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

By

Ishaan Kapoor

Dissertation submitted in partial fulfillment of the requirements of the degree

MBA Hospital and Health Management

Academic year, 2018-2020

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Managed by Narayana Health

The certificate is awarded to

Ishaan Kapoor

In recognition of having successfully completed his
Internship in the department of

Oncology Collegium

And has successfully completed his Project on

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

Date: February 28th to May 29th, 2020

Organization: Shri Mata Vaishno Devi Narayana Superspeciality Hospital

He comes across as a committed, sincere & diligent person who has
A strong drive and zeal for learning.

We wish him all the best for future endeavours

04/06/2020

Dr. Rakesh Chander Sahni
(Medical Superintendent)

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(Head Human Resource)

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This is to certify that the dissertation titled '**Classifying Pre-Analytical Failure Mode Events in Clinical Laboratory: A Systematic Review and Meta-Analysis**' and submitted by **Dr. Ishaan Kapoor** Enrollment No.**0752** under the supervision of **Dr. Anshuman Sewda** for award of MBA in Hospital and Health Management of the University carried out during the period from **2nd March** to **2nd June2020** embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other institute or other similar institution of higher learning.

Signature

ABSTRACT

Introduction: Failure mode and effects analysis (FMEA) is a tool used in healthcare to analyze quality failures and improve patient safety. Clinical laboratories being prone to errors have adopted FMEA for risk mitigation. Nearly all the studies on risk management using FMEA in clinical laboratories have broadly classified the failure mode events operationally under three phases, namely pre-analytical, analytical, and post-analytical phase. This study focused on reviewing the current literature to identify the operational step primarily responsible for failure mode events in clinical laboratories. **Methods:** A systematic review and meta-analysis of eligible studies was conducted to assess the failure mode events in different stages of clinical laboratory processes. Furthermore, the severity of these failure mode events was evaluated using a previously published severity index. **Results:** Five studies that met the inclusion criteria were further analyzed. The majority of the failure mode events in these studies were pre-analytical (n = 40) and were further classified into different sub-phases. Most of the failure mode events (45%) occurred during sample collection and transportation. Moreover, most of these events had a high severity index rating. **Conclusions:** A large number of failure mode events in clinical laboratories were consistently pre-analytical, specifically the sample collection and transportation process. An in-depth evaluation and classification may help in efficiently and cost-effectively improve the healthcare quality and patient safety.

ACKNOWLEDGEMENTS

The internship at **Shri Mata Vaishno Devi Narayana Superspeciality Hospital (SMVDNSH), Jammu,** was an amazing opportunity for my professional learning and development. I interacted with great professionals who provided valuable guidance throughout my dissertation. My gratitude extends to **Dr. Rakesh Chander Sahni** (Medical Superintendent, SMVDNSH, Jammu) for his valuable time and motivation, and for imparting his tremendous knowledge to me. I am also very grateful to the hospital's quality department for helping me understand the basics for my project.

I sincerely thank the **IIHMR University** and **Mr. Akshay Oleti** (Oncology Business Head, Narayana Health) for giving me this opportunity to work, learn, and grow at Narayana.

I am very grateful to **Dr. Anshuman Sewda** (Assistant Professor, IIHMR University, Jaipur) for his support, advice, guidance, and expertise throughout this study. It is the result of his encouragement and cooperation that I am able to complete my dissertation during the current global situation and restrictions.

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ABBREVIATIONS

FMEA: Failure mode and effects analysis

FMECA: Failure mode effects and criticality analysis

FMS: Facility Management and Safety

HIRA: Hazard identification and risk analysis

JCAHO: Joint Commission on Accreditation of Healthcare Organizations

JCI: Joint Commission International

NABH: National Accreditation Board for Hospitals and Healthcare Providers

PDCA: Plan-Do-Check-Act

RCA: Root cause analysis

ROM: Responsibilities of Management

RPN: Risk Priority Number

1. INTRODUCTION

Failure mode and effects analysis (FMEA) or failure mode effects and criticality analysis (FMECA) 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-mitigating actions. FMEA in healthcare can be used as a systematic tool for conducting a hazard identification and risk assessment on processes involving medical equipment and patient interactions. FMEA, like other process improvement methodologies, requires a dedicated team of experts from different departments who possess a thorough understanding of the processes that are being evaluated.

