

PROCESS INNOVATION IN LABORATORY SERVICE SYSTEMS: ENHANCING OPERATIONAL PERFORMANCE AND RISK REDUCTION THROUGH FMEA

Yasemin Aslan¹
Dolunay Özlem Zeybek
Buse Dursun

Received 02.02.2026.

Revised 19.04.2026.

Accepted 05.05.2026.

Keywords:

*Process innovation, FMEA, Risks
Management, Quality of Health Care.*

Original research



ABSTRACT

This study aimed to conduct a prospective risk analysis of pre-analytical processes in a central laboratory to enhance patient safety. Failure Mode and Effects Analysis (FMEA) was conducted in the central laboratory of a private hospital in Türkiye. A multidisciplinary risk assessment team consisting of 10 members with expertise in laboratory, clinical, quality, and safety processes was established. The pre-analytical risk assessment process was examined under five main processes: specimen collection, analysis ordering, patient records, transport and temporary storage, and barcoding. Brainstorming, flowchart diagrams, and the multi-voting technique were used to identify and prioritize failure modes and their causes, assess severity, occurrence, and detectability, and propose corrective actions. Risk Priority Numbers (RPNs) were calculated by multiplying severity, occurrence, and detectability scores assigned by the team. A total of 36 potential failure modes were identified, and their causes, effects, and corrective actions were analyzed. The highest-risk failure modes included failure to order or incomplete ordering of tests by physicians (RPN: 80), blood sample collection using syringes (RPN: 80), incorrect test ordering (RPN: 64), registration under the wrong patient (RPN: 64), improper application of the tourniquet (RPN: 60), incorrect transfer of blood collected by syringe into tubes resulting in hemolysis or insufficient/excessive sample volume (RPN: 64), and loss of specimens (RPN: 64). Following the implementation of corrective actions, overall risk levels were reduced by 66.75%. This study demonstrates that FMEA is an effective and practical tool for identifying, prioritizing, and reducing risks in pre-analytical processes within a central laboratory of a hospital.

© 2026 Journal of Innovations in Business and Industry

1. INTRODUCTION

Risk is an unavoidable part of daily life and cannot be completely eliminated in complex systems (Arimbi et al., 2019). It is generally defined as the possibility that an event may occur and negatively affect the achievement of organizational objectives. Risk management, in turn, includes all activities related to identifying risks, assessing their potential impact, selecting appropriate

control measures, and continuously monitoring outcomes (La Russa & Ferracuti, 2022; Pascarella et al., 2021). As planned outcomes may not always be achieved, risk management has emerged as a priority for individuals, organizations, and governments (Pascarella et al., 2021). Risk assessment is commonly described as a structured process consisting of three main stages: risk identification, risk analysis, and risk evaluation (Güneş, 2025; La Russa and Ferracuti, 2022; Pascarella et al.,

¹ Corresponding author: Yasemin Aslan
Email: yaseminaslan@bandirma.edu.tr

2021). Among different sectors, healthcare is widely recognized as one of the highest-risk environments due to its complex workflows, heavy workload, time pressure, and direct impact on patient safety (Adekoya et al., 2025; La Russa & Ferracuti, 2022).

In healthcare settings, the main goal of risk management is to systematically identify and evaluate risks and to prevent adverse events affecting both patients and healthcare professionals through proactive approaches. Rather than focusing solely on responding to incidents after they occur, this perspective emphasizes anticipating potential failures within complex healthcare processes before harm arises (DeRosier et al., 2002; Joint Commission Resources, 2010). Accordingly, healthcare risk management relies on continuous assessment, structured planning, and the use of systematic tools to identify vulnerabilities across clinical and organizational workflows (Liu et al., 2020; Pascarella et al., 2021). This approach draws attention not only to emerging risks associated with technological advancements and digitalization, but also to persistent system weaknesses related to human factors, communication failures, and process variability (La Russa & Ferracuti, 2022; Simsekler et al., 2019). Effective risk management therefore, plays a key role in improving the quality of care, enhancing patient safety, and strengthening the resilience of healthcare systems (Adekoya et al., 2025; Aslan, 2023; Baehr et al., 2020; Hu et al., 2022; La Russa & Ferracuti, 2022).

Failure Mode and Effects Analysis (FMEA), as a risk management methodology, has in recent years been positioned not only within healthcare but also as an integral component of operational excellence and innovation strategies in the broader framework of service systems. New approaches supported by artificial intelligence, ontology-based information systems, and digital technologies have extended the traditional boundaries of FMEA, delivering measurable efficiency gains and economic benefits (Younus et al., 2024). In modern manufacturing environments, the integration of FMEA with artificial intelligence and the Internet of Things (IoT) enhances process reliability while simultaneously reducing costs and improving product quality (Thomas, 2025). These developments demonstrate that FMEA is not merely a tool for error prevention but also a strategic innovation mechanism that fosters sustainable value creation and service quality improvement. Particularly in the automotive, aerospace, and energy sectors, FMEA has shown strong results in terms of process optimization and risk reduction (Ratajszczak et al., 2025).

2. LITERATURE REVIEW

Healthcare organizations are complex and high-risk systems in which professional, technological, and managerial components are closely interconnected. Failures in one component may rapidly affect the entire system. In such environments, even low-probability

events can lead to serious consequences for patients, healthcare professionals, organizational costs, and institutional reputation. To manage these risks, healthcare has increasingly adopted risk assessment and prioritization tools originally developed for high-reliability industries such as nuclear power, manufacturing, and aviation (Pascarella et al., 2021). Within this framework, risk analysis involves identifying potential sources of risk, evaluating their possible consequences, and estimating the likelihood of occurrence. This process helps distinguish acceptable clinical risks from unacceptable ones and supports informed, evidence-based decision-making in risk management (Pascarella et al., 2021). These characteristics highlight the need for structured and proactive risk analysis methods, such as Failure Mode and Effects Analysis (FMEA), particularly in complex healthcare processes (Lago et al., 2012; Ullah et al., 2022; Yousefinezhadi et al., 2016).

Medical laboratories are essential components of healthcare systems, supporting both diagnostic and therapeutic decision-making. Clinical laboratories play a critical role in diagnosis, prognosis, treatment monitoring, and disease prevention by providing accurate, reliable, and timely test results (Adekoya et al., 2025; Inal et al., 2018; Letelier et al., 2021). Beyond diagnosing infections, metabolic disorders, and malignancies, laboratories also contribute to personalized medicine through genetic and molecular analyses and ensure test reliability through robust quality control practices (Adekoya et al., 2025). Laboratory services rely on well-coordinated workflows with clinical and administrative healthcare units, as well as on comprehensive quality systems that ensure reliability and patient safety across the pre-analytical, analytical, and post-analytical phases of testing (Adekoya et al., 2025; Englezopoulou et al., 2016; Perrotta et al., 2020). Although advances in standardization, instrumentation, staff training, and laboratory information systems have reduced error rates in the analytical and post-analytical phases, most laboratory errors still occur during the pre-analytical phase (Englezopoulou et al., 2016; Flegar-Meštrić et al., 2017; Nordin et al., 2024; Persoon et al., 2006). This phase includes test ordering, patient preparation, specimen collection, handling, transport, and delivery to the laboratory, all of which are highly vulnerable to biological, environmental, and technical factors (Ellervik & Vaught, 2015; Englezopoulou et al., 2016; Grankvist et al., 2019; Perrotta et al., 2020). The pre-analytical phase consists of two main stages: an extra-laboratory stage, which includes test ordering, patient preparation, specimen collection, transport, and temporary storage; and an intra-laboratory stage, involving sample reception, acceptance, labeling, centrifugation, distribution, and preparation for analysis (Ellervik & Vaught, 2015; Flegar-Meštrić et al., 2017; Grankvist et al., 2019). Due to its complexity and limited controllability, the pre-analytical phase remains a critical area for quality improvement and risk management initiatives.

Quality risk management aims to systematically assess, control, communicate, and review risks at every stage of healthcare processes (Elmadhoun et al., 2025). Various risk assessment methods, such as Failure Mode and Effects Analysis (FMEA), Fine-Kinney, root cause analysis, decision matrix risk assessment, fault tree analysis, and lean management approaches, have been applied in healthcare settings (Kammoun et al., 2021; Letelier et al., 2021; Pascarella et al., 2021; Yousofnejad et al., 2024; Zhang et al., 2025). Among these, FMEA stands out as a proactive and systematic method that identifies potential failure modes, analyzes their causes and effects, and supports the implementation of preventive actions before errors occur (Lago et al., 2012; Manrique-Rodríguez et al., 2014; Najafpour et al., 2017). While FMEA is widely recognized as a proactive risk assessment tool, it is often compared with alternative methods such as Root Cause Analysis (RCA), Fault Tree Analysis (FTA), and Lean Six Sigma approaches. Unlike reactive methods such as RCA, which focus on analyzing errors after they occur, FMEA enables prospective identification and prioritization of potential failures before they impact system performance (Liu et al., 2020). Similarly, compared to FTA, which models causal relationships in a top-down manner, FMEA offers a more process-oriented and operationally applicable framework for frontline risk management (Pascarella et al., 2021). In recent years, hybrid and enhanced models, such as fuzzy FMEA, artificial intelligence-supported risk assessment, and data-driven decision systems, have been proposed to overcome limitations of traditional scoring systems and improve prioritization accuracy (En-Naaoui et al., 2023; Liu et al., 2020). These advancements position FMEA not only as a classical quality tool but also as an evolving methodology integrated with digital technologies, thereby strengthening its innovation potential and applicability across complex service systems.

