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Optimization of a colorectal cancer screening program through the implementation of a failure modes and effects analysis

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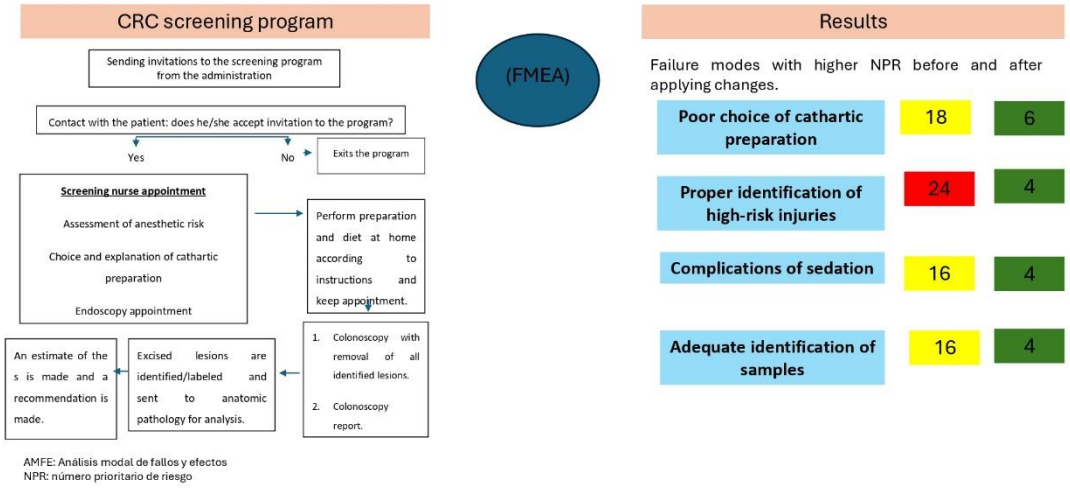

LAY SUMMARY

The survival benefit offered by population-based colorectal cancer (CRC) screening justifies campaigns to encourage participation among asymptomatic individuals. However, exposure to the healthcare system entails certain risks due to the potential for adverse events. According to the World Health Organization (WHO), the quality of healthcare is defined as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. There are tools available to measure the potential risk of errors or adverse events in a given process (in this case, CRC screening). One such tool is Failure Modes and Effects Analysis (FMEA). In this study, we applied this methodology to our screening program and analyzed the outcomes.

A B S T R A C T

Introduction: Colorectal cancer (CRC) screening is a strategy aimed at the early detection and treatment of this condition. Inviting asymptomatic individuals to participate in the program offers potential health benefits but also exposes them to possible complications associated with the process.

Material and Methods: We conducted a single-center, descriptive risk management study using the Failure Modes and Effects Analysis (FMEA) methodology. In the first phase, failure modes were identified through brainstorming sessions involving all relevant personnel. These were then categorized based on their Risk Priority Number (RPN), and a risk matrix was used to prioritize corrective and preventive measures for high-risk errors. Finally, interventions targeting the identified failure modes were implemented, and their impact was monitored at six months.

Results: A total of 12 failure modes were identified, four of which were classified as high-risk (RPN > 15). The proposed interventions were applied to mitigate these failure modes, resulting in a significant reduction in RPN scores.

Conclusion: The application of the FMEA methodology enabled the identification of high-risk errors in the CRC screening process and the implementation of measures to mitigate them, leading to improvements in the safety and quality of the program.

INTRODUCTION

Colorectal cancer (CRC) is the third most common malignancy worldwide. Its favorable response to treatment when diagnosed at early stages justifies the implementation of screening programs [1]. A particular feature of health screening programs is that it is not the patient who seeks medical attention, but rather the healthcare system that reaches out to the individual to offer a medical test.

CRC screening involves an initial fecal occult blood test (FOBT), with a positive result indicating the need for a colonoscopy, which is considered the gold standard. Prior to

undergoing colonoscopy, patients must complete a bowel preparation. There are various cathartic preparations available, which may lead to fluid and electrolyte imbalances and pose risks for patients with cardiac conditions or chronic kidney disease [2].

Although colonoscopy is an invasive procedure, its complication rate is relatively low, though not negligible. The most frequent complications tend to be mild, typically involving pain during or after the procedure, hypotension related to sedation, and dehydration caused by the bowel preparation. More serious potential risks include perforation, post-polypectomy syndrome, and post-procedural abdominal pain [3]. Additionally, it is important to highlight the risks associated with sedation administered during the procedure.