Risk management 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, involving error prevention and minimizing adverse event occurrences in a healthcare setting. The National Accreditation Board for Hospitals and Healthcare Providers (NABH) in their accreditation standard Responsibilities of Management 6a directs the management of healthcare facilities to ensure proactive risk management across the organization. Similarly, standard Facility Management and Safety (FMS) 2 of the Joint Commission International (JCI) and FMS 1a of the NABH focus on hazard identification and risk analysis exercises for hospitals and make it mandatory for the facility to take all the necessary steps to eliminate or reduce hazards and associated risks. These major accreditation agencies make it essential for the hospitals to record and monitor all the adverse events, near-misses, and sentinel events transpiring in different departments of the facility.

Contemporarily, apart from FMEA, many approaches like the plan-do-check-act model (PDCA), root cause analysis (RCA), and Lean Six Sigma in healthcare are used to assess, measure, monitor, and evaluate different hospital processes for risks and errors and identify areas for improvement. FMEA involves identifying the flaws or ‘failure mode events’ in a process. Subsequently, the effects of these failure mode events are studied in the patients and prioritized based on severity using a risk priority number, which is the product of severity caused by the failure mode event, probability of failure mode occurrence, and the ease of detection of the failure mode before it has an impact on the process. These failure modes are then mitigated accordingly.

It is appropriate to say that FMEA is a useful tool for proposing a risk reduction plan to improve system safety and reliability.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) formed a roadmap for conducting FMEA in healthcare. The steps include:

1) Forming a flow chart of the process to be studied for errors and describing the effect of each failure mode
2) Describing the causes of each failure mode using a fishbone diagram
3) Assigning a numeric value to each failure mode event according to the severity, probability of occurrence, and detection capabilities, and inferring the risk priority number from these values
4) Proposing and implementing mitigating actions for causes of the identified failure modes

Laboratories play a cardinal role in hospitals. Without laboratories, it would often be impossible for the doctors to conclusively reach a clinical decision and plan a patient's treatment management. Laboratory services comprise all the tests conducted on specimens, such as tissues, blood, and other body fluids from a patient for better diagnosis and treatment. A short turnaround time, accuracy of the results, and high quality are important factors for the efficiency of a laboratory. The process of clinical laboratories can be classified under pre-analytical, analytical, and post-analytical phases (Figure 1.1). Laboratories play an important role in the hospitals, and even the slightest of mistakes could hugely impact the facility as well as the patient.

Therefore, it is essential to check the laboratory processes regularly. FMEA is an effective tool for predicting and managing risks in a process. Applying FMEA to laboratory processes can help the hospital management in identifying the risks and plan corrective measures to reduce and eliminate the identified risks. Several hospitals across the globe have started conducting FMEA as a regular practice in their laboratories; most of them classify failure mode events into three phases of a clinical laboratory (Figure 1.1).

