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RESEARCH ARTICLE

RISK ASSESSMENT OF GASTROENTEROLOGY INFECTION CONTROL: A FAILURE MODE AND EFFECTS ANALYSIS

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ABSTRACT

This study aims to assess the risk analysis of gastroenterology processes in a private hospital located in Istanbul using the Failure Mode and Effects Analysis (FMEA). The study, designed as a cross-sectional descriptive study, was conducted to identify risks in the gastroenterology department based on written procedures, specialist opinions, and past incident records, by the risk assessment team between August 1 and August 15, 2024. The data collection form included the main and sub-processes, possible failures, their causes and effects, probability, severity, and detectability scores, pre-risk scores, risk priority, precautions, a timeline, and post-risk scores. A total of 62 risks were identified. Before applying FMEA, 33.9% of the risks were classified as high, 3.2% as medium, and 62.9% as low or very low, but after corrective actions were implemented, the rate of high risks decreased to 11.3% and the rate of medium risks increased to 25.8%. The highest risk scores were associated with the organic residues on gastroscopes and colonoscopes becoming a suitable medium for microbial growth, incorrect concentration of high-level disinfectants, lack of minimum effective concentration testing for disinfectants, missing records of washing machine programs, inability to detect adenosine triphosphate (ATP) residues on the environment and surfaces of endoscopes, and the risk of infection due to devices being used on different patients without sufficient re-cleaning. In addition, items such as improper storage of gastroscopes and colonoscopes, insufficiently qualified personnel, and lack of attention to hand hygiene and glove use were found to have high risk scores. The total risk priority number initially was 3960 and decreased to 2677 following the corrective actions. The study results indicate that the gastroenterology unit involves high risks for infection control, which should be prioritized to ensure the safety of both patients and staff. Failure Mode and Effects Analysis can be used as an effective risk assessment tool in healthcare.

Keywords: *Risk assessment, infection control, failure mode and effects analysis, hospital*

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ARAŞTIRMA MAKALESİ

GASTROENTEROLOJİ ENFEKSİYON KONTROL RİSK DEĞERLENDİRMESİ: HATA TÜRLERİ VE ETKİLERİ ANALİZİ

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ÖZ

Bu çalışmada, İstanbul'da bulunan özel bir hastanede gastroenteroloji süreçleri risk analizinin Hata Türü ve Etkileri Analizi (FMEA) yöntemi kullanılarak değerlendirilmesi amaçlanmıştır. Tanımlayıcı nitelikte kesitsel olarak tasarlanan çalışmanın evrenini 01.08.2024-15.08.2024 tarihleri arasında risk değerlendirme ekibi tarafından bölümün yazılı prosedürlerinden, uzman görüşlerinden ve geçmiş dönem olay kayıtlarından faydalanılarak tespit edilen riskler oluşturmaktadır. Veri toplama formunda ana ve alt süreçler, olası hatalar, nedenleri ve etkileri, olasılık, şiddet ve saptanabilirlik puanları, risk öncesi puan, iyileştirme önlemleri, zaman planı ve iyileştirme sonrası risk puanı bilgilerine yer verilmiştir. FMEA uygulamadan önce risklerin %33,9'u yüksek, %3,2'si orta ve %62,9'u düşük veya çok düşük olarak sınıflandırılırken, düzeltici eylemler uygulandıktan sonra yüksek risklerin oranı %11,3'e düşmüş olup orta risklerin oranı %25,8'e yükselmiştir. Risk puanı en yüksek maddelerin; gastroskop ve kolonoskoplar üzerindeki organik artıkların uygun bir besiyeri haline gelmesi, yüksek düzey dezenfektanların hatalı kullanım konsantrasyonu, dezenfektanlarda minimum etkinlik konsantrasyon testi yapılmaması, yıkama makinesi programı kayıt eksikliği, endoskopların ortam ve yüzeylerinde adenozin trifosfat (ATP) kalıntısı tespitinin yapılamaması, cihazların yeterli düzeyde tekrar temizlenmeden farklı hastalarda kullanılmasına bağlı enfeksiyon riski maddeleri olduğu tespit edilmiştir. Ayrıca gastroskop ve kolonoskopların uygunsuz şekilde depolanması, kalifiye personel eksikliği, el hijyenine ve eldiven kullanımına dikkat edilmemesi maddelerinin de puanı yüksek bulunmuştur. Toplam risk öncelik puanı başlangıçta 3960 iken düzeltici eylemlerin ardından 2677'ye düşmüştür. Çalışma sonuçları gastroenteroloji ünitesinin enfeksiyon kontrolü açısından yüksek riskler içerdiğini, hasta ve çalışan güvenliğinin sağlanması için enfeksiyon kontrolüne öncelik verilmesi gerektiğini göstermektedir. Hata Türü ve Etkileri Analizi sağlık hizmetlerinde etkili bir risk değerlendirme yöntemi olarak kullanılabilir.

Anahtar Kelimeler: *Risk değerlendirmesi, enfeksiyon kontrolü, hata türleri ve etkileri analizi, hastane*

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I. INTRODUCTION

Endoscopy, as a minimally invasive and cost-effective approach to diagnosis and treatment, has become a fundamental part of modern medicine. The number, complexity, and invasiveness of endoscopic procedures are expected to increase in the coming years (Rauwers et al., 2019). These units are considered high risk in terms of infection control. Especially, infections linked to contaminated endoscopes continue to be reported across the globe (Rauwers et al., 2019; Rubin et al., 2018; Petersen et al., 2016; Higa et al., 2016). Multiple factors have been associated with reported outbreaks (Deb et al., 2022; van der Ploeg and Bruno, 2022; McCafferty et al., 2018; Higa, 2019; Jing et al., 2022; Khoury et al., 2024; Holzwanger et al., 2020). According to a worldwide survey, nearly one in five responding institutions reported having at least one endoscope-associated outbreak (Kenters et al., 2015).

