre-analytical in nature.

• For having a more explicit outlook on the pre-analytical failure mode events this study has further classified the pre-analytical phase into sub-phases based on the activities performed, that are

1. **Request Form**
2. **Appointment System**
3. **Patient Preparation**
4. **Sample Collection and Transportation**
5. **Reception and Preparation of Samples**

- These sub-phases had helped in associating each failure mode to a specific activity which causes it

• The analysis shows that maximum number of pre-analytical failure mode events that is 18 out of 40 (45% of the total) failure mode events are associated with sample collection and transportation phase

• A five scaled already published severity index particularly for clinical laboratories was used to assign a rating to each of the forty failure mode events identified.

• Total of 24 failure mode events were given a rating 3 or above.

• Of these 24 events 15 (62.5%)were related to sample collection and transportation.

Conclusion

We conclude that sub-phases with higher human involvement have a higher probability of jeopardizing patient safety. Therefore, clinical laboratories should focus on training and development of employees to improve quality. FMEA has shown its application in bioethics as a support instrument to improve the accuracy of patient information and the drug distribution system. FMEA may help us understand the involved processes by highlighting the risks and developing counter measures.

Therefore, FMEA enables knowledge transfer and development of a multidisciplinary team. Information derived from our meta-analysis will help in directing a more tailored FMEA approach in clinical laboratories.

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Thank You