Given the above, inviting a patient to participate in a screening program not only offers the possibility of detecting disease but also exposes the individual to potential risks [4].

In recent years, the concept of colonoscopy quality has been extensively discussed, especially in the context of CRC screening [5–7]. In order for a colonoscopy to be considered high-quality—meaning its findings accurately reflect reality —certain criteria must be met, as outlined in various endoscopy guidelines. These criteria include: adequate bowel cleanliness (assessed by the Boston Bowel Preparation Scale), cecal intubation, photographic documentation, and proper characterization of any detected lesions [8].

To enhance the quality and safety of gastrointestinal procedures, recent studies have sought to identify and address high-risk points, with perforations and sedation-related complications emerging as major concerns [9]. FMEA is a prospective and systematic analytical method that enables the identification of situations where a process or its design may fail, the reasons for those failures, their prioritization, and the development of strategies to prevent them [10–12]. Originally developed to assess aircraft system safety and later adopted by industrial assembly lines, FMEA has since been validated for risk analysis in healthcare systems in general and specific clinical processes in particular [13,14]. This approach also allows prioritization of actions aimed at preventing failures from occurring.

Based on the existing literature, we proposed conducting a Failure Modes and Effects Analysis (FMEA) to identify areas for improvement in our CRC screening process.

MATERIALS AND METHODS

We applied the FMEA methodology, as outlined in the timeline shown in Figure 1.

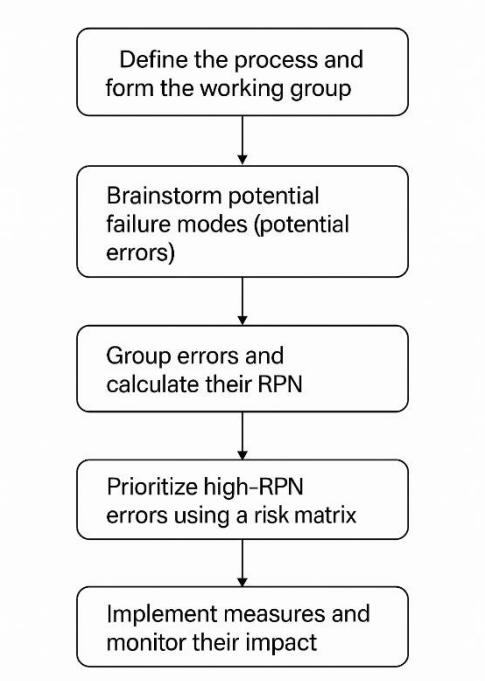

Figure 1. Simplified FMEA methodology diagram.

The first step was to define the process under analysis: safety within the colorectal cancer (CRC) screening program. A multidisciplinary team was assembled, consisting of 10 healthcare professionals, 5 gastroenterologists and 5 nurses specialized in endoscopy. Potential risk scenarios were identified through several days of brainstorming sessions, during which all subjective contributions from team members were accepted.

To simplify classification, errors were grouped according to their timing: before, during, or after the procedure. Identified failure modes were then consolidated by combining similar items and eliminating duplicates.

Each failure mode was assigned a Risk Priority Number (RPN), calculated as the product of severity, detectability, and frequency scores. These parameters were rated on a scale from 1 to 5 (Figure 2).