The multiple benefits associated with endoscopic procedures outweigh the potential risks. However, contaminated reusable endoscopes have been linked to higher rates of patient infections and outbreaks compared to other reusable medical devices (Rutala and Weber, 2021). The exact risk of patient infection due to a contaminated endoscope is not yet fully understood (Rauwers et al., 2019). However, it has been noted that delayed pre-cleaning, inadequate cleaning and drying, and faulty design of coverings can also lead to contamination (Rahman et al., 2019). Due to the rise of antibiotic-resistant bacteria and related fatalities, safe endoscopic practices aimed at reducing preventable microbiological transmission risks have become increasingly important. Such measures can only be achieved if all stakeholders-including gastroenterologists, medical microbiologists, government agencies, regulatory bodies, and manufacturers-acknowledge the problem and collaborate effectively (Cassini et al., 2019; Pedrani, 2025).

Effective infection control in these units requires efficient communication, process control, evidence-based sterilization and disinfection practices, and consideration of risk factors associated with endoscopes (Rauwers et al., 2019). The primary goal of risk analysis is to ensure a safe environment for patients and staff by proactively preventing errors before they occur. One of the methods used for risk analysis is Failure Mode and Effects Analysis (FMEA).

FMEA is a systematic method used to identify systems, products, and processes before errors occur and to prevent potential issues. The goal of FMEA is to eliminate or reduce errors by starting with high-risk areas to facilitate continuous improvement (Chia et al., 2024; Baig and Prasanthi, 2013; Roseen et al., 2024). The FMEA technique is also user-friendly and serves as an effective tool for identifying potential failures to increase the reliability and safety of high-risk complex systems (Roseen et al., 2024; El-Awady et al., 2023; Hazwani et al., 2024).

FMEA was first defined in the 1949 U.S. Armed Forces Military Procedures document MIL-HDBK-1629 and was revised in 1980 as MIL-STD-1629A. It then found application in aerospace/rocket development, such as in the Apollo Space Program, to prevent errors in expensive rocket technology with small sample sizes. In the 1960s, it was used while searching for ways to safely send humans to the Moon, Earth's satellite, and return them safely to Earth. In the late 1970s, Ford Motor Company introduced FMEA to the automotive industry, applying the same approach to FMEA processes to consider potential process-related failures before production began. FMEA is most commonly used when designing a process, product, or service, or implementing it in a new way (Baig and Prasanthi, 2013).

Risk management tools in the healthcare sector can help improve the effectiveness of patient care, reduce medical errors, and protect healthcare providers (El-Awady, 2023; Hazwani et al., 2024; Ferdosi et al., 2020; Putri Giri et al., 2024). In line with this, several national and international accreditation standards recommend the use of FMEA (Joint Commission International, 2024; Ministry of Health, 2021; Vecchia et al., 2025). FMEA has been applied across a wide range of healthcare domains, including hospital management, surgical processes, infectious disease risk assessment, medication safety, evaluation of medical equipment, radiation therapy, early warning systems, blood

transfusion safety, and radiology services (Anjalee et al., 2021; Aly et al., 2020; Benavente et al., 2024; DeRosier et al., 2002; Simsekler et al., 2019; Soykan et al., 2014; Sumarwoto et al., 2023; Ullah et al., 2022; Weber et al., 2022; Vecchia et al., 2025).

Although the routine application of FMEA as a standard risk assessment tool in healthcare is challenging, it has proven to be effective in identifying critical areas and promoting improvements in patient and staff safety (Vecchia et al., 2025). Its use has expanded in recent years, mainly due to the increasing complexity of healthcare processes, driven by advances in medical technology, and the urgent need for effective infection prevention and control strategies against multidrug-resistant organisms, which represent a major public health threat in the 21st century (Vecchia et al., 2025).

FMEA is a risk assessment methodology consisting of six steps (DeRosier et al., 2002; Al-Baadni and Al Magrabi, 2023; Shaikh, 2020);

1. Step- Define the Scope and Objectives: The topic is essential for FMEA, and it should be selected based on data to ensure quality assurance. Incident reporting system records, patient complaints, facility tours, audits, and previous FMEA processes can be utilized.
2. Step- Assemble the Team: The team must be dedicated to identifying improvement opportunities and implementing and supporting changes. Given that FMEA is both time-consuming and resource-intensive, sufficient time and resources should be allocated to team members to ensure the process's success. The team should include a team leader, a reporter, a nurse, a patient representative, representatives from biomedical and technical services, and a risk manager, depending on the process being improved. Leadership participation and support are essential for FMEA's success. The team leader plays a crucial role in facilitating the process.
3. Step- Creating a Process Map: At this stage, a detailed process flowchart should be created to ensure a complete understanding of all steps in the process selected for improvement.
4. Step- Conducting Risk or Hazard Analysis for Each Sub-process: At this stage, all sub-processes that could potentially lead to errors or failures should be identified. The likelihood, severity, and detectability scores for each subprocess should be evaluated by the team. One important consideration is that even if a failure mode does not have a direct impact on the patient, procedural delays, equipment failures, reductions in patient throughput, and situations affecting patient care and customer service should also be considered. Tables 1, 2, and 3 provide the scoring. The risk priority number for each failure mode is determined by multiplying the severity, occurrence, and detectability scores.
5. Step- Developing and Implementing an Action Plan to Redesign the Process: After identifying the primary causes of a failed process, strategies should be developed and implemented to prevent future occurrences. Whenever possible, such an action plan should include specific corrective action items, staff training, defined outcome criteria, and timelines, along with individuals responsible for monitoring results.
6. Step- Monitoring, Maintaining, Sharing, and Reassessing Improvements: Improvements made at the departmental level should be monitored, outcomes evaluated, and if successful, the results should be disseminated to other departments.