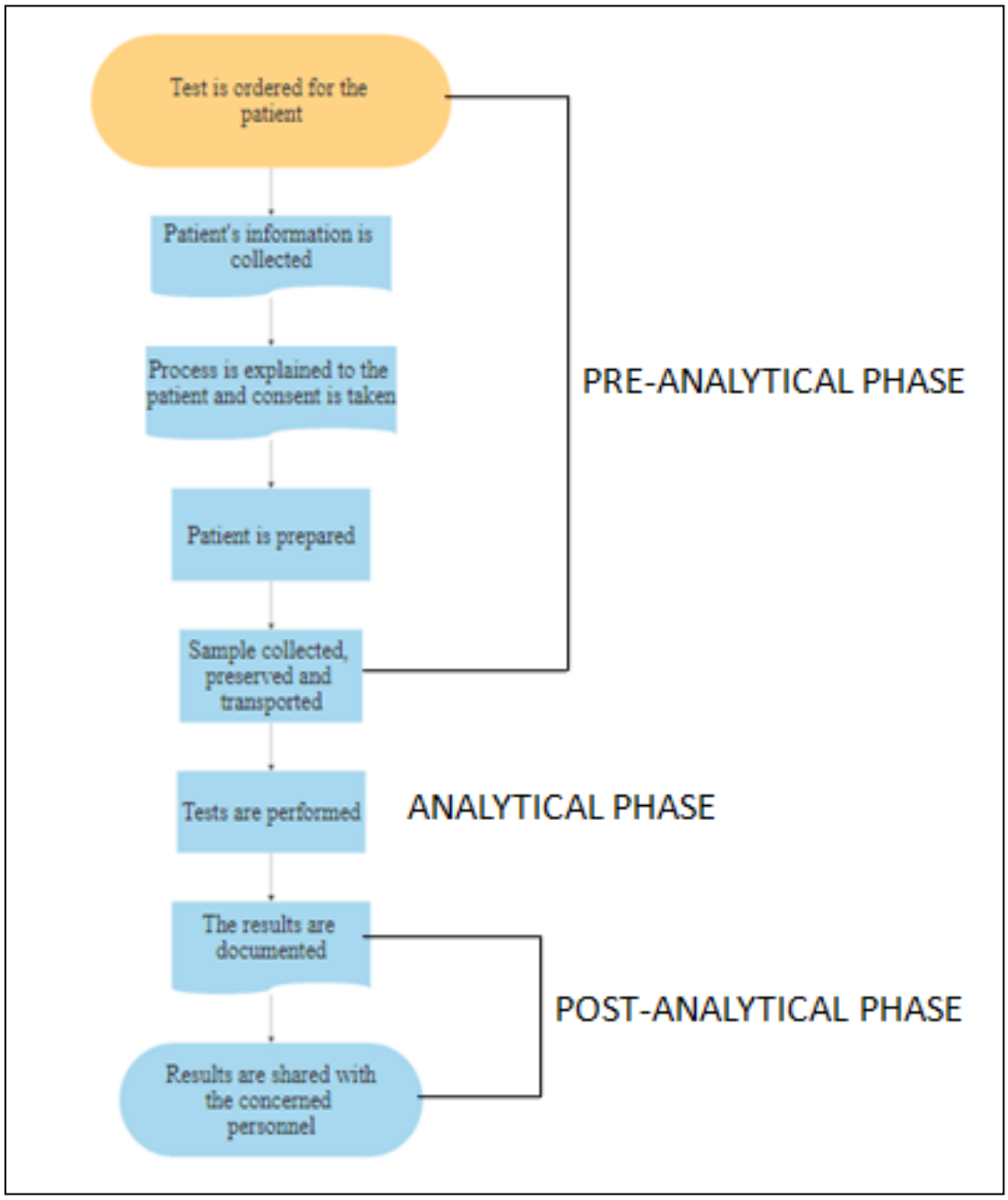

Figure 1.1. The process flow in a clinical laboratory and the corresponding phases.

1.1. Rationale

Classification of data has always helped in making the information simple, brief, comparable, and easy to understand. Classifying failure mode events of a clinical laboratory, as identified using FMEA, can help the management to effectively and efficiently utilize organizational resources by narrowing down their improvement plans to a specific process associated with the highest number of failure mode events. Additionally, the National Accreditation Board of Testing and Calibration Laboratories makes it essential to perform a gap analysis in laboratories and identify areas for improvement. Having a proactive tool for risk management has made it easy to predict potential errors. Risk classification improves the quality, reliability, and safety by making the mitigation more focused and precise in clinical laboratories.

1.2. Research Aims

This study aimed to identify the phase in a clinical laboratory with the maximum number of recorded failure mode events and further classify those events into subcategories. The purpose was to understand the causes of different failure mode events and scientifically arrange them to ensure easy and systematic planning of improvement. Studies that used FMEA as a tool for identifying risks in the laboratory process flow were selected, and the failure mode events identified in them were classified, to visualize the processes that should be prioritized during improvement planning to ensure maximum benefit relative to the incurred cost.

1.3. Objectives

This study had the following research objectives:

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

2. LITERATURE REVIEW

In 1999, the Institute of Medicine published a landmark report entitled "To Err is Human: Building a Safer Health System" that startled the healthcare industry, and encouraged them to recognize, review, and alter their conventional approach to error prevention. Research has shown that more people die of medical errors than AIDS, motor vehicle accidents, or breast cancer (1). In a hospital, 80%–90% of all diagnoses are made on the basis of laboratory tests. Laboratory errors have a reported frequency of 0.012%–0.6% of all test results (2). Traditionally, a reactive approach was used for error prevention in healthcare; that is, the errors were handled after they had occurred. However, experts soon realized that patient safety could only be enhanced by preventing error events, that is, detecting them before they occur and eliminating their effects (3). The healthcare fraternity needed a more proactive methodology for error detection and prevention.