Over the past decade, FMEA has been widely applied across diverse healthcare domains, including medication safety, diagnostic services, intensive care units, blood transfusion processes, and hospital management, demonstrating its effectiveness in reducing risks and improving patient safety (Abbasgholizadeh Rahimi et al., 2015; Anjalee et al., 2021; La Russa et al., 2022; Najafpour et al., 2017). In addition to improving patient safety, implementing FMEA in the pre-analytical laboratory process demonstrated measurable operational efficiency gains and potential economic benefits. The reduction in high-risk failure modes is likely to decrease sample rejection rates, minimize the need for repeat testing, and shorten turnaround times, thereby improving workflow continuity and resource utilization. From an operational perspective, fewer process disruptions and errors contribute to increased productivity and reduced workload for healthcare professionals. Economically, preventing pre-analytical errors can lead to significant cost savings by reducing material waste, labor time, and indirect costs associated with delayed diagnosis or extended hospital stays. These findings align with previous studies indicating that quality improvement and

risk management interventions, such as FMEA, can enhance efficiency while simultaneously lowering operational costs in laboratory and healthcare settings (John et al., 2025; Wei et al., 2026).

Beyond healthcare, Failure Mode and Effects Analysis (FMEA) has been widely applied across various industries as a core tool for achieving operational excellence, enhancing process reliability, and supporting innovation in service systems. In manufacturing, aerospace, automotive, and energy sectors, FMEA contributes to reducing process variability, improving system performance, and minimizing operational risks through proactive failure identification and continuous improvement practices (Fragassa & Ippoliti, 2016; Wu et al., 2021). In industrial engineering contexts, FMEA is frequently integrated with Lean and Six Sigma methodologies to support process optimization, waste reduction, and performance improvement, thereby strengthening its role as a key instrument of operational excellence (Omisola et al., 2024).

Within the broader service systems perspective, organizations are viewed as interconnected networks of people, technologies, and processes that co-create value, where risk management tools such as FMEA play a critical role in ensuring efficiency, service quality, and sustainability (Gomaa, 2025). Moreover, the integration of FMEA with digital technologies, artificial intelligence, and data-driven decision-making approaches has further expanded its role as an innovation-enabling tool in complex systems (En-Naaoui et al., 2023). Therefore, positioning FMEA within an operational excellence and service systems framework highlights its applicability not only in healthcare but also across diverse sectors, reinforcing its value as a strategic tool for process optimization and performance improvement.

In FMEA, each potential failure mode is assigned a Risk Priority Number (RPN) based on severity, occurrence, and detectability scores, allowing risks to be systematically prioritized (Elmadhoun et al., 2025; Fragassa and Ippoliti, 2016; Jin et al., 2024; Joint Commission, 2010). Accordingly, the present study aimed to conduct a prospective risk analysis of pre-analytical processes, from specimen collection to sample acceptance in the laboratory, within a central laboratory setting. By applying FMEA to the entire pre-analytical workflow, this study seeks to support targeted risk reduction strategies and contribute to improved patient safety. The specific objectives of the study were to:

- identify potential risks and failure modes in pre-analytical laboratory processes;
- evaluate the possible effects of these failures on patient safety;
- determine the main causes of pre-analytical failures;
- identify failure modes with the highest Risk Priority Numbers (RPNs); and
- propose corrective actions to reduce identified risks.

3. MATERIALS AND METHODS

3.1 Type of the Research

This is a descriptive, prospective, and cross-sectional study.

3.2 Study Population

The scope of the study included all risks identified by the risk assessment team during the pre-analytical processes in the central laboratory of a private hospital in Ankara between November 1 and December 31, 2024. All identified risks were evaluated without sampling.

3.3 Study design

The FMEA was performed following the systematic stepwise framework recommended by ISMP-Canada (Greenall et al., 2007). The process began with selecting the process of interest and assembling the team (Step 1). Next, the process was diagrammed to ensure a clear understanding of each component and workflow (Step 2). Following this, the team brainstormed potential failure modes and identified their possible effects (Step 3), and then determined the underlying causes of each failure mode (Step 4). Based on these findings, the failure modes were prioritized according to their level of risk (Step 5). The team then proceeded to redesign the process to address the identified risks (Step 6). Afterward, the proposed changes were analyzed and tested (Step 7). Finally, the redesigned process was implemented and monitored to ensure sustained improvement and safety (Step 8) (Greenall et al., 2007). FMEA phases and tools are given in Table 1.

Table 1. FMEA Phase and Tools

No	FMEA phase	Tool(s)		
		Brain storming	Flow chart diagram	Multi-voting technique
1	Selection of processes and establishment of the multidisciplinary team	The hospital administration and the research team		
2	Assemble the team	The hospital administration and the research team		
3	Process mapping	✓	✓	
4	Risk assessment of each sub-process	✓		✓
5	Implementing corrective actions to restructure the process	✓		✓
6	Monitoring and reassessment of improvements	✓		✓

3.4 FMEA Steps

3.4.1 Process selection and team assembly

The pre-analytical phase of central laboratories was selected as the focus of this study because it involves multiple stakeholders, decentralized processes, and high

variability, making it particularly vulnerable to errors that may directly affect patient safety. Central laboratories handle large test volumes from different clinical units, increasing process complexity and the potential for systemic failures. Despite technological advancements, pre-analytical errors remain the most frequent source of laboratory-related risks, highlighting the need for a comprehensive and proactive risk assessment approach in this critical phase (Adekoya et al., 2025; Ellervik and Vaught, 2015; Flegar-Meštrić et al., 2017; Letelier et al., 2021). Focusing on this stage aligns with quality and accreditation standards and offers significant opportunities for process standardization and improvement.

To build an effective team, we used the risk-management recommendations of the American Society for Healthcare Risk Management (ASHRM) and ISMP Canada. ASHRM recommends that an FMEA team include subject-matter experts, a team leader, a facilitator familiar with the FMEA process, and a neutral member who can provide an outside perspective (Barker et al., 2002). According to ISMP Canada, the FMEA team should include front-line practitioners and managerial staff, who together offer detailed insight into daily operations and a broader perspective on resource allocation (Barker et al., 2002).

Table 2. Risk Assessment Team

No	Job title	Duty	Work experience (year)	FMEA evaluation	Experience in risk assessment
1	Laboratory physician in charge	Head of risk assessment team	18	✓	Medium
2	Deputy hospital director	Vice President	15	✓	Medium
3	Occupational safety specialist 1	Reporter	8	✓	High
4	Occupational safety specialist 2	Member	5	✓	High
5	Quality manager	Member	12	✓	High
6	Education nurse	Member	7	✓	Medium
7	Supervisor nurse	Member	9	✓	Medium
8	Laboratory coordinator	Member	15	✓	Medium
9	Director of nursing	Member	18	✓	Medium
10	Deputy quality manager	Member	12	✓	High

The FMEA team consisted of ten members with diverse roles and experience in the hospital and laboratory setting (Table 2). The team was led by the laboratory physician in charge, who served as the head of the risk assessment team, supported by the deputy hospital director. Core

team members included occupational safety specialists, a quality manager, a deputy quality manager, a laboratory coordinator, education and supervisory nurses, and the director of nursing. Team members had between 5 and 18 years of professional experience, with varying levels of prior experience in risk assessment, ranging from medium to high. All participants were actively involved in the FMEA evaluation process (Table 2).

3.4.2 Mapping the process

Workflow mapping provides a structured way to evaluate work processes and identify activities that do not contribute value (Perrotta et al., 2020).

Table 3. GANT Chart

No	Mission	2024							
		November				December			
		1	2	3	4	1	2	3	4
1	Identification of the appropriate study area for FMEA								
1.1	Establishment of the FMEA team: designation of the team leader and members								
1.2	Determination of the meeting schedule								
2	Initial meeting with FMEA team members								
2.1	Definition of the pre-analytical process flow related to materials sent to the laboratory								
2.2	Identification of sub-processes								
3	FMEA team meeting								
3.1	Conducting observations and assessments with team members in all departments where specimens are collected, such as the emergency department, intensive care units, outpatient clinics, and inpatient wards								
3.2	Evaluating the accuracy of the main process and sub-process stages based on observations and assessments, and making final decisions								
3.3	Conducting brainstorming sessions on failure modes and identifying problems through majority voting								
4	Performing site visits, including areas where specimens are collected								
5	FMEA team meeting								
5.1	Refining and updating failure modes based on information provided by staff involved in the processes								
5.2	Assigning team members to interview staff involved in the processes to contribute to the identification of failure modes and their underlying causes								
6	FMEA team meeting								
6.1	Refining and updating failure modes based on information provided by staff involved in the processes								
6.2	Recording identified failure modes and their underlying causes in the FMEA data collection form								
6.3	Evaluating each failure mode and its causes to determine probability (occurrence), severity, and detectability scores								
7	FMEA team meeting								
7.1	Defining corrective actions and assigning responsible persons and timelines for monitoring								
7.2	Continuing risk analysis and the identification of corrective actions to reduce Risk Priority Numbers								
8	FMEA team meeting								
8.1	Assigning team members to monitor staff responsible for implementing corrective actions								
9	FMEA team meeting								
9.1	Refining and updating failure modes based on information provided by staff involved in the processes								
10	FMEA team meeting								
10.1	Testing the proposed changes and evaluating data related to process modifications that document their effectiveness								
11	FMEA team meeting								
11.1	All actions decided upon must be approved in consultation with hospital management.								
12	FMEA team meeting								
12.1	Preparation of the HTEA report								
12.2	Review of the HTEA report with the Hospital Director, Quality Group Manager, and all team members, presentation on the study, and completion of the project.								
13	Evaluation of improvement results								

March 2025



Figure 1. Simple process map

The pre-analytical process workflow diagram for the central laboratory is given in Figure 1.