This study aims to evaluate the risk analysis of infection control processes in the gastroenterology unit of a private hospital using FMEA. The gastroenterology unit was selected for evaluation based on consultations with institutional leadership, which highlighted audit findings indicating specific risks to patient safety and underscoring the need for targeted improvements within the unit. In addition, some infection risks related to the gastroenterology unit were also documented in facility tours and incident reporting systems. Furthermore, as this department performs invasive procedures, it represents a significant risk to patient and staff safety. The research questions of the study:

1. What factors pose risks to patient and staff safety in the gastroenterology unit?
2. What is the level of the identified risks regarding patient and staff safety?

3. What measures can be taken to address the risks identified and categorized as unacceptable in terms of patient and staff safety?
4. What impact do FMEA corrective actions have on risk scores?

II. METHODS

2.1. Type of the Research

This descriptive, prospective, and cross-sectional study.

2.2. Study Population

The universe of the study consists of risks identified by the risk assessment team during the gastroenterology risk assessment processes of a private hospital in Istanbul from August 1, 2024, to August 15, 2024. All identified risks were evaluated without sample selection.

2.3. Data Colection

Brainstorming, flowchart diagrams, and the multi-voting technique were used in the data collection process (Simsekler et al., 2019; Al-Baadni and Al Magrabi, 2023) (Table 1). Brainstorming is a widely used effective tool in systems thinking approaches and is defined as a technique used to support the creative thinking processes of groups. This process allows participants to freely generate ideas on a specific problem or topic and is generally based on the principle of recording all ideas without criticism. This technique is often used to break down and understand a process, generate new and creative ideas, foster an environment of free thinking, offer a wide range of options, and ensure the participation of the entire team (Gogatz and Azavedo, 2023; Al-Baadni and Al Magrabi, 2023). A flowchart diagram or process map is considered the essential tool used to diagram the flow of the process. A flowchart diagram is defined as a graphical way that depicts a process flow in sequential order. Flowchart makes it easier to understand, analyze and improve complex processes (Al-Baadni and Al Magrabi, 2023; Elahi, 2022). Also known as the nominal group technique, the multi-voting technique is defined as a structured series of votes conducted by a team to narrow a broad set of options into a smaller prioritized list. This technique, often used with brainstorming, is regarded as a time-efficient and cost-effective approach to decision-making (Al-Baadni and Al Magrabi, 2023; Harvey et al., 2024).

Table 1. FMEA Phase and Tools

No	FMEA phase	Tool(s)		
		Brainstorming	**Flow chart diagram**	**Multi-voting technique**
1	Define the scope and objectives	The institution's management and the researchers		
2	Assemble the team	The institution's management and the researchers		
3	Creating a process map	✓	✓	
4	Conducting risk or hazard analysis for each sub-process	✓		✓
5	Developing and implementing an action plan to redesign the process	✓		✓
6	Monitoring, maintaining, sharing, and reassessing improvements	✓		✓

During the data collection process, firstly, the researchers conducted a literature review and prepared a gastroenterology risk assessment form in the Microsoft Excel program. This form included the main process and sub-processes, possible failures, causes and effects of failures, probability, severity, and detectability scores, pre-risk score, risk priority, precautions, timeline, responsible, and post-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 gastroenterology. Documents were obtained from the quality management system. Previous incident reports were obtained from the quality management unit, the occupational health and safety department, and the gastroenterology department's archives. The data were obtained from multidisciplinary risk assessment team meetings held between August 1 and August 15, 2024, conducted twice a week for four hours per day, totaling 16 hours. The risk assessment team, consisting of 15 specialists from relevant departments, is presented in Table 2.

Table 2. Risk Assessment Team

No	Job title	Duty	Work experience (year)	Gastroenterology evaluation	FMEA evaluation	Experience in risk assessment
1	Deputy Chief Physician	Head of risk assessment team	24	✓		
2	Occupational Safety Specialist 1	Vice President	12	✓	✓	High
3	Director of Quality Management	Reporter	23	✓	✓	High
4	Occupational Safety Specialist 2	Member	8	✓	✓	High
5	Occupational Physician	Member	18	✓	✓	Medium
6	Occupational Nurse	Member	15		✓	Medium
7	Chief of Gastroenterology	Member	28	✓		
8	Charge Nurse in the Gastroenterology	Member	16	✓		
9	Gastroenterologist	Member	25	✓		
10	Head Nurse	Member	14	✓		
11	Technical Services Manager	Member	16	✓		
12	Infection Control Physician	Member	12	✓		
13	Infection Control Nurse	Member	10	✓		
14	Polyclinic Charge Nurse	Member	28	✓		
15	Director of Biomedical Services	Member	12	✓		