In the 1940s, the US military originally developed FMEA as a reliability analysis tool, which was then used by National Aeronautics and Space Administration in the 1960s to enhance the safety and quality of their projects (4). FMEA gained popularity among different industries. Starting with the aerospace industry, FMEA made its way into a variety of sectors, including automobile, food services, semiconductor pressing, plastic, software, and healthcare (5). In the healthcare industry, FMEA became such a comprehensive and valuable tool that major accreditation agencies, such as JCI and NABH, included FMEA as an essential aspect for quality improvement of healthcare facilities. JCI even published FMEA for healthcare in the Joint Commission Resources (JCR) which is a non-profit affiliate of the JCI designated to publications and multimedia for education and consultation. In 2002, FMEA was recommended by JCAHO in the standard LD5.2 for regular examining healthcare systems for the prevention of healthcare failures (6).

Today, FMEA is applied to almost all processes of a hospital. Several studies have provided evidence that FMEA is an effective tool for healthcare processes (2,7). Hospital laboratory processes are no exception. Excellent quality in laboratory medicine should be ensured to perform each step correctly, thus reliably contributing to decision making and effective patient care (8). Any failure in the laboratory processes can lead to severe consequences for the patients (9).

Therefore, we have to implement improvement plans to identify and manage these failures. 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 (9). Studies have shown these processes by designing indicators related to customer services, competency of professionals and other operational, strategic, and support processes of a laboratory (10). Majority of publications focused on one or more aspects of operational processes, namely pre-analytical, analytical, and post-analytical processes. However, only a few studies further classified operational failure mode events. Systematic segregation of these operational failures under categories may aid in their management and help facilitate a strategic plan to mitigate or eliminate them.

Table 2.1 discusses the literature on clinical laboratory FMEA. The reviewed articles confirm that FMEA is an efficient tool to use in the clinical laboratory for risk management. FMEA identified that the majority of failure mode events in a clinical laboratory occur during the pre-analytical phase, possibly because it involves more components than the other phases. Moreover, technological advancements in the analytical phase have reduced the error probability.

Table 2.1. Research articles reviewed for the systematic review and meta-analysis.

S. No.	Title and Author	Year	Study Location	Study Findings and Conclusions
1	Engineering for Safety: Use of Failure Mode and Effects Analysis in the Laboratory (Woodhouse)	2005	USA	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)	2006	Italy	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.)	2009	Netherlands	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.)	2009	Italy	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.)	2013	Brazil	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.

S. No.	Title and Author	Year	Study Location	Study Findings and Conclusions
6	Measurement of Errors in Clinical Laboratories (Agarwal)	2013	India	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)	2014	Netherlands	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.)	2015	Turkey	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.)	2016	Israel	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.)	2017	Spain	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.

S. No.	Title and Author	Year	Study Location	Study Findings and Conclusions
11.	Health Safety Management: The Model of FMEA/FMECA in Anatomic Pathology Service (Ianni et al.)	2018	Italy	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.).	2018	India	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.).	2018	Spain	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.).	2018	India	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).	2019	Macedonia	Classified failure mode events identified in the laboratory medicine under environmental, operator, specimen and analysis according to the cause of the event.

3. METHODOLOGY

3.1. Research Questions

1) What are the different classification categories of pre-analytical failure mode events in a clinical laboratory?
2) Which of these pre-analytical phase categories have the maximum and most severe failure mode events?

3.2. Research Design

A descriptive study design was implemented to collect secondary data for the analysis.

3.3. Study Selection

A two-stage screening process was used to identify articles to be included in the meta-analysis. In the first stage, articles and papers that examined the risk perception in clinical laboratories using an FMEA tool were identified. Google Scholar and Pub Med databases were searched for articles whose titles, abstracts or keywords included a reference to FMEA in clinical laboratories or laboratory medicine.

In the second stage, it was determined whether the studies satisfied the inclusion criteria. A study was included in our meta-analysis if it was based on primary data and 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. Studies that fulfilled the inclusion criteria were explored further for failure mode events in the pre-analytical phase, which was further divided into sub-phases to classify the identified events.

Studies that had provided the list of identified failure mode events were included in the meta-analysis.

4. RESULTS

Of all the primary studies on clinical laboratory FMEA, five articles were shortlisted for the meta-analysis. Based on these studies, forty different failure mode events in the pre-analytical phase were identified.

The pre-analytical phase of laboratory medicine was operationally divided into the following sub-phases:

1) Request form sent for the test
2) Appointment system
3) Patient preparation
4) Sample collection and transportation
5) Reception and preparation of samples

Table 4.1. Pre-analytical failure mode events categorized by sub-phases.