3.4.3 GANT Chart

The Gantt chart for the work and time planning of the central laboratory pre-analytical process is presented below (Table 3).

3.5 Data Collection

Brainstorming, multi-voting technique, and the flowchart diagrams were used in the data collection process (Simsekler et al., 2019; Al-Baadni and Al Magrabi, 2023) (Table 1). Brainstorming is a commonly applied and effective technique within systems-thinking approaches, designed to stimulate group creativity. It enables participants to openly share ideas on a defined issue without immediate evaluation or criticism. Through this process, teams can better analyze and understand workflows, develop innovative solutions, encourage open and flexible thinking, explore diverse alternatives, and promote active involvement of all members (Al-Baadni and Al Magrabi, 2023; Gogatz and Azavedo, 2023). A flowchart, also known as a process map, is a basic tool used to visually represent the steps of a process in sequence. It helps simplify complex workflows, making them easier to understand, examine, and improve (Al-Baadni and Al Magrabi, 2023; Elahi, 2022). Multi-voting, also called the nominal group technique, is a structured method in which a team uses several rounds of voting to reduce many ideas to a smaller, prioritized set. It is often combined with brainstorming and is considered a practical, quick, and cost-effective way to support group decision-making (Al-Baadni and Al Magrabi, 2023; Harvey et al., 2024).

At the data collection stage, the researchers first reviewed the literature and then developed a pre-analytic risk assessment form using Microsoft Excel. The form covered the main and sub-processes, potential failure modes, their causes and effects, probability, severity, and detectability scores, risk priority number, corrective actions, timelines, responsible personnel, and post-intervention risk scores (DeRosier et al., 2002; Simsekler et al., 2019; Weber et al., 2022). The determination of probability, severity, and detectability scores was based on the opinions of the risk assessment team, previous incident reports, and documents related to the pre-analytical process of the central laboratory. Documents were obtained from the quality management system. Previous incident reports were obtained from the quality management department, the occupational health and safety department, and the central laboratory's archives. The data were obtained from multidisciplinary risk assessment team meetings held between November 1 and December 31, 2024, conducted once a week for three hours per day, totaling 24 hours. The risk assessment team, consisting of 10 specialists from relevant departments, is presented in Table 2.

First, all participants were informed about the aim of the study, the method to be used, and how the data would be collected. Then, a process flowchart was developed (Figure 1). Next, the procedures, instructions, and workflow charts of the central laboratory pre-analytical process were reviewed. Using brainstorming and multi-voting, the team identified the main and sub-processes, as well as possible failures, their causes, and effects, based on the opinions of all specialists. This stage took about 12 hours, and all views were recorded. After each session, the researchers summarized the results and

shared them with the participants by e-mail before the next meeting. The identified risks were then scored for probability, severity, and detectability. Individual scores were averaged and shared with the team before the final session. In the final stage, all items were reviewed to reach consensus, and preventive actions, timelines, and responsibilities were defined, giving priority to very high-risk items, followed by high- and medium-risks (Table 7). This stage lasted approximately six hours. To improve reliability and validity, individual evaluations were shared with all team members, and their consistency was confirmed through group discussion using multi-voting and brainstorming. After the corrective actions were implemented, the same group of specialists met for six hours in March 2025 to assess the effectiveness of the FMEA and calculate the post-intervention risk scores (Table 7).

3.6 Statistical Analysis

Data were analyzed using the FMEA method. In this approach, the team evaluates each risky situation by scoring its probability, severity, and detectability, and improvement actions are prioritized for risks considered unacceptable.

Table 4. Rating scales used to assign values to the occurrence (O), severity (S), and detection (D) scores in the failure mode and effect analysis

Occurrence (O)		Severity (S)		Detection (D)	
Score	Failure mode probability	Score	Description of injury	Score	Likelihood of detection
1	Remote: the failure rarely occurs, with an estimated frequency of 1 in 10,000 events	1	No harm to the patient, and monitoring alone is sufficient.	1	Very high: detected 9/10 times
2	Low: unlikely to happen, observed in 1 per 1,000 events	2	Temporary injury requiring additional intervention or treatment.	2	High: detected 7/10 times
3	Moderate: happens intermittently, observed in 200 instances	3	Temporary injury with a longer hospital stay or an increased level of care	3	Medium: detected 5/10 times
4	High: happens frequently, observed in 1 per 100 events	4	Permanent effects on body functions	4	Low: detected 2/10 times
5	Very High: happens frequently, observed in 1 per 20 events	5	Death or permanent loss of major body functions	5	Remote: detected 0/10 times

Source: Joint Commission, 2010

Occurrence reflects how often a risk may happen, severity indicates how serious its impact would be, and detectability refers to how easily the risk can be identified before it occurs. The Risk Priority Number (RPN) is calculated by multiplying these three scores. All values are rated on a 5-point scale, as shown in Table 4. Higher RPN scores point to areas that require priority improvement (Elmadhoun et al., 2025; Greenall et al., 2007; Joint Commission, 2010; Stojković et al., 2017). An action plan was established to address high-risk failure modes.

3.6.1 Severity, Occurrence, and Detection of the FMEA

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), it prescribes assigning a value on a scale from 1 to 5 to measure the likelihood of a potential risk occurring, its severity, and the chance of detecting and preventing the event before it occurs. Here, 1 represents the lowest risk, while 5 represents the highest risk (Joint Commission, 2010; Stojković et al., 2017) (Table 5). Toplam risk puanı occurrence (O), severity (S), and detection puanlarının çarpımıyla bulunur. Tablo 2’de görüldüğü üzere yeşil alanlar düşük riski, sarı alanlar orta riski ve kırmızı alanlar yüksek riski ifade eder. Risk önceliklendirme matrisinde öncelikle kırmızı alanlardan başlayarak iyileştirme çalışmaları yapılmalıdır (Elmadhoun et al., 2025).

Table 5. Risk Priority Number matrix (Green: low; Yellow: Medium; Red: High)

Severity	Occurrence						Detectability
		1	2	3	4	5	
	5	25	50	75	100	125	
	4	16	32	48	64	80	
	3	9	18	27	36	45	
	2	4	8	12	16	20	
	1	1	2	3	4	5	

Source: Elmadhoun et al. (2025)

3.7 Ethics Committee Approval

This study was approved by the Bandırma Onyedi Eylül University Health Sciences Non-Interventional Research Ethics Committee with the date 21.10.2024 and number 2024-9/223. In addition, written permission was obtained from the institution where the study was conducted.

4. RESULTS

4.1. Identification of potential failure modes, causes, effects, and prioritization of failure modes

Each failure mode was evaluated using an RPN based on severity, occurrence, and detectability scores, allowing systematic ranking of risks. Occurrence estimates were based on both empirical data and the experiential knowledge of the multidisciplinary team (Table 6).

Table 6. Top critical failure modes, effects, underlying causes, risk priority number, corrective actions, and post-risk score

Process	Possible failures	Effects	Causes	Severity	Probability	Detection	Risk Priority Number (RPN)	Corrective Actions	Responsible	Timeline	Severity	Probability	Detection	Post-risk score
Analysis ordering	Failure to order or incomplete ordering of tests by the physician	*Extended turnaround time for the testing process *Prolonged treatment or intervention period *May result in inappropriate treatment or intervention	*Lack of information of *High workload *Lack of attention *Technical issues	4	4	5	80 (High)	*Reminding physicians to place test orders through the hospital information system *Enabling the use of printed test request forms in the automation system	Hospital Management	March 2025	4	2	5	40 (Medium)
	Incorrect test ordering	*Prolongation of the testing process *Delay in the treatment and intervention process *May lead to inappropriate treatment or interventions	*Lack of knowledge *High workload or carelessness *Technical problems *Communication errors	4	4	4	64 (High)	*Update shortcut menus in the automation system for physicians' routinely requested tests *Eliminate manual (paper-based) test request forms *Provide training for physicians, nurses, and patient registration officers	Hospital Management Hospital Information Systems Hospital Directorate	March 2025	4	3	4	48 (Medium)

Process Innovation in Laboratory Service Systems: Enhancing Operational Performance and Risk Reduction Through FMEA