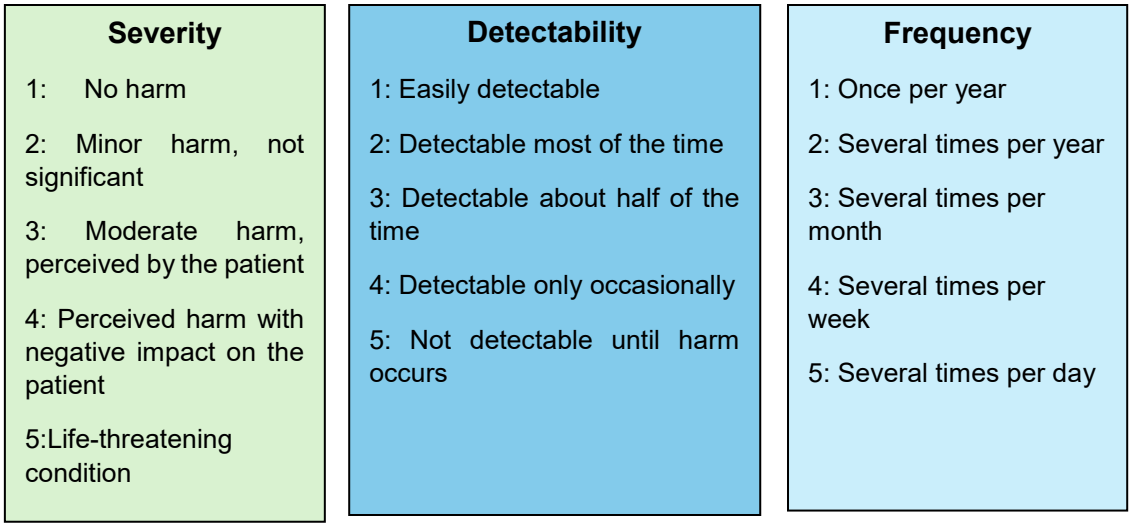

Figure 2. Scoring scales for failure modes.

Failure modes were then prioritized using a risk matrix, and a cut-off value was established to identify those with the greatest potential benefit from intervention. For each critical failure mode, related adverse events were described and targeted improvement strategies proposed. In addition, a designated team member was assigned responsibility for implementing each action.

Six months after implementing the proposed measures, the same parameters were reassessed, and RPNs recalculated to evaluate the impact of the interventions.

RESULTS

The first step involved mapping the CRC screening process, distinguishing the different stages. A brainstorming session was then conducted to identify potential adverse events that could occur at each phase, and similar items were grouped together. Each potential adverse event was assigned a Risk Priority Number (RPN), and these were prioritized using a risk matrix (Figure 3).

SEVERITY

	Mild	*Moderate*	*Medium*	*Major*	*Maximum*	
Very high	*25*	*50*	*75*	*100*	*125*	*None*
High	*16*	*32*	*48*	*64*	*80*	*Occasional*
Medium	*9*	*18*	*27*	*36*	*45*	*Medium*
Occasional	*4*	*8*	*12*	*16*	*20*	*Moderate*
Low	*1*	*2*	*3*	*4*	*5*	*High*

FREQUENC

DETECTABILITY

Figure 3. Risk matrix applying the RPN calculation.

For each subprocess analyzed—before, during, and after the colonoscopy—failure modes were classified based on their RPN.

The potential errors identified were:

- Before: failure to contact the patient, poor communication during the interview, inappropriate choice of bowel preparation.
- During: lack of patient information, failure to detect pre-neoplastic or neoplastic lesions, sedation complications, complications during polypectomies, lack of asepsis in endoscopes, or technical equipment failure.
- After: improper sample identification, inadequate endoscopy report, inadequate characterization of high-risk lesions in pathology.

Using the formula i = (75/100) × N, the 75th percentile (p75) of the RPNs was calculated, where N is the number of failure modes analyzed—in this case, 12. A cut-off RPN value of 16 was established as p75. Failure modes with RPN ≥ 16 were considered high-risk.

An evaluation was conducted to determine the causes and consequences of each error. Improvement strategies were proposed for those with RPN ≥ 16, and a person responsible for implementing each corrective measure was designated. Six months later, the RPNs were reassessed to evaluate the impact of the interventions.

The results are detailed in Tables 1, 2, and 3.

Table 1. Failure Modes Identified Before the Procedure and Their RPN Before and After Implementation of Measures.

Potential risks	Monitoring	Severity	Frequency	Detectability	NPR
Unable to contact the patient	Measurement 1	4	2	1	8
	Measurement at 6 months	4	2	1	8
Poor communication during the interview	Measurement 1	3	2	2	12
	Measurement at 6 months	3	1	1	3
Poor choice of cathartic preparation	Measurement 1	3	2	3	18
	Measurement at 6 months	3	1	2	6

Table 2. Failure Modes Identified During the Procedure and Their RPN Before and After Implementation of Measures

Potential risks	Monitoring	Severity	Frequency	Detectability	NPR
Lack of patient information	Measurement 1	3	2	2	12
	Measurement at 6 months	3	1	2	6
Failure to identify preneoplastic or neoplastic lesions	Measurement 1	4	2	3	24
	Measurement at 6 months	4	1	1	4

Complications of sedation	Measurement 1	4	2	2	16
	Measurement at 6 months	4	1	1	4
Complications of polypectomies	Measurement 1	3	2	2	12
	Measurement at 6 months	3	1	1	3
Lack of asepsis in endoscopes	Measurement 1	3	1	3	9
	Measurement at 6 months	3	1	3	9
Technical failure of the equipment	Measurement 1	4	2	1	8
	Measurement at 6 months	4	1	1	4

Table 3. Failure Modes Identified After the Procedure and Their RPN Before and After Implementation of Measures.