S. No.	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

S. No.	Failure Mode Event
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

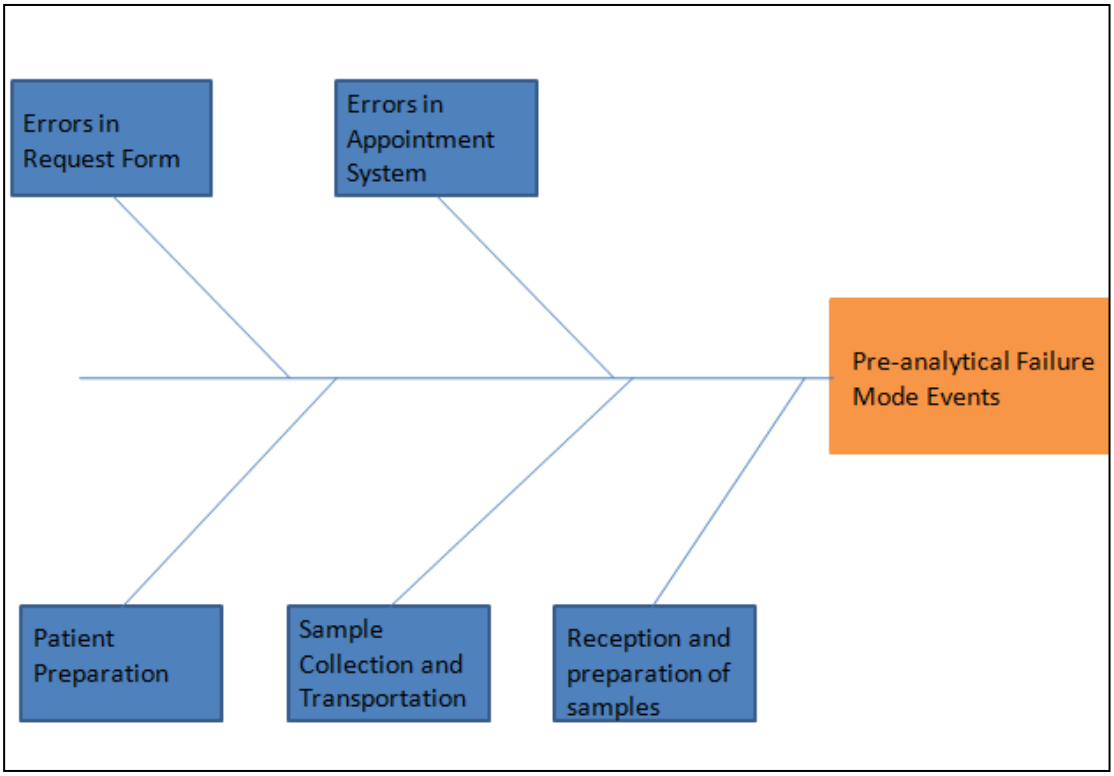

Figure 4.1. Fishbone diagram depicting the reasons for pre-analytical failure mode events in clinical laboratories which forms the bases for classification of the sub-phases.