	Missing or incomplete patient information on the test request	*Prolongation of the reporting process *Incorrect interpretation of test results *Delay in the treatment and intervention process	*High workload *Inattention or carelessness *Technical problems *Communication errors	4	3	2	24 (Medium)	*Place test orders through the automation system *Ensure complete and accurate entry of patient information *Provide comprehensive training on blood collection clinical guidelines *Implement standardized workflow procedures across all pre-analytical processes	Patient Services	March 2025	4	2	2	16 (Low)
Analysis ordering	Failure to specify the sampling site in the test order	*Incorrect interpretation of test results *Delay or negative impact on the treatment or intervention process	*High workload *Inattention or carelessness *Technical problems *Communication errors	4	3	1	12 (Low)	*Provide information during physician meetings *Do not process incomplete forms; contact the physician to ensure completion *Send an informational e-mail to physicians via the laboratory medical director	Hospital Management Laboratory Responsible Physician	March 2025	4	2	1	8 (Low)
	Not specifying the patient's critical medications in the test request/patient not reporting them	*Incorrect interpretation of test results *May negatively impact the treatment or intervention process	*High workload *Inattention or carelessness *Technical problems *Communication errors	4	2	4	32 (Medium)	*Provide relevant information during physician meetings *Contact the responsible physician to complete any missing patient information identified by the laboratory team *Remind nurses of LIS-generated alerts during staff meetings *Implement standardized workflow procedures across the pre-analytical process	Hospital Management Laboratory Responsible Physician	March 2025	4	2	4	32 (Medium)
	Absence of a consent form for tests requiring informed approval	*Prolongation of the testing and reporting process *May delay the treatment or intervention process	*High workload *Inattention *Lack of knowledge *Negligence or lack of due importance	2	4	1	8 (Low)	*Provide relevant information during physician meetings *Verify the presence of informed consent as a final check before sending the sample to the laboratory and before the patient leaves the unit *Remind nurses of LIS-generated alerts during staff meetings *Implement standardized workflow procedures across the pre-analytical process	Hospital Management Central Laboratory Responsible Physician	March 2025	2	3	1	6 (Low)
Patient record	Incorrect patient record	*Prolongation of the reporting process *May lead to inappropriate treatment or intervention due to incorrect reporting	*Noncompliance with established procedures *Lack of training *High workload *Inattention *Communication errors	4	4	4	64 (High)	*Provide information to patient advisors *Ensure all patient records are fully reviewed with proper patient identification	Patient Services	March 2025	4	3	4	48 (Medium)
	Opening records through the physician module	*May prolong the reporting process	*Lack of training *Inattention	3	3	2	18 (Low)	*Implement the required system enhancements by BILMED Information Systems *Implement standardized workflow procedures across the pre-analytical process	Hospital Information Systems Directorate	March 2025	3	3	2	18 (Low)
Patient	Duplicate test order	*May prolong the reporting process *May lead to misinterpretation of test results	*Lack of training *High workload *Inattention	4	3	4	48 (Medium)	*Provide information to patient advisors	Patient Services	March 2025	4	3	4	48

Barcoding	Duplicate patient record	*May prolong the reporting process *May lead to misinterpretation of test results	*Lack of training *High workload *Inattention *Communication errors	4	3	4	48 (Medium)	*Merge duplicate patient records	Patient Services Hospital Inf. Systems Directorate Archive	March 2025	4	2	4	32 (Medium)
	Unreadable or damaged label	*May prolong the reporting process *May lead to misinterpretation of test results	*Barcode printer malfunction *Adverse physical conditions affecting the label	4	4	1	16 (Low)	*Replace faulty barcode printers *Provide training for nurses involved in sampling	Nursing Management Department	March 2025	4	2	1	8 (Low)
Specimen collection	Improper labeling of the sampling container	*May delay the testing and reporting process	*Non-compliance with procedures *High workload *Inattention *Technical issues	2	3	2	12 (Low)	*Provide training sessions for nurses *Correct identified errors on-site through field visits	Nursing Management Department Central Laboratory Responsible Physician	March 2025	2	2	2	8 (Low)
	Sampling collected in an inappropriate tube/container	*May prolong the reporting process	*Non-compliance with procedures *Lack of knowledge *Inattention	4	4	1	16 (Low)	*Provide training sessions for nurses *Correct identified errors on-site through field visits *Implement standardized workflow procedures across the pre-analytical process	Hospital Management Nursing Management Department Central Laboratory Responsible Physician	March 2025	4	2	1	8 (Low)
Specimen collection	Inadequate fixation of collected tissue samples	*Necessity to re-collect samples from the patient *May prolong the reporting process	*Non-compliance with procedures *Lack of knowledge *Inattention	5	2	1	10 (Low)	*Provide training sessions for nurses *Implement standardized workflow procedures across the pre-analytical process	Nursing Management Department Central Laboratory Responsible Physician	March 2025	5	1	1	5 (Low)
	Sampling contamination	*May lead to misinterpretation of test results *May delay the testing and reporting process	*Non-compliance with procedures *Lack of knowledge *Inattention *Failure to properly inform the patient	4	2	4	32 (Medium)	*Provide training *Correctly identify errors on-site through field visits *Implement standardized workflow procedures across the pre-analytical process	Hospital Management Nursing Management Department Central Laboratory Responsible Physician	March 2025	4	2	4	32 (Medium)
Specimen collection	Placement of tissue samples from different sites in the same container	*May prolong the reporting process *May result in incorrect measurement of test results *May lead to incorrect reports resulting in inappropriate treatment or intervention	*Non-compliance with procedures *Lack of knowledge *Inattention	3	2	4	24 (Medium)	*Provide training to physicians and nurses *Address problems encountered in daily operations *Conduct site visits to monitor process effectiveness *Implement standardized workflow procedures across the pre-analytical process	Hospital Management Nursing Management Department Central Laboratory Responsible Physician	March 2025	3	1	4	12 (Low)

Process Innovation in Laboratory Service Systems: Enhancing Operational Performance and Risk Reduction Through FMEA

Specimen collection	Sampling taken in an incorrect position	*May prolong the testing and reporting process *May result in incorrect measurement of the test result *May lead to erroneous reports resulting in inappropriate treatment or intervention	*Non-compliance with procedures *Lack of knowledge	4	2	4	32 (Medium)	*Assess compliance with the process through training sessions and on-site visits *Implement standardized workflow procedures across the pre-analytical process	Nursing Management Department Central Laboratory Responsible Physician	March 2025	4	1	4	16 (Low)
	Mislabelling of cerebrospinal fluid samples at the time of collection	*May lead to incorrect reports resulting in inappropriate treatment or intervention	*Non-compliance with procedures *Lack of knowledge	4	1	1	4 (Low)	*Provide training to physicians and nurses *Address problems encountered in daily operations *Conduct site visits	Hospital Management Nursing Management Department Central Laboratory Responsible Physician	March 2025	4	1	1	4 (Low)
	Insufficient collection of the laboratory sample	*May prolong the testing and reporting process	*Non-compliance with procedures *Lack of knowledge	4	5	1	20 (Medium)	*Provide training sessions for nurses *Address problems encountered in daily operations *Conduct site visits *Implement standardized workflow procedures across the pre-analytical process	Nursing Management Department Central Laboratory Responsible Physician	March 2025	4	3	1	12 (Low)
	Excessive collection of laboratory samples	*May result in incorrect reporting of test results	*Non-compliance with procedures *Lack of knowledge	4	3	1	12 (Low)		Nursing Management Department Central Laboratory Responsible Physician	March 2025	4	2	1	8 (Low)
	Use of material unsuitable for the test	*May result in incorrect reporting of test results	*Non-compliance with procedures *Lack of knowledge *Inattention	4	2	1	8 (Low)	*Provide training sessions for nurses *Address problems encountered in daily operations *Conduct site visits *Implement standardized workflow procedures across the pre-analytical process	Nursing Management Department Central Laboratory Responsible Physician	March 2025	4	1	1	4 (Low)
	Improper application of the tourniquet	*May result in incorrect reporting of test results	*Non-compliance with procedures *Lack of knowledge *Inattention	4	3	5	60 (High)		Nursing Management Department Central Laboratory Responsible Physician	March 2025	4	2	5	40 (Medium)
	Collection of a lipemic blood sample	*May result in incorrect reporting of test results	*Non-compliance with procedures *Lack of knowledge *Inattention	4	4	1	16 (Low)	*Provide training sessions for nurses	Nursing Management Department Central Laboratory Responsible Physician	March 2025	4	3	1	12 (Low)
	Collection of a hemolyzed blood sample	*May result in incorrect reporting of test results	*Non-compliance with procedures *Lack of knowledge *Inattention	4	4	1	16 (Low)	*Provide training sessions for nurses *Address problems encountered in daily operations *Conduct site visits	Nursing Management Department Central Laboratory Responsible Physician	March 2025	4	3	1	12 (Low)