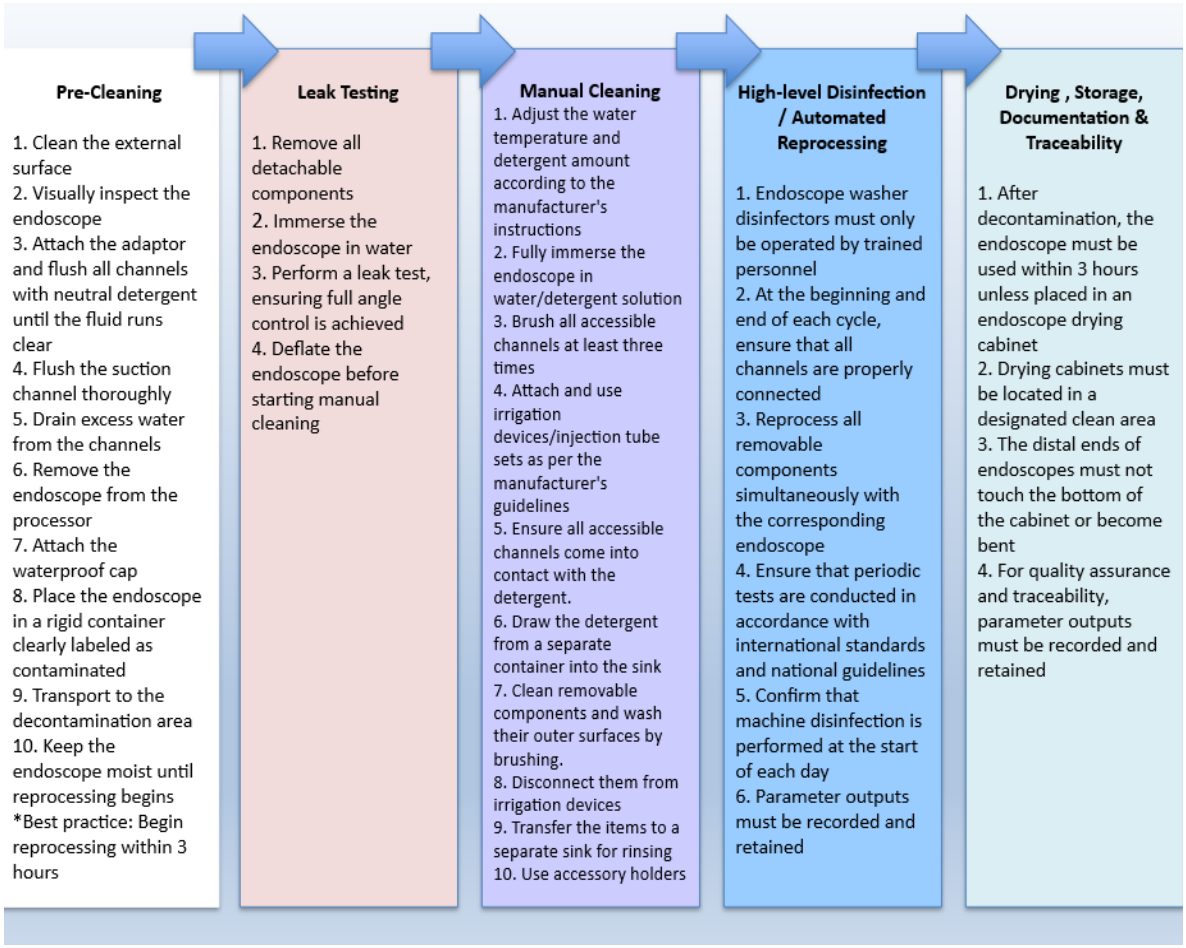
In the first step, all participants were informed about the study's purpose, methodology, and data collection process. In the following phase, a process flowchart was created (Figure 1). Subsequently, procedures, instructions, and workflow diagrams related to gastroenterology were reviewed, and main and sub-processes, along with possible failures, causes, and effects, were identified through brainstorming and multi-voting, incorporating the opinions of each specialist. This phase lasted approximately eight hours, and all specialists' opinions were recorded throughout. After each session, the findings were compiled by the researchers and shared with the participants via e-mail before the next meeting. Then, the identified risks were assessed for probability, severity, and detectability, followed by pre-risk scoring and prioritization. The specialists' scores were recorded individually, averaged, and shared via e-mail before the final session. In the concluding stage, all items were reviewed to ensure consensus, and precautions, timelines, and responsibilities were determined, prioritizing items in the very high-risk category, followed by high- and medium-risk items (Table 7). To enhance reliability and validity, individual assessments were distributed to all team members, and their accuracy was confirmed through collective multi-voting and brainstorming.

After the corrective actions were completed, a 4-hour meeting was scheduled with the same team of specialists to evaluate the effectiveness of the FMEA, and post-risk scores were calculated (Table 7).

2.4. Process Map

The process flowchart for gastroenterology infection control is presented below (Figure 1). This process begins with pre-cleaning and continues with leak testing, manual cleaning, automated reprocessing, and finally drying and storage.

Figure 1. Flowchart to Endoscope Decontamination Process



2.5. Statistical Analysis

FMEA method was used in the analysis of the data. In FMEA, the probability, severity, and detectability values of the risky situation are determined by the team's opinion, and priority improvement actions are identified for risks categorized as unacceptable. Occurrence indicates the frequency of the risks, severity shows the seriousness of the risk, and detectability refers to the likelihood of predicting the risks before they occur. The Risk Priority Number (RPN) is the value obtained by multiplying the severity, occurrence, and detectability scores. These values are evaluated using a 10-point scale, as presented in Table 3, Table 4, and Table 5. High values obtained from this multiplication indicate the areas that should be prioritized for improvement. The assigned scores for occurrence, severity, and detectability used in the data evaluation process are detailed in the tables below (Baig and Prasanthi, 2013; Dağsuyu et al., 2016; Kilic et al., 2023);

Table 3. Failure Mode and Effects Analysis Severity Values

Rank	Effect rate	Criteria
10	Hazardous-without warning	A very high severity rating is assigned when a potential failure mode impacts personal safety, compromises the safe operation of an item, and/or results in non-compliance with government regulations, all without prior warning.
9	Hazardous- with warning	A very high severity rating is applied when a potential failure mode compromises the safe operation of an item and/or leads to non-compliance with government regulations, even with prior warning.
8	Very high	The item becomes inoperable, resulting in the loss of its primary function.
7	High	The item remains functional, but its performance is diminished, leading to customer dissatisfaction.
6	Moderate	The item is operational, but it causes discomfort to the customer.
5	Low	The item is functional, but comfort or convenience features operate at a reduced level, leading to some customer dissatisfaction.
4	Very low	Defect noticed by average customers.
3	Minor	Defect noticed by most customers.
2	Very minor	Defect noticed by discriminating customers.
1	None	No effect