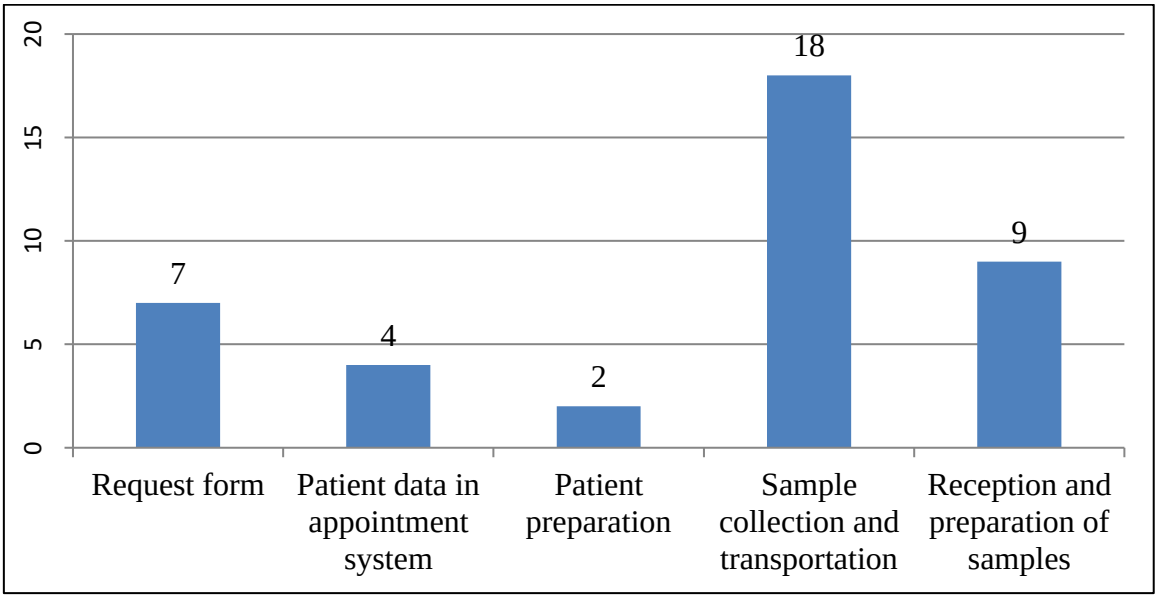

Figure 4.2. Graphical representation of the number of pre-analytical failure mode events classified and different sub-phases. Sample collection and transportation have the highest frequency of failure mode events.

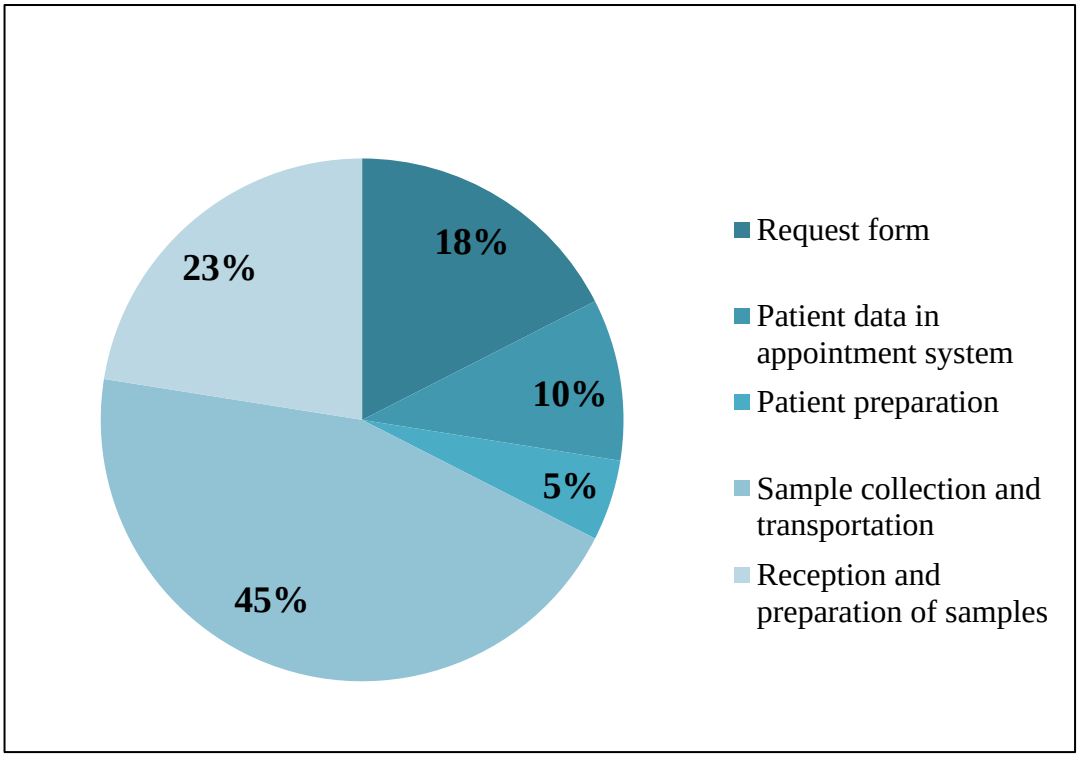

Figure 4.3. Pie chart showing that 45 per cent of all pre-analytical failure mode events occur due to errors in sampling and transportation.

Table 4.2. Pre-analytical failure mode events with their sub-phases and severity index number.

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	

Table 4.3. Severity index for clinical laboratories (11).

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 hypo glycemic medication
Catastrophic	5	Significant adverse clinical outcome, e.g., significant morbidity or mortality