Specimen collection	Collection of a clotted blood sample	*May result in incorrect reporting of test results	*Non-compliance with procedures *Lack of knowledge *Inattention	4	4	2	32 (Medium)		Nursing Management Department Central Laboratory Responsible Physician	March 2025	4	3	2	24 (Medium)
	Intravenous fluid contamination	* May result in incorrect reporting of test results	*Non-compliance with procedures *Lack of knowledge *Inattention	4	2	4	32 (Medium)	*Provide training sessions for nurses	Central Laboratory Responsible Physician	March 2025	4	1	4	16 (Low)
	Samples taken post-exercise in tests influenced by physical activity	*May result in incorrect reporting of test results *May lead to incorrect reports resulting in inappropriate treatment or intervention	*Non-compliance with procedures *Lack of knowledge	4	1	4	16 (Low)	*Provide training sessions for nurses *Implement standardized workflow procedures across the pre-analytical process	Central Laboratory Responsible Physician	March 2025	4	1	4	16 (Low)
	Samples taken under stress in tests influenced by stress	*May result in incorrect reporting of test results *May lead to incorrect reports resulting in inappropriate treatment or intervention	*Non-compliance with procedures *Lack of knowledge	4	1	4	16 (Low)		Central Laboratory Responsible Physician	March 2025	4	1	4	16 (Low)
	Samples taken while using medication in tests are influenced by drug interactions	*May result in incorrect reporting of test results *May lead to incorrect reports resulting in inappropriate treatment or intervention	*Non-compliance with procedures *Lack of knowledge	4	2	4	32 (Medium)		Central Laboratory Responsible Physician	March 2025	4	2	4	32 (Medium)
	Blood sample collection using syringes	*May result in incorrect reporting of test results *May lead to incorrect reports resulting in inappropriate treatment or intervention	*Non-compliance with procedures *Lack of knowledge	4	5	4	80 (High)	*Provide training sessions for nurses *Educate nurses on the importance of using vacutainers for blood collection *Procure vacutainer sets suitable for different age groups *Implement standardized workflow procedures across the pre-analytical process	Nursing Management Department Central Laboratory Responsible Physician	March 2025	4	3	4	48 (Medium)
Specimen collection	Improper transfer of blood collected with a syringe into tubes, resulting in hemolysis or under/over-collection	*May result in incorrect reporting of test results *May lead to incorrect reports resulting in inappropriate treatment or intervention	*Non-compliance with procedures *Lack of knowledge	4	4	4	64 (High)	*Provide training sessions for nurses *Assess compliance with the process through training sessions and on-site visits *Encourage wider use of vacutainers *Implement standardized workflow procedures across the pre-analytical process	Nursing Management Department Central Laboratory Responsible Physician	March 2025	4	2	4	32 (Medium)
	Collection of the sample at an inappropriate time	*May result in incorrect reporting of test results *May lead to incorrect reports resulting in inappropriate treatment or intervention	*Non-compliance with procedures *Lack of knowledge	4	3	2	24 (Medium)	*Provide training to nurses *Correct errors identified during field visits via on-site feedback *Remind nurses of LIS-generated alerts during charge nurse meetings *Implement standardized workflow procedures across the pre-analytical process	Nursing Management Department Central Laboratory Responsible Physician	March 2025	4	2	2	16 (Low)

Process Innovation in Laboratory Service Systems: Enhancing Operational Performance and Risk Reduction Through FMEA

Transport and temporary storage	Sample being held, stored, or transported under unsuitable conditions	*May result in incorrect reporting of test results *May lead to incorrect reports resulting in inappropriate treatment or intervention *May prolong the testing and reporting process	*Non-compliance with procedures *Lack of knowledge *Transport of samples via the pneumatic tube system when not appropriate	4	3	2	24 (Medium)	*Provide department-specific sample transfer containers *Provide training to nurses, laboratory staff, and porters *Continue monthly training sessions for new staff *Correct errors identified during site visits via on-site feedback	Hospital Management Nursing Management Central Laboratory Responsible Physician	March 2025	4	2	2	16 (Low)
	The laboratory sample was sent to the wrong laboratory, not sent, or sent incompletely	*May prolong the treatment and intervention process *May harm the patient	* Non-compliance with procedures *Inattention *Lack of training *High workload *Communication errors	4	1	2	8 (Low)	*Provide training to all staff involved in the sample collection and transfer process *Conduct frequent monitoring of the sample holding area *Implement standardized workflow procedures across the pre-analytical process	Central Laboratory Responsible Physician	March 2025	4	1	2	8 (Low)
Transport and temporary	Breakage or spillage of the sample during transport	*May prolong the testing process *May prolong the treatment and intervention process	*Inattention	4	3	1	12 (Low)	*Provide training to all staff involved in the sample collection and transfer process	Central Laboratory Responsible Physician	March 2025	4	1	1	4 (Low)
	Loss of the sample	*May prolong the testing process *May prolong the treatment and intervention process	*Non-compliance with procedures * Technical failures of the pneumatic tube system * Inattention	4	4	4	64 (High)	*Provide training to all staff involved in the sample collection and transfer process *Implement standardized workflow procedures across the pre-analytical process	Central Laboratory Responsible Physician	March 2025	4	2	2	16 (Low)
Pre-Post Risk Score				1080						721				

Before the improvement process, the items with the highest risk scores were identified as follows: the physician failing to place or incompletely placing test orders (80 points), blood samples collected using syringes (80 points), incorrect test orders (64 points), improper transfer of blood collected with a syringe into tubes leading to hemolysis or under/over-collection (64 points), loss of samples (64 points), incorrect patient records (64 points), improper use of the tourniquet (60 points), and incorrect transfer of syringe-collected blood into tubes (64 points) (Table 6).

Table 7 shows the distribution of items in low, medium, and high-risk categories before and after the implementation of improvement measures.

Table 7. Risk Priority Number Before and After FMEA

	Pre-Risk	Post-Risk
High	7 (19.4%)	0 (0%)
Medium	13 (36.1%)	12 (33.3%)
Low	16 (44.5%)	24 (66.7%)
Total	36 (100%)	36 (100%)

Table 7 shows that, following the improvement measures, the proportion of items in the high-risk category, which was 19.4% before the interventions, decreased to 0%. The proportion of items in the medium-risk category, which was 36.1%, decreased to 33.3%, while the proportion of items in the low-risk category increased from 44.5% to 66.7%.

Table 8 presents the pre-analytical activities, the number of failure modes, and the total risk scores. It can be observed that more than half of the risks are related to the sample collection process.

Table 8. Pre-Analytical Activity, Number of Failure Modes, and Total Pre-Risk Score

No	Pre-Analytical Activities	Number of Failure Modes	Total Pre-Risk Score
1	Specimen collection	20 (%55.6)	546
2	Analysis ordering	6 (%16.7)	220
3	Patient record	4 (%11.1)	178
4	Transport and temporary storage	4 (%11.1)	108
5	Barcoding	2 (%5.6)	28
Total		36	1080

Table 9 shows the pre- and post-risk scores for each failure mode.

Table 9. Failure Mode, Pre- and Post-Risk Score

No	Failure Mode	Pre-Risk Score	Post-Risk Score
1	Failure to order the test/incomplete test ordering	80	40
2	Blood sample collection using syringes	80	48

3	Incorrect test ordering	64	48
4	Incorrect patient record	64	48
5	Improper transfer of blood collected with a syringe into tubes, resulting in hemolysis or under/over-collection	64	32
6	Loss of the sample	64	16
7	Improper application of the tourniquet	60	40
8	Duplicate test order	48	48
9	Duplicate patient record	48	32
10	Specimen contamination	32	32
11	Specimen taken in an incorrect position	32	16
12	Intravenous fluid contamination	32	16
13	Not specifying the patient's critical medications in the test request/patient not reporting them	32	32
14	Collection of clotted blood sample	32	24
15	Specimens collected while patients are using medications that may affect test results due to drug interactions	32	32
16	Collection of the sample at an inappropriate time	24	16
17	Sample being held, stored, or transported under unsuitable conditions	24	16
18	Placement of tissue samples from different sites in the same container	24	12
19	Missing or incomplete patient information on the test request	24	16
20	Insufficient collection of the laboratory sample	20	12
21	Opening records through the physician module	18	18
22	Samples taken post-exercise in tests influenced by physical activity	16	16
23	Samples taken under stress in tests influenced by stress	16	16
24	Collection of a hemolyzed blood sample	16	12
25	Sampling collected in an inappropriate tube/container	16	8
26	Unreadable or damaged label	16	8
27	Collection of a lipemic blood sample	16	12
28	Failure to specify the sampling site in the test order	12	8
29	Improper labeling of the sampling container	12	8
30	The sampling is being collected in an excessive amount	12	8

31	Breakage or spillage of the sample during transport	12	4
32	Inadequate fixation of collected tissue samples	10	5
33	The laboratory sample was sent to the wrong laboratory, not sent, or sent incompletely	8	8
34	Using material unsuitable for the test	8	4
35	Absence of a consent form for tests requiring informed approval	8	6
36	Mislabeled of cerebrospinal fluid samples at the time of collection	4	4
Total		1080	721

5. DISCUSSIONS

In this study, central laboratory pre-analytical process failures were examined under five categories: specimen collection, analysis ordering, record keeping, transport and temporary storage, and barcoding. This categorization is consistent with previous studies that have adopted a process-based approach to the pre-analytical phase. In particular, Erbayraktar and Gldař (2020) similarly classified pre-analytical errors in medical laboratories into test request, sampling, identification, barcoding, and transfer processes. Comparable process-based frameworks have also been reported in international studies, including the CAP Q-Probes investigation by Perrotta et al. (2020), which examined pre-analytical testing through workflow mapping, as well as quality indicator-based analyses by Flegar-Meřtrić et al. (2017) and Englezopoulou et al. (2016), emphasizing errors related to test ordering, specimen collection, identification, documentation, and transport. More recently, Nordin et al. (2024) reaffirmed that pre-analytical errors predominantly arise from these same process steps, underscoring the robustness and relevance of the categorization used in the present study. Additionally, several studies have demonstrated that addressing high-risk pre-analytical errors through structured risk management approaches, such as FMEA, improves laboratory process reliability and contributes to enhanced patient safety (Erbayraktar & Gldař, 2020; Flegar-Meřtrić et al., 2017; Liu et al., 2020).