Table 4. Occurrence of the FMEA

Rank	Failure Rate	Criteria
10	< 1 in 2	Very high: Failure almost inevitable
9	1 in 3	
8	1 in 8	High: Repeated failures
7	1 in 20	
6	1 in 80	Moderate: Occasional failures
5	1 in 400	
4	1 in 2000	
3	1 in 15 000	Low: Relatively few failures
2	1 in 150 000	
1	1 in 1 500 000	Remote: Failure is unlikely

Table 5. Detection of the FMEA

Rank	Dedection rate	Criteria
10	Absolute uncertainty	It is almost impossible to detect the failure mode.
9	Very remote	It is very unlikely that the failure mode will be detected.
8	Remote	It is unlikely that the failure mode will be detected.
7	Very low	The chance of detecting the failure mode is very low.
6	Low	The chance of detecting the failure mode is low.
5	Moderate	Detection of the failure mode is subject to a moderate degree of chance.
4	Moderately high	Detection of failure mode is medium-high.
3	High	There is a high probability of detecting the failure mode.
2	Very high	The probability of detecting the failure mode is very high.
1	Almost certain	The probability of detecting the failure mode is almost certain.

The class intervals in Table 6 were used to determine the risk class obtained by multiplying the probability, severity, and detectability scores (Dağsuyu et al., 2016).

Table 6. Risk Class Ranges for 5-Scale FMEA

Risk class	Class range	Explanation
1	0-17	Very low
2	18-44	Low
3	45-115	Moderate
4	116-302	High
5	303-1000	Very high

2.6. Ethics Committee Approval

The study was approved by the Bandırma Onyedi Eylül University Health Sciences Non-Interventional Research Ethics Committee with the date 08.07.2024 and number 2024-7/197. In addition, written permission was obtained from the institution where the study was conducted.

III. FINDINGS

The findings obtained regarding the risk assessment of gastroenterology processes are presented Table 7.

Table 7. FMEA Risk Assessment for Gastroenterology *

No	Main process	Sub-process	Possible failure	Causes of failure	Effects of failure	Probability	Severity	Dedection	Pre-Risk Score	Risk priority number	Corrective Actions	Timeline and Responsibilities	Probability	Severity	Dedection	Post-Risk Score ve Risk Priority Number
1	Contaminated endoscope, colonoscope, and connections	Incorrect decontamination practices	Inadequate and improper cleaning	Lack of information	Risk of infection due to organic residues (blood and body fluids) on gastroscopes and colonoscopes becoming a suitable medium.	7	7	5	245	High	•Practical training on cleaning parameters related to decontamination measures should be provided to staff •Compliance with the process should be monitored through audits. •Procedures and instructions should be reviewed and made available to staff.	September 15, 2024 •Chief of Gastroenterologyand Infection Control Physician	7	7	5	245 (High)
2			Improper storage of gastroscopes and colonoscopes	Lack of education, inadequacy of materials	Risk of infection due to biofilm formation resulting from improper storage of gastroscopes and colonoscopes, where control valves, caps, and distal parts are not properly attached and the instruments are hung vertically without contact with each other.	7	7	3	147	High	•Training should be provided to how to dry and store endoscopes and colonoscopes after decontamination before using them on new patients •Two cabinets and hangers should be provided to store endoscopes and colonoscopes after cleaning •Culture samples should be taken from endoscopes and colonoscopes at regular intervals.	November 15, 2024 •Chief of Gastroenterology •Infection Control Physician •Director of Biomedical Services	5	7	3	105 (Moderate)
3			Inadequate drying of gastroscopes and colonoscopes before storage	Lack of information	Risk of microorganism spread due to contamination in a wet environment	7	7	4	196	High	•Staff should be trained •The operation of the drying machines should be checked •If necessary, new cabinets should be provided.	August 30, 2024 •Chief of Gastroenterology •Director of Biomedical Services	5	7	3	105 (Moderate)

4		Improper use of disinfectants	Improper concentrations	Lack of information	Risk of infection and shortened device lifespan due to failure to obtain documentation containing device information from the manufacturer, development of resistance, and wear caused by disinfectants on the device	6	7	5	210	High	•Training should be provided by the company regarding the concentrations of disinfectants •The disinfectant usage plan should be posted in an area visible to all employees •Wear and tear on devices due to disinfectants should be checked and culture samples should be taken at regular intervals.	November 15, 2024 •Chief of Gastroenterology •Infection Control Physician	6	7	5	210 (High)
5			Contaminated or expired solutions	Lack of system Ineffective material tracking system	Risk of infection due to loss of effectiveness of the solution used	6	7	4	168	High	•Minimum activity concentration monitoring system should be developed •The expiration of disinfectants used in the area should be closely monitored •Training should be provided to staff	September 15, 2024 •Chief of Gastroenterology •Infection Control Physician	4	7	3	84 (Moderate)
6			Use of disinfectants without minimum activity concentration testing	High number of patients Lack of information	Risk of infection due to loss of effectiveness of the solution used	6	7	5	210	High	•Employees should be informed about the use of devices that receive daily disinfectant or 24-hour disinfectant changes •Minimum activity concentration monitoring for disinfectants should be done and recorded	September 15, 2024 •Chief of Gastroenterology •Infection Control Physician	4	7	3	84 (Moderate)
7			Contact time	High number of patients	Risk of infection Device damage	6	5	5	150	High	•Requests for new devices should be made as many times as needed, according to the number of patients •The manufacturer's device information visual should be kept •Training should be provided to employees by the relevant manufacturer •After each patient, an effective wash should be performed, and the device should be dried under appropriate conditions before being used again on a different patient •The daily appointment schedule should be planned according to the number of devices on hand.	November 15, 2024 •Chief of Gastroenterology •Infection Control Physician •Director of Biomedical Services	6	5	5	150 (High)