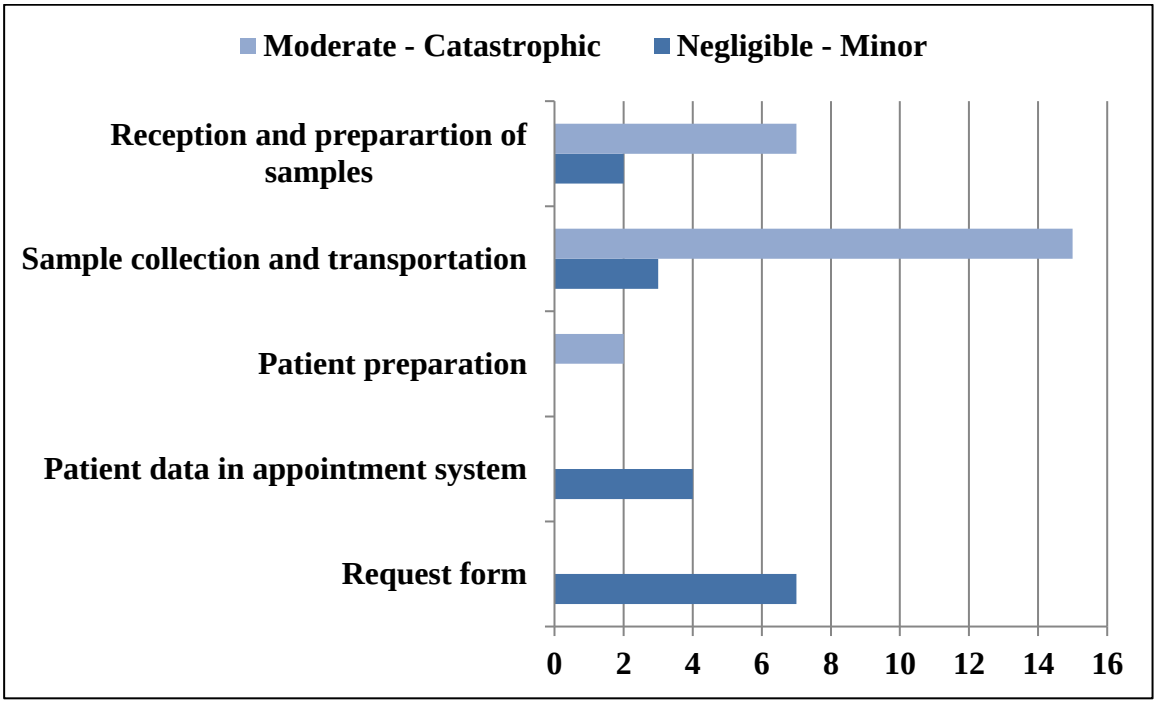

Figure 4.4. Severity of failure mode events in different pre-analytical sub-phases. Sample collection and transportation sub-phase has the highest frequency of moderate-to-catastrophic failure mode events.

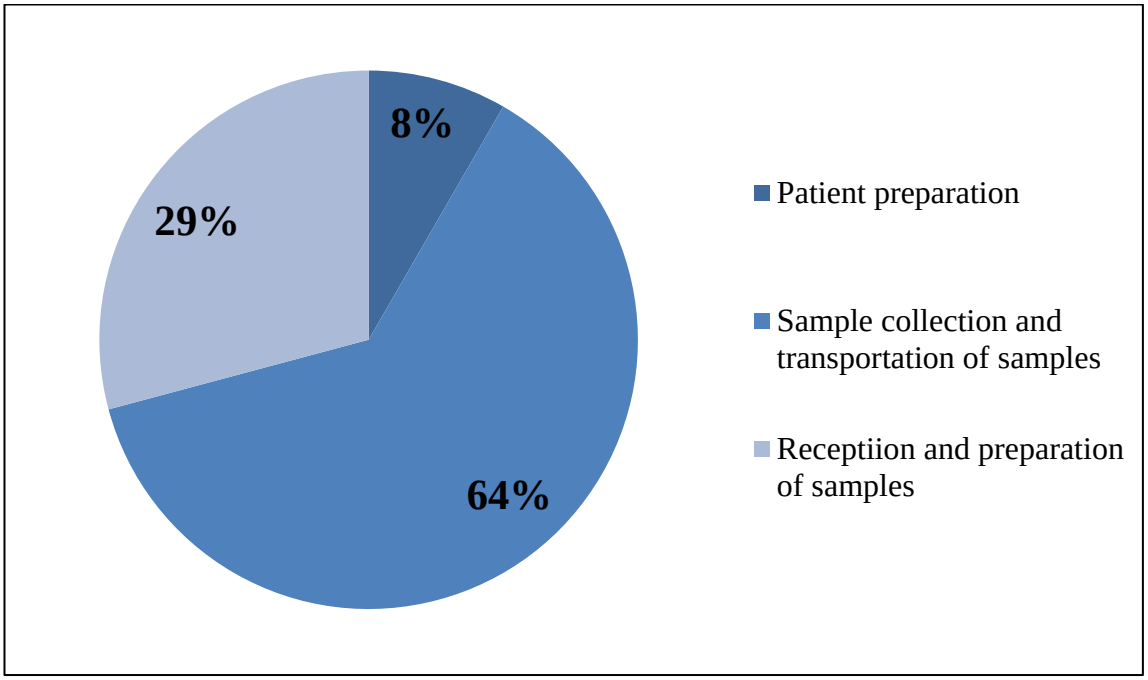

Figure 4.5. Sub-phases of pre-analytical phase associated with severity rating of 3 and above.