One of the highest-risk items before the improvement process was failure to order tests or incomplete test ordering (RPN = 80). This finding emphasizes that errors in test ordering represent a critical point in the pre-analytical workflow, potentially leading to delays in patient care and incorrect treatment decisions. Similar observations have been reported in the literature, where test ordering errors were identified among the most frequent and high-risk failures in medical laboratories (Erbayraktar & Gldař, 2020; Flegar-Meřtrić et al., 2017). Moreover, systematic reviews on FMEA applications in healthcare highlight that proactive

identification and mitigation of such high-risk process failures significantly improve laboratory quality and patient safety (Liu et al., 2020).

Another high-risk failure was blood sample collection using syringes (RPN = 80) and the improper transfer of blood collected with a syringe into tubes, which could result in hemolysis or under/over-collection (RPN = 64). These findings underscore the critical impact of sample collection and handling on the integrity and reliability of laboratory results. Previous studies have similarly shown that incorrect sampling techniques, particularly the use of syringes instead of vacutainers, unsafe needle removal and blood transfer to test tubes are among the most frequent pre-analytical errors leading to hemolysis, incorrect test results, and delays in patient care (Addisu et al., 2023; Erbayraktar & Gldař, 2020; Flegar-Meřtrić et al., 2017). Furthermore, the implementation of process improvement strategies, such as Lean and Six Sigma methodologies, has been shown to reduce such errors by standardizing sample collection and transfer procedures, thereby enhancing overall laboratory quality and patient safety (Persoon et al., 2006; Inal et al., 2018; Liu et al., 2020).

Wrong test orders (RPN = 64) and incorrect patient records (RPN = 64) were also identified as high-risk failures in the present study. These errors are critical because they may adversely affect the accuracy of laboratory results and subsequent clinical decision-making. Similar findings have been reported in the literature, where errors related to test ordering and patient records have been identified among the most frequent and critical pre-analytical failures in medical laboratories (Addisu et al., 2023; Erbayraktar & Gldař, 2020; Flegar-Meřtrić et al., 2017; Perrotta et al., 2020). Furthermore, systematic reviews on FMEA applications emphasize that proactive identification and mitigation of such failures contribute to improvements in laboratory process quality and patient safety (Liu et al., 2020).

Sample loss was identified as another high-risk pre-analytical error, with an RPN of 64 in the present study. This finding is consistent with the broader literature, which indicates that lost or missing specimens represent a critical vulnerability in pre-analytical processes and may compromise diagnostic accuracy and patient care (Erbayraktar & Gldař, 2020; Flegar-Meřtrić et al., 2017; Liu et al., 2020). Previous studies have shown that non-received or misplaced specimens are among the common causes of pre-analytical errors in hospital laboratories and may result in delayed test reporting, inappropriate clinical decisions, and increased patient safety risks (Alavi et al., 2020; Englezopoulou et al., 2016; Nordin et al., 2024). Such errors are frequently attributed to deficiencies in sample handling, transportation, and interdepartmental communication, underscoring the need for standardized procedures and continuous staff training (Alcantara et al., 2022; Perrotta et al., 2020). Evidence further suggests that implementing corrective strategies, such as enhanced workflow monitoring, dedicated transport protocols, and targeted staff education, is

associated with reductions in sample loss and related risks (Liu et al., 2020; Nordin et al., 2024).

Finally, improper application of the tourniquet (RPN = 60) was identified as a high-risk failure in the present study, indicating that suboptimal venipuncture technique remains a significant source of pre-analytical laboratory error. Evidence suggests that inappropriate tourniquet use, particularly prolonged application beyond recommended limits, may lead to venous stasis and hemoconcentration, resulting in alterations in analyte concentrations and compromising test accuracy, with potential indirect implications for patient safety. Current pre-analytical guidelines recommend releasing the tourniquet as soon as blood flow is established to prevent artificial changes in sample composition (Magnette et al., 2016). Observational studies of phlebotomy practices have documented procedural deviations, including prolonged tourniquet application and other collection errors (e.g., Addisu et al., 2023). Pre-analytical literature more broadly identifies sample collection and handling as frequent sources of error, underlining the importance of technique-focused training and adherence to standardized procedures to reduce pre-analytical failures (Alavi et al., 2020; Flegar-Meřtrić et al., 2017; Nordin et al., 2024).

Beyond the clinical implications, the findings of this study also highlight the broader managerial and economic relevance of FMEA. Recent evidence demonstrates that digital and AI-supported FMEA frameworks can deliver measurable efficiency gains by reducing sample rejection rates, minimizing repeat testing, and shortening turnaround times, thereby lowering operational costs and improving workflow continuity (Gomaa, 2025; Waseem et al., 2025). Compared with reactive approaches such as Root Cause Analysis, FMEA offers a proactive methodology that anticipates failures before they occur, while its integration with Lean Six Sigma and Statistical Process Control has been shown to support zero-defect production and predictive quality assurance in complex systems (Omisola et al., 2024). Furthermore, AI-driven FMEA applications enhance the speed and accuracy of risk prioritization, positioning the method as an innovative tool for modern healthcare and industrial contexts (El Hassani et al., 2025).

Recent advances in hybrid intelligence approaches provide further support for positioning FMEA as a strategic innovation mechanism that extends beyond healthcare. Mokhtarzadeh et al. (2025) conducted a comprehensive literature review of failure analysis in Industry 4.0, demonstrating that hybrid intelligence, combining expert judgment with AI-driven analytics, significantly enhances diagnostic accuracy, predictive capabilities, and cost-effectiveness. Their findings show that hybrid FMEA frameworks reduce production stoppages, optimize resource utilization, and enable real-time risk monitoring, thereby reinforcing the measurable efficiency and economic outcomes of proactive risk management. Compared with traditional reactive methods such as Root Cause Analysis, hybrid

intelligence models integrate seamlessly with Lean Six Sigma and digital technologies to achieve zero-defect production and predictive maintenance goals. Importantly, the applicability of these approaches extends to industrial domains such as automotive, aerospace, and energy, where hybrid intelligence failure analysis has been successfully employed to strengthen process reliability and service quality. These insights highlight that methodological innovations surrounding FMEA not only improve patient safety in laboratory contexts but also contribute to operational excellence and sustainable value creation across diverse service systems. This study has several limitations. First, it was conducted as a single-center study. Second, it only covers the pre-analytical processes up to the transfer of samples to the laboratory. Third, the findings are limited to the expert opinions included in the study. Finally, due to the lack of access to cost-related data, the cost of FMEA-based improvements could not be included in the analysis. Future studies are recommended to be multicenter, focus on specific laboratory types, and include cost analyses where possible.

6. CONCLUSIONS

This study evaluated pre-analytical risks in the central laboratory of a private hospital in Ankara using the FMEA method. The results demonstrated that the highest-risk failure modes were related to sample collection, test ordering, patient records, sample handling, and improper tourniquet application. Corrective measures implemented for high- and medium-risk items led to a substantial reduction in overall risk, with the proportion of high-risk items decreasing from 19.4% to 0%, and the proportion of low-risk items increasing from 44.5% to 66.7%. These findings highlight the effectiveness of proactive risk assessment and targeted interventions in improving laboratory quality and patient safety.

The study emphasizes that errors in sample integrity, identification, and handling, such as hemolysis, sample loss, improper use of syringes, and tourniquet misuse, represent critical vulnerabilities in pre-analytical processes. Addressing these errors through structured risk management, staff training, and workflow standardization can significantly reduce the likelihood of

inaccurate test results, delays in patient care, and potential adverse outcomes. The results also reinforce that the majority of pre-analytical risks are associated with specimen collection, underlining the importance of focusing quality improvement efforts on this step.

Based on these findings, it is recommended that laboratories implement regular, competency-based training programs for both laboratory and clinical staff to ensure proper sample collection, handling, and tourniquet application. Standardized protocols should be established for test ordering, sample labeling, collection, and transport to reduce variability and minimize errors. High-risk processes should be continuously monitored, with periodic audits and feedback loops in place to promptly identify and address deviations. The use of appropriate materials, such as vacutainers instead of syringes, should be promoted, ensuring that age- and test-specific collection sets are readily available. Clear communication channels must be established for reporting missing or incomplete information and misrouted samples to prevent delays, while technological support, including automation and barcode systems, should be effectively utilized to reduce human errors and enhance specimen traceability.

These results show that the use of structured risk management tools such as FMEA contributes not only to patient safety, but also to better workflow organization, more efficient use of resources, and overall improvement in laboratory system performance. In addition, this approach can be applied in other laboratories and healthcare institutions, where it may support process standardization and further improvements in operational quality.