Potential risks	Monitoring	Severity	Frequency	Detectability	NPR
Inadequate sample identification	Measurement 1	4	2	2	16
	Measurement at 6 months	4	1	1	4
Inadequate endoscopy report	Measurement 1	3	2	2	12
	Measurement at 6 months	3	1	1	3

Inadequate identification of high-risk lesions	Measurement 1	3	3	2	12
	Measurement at 6 months	3	1	1	3

DISCUSSION

The effectiveness of CRC screening in the early detection of pre-neoplastic and neoplastic lesions and its benefit in terms of life-years gained has been demonstrated in recent studies [15]. The success of the screening program depends on appropriate patient recruitment by the healthcare system, as well as the competence of the professionals involved—ranging from proper selection of bowel preparation and anesthetic risk assessment by nursing staff to the correct identification and removal of lesions by the endoscopist.

A high-quality screening program must optimize available resources (endoscopy suites, time, trained personnel, availability of anesthesia days) in order to reach the largest number of people in the most equitable and fair way possible.

In such programs, the risk management strategy must be proactive rather than reactive—responding only after incidents occur. The quality and safety of these processes must be unquestionable to ensure public participation and to achieve the desired increase in quality-adjusted life years.

We emphasize that the first failure mode identified—colon preparation—is critical both in its simplicity and in its fundamental role in preventing repeated procedures, accurately identifying high-risk lesions, and safely removing them. Bowel preparation is often the most dreaded aspect of the procedure for patients, who may not fully understand its importance—an issue that is also being explored in recent studies [16].

To ensure the implementation of proposed measures within a program, it is important to promote the participation of all team members, facilitate communication and incident reporting, and appoint a person responsible for each measure who can take on a leadership role. Our work has demonstrated that risk situations may arise both from patient-related errors and from errors by healthcare personnel. Proper training of screening nurses and endoscopists, access to high-quality endoscopic equipment for lesion detection, and the presence of a well-trained endoscopy team (including nurses, support staff, and orderlies) are essential to prevent errors and their associated adverse events.

However, it must be acknowledged that up to 20% of patients with a positive fecal occult blood test (FOBT) will undergo colonoscopy without any polyp findings, and in such cases, the risk of exposure to the procedure would not be justified. Ongoing research

aims to refine patient selection for colonoscopy by identifying individuals not only with positive FOBT results but also with other positive risk markers [17,18] The future of screening colonoscopy will likely involve individualized risk stratification based on both CRC risk and procedural risk due to patient comorbidities, as already suggested by some studies [19].

In conclusion, applying the FMEA model to our process allowed us to anticipate complications that carried a significant risk of occurring. By implementing targeted risk-reduction measures, we improved the safety and quality of the CRC screening process in our healthcare area. A specific example is the significant improvement in Propofol sedation safety achieved by enhancing staff training, strengthening the emergency response protocol with anesthesiology and ICU teams, maintaining a highly experienced team, and increasing the availability of capnographs.

The strengths of this study include its originality and the robustness of the results obtained. Its limitations lie in being a single-center study conducted in a small and developing unit, which may limit its external validity. It should also be noted that our center is a secondary-level hospital serving a population of approximately 280,000 people. CRC screening is currently offered only to individuals aged 55 to 75, meaning our population may be older, with greater comorbidity and a higher risk of complications compared to other centers.

The simplicity of the FMEA model and its negligible cost make it feasible for implementation in any CRC screening unit worldwide. Thus, it would be beneficial to compare results with those from other groups. It could even be used as a practical exercise during daily clinical meetings. In the future, longitudinal, multicenter studies could help validate this strategy and potentially establish it as a quality criterion in CRC screening programs, recommending periodic use of such analysis.

While a specific cost-effectiveness study in this area is warranted, existing literature already supports that safety-related investments in healthcare are cost-effective. The resolution of harm to a patient—if even possible—carries serious personal, social, and of course, economic consequences [20–22].

The implementation of quality and safety improvement measures, such as revising emergency protocols, investing in equipment, and ongoing training in sedation and emergency situations, benefits not only patients. Healthcare professionals working in safe, well-managed environments also report higher job satisfaction and are less likely to experience burnout as a result of clinical pressure and repeated exposure to potential conflict with patients. Moreover, strategies like FMEA promote better team communication, offer new perspectives through structured discussion, and provide leadership development opportunities for team members tasked with carrying out improvement measures.

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