5. DISCUSSION

The concept of quality is multifaceted and comprehensive, whose measurements shift in significance relying on the circumstances. In clinical laboratories, speculation and mitigation of risks is an essential aspect of quality. Even 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. Plausible risk investigation for high-risk procedures in a clinical laboratory can be performed with the assistance of FMEA.

The empirical literature available on the application of FMEA in clinical laboratories provides evidence that FMEA has an overall positive effect on the laboratory process, and a high degree of consistency was observed in different failure mode events under the three phases of laboratory (Table 2.1). The studies included in our systematic review and meta-analysis showed that the failure mode events in clinical laboratories were by and large classified under three operational phases, namely pre-analytical, analytical, and post-analytical phase (Figure 1.1). The studies also depicted that the majority of failure mode events in clinical laboratories were pre-analytical in nature. The rationale behind these observations is the length of the pre-analytical phase, and the fact that most activities in the pre-analytical phase are performed by people and most of the mistakes and errors are related to cognitive and behavioural factors.

For having a more explicit outlook on the pre-analytical failure mode events, this study further classified the pre-analytical phase into sub-phases based on the activities performed (Figure 4.1):

1) Request form: When the patient is advised for an investigation, and the doctor sends the test order to the laboratory
2) Appointment system: Patient's data entry for setting up an appointment
3) Patient preparation: The initial instructions given to the patient for making him/her ready for the test
4) Sample collection and transportation: Collection of the specimen and transportation of the specimen for analysis under suitable conditions
5) Reception and preparation of samples: Receiving the specimen safely and initial preparation of the specimen

These sub-phases helped in associating each failure mode to a specific activity (Table 4.1). The analysis showed that the maximum number of pre-analytical failure mode events (45% or 18 out of 40) were associated with the sample collection and transportation phase (Figure 4.2 and 4.3). This can be attributed to the fact that sample collection and transportation has maximum human involvement, thus a greater probability of errors. In order to improve the error rate, the management should focus on making these processes simplified, standardized, and automated whenever possible. Furthermore, redesigning the processes and training and motivation of the involved staff should be performed.

This meta-analysis also presents the severity index for clinical laboratories (Table 4.2). A previously published, five-scaled severity index particularly designed for clinical laboratories, was used to assign a rating to each of the forty failure mode events that were identified (Table 4.3). A total of 24 failure mode events received a rating of 3 or above. Of these 24 events, 15 (62.5%) were related to sample collection and transportation, seven (29.1%) were associated with reception and preparation of samples, and two (8.3%) with patient preparation (Figure 4.4 and 4.5). This indicated that sample collection and transportation was the sub-phase with the most severe errors. This accounts from the fact that the patient is under risk when the sample is being collected, and if the sample is contaminated or lost during transportation, the patient has to undergo sampling again and is once more exposed to the related risks. This study helps to understand the basic outline of the laboratory processes and support in pinpointing at what step most sever errors can occur, another strength of this study is that it goes beyond the three basic phases of a laboratory process (Figure1.1). The study also helps in prioritizing the failure mode events according to the severity by adopting the severity index exclusively published for clinical laboratories (Table 4.3). Although there are some limitations to this study, risk priority number for an FMEA is a product of the severity number, probability of occurrence of the errors and probability of detection of the errors but this study considers only the severity number. Another limitation is that this study mainly focused on the pre-analytical phase of the laboratory as according to the literature, it is the most flawed phase; however, for a different laboratory setting this can change.

6. CONCLUSIONS

Healthcare providers are making efforts to make their organizations more patient-centric, for which process analysis, error handling, and assessments of programs for risk reduction are considered important aspects of corporate policies of quality assurance in healthcare. FEMA, an engineering approach of predicting failure events, is useful for healthcare organizations in predicting errors and improving patient safety.

The pre-analytical phase of a clinical laboratory, especially the sample collection and transportation sub-phase, was the most severe and common failure mode event. 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. Furthermore, 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 countermeasures. 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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