In conclusion, the application of FMEA in the pre-analytical phase proved to be a highly effective strategy for identifying, prioritizing, and mitigating laboratory risks. The combination of structured risk assessment, targeted corrective actions, and continuous staff education can significantly improve laboratory quality, patient safety, and overall healthcare outcomes, and future studies may extend this approach to other laboratory phases and clinical settings to further optimize patient care and process reliability.

Acknowledgement: The study was conducted in accordance with national and international ethical principles and the Declaration of Helsinki at all stages.

References:

- Abbasgholizadeh Rahimi, S., Jamshidi, A., Ait-Kadi, D., & Ruiz, A. (2015). Using fuzzy cost-based FMEA, GRA and profitability theory for minimizing failures at a healthcare diagnosis service. *Quality and Reliability Engineering International*, 31(5), 601-615. DOI: 10.1002/qre.1619
- Addisu, B., Kelem, A., & Hirigo, A. T. (2023). Observational assessment of pre-analytical errors in request format and phlebotomy practice in hematology tests at Hawassa University Comprehensive Specialized Hospital in Sidama Zone, Southern Ethiopia. *Pathology and Laboratory Medicine International*, 15, 83-89. DOI: 10.2147/PLMI.S439227
- Adekoya, A., Okezue, M. A., & Menon, K. (2025). Medical laboratories in healthcare delivery: A systematic review of their roles and impact. *Laboratories*, 2(1), 8. DOI: 10.3390/laboratories2010008

- Alavi, N., Khan, S. H., Saadia, A., & Naeem, T. (2020). Challenges in preanalytical phase of laboratory medicine: Rate of blood sample nonconformity in a tertiary care hospital. *EJIFCC*, 31(1), 21-27.
- Al-Baadni, M. M., & Al Magrabi, R. H. (2023). *Connect the dots in applying failure mode & effect analysis (FMEA) approach: Lessons learned from healthcare system* (1st ed.). Private Publisher.
- Alcantara, J. C., Alharbi, B., Almotairi, Y., Alam, M. J., Muddathir, A. R. M., & Alshaghдали, K. (2022). Analysis of preanalytical errors in a clinical chemistry laboratory: A 2-year study. *Medicine*, 101(27), e29853. DOI: 10.1097/MD.00000000000029853
- Anjalee, J. A. L., Rutter, V., & Samaranayake, N. R. (2021). Application of failure mode and effect analysis (FMEA) to improve medication safety: A systematic review. *Postgraduate Medical Journal*, 97(1145), 168-174. DOI: 10.1136/postgradmedj-2019-137484
- Arimbi, H., Puspasari, M., & Syaifullah, D. (2019). Hazard identification, risk assessment and risk control in a woodworking company. *IOP Conference Series: Materials Science and Engineering*, 505, 012038. DOI: 10.1088/1757-899X/505/1/012038
- Aslan, Y. (2023). Assessment of the risk analysis of hospital facility management processes with the Fine-Kinney method. *Hacettepe Journal of Health Administration*, 26(4), 935-958. DOI: 10.61859/hacettepesid.1289176
- Baehr, A., Oertel, M., Kröger, K., Eich, H. T., & Haverkamp, U. (2020). Implementing a new scale for failure mode and effects analysis (FMEA) for risk analysis in a radiation oncology department. *Strahlentherapie und Onkologie*, 196(12), 1128–1134. DOI: 10.1007/s00066-020-01686-w
- Barker, D., Berry, M., Driver, J., Hoppes, M., Santoro, M., Sine, D., & Summy, E. A. (2002). Strategies and tips for maximizing failure mode and effect analysis in an organization. *Journal of Healthcare Risk Management*, 22(3), 9-12. DOI: 10.1002/jhrm.5600220304
- DeRosier, J., Stalhandske, E., Bagian, J. P., & Nudell, T. (2002). Using health care failure mode and effect analysis: The VA National Center for Patient Safety's prospective risk analysis system. *Joint Commission Journal on Quality Improvement*, 28(5), 248-267. DOI: 10.1016/s1070-3241(02)28025-6
- Elahi, B. (2022). *Safety risk management for medical devices* (2nd ed.). Academic Press.
- Ellervik, C., & Vaught, J. (2015). Preanalytical variables affecting the integrity of human biospecimens in biobanking. *Clinical Chemistry*, 61(7), 914. DOI: 10.1373/clinchem.2014.228783
- El Hassani, I., Masrour, T., Kourouma, N., & Tavčar, J. (2025). AI-driven FMEA: integration of large language models for faster and more accurate risk analysis. *Design Science*, 11, e10. DOI: 10.1017/dsj.2025.7
- Elmadhoun, B., Alsaidalani, R., & Burczynski, F. (2025). Quality risk management in the final operational stage of sterile pharmaceutical manufacturing: A case study highlighting the management of sustainable related risks in product sterilization, inspection, labeling, packaging, and storage processes. *Sustainability*, 17(4), 1670. DOI: 10.3390/su17041670
- Englezopoulou, A., Kechagia, M., Chatzikiriakou, R., Kanellopoulou, M., Valenti, M., & Masedu, F. (2016). Pre-analytical errors as quality indicators in clinical laboratory. *Austin Journal of Public Health and Epidemiology*, 3(5), 1048.
- En-Naaoui, A., Gallab, M., & Kaicer, M. (2023). Intelligent model for improving risk assessment in sterilization units using revised FMEA, fuzzy inference, k-nearest neighbors and support vector machine. *Journal of Applied Research and Technology*, 21(5), 772-786. DOI: 10.22201/icat.24486736e.2023.21.5.2116
- Erbayraktar, B., & GÜltaş, N. (2020). Implementation of a risk management model to identify and prevent preanalytical errors in medical laboratories. *Journal of Basic and Clinical Health Sciences*, 4(2), 180-186. DOI: 10.30621/jbachs.2020.1081
- Flegar-Meštrić, Z., Perković, S., Radeljak, A., Kardum, P. M. M., Prkačin, I., & Devčić-Jeras, A. (2017). Risk analysis of the preanalytical process based on quality indicators data. *Clinical Chemistry and Laboratory Medicine*, 55(3), 368. DOI: 10.1515/ccbm-2016-0235
- Fragassa, C., & Ippoliti, M. (2016). Failure mode effects and criticality analysis (FMECA) as a quality tool to plan improvements in ultrasonic mould cleaning systems. *International Journal for Quality Research*, 10(4), 847-870. DOI: 10.18421/IJQR10.04-14
- Gogatz, A. D., & Azavedo, M. (2023). Brainstorming: The need for professionalization of facilitators and participants. *Journal of Business and Management Studies*, 5(2), 72–82. DOI: 10.32996/jbms.2023.5.2.9
- Gomaa, A. H. (2025). Transforming Manufacturing from Industry 4.0 to Industry 6.0: A comprehensive review, gap analysis, and strategic framework. *Interdisciplinary Systems for Global Management*, 1(1), 29-51. DOI: 10.55578/ism.2508.003
- Grankvist, K., Gomez, R., Nybo, M., Lima-Oliveira, G., & von Meyer, A. (2019). Preanalytical aspects on short and long-term storage of serum and plasma. *Diagnosis*, 6(1), 51. DOI: 10.1515/dx-2018-0037