8		Employee qualifications	Wrong and incomplete practices Lack of sufficient qualifications of personnel	Lack of information	Infection risk Staff health and safety	6	6	5	180	High	•Infection control training should be provided in gastroenterology units •Newly hired department staff should be required to have professional experience •Orientation training should be planned for new staff •The quality of employees should be increased with regular in-service training meetings.	February 15, 2024 •Chief of Gastroenterology •Infection Control Physician	6	6	5	180 (High)
9		Inadequate time	Not allowing enough time between two patients for decontaminatio n procedures	Time constraints Patient planning errors	Patient and staff safety	6	7	5	210	High	•Patient appointments should be planned according to the number of doctors, other staff, beds and devices in the unit •An appointment system should be planned so that decontamination procedures are carried out between every two patients	September 15, 2024 •Chief of Gastroenterology	6	7	5	210 (High)
10		Contaminated disinfectors	Contaminated rinse water	Lack of information	Transmission of endoscope-related infections between patients as a result of not performing the final rinse with filtered water	6	5	3	90	Moderate	•Staff should be trained on infection control in the use of gastroscopy and colonoscopy •The process should be documented and made accessible to all staff •The effectiveness of the process should be evaluated with audits.	September 15, 2024 •Chief of Gastroenterology •Infection Control Physician	6	5	3	90 (Moderate)
11			Failure to replace bacterial filters	Lack of information	Transmission of endoscope and colonoscope-related infections between patients	6	5	4	120	High	•Bacterial filters should be changed at intervals determined by the infection control committee and if necessary •Culture samples should be taken from the environment and devices at certain intervals •Replaced filters should be disposed of in accordance with waste management principles.	November 15, 2024 •Chief of Gastroenterology •Infection Control Physician	4	5	3	60 (Moderate)
12	Quality control system applications	Failure to use a numbering system	Using devices without numbering and not recording them	Lack of information Lack of system	Inability to access retrospective records	6	6	5	180	High	•A system should be developed in the unit to number each gastroscope and colonoscope and record which patient it was used on •Staff should be informed about the system	September 15, 2024 •Chief of Gastroenterology	4	6	3	72 (Moderate)
13		Incomplete maintenance of decontaminati on records	Inability to track data retrospectively	Lack of information Lack of system	Inability to monitor diseases transmitted through endoscopy	6	6	5	180	High	•A system should be developed to record the name and packaging number of the solution used in automatic washing or manual washing •Staff should be trained	September 15, 2024 •Chief of Gastroenterology	4	6	3	72 (Moderate)

14		Lack of minimal activity concentration	Loss of effectiveness of the solution	Time constraints, Lack of information	Risk of infectious disease from use of contaminated solution	6	7	5	210	High	•At the beginning of the day, minimal activity concentration tests of solutions should be performed and recorded •Staff should be informed about the importance of the minimal activity concentration •The process regarding minimal activity concentration control should be documented •Compliance with the process should be monitored through audits	September 15, 2024 •Chief of Gastroenterology •Infection Control Physician	4	7	3	84 (Moderate)
15		Record deficiency in the washing machine program	It is not known which patient, which cycle and which device was washed	Lack of information , Lack of system	Failure to monitor endoscopy-related diseases	6	7	5	210	High	•A record system should be developed that shows which program the instruments are washed in and which patient they are used on •The process should be documented and made accessible to staff •Compliance with the process should be monitored through audits	September 15, 2024 •Chief of Gastroenterology •Infection Control Physician	4	7	3	84 (Moderate)
16		Lack of warning system	Failure to detect leaks in channels	Lack of materials and equipment	Failure to provide adequate disinfectant transfer	6	6	5	180	High	•Washing machines should be replaced with warning systems •Staff should be trained	November 15, 2024 •Chief of Gastroenterology •Director of Biomedical Services	4	6	4	96 (Moderate)
17		Inability to detect adenosine triphosphate (ATP) residues in the environment and surfaces of endoscopes	Inability to track the amount of organic dirt in devices	Lack of materials and equipment	Risk of infection after use of a dirty device on the patient	6	7	5	210	High	•A meeting should be held with the management regarding the ATP swab purchase required to measure and record the level of intraluminal cleanliness •ATP measurements should be made regularly and recorded •Staff should be trained and the process should be monitored with audits	November 15, 2024 •Deputy Chief Physician •Chief of Gastroenterology •Infection Control Physician	4	7	4	112 (Moderate)
18		Failure to record patient information in patient reports	Failure to establish a connection between the patient and the devices during each use	Lack of information	Inability to access retrospective patient records	6	5	5	150	High	•Before all procedures, staff should be trained to start the process after entering patient information into the device •Patient information should be added to the device output reports •Integration should be established between the devices and the hospital operating system to ensure that patient reports are archived securely	September 14, 2024 •Chief of Gastroenterology •Director of Biomedical Services	4	5	3	60 (Moderate)

19	Disinfection process of scopes in case of need and start of the day	Using the devices on different patients without cleaning them again	Risk of reproduction in devices with expired waiting period	Lack of time, Lack of planning, Lack of staff, High number of patients	Risk of infection as a result of using a dirty device on the patient	6	7	5	210	High	•A meeting should be held with senior management regarding the request for programmable washing devices at the beginning of the day and a request to purchase new devices should be made from the biomedical department •A workload analysis should be conducted in the department to determine the number of personnel needed and a request for personnel should be made from the human resources department •The issue should be brought to the hospital's infectious control committee as an agenda item •Staff should be informed about the risks of the procedure	November 15, 2024 •Deputy Chief Physician •Chief of Gastroenterology •Infection Control Physician •Director of Biomedical Services	4	7	4	112 (Moderate)
20	Failure to ensure staff safety	Lack of attention to hand washing and glove use	Failure to comply with infection control principles for patient and staff safety	Lack of materials Lack of training	Risk of cross contamination	6	7	4	168	High	•Training should be provided on hand hygiene and glove use •Visual materials that can be of a cautionary and warning nature should be hung for employees •The department's compliance with the highest hygiene standards should be monitored as an indicator •If there are any missing materials for hand hygiene in the area, they should be provided	November 15, 2024 •Chief of Gastroenterology	6	7	4	168 (High)
21		Use of jewelry	Since jewelry contains microorganisms , it can negatively affect employee health by preventing effective hand washing	Lack of information	Risk of cross contamination	5	6	3	90	Moderate	•Training should be provided on the risks of using jewelry in the department •Audit should be conducted and compliance with the process should be monitored	November 15, 2024 •Chief of Gastroenterology •Infection Control Physician	5	6	3	90 (Moderate)

22		Failure to transport the equipment under appropriate conditions after drying	Contaminated equipment must not be transported to the disinfection room using special containers	Lack of training Lack of materials	Increased risk of infection	6	7	3	126	High	•Containers should be purchased to ensure that gastroscopes and colonoscopes used on patients are transported safely to the disinfection room •Training should be provided to staff	November 15, 2024 •Chief of Gastroenterology	4	7	3	84 (Moderate)
23		Failure to take personal protective measures	Contamination due to blood and body fluids	Insufficient time Lack of materials	Risk of infection	6	5	4	120	High	•Staff should be trained on the importance of using personal protective equipment •Personal protective equipment should be available in the area in the quantity and quality that may be needed •Staff should be informed about what to do in case of contamination with blood and body fluids •Periodic audits should be carried out •Personal protective equipment usage should be assessed by conducting audit	September 15, 2024 •Occupational physician •Occupational Nurse	6	5	4	120 (High)
Total risk score						**3960**					**2677**					

***** Very low and low risks are not included in the table.

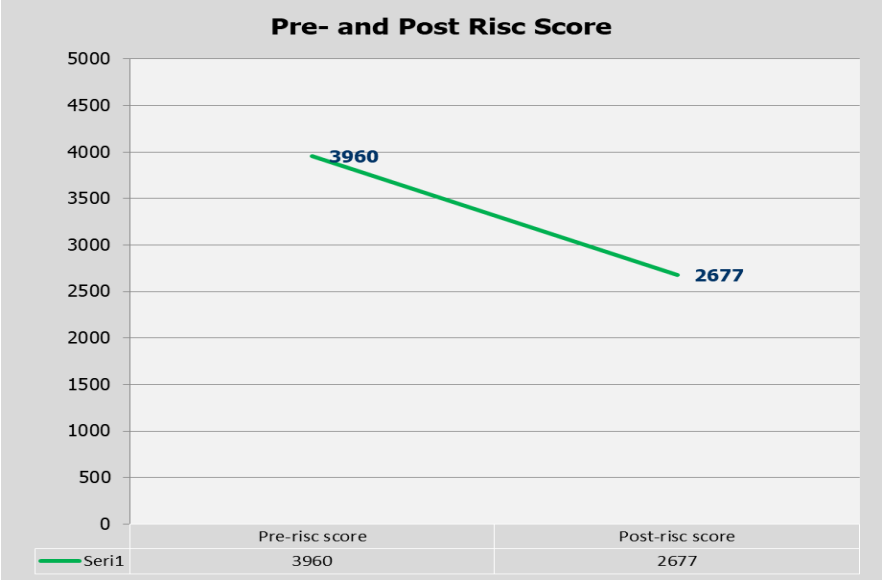
Before FMEA, 33.9% of the risks were classified as high, 3.2% as moderate, and 62.9% as low/very low. Following the implementation of FMEA, there was no change in the very low and low risk score, while the moderate risk score increased to 25.8% and the high risk score decreased to 11.3% (Table 8).

Table 8. Distribution of Pre- and Post-risk Scores

Risk class	Pre-Risk Score		Post-Risk Score	
	n	%	n	%
Very low	13	21	13	21
Low	26	41.9	26	41.9
Moderate	2	3.2	16	25.8
High	21	33.9	7	11.3
Very high	0	0	0	0
Total	**62**	**100**	**62**	**100**

The initial total Risk Priority Number (RPN) for this FMEA was 3960, which was reduced to 2677 following the implementation of corrective actions (Figure 2).

Figure 2. Pre-and Post Risc Score



The cost of FMEA corrective actions is given in Table 9. Overall, the estimated measurable cost of infection control improvement initiatives in the gastroenterology unit is approximately 4.4 million Turkish Lira.

Table 9. Cost of FMEA

Medical Equipment	Piece	Cost (₺)
Automatic endoscope washer-disinfectant machine	2	330.000
Endoscope storage and drying cabinets	2	280.000
Endoscopy telescope	2	1.235.000
Colonoscopy telescope	2	1.316.000
Transport cabinet	1	53.500
Endoscopy tower system	2	1.176.000
Total cost		4.390.500

*Costs are calculated based on the exchange rate at the time (1 dollar is 41 Turkish Lira)

IV. DISCUSSION AND CONCLUSION

Risk assessment is an important component of patient and staff safety management in healthcare. In the gastroenterology unit, 33.9% of infection control risks were initially classified as high, with the most critical risk involving contamination from organic residues on endoscopes due to inadequate decontamination. Reusable endoscopes, characterized by complex structures and exposure to high bacterial loads, require meticulous reprocessing and high-level disinfection to ensure patient safety (van der Ploeg and Bruno, 2023). Despite these precautions, studies indicate that 5% to 30% of endoscopes remain contaminated after reprocessing (Goyal et al., 2022; Okamoto et al., 2022; Houri et al., 2021). Enhancing the usability of reprocessing instructions, strengthening staff competence, and optimizing duodenoscope design have been shown to reduce risk (Okamoto et al., 2022).