- Greenall, J., Walsh, D., & Wichman, K. (2007). Failure mode and effects analysis: A tool for identifying risk in community pharmacies. *Canadian Pharmacists Journal*, 140(3), 191–193. DOI: 10.1177/171516350714000324
- Güneş, H. (2025). Risk analysis in healthcare: a review on basic concepts, methods, and case studies. *SDU Journal of Health Management*, 7(2), 190-210.
- Harvey, D., White, S., Reid, D., & Cook, C. (2024). A consensus-based agreement on a definition of a process variable: Findings from a New Zealand nominal group technique study. *BMC Health Services Research*, 24(1), 1416. DOI: 10.1186/s12913-024-11909-w
- Hu, Q., Hu, H., Hu, M., Zhang, J., Gou, L., Shi, S., Zhou, J., Zhou, N., & Huang, Z. (2022). Use of failure mode and effect analysis to reduce patient safety risks in purchasing prescription drugs from online pharmacies in China. *Frontiers in Medicine*, 9, 913214. DOI: 10.3389/fmed.2022.913214
- Inal, T. C., Goruroglu, O. O., Kibar, F., Cetiner, S., Matyar, S., Daglioglu, G., & Yaman, A. (2018). Lean Six Sigma methodologies improve clinical laboratory efficiency and reduce turnaround times. *Journal of Clinical Laboratory Analysis*, 32(1), e22180. DOI: 10.1002/jcla.22180
- Jin, L., Ye, M., Lin, W., Ye, Y., Chuang, Y.-C., Luo, J.-Y., & Tang, F. (2024). Identification of key potential infection processes and risk factors in the computed tomography examination process by FMEA method under COVID-19. *BMC Infectious Diseases*, 24, 257. DOI: 10.1186/s12879-024-09136-z
- Joint Commission Resources. (2010). *Joint Commission International: Failure mode and effects analysis in health care: Proactive risk reduction* (3rd ed.). USA.
- John, G. K., Favaloro, E. J., Austin, S., Islam, M. Z., & Santhakumar, A. B. (2025). From errors to excellence: the pre-analytical journey to improved quality in diagnostics. A scoping review. *Clinical Chemistry and Laboratory Medicine*, 63(7), 1243-1259. DOI: 10.1515/cclm-2024-1277
- Kammoun, A., Hachicha, W., & Aljuaid, A. M. (2021). Integrating quality tools and methods to analyze and improve a hospital sterilization process. *Healthcare*, 9(5), 544. DOI: 10.3390/healthcare9050544
- La Russa, R., & Ferracuti, S. (2022). Clinical risk management: A modern tool for prevention and management of care and occupational risk. *International Journal of Environmental Research and Public Health*, 19(2), 831. DOI: 10.3390/ijerph19020831
- Lago, P., Bizzarri, G., Scalzotto, F., Parpaiola, A., Amigoni, A., Putoto, G., & Perilongo, G. (2012). Use of FMEA analysis to reduce risk of errors in prescribing and administering drugs in paediatric wards: A quality improvement report. *BMJ Open*, 2(6), e001249. DOI: 10.1136/bmjopen-2012-001249
- Letelier, P., Guzmán, N., Medina, G., Calcumil, L., Huencho, P., Mora, J., Quiñones, F., Jara, J., Reyno, C., Fariás, J.G., Herrera, B.L., Brebi, P., Riquelme, I., & San, M.A. (2021). Workflow optimization in a clinical laboratory using Lean management principles in the pre-analytical phase. *Journal of Medical Biochemistry*, 40(1), 26-32. DOI: 10.5937/jomb0-26055
- Liu, H. C., Zhang, L. J., Ping, Y. J., & Wang, L. (2020). Failure mode and effects analysis for proactive healthcare risk evaluation: A systematic literature review. *Journal of Evaluation in Clinical Practice*, 26(4), 1320-1337. DOI: 10.1111/jep.13317
- Magnette, A., Chatelain, M., Chatelain, B., Ten Cate, H., & Mullier, F. (2016). Pre-analytical issues in the haemostasis laboratory: Guidance for the clinical laboratories. *Thrombosis Journal*, 14, 49. DOI: 10.1186/s12959-016-0123-z
- Manrique-Rodríguez, S., Sánchez-Galindo, A. C., López-Herce, J., Calleja-Hernández, M. Á., Iglesias-Peinado, I., Carrillo-Álvarez, A., Sáez, M.S., & Fernández-Llamazares, C.M. (2014). Risks in the implementation and use of smart pumps in a pediatric intensive care unit: Application of the failure mode and effects analysis. *International Journal of Technology Assessment in Health Care*, 30(2), 210-217. DOI: 10.1017/S0266462314000051
- Mokhtarzadeh, M., Rodríguez-Echeverría, J., Semanjski, I., & Gautama, S. (2025). Hybrid intelligence failure analysis for industry 4.0: a literature review and future prospective. *Journal of Intelligent Manufacturing*, 36, 2309-2334. DOI: 10.1007/s10845-024-02376-5
- Najafpour, Z., Hasoumi, M., Behzadi, F., Mohamadi, E., Jafary, M., & Saeedi, M. (2017). Preventing blood transfusion failures: FMEA, an effective assessment method. *BMC Health Services Research*, 17, 453. DOI: 10.1186/s12913-017-2380-3
- Nordin, N., Ab Rahim, S. N., Wan Omar, W. F. A., Zulkarnain, S., Sinha, S., Kumar, S., & Haque, M. (2024). Preanalytical errors in clinical laboratory testing at a glance: Source and control measures. *Cureus*, 16(3), e57243. DOI: 10.7759/cureus.57243
- Omisola, J. O., Shiyanbola, J. O., & Osho, G. O. (2024). A predictive quality assurance model using Lean Six Sigma: Integrating FMEA, SPC, and root cause analysis for zero-defect production systems. *International Journal of Advanced Multidisciplinary Research Studies*, 4(6), 1481-1497. DOI: 10.62225/2583049X.2024.4.6.4051
- Pascarella, G., Rossi, M., Montella, E., Capasso, A., De Feo, G., Botti, G., Nardone, A., Montuori, P., Triassi, M., D'Auria, S., & Morabito, A. (2021). Risk analysis in healthcare organizations: Methodological framework and critical variables. *Risk Management and Healthcare Policy*, 14, 2897-2911. DOI: 10.2147/RMHP.S309098

- Perrotta, P., Novis, D. A., Nelson, S., Blond, B., Stankovic, A., & Talbert, M. (2020). Workflow mapping—A Q-Probes study of preanalytic testing processes: A College of American Pathologists Q-Probes study of 35 clinical laboratories. *Archives of Pathology & Laboratory Medicine*, 144(12), 1517-1524. DOI: 10.5858/arpa.2020-0043-CP
- Persoon, T. J., Zaleski, S., & Frerichs, J. (2006). Improving preanalytic processes using the principles of lean production (Toyota Production System). *American Journal of Clinical Pathology*, 125(1), 16. DOI: 10.1309/865v7umfpukgcf8d
- Ratajszczak, K., Oancea, A.-V., Misztal, A., Ionescu, N., Ionescu, L. M., & Wencek, A. (2025). Intelligent operational risk management using the enhanced FMEA method and artificial intelligence-A case study. *Applied Sciences*, 15(24), 13199. DOI: 10.3390/app152413199
- Simsekler, M. C. E., Kaya, G. K., Ward, J. R., & Clarkson, P. J. (2019). Evaluating inputs of failure modes and effects analysis in identifying patient safety risks. *International Journal of Health Care Quality Assurance*, 32(1), 191-207. DOI: 10.1108/IJHCQA-12-2017-0233
- Stojković, T., Marinković, V., Jaehde, U., & Manser, T. (2017). Using failure mode and effects analysis to reduce patient safety risks related to the dispensing process in the community pharmacy setting. *Research in Social and Administrative Pharmacy*, 13, 1159-1166. DOI: 10.1016/j.sapharm.2016.11.009
- Thomas, D. (2025). Rethinking FMEA for today's manufacturing landscape considering innovation in risk analysis. *Journal of Failure Analysis and Prevention*, 25, 1-3. DOI: 10.1007/s11668-025-02092-z
- Ullah, E., Baig, M. M., GholamHosseini, H., & Lu, J. (2022). Failure mode and effect analysis (FMEA) to identify and mitigate failures in a hospital rapid response system (RRS). *Heliyon*, 8(2), e08944. DOI: 10.1016/j.heliyon.2022.e08944
- Waseem, H.M., Islam, S.U., Harrison, S., Epiphanou, G., Matragkas, N., Arvanitis, T.N., & Maple, C. (2025). Data-driven FMEA approach for hazard identification and risk evaluation in digital health. *Scientific Reports*, 15(1), 26856. DOI: 10.1038/s41598-025-11929-4
- Weber, L., Schulze, I., & Jaehde, U. (2022). Using failure mode and effects analysis to increase patient safety in cancer chemotherapy. *Research in Social and Administrative Pharmacy*, 18(8), 3386-3393. DOI: 10.1016/j.sapharm.2021.11.009
- Wei, M., Li, M., Lin, Y., Li, B., Xue, H., & Xia, Y. (2026). A hybrid qualitative-quantitative FMEA model for risk management in clinical laboratory automation: A case study integrating ISO 15189:2022. *Journal of Clinical Laboratory Analysis*, 40(7), e70194. DOI: 10.1002/jcla.70194
- Wu, Z., Liu, W. & Nie, W. (2021). Literature review and prospect of the development and application of FMEA in manufacturing industry. *The International Journal of Advanced Manufacturing Technology*, 112, 1409-1436. DOI: 10.1007/s00170-020-06425-0
- Younus, H., Kabir, S., Campean, F., Bonnaud, P., & Delaux, D. (2024). AI- and ontology-based enhancements to FMEA for advanced systems engineering: Current developments and future directions. *arXiv*. DOI: 10.48550/arXiv.2511.17743
- Yousefinezhadi, T., Nobari, F. A. J., Goodari, F. B., & Arab, M. (2016). A case study on improving intensive care unit (ICU) services reliability by using process failure mode and effects analysis (PFMEA). *Global Journal of Health Science*, 8, 207. DOI: 10.5539/gjhs.v8n9p207
- Yousofnejad, Y., & Es'haghi, M. (2024). Reliability evaluation of a medical oxygen supply system by FTA based on intuitionistic fuzzy sets. *Heliyon*, 10(15), e34649. DOI: 10.1016/j.heliyon.2024.e34649
- Zhang, L., He, X., Wang, Y., Huang, L., Du, X., & Liu, M. (2025). Using failure mode and effects analysis for risk management of anesthetic and class I psychotropic drugs in inpatient pharmacy: A pilot study. *Scientific Reports*, 15, 29613. DOI: 10.1038/s41598-025-13377-6

Yasemin Aslan

Bandırma Onyedi Eylül University
Türkiye.
yaseminaslan@bandirma.edu.tr
ORCID: 0000-0001-6292-2332

Dolunay Özlem Zeybek

Bandırma Onyedi Eylül University
Türkiye.
dkilit@bandirma.edu.tr
ORCID: 0000-0003-1219-3308

Buse Dursun

Bandırma Onyedi Eylül University
Türkiye.
busedursun@ogr.bandirma.edu.tr
ORCID: 0009-0008-8780-6942