Additional high-risk factors identified in the unit include improper disinfectant concentrations, device deterioration, reuse of inadequately cleaned instruments, and undetected contamination-all contributing to cross-contamination (Kenters et al., 2015; van der Ploeg and Bruno, 2023). Failures in cleaning, rinsing, disinfection, drying, and maintaining device integrity exacerbate microbial transmission and have been linked to infection outbreaks in endoscopy units (Ofstead et al., 2016; Parr et al., 2016; Larsen et al., 2020a; Hu et al., 2024). These findings highlight the multifactorial nature of infection control risks in gastroenterology settings and underscore the need for comprehensive preventive strategies.

Due to the heat-sensitive nature of endoscopes, autoclave sterilization is not feasible, necessitating alternative decontamination methods (Collins, 2021; Wang et al., 2018). Inadequate drying, in particular, promotes biofilm formation and persistent contamination. To prevent cross-contamination, strict adherence to nine reprocessing steps is essential-from point-of-use precleaning to proper drying and storage (Collins, 2021; Kenters et al., 2015). Additionally, post-procedure surveillance programs can aid in early detection of colonized patients and support infection control strategies against multidrug-resistant organisms.

Biofilm formation due to insufficient drying before storage constitutes another significant risk. Improper storage practices, such as placing endoscopes vertically without proper attachment of control valves, caps, and distal parts, or allowing devices to come into contact with one another, significantly increase this risk. Evidence indicates that inadequate drying enables the proliferation of microorganisms such as Staphylococcus, Escherichia coli, Bacillus maltophilia, Klebsiella species, Pseudomonas aeruginosa, Enterobacter species, and enterococci, whereas effective drying substantially reduces biofilm development (Tian et al., 2021; Alfa and Singh, 2020; Beilenhoff, 2023). Current guidelines recommend forced-air drying for a minimum of 10 minutes (Ofstead et al., 2024). Automated endoscope reprocessors combined with systems such as the Dri-Scope Aid, or storing endoscopes in drying cabinets for up to 72 hours, have been proposed as effective solutions (Tian et al., 2021).

Another critical factor is the infection risk posed by disinfectant solutions when minimum effective concentration (MEC) testing is not routinely performed. Studies reveal that high-level disinfectants frequently fail to achieve the required concentration levels, and testing can identify issues related to single-use products, process complexities, or non-adherence to guidelines (Ofstead et al., 2020). Accreditation standards for infection prevention in endoscopy units mandate routine verification of the minimal effective concentrations (MEC) of high-level disinfectants-both at the start of each disinfection cycle and after solution replacement. Disinfectants that fail to meet efficacy thresholds or have expired must be discarded. Adherence to manufacturer-recommended replacement intervals is essential to ensure consistent disinfection performance (Shin et al., 2019)

The total risk priority number initially was 3960 and decreased to 2677 following the corrective actions. Similarly, in an FMEA study conducted in India, the risk priority number decreased from 450 to 90 after implementing corrective measures (Shaikh, 2020). Other FMEA studies on patient safety in

hospitals have also reported a significant decrease in risk following the implementation of corrective actions (Liu et al., 2025; Ding et al., 2025; He et al., 2023; Liu et al., 2020).

The measurable cost of the improvement initiative has been calculated as approximately 4.4 million Turkish Lira. Bomman et al. (2021) emphasize that infection control interventions in gastroenterology units are effective but costly, highlighting the need for future innovations that ensure patient safety and cost-effectiveness. Larsen et al. (2020b) found that the cost of hospitalization due to colonoscopy-related infection ranged from $20 to $47 per procedure. In Italy, the annual additional direct costs of post-endoscopic retrograde cholangiopancreatography (ERCP) procedure infections were estimated at approximately €2.9 million (Sciattella et al., 2024). Economic evaluations indicate that enhanced reprocessing strategies significantly increase procedural costs. Cost-utility analyses indicate that while these interventions reduce the risk of infection, their incremental cost per quality-adjusted life year may be high, particularly in settings with low baseline infection rates. Therefore, both infection prevention and economic impact should be considered when selecting endoscope reprocessing strategies, and innovations must be developed to ensure patient safety while preserving cost-effectiveness (Zanganeh et al., 2025).

This study indicates that gastroenterology units involve high infection risks that threaten both patient and staff safety. The application of FMEA enabled the identification of critical hazards and the implementation of targeted corrective actions, resulting in a substantial reduction in risk scores. These findings demonstrate the value of structured risk assessment tools in improving healthcare safety processes and emphasize the importance of multidisciplinary collaboration in executing effective interventions. This approach contributes meaningfully to the advancement of patient safety and healthcare quality

This study has some limitations. Firstly, the risk assessment was conducted only in the gastroenterology unit of a single private hospital within a specific time period, which may limit the generalizability of the findings to other hospitals, departments, or healthcare settings. Secondly, the risk classification and scoring process relied on the subjective judgments of the specialist assessment team, the hospital's written procedures, and past incident records. This reliance on subjective evaluation may introduce potential bias into the scoring process. Furthermore, variations in institutional policies, staff training, resource availability, and organizational culture across different hospitals could lead to different results if the study were replicated in other settings. Therefore, future studies involving multiple institutions, diverse clinical departments, and larger samples of specialists are needed to assess the long-term impact and sustainability of corrective measures, and to strengthen the external validity of FMEA findings, particularly in relation to infection rates, staff adherence, and cost-effectiveness.

Ethics Committee Approval: The study was approved by the Bandırma Onyedi Eylül University Health Sciences Non-Interventional Research Ethics Committee with the date 08.07.2024 and number 2024-7/197. In addition, written permission was obtained from the institution where the study was conducted.

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