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## Usefulness of failure mode and effects analysis for improving mobilization safety in critically ill patients

### Utilidad de análisis modal de fallos y efectos para mejorar la seguridad en la movilización del paciente crítico intubado

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**Palabras clave:** Intubación Intratraqueal, Seguridad del Paciente, Unidad de Cuidados Intensivos, Análisis de Modo y Efecto de Fallas en la Atención de la Salud, Gestión de Riesgo

## Abstract

**Introduction:** Patient safety has become a core value in health organizations, requiring the use of significant resources in order to avoid accidents during hospital stay. Health care can create risks, and patient safety is the most important objective in care quality. Failure Mode and Effects Analysis (FMEA) is a preventive tool that helps anticipate potential errors and adverse events, setting up barriers to prevent them from happening, or mitigating their effects or, in the event they do happen, mitigating their impact on the most vulnerable link in health care, namely, the patient.

**Objectives:** To analyze, using the FMEA tool, mobilization of intubated critical ill patients in the Intensive Care Unit.

**Method:** A brainstorming session was held within the service to identify the most frequent potential errors in the process. Subsequently, the FMEA method with its different phases was

applied, prioritizing risk according to the RPN (Risk Priority Number) index and selecting improvement actions for those with an RPN greater than 300.

**Results:** The result was the identification of 101 failure modes, of which 46 exceeded the RPN of 300. As a result of this work, 63 improvement actions have been proposed for those failure modes with NPR scores above 300.

**Conclusion:** The conclusion of the study is that FMEA was a useful tool for anticipating potential failures in the process and proposing improvement actions for those that exceeded an RPN of 300.

## Resumen

**Introducción:** La seguridad del paciente ha adquirido un valor estratégico en las organizaciones sanitarias, empleando numerosos recursos para evitar accidentes durante la estancia hospitalaria. La

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asistencia sanitaria puede generar un riesgo y la seguridad del paciente es el objetivo más importante de la calidad asistencial. AMFE es una herramienta preventiva, lo que supone una anticipación a los posibles errores y eventos adversos, poniendo barreras para que no sucedan o si lo hacen mitigar sus efectos sobre la parte más vulnerable de la atención sanitaria, el paciente.

**Objetivos:** Analizar, a través de la herramienta AMFE (Análisis Modal de Fallos y Efectos), la movilización del paciente crítico intubado en la Unidad de Cuidados Intensivos.

**Metodo:** Para ello se realizó una tormenta de ideas dentro del servicio para decidir los posibles errores más frecuentes en el proceso. Posteriormente, se aplicó el método AMFE, con sus fases, priorizando el riesgo conforme al índice NPR (Numero de Priorización de Riesgo), seleccionando acciones de mejora en los que tienen un NPR mayor de 300.

**Resultados:** Como resultado hemos obtenido 101 modos de fallo de los cuales 46 superaban el NPR de 300. Tras nuestro resultado, se han propuesto 63 acciones de mejora en aquellos modos de fallo con puntuaciones NPR superiores a 300.

**Conclusiones:** La conclusión del estudio es que AMFE permite anticiparnos a los posibles fallos del proceso para proponer acciones de mejora en aquellos que superan un NPR de 300.

## Introduction

Patient safety has become a strategic pillar in health care organizations, requiring significant resources with the aim of avoiding accidents during hospital stay. Considering that error is inherent to human nature, its consequences need to be minimized.

Health care may create risks, and patient safety is the most important care quality objective. Nursing care represents one of the biggest risks, particularly in the intensive care unit (ICU), given the complexity of care, procedures, techniques, and technologies. This has been demonstrated in various international<sup>1</sup> and national<sup>2,3</sup> publications since the late 1990s.

Safety in health care must be enhanced using different tools such as Failure Mode and Effects Analysis (FMEA),<sup>4</sup> which, in this paper, will be considered in relation to the mobilization of the intubated patient.

FMEA seeks to solve problems that may arise as part of a process, even before they manifest themselves. It identifies every potential failure in order to assess the severity of potential effects and the frequency of the causes that give rise to them, establishing priority actions with the aim of improving process design. FMEA implementation in the health sector has been slow despite its strong implementation in the industrial arena, particularly in the aerospace field in the United States, where the margin of error is very tight and consequences are very difficult to address. FMEA allows to prioritize potential failures according to risk, probability, and possibility of detection in order to implement improvement actions designed to eliminate or reduce

the probability of them happening. For this reason, it is important to identify the weakest links in the health system, where protection is most needed. Moreover, being a preventive method, its study does not require the actual occurrence of errors.<sup>5</sup>

FMEA results in improved care quality, early identification and removal of process failures, prioritizing deficiencies, strengthening prevention, guiding control and development improvement, and fostering multi-disciplinary work. In intensive care medicine, FMEA may be of significant use, although few studies have been conducted so far.

Critically ill patients are more prone to develop pressure ulcers due to immobility, disease, old age, long hospital stay, hemodynamic and gas exchange disorders,<sup>6</sup> shearing, friction and medications, nursing care, the environment and patient-related factors.<sup>7</sup> Early mobilization is key in order to avoid ICU-acquired weakness (ICUAW),<sup>8</sup> and it is the best preventive strategy.<sup>9</sup> Postural changes benefit the critically ill patient, preventing the development of pressure ulcers, although mobilization of patients connected to different devices such as endotracheal tubes (ETTs) and central catheters may result in severe consequences. Moreover, there is a need for frequent mobilization.

The health system works hard to ensure patient safety, but errors leading to adverse effects (AEs) continue to occur.<sup>10</sup> An AE is nonintentional harm caused by health care actions that results in measurable disability. Synonyms include harmful health effect, adverse consequences, and negative impact. Adverse events cause measurable harm to the patient, while near-misses do not cause harm to the patient but could have resulted in serious consequences had they occurred.

The FMEA tool can now be used to improve safety by means of systematic risk analysis and improvement actions.<sup>11</sup>

## Method

### Hypothesis

The FMEA method can be used to make proposals for improving patient safety in the ICU during the process of mobilization, analyzing potential risks, and proposing systematic improvement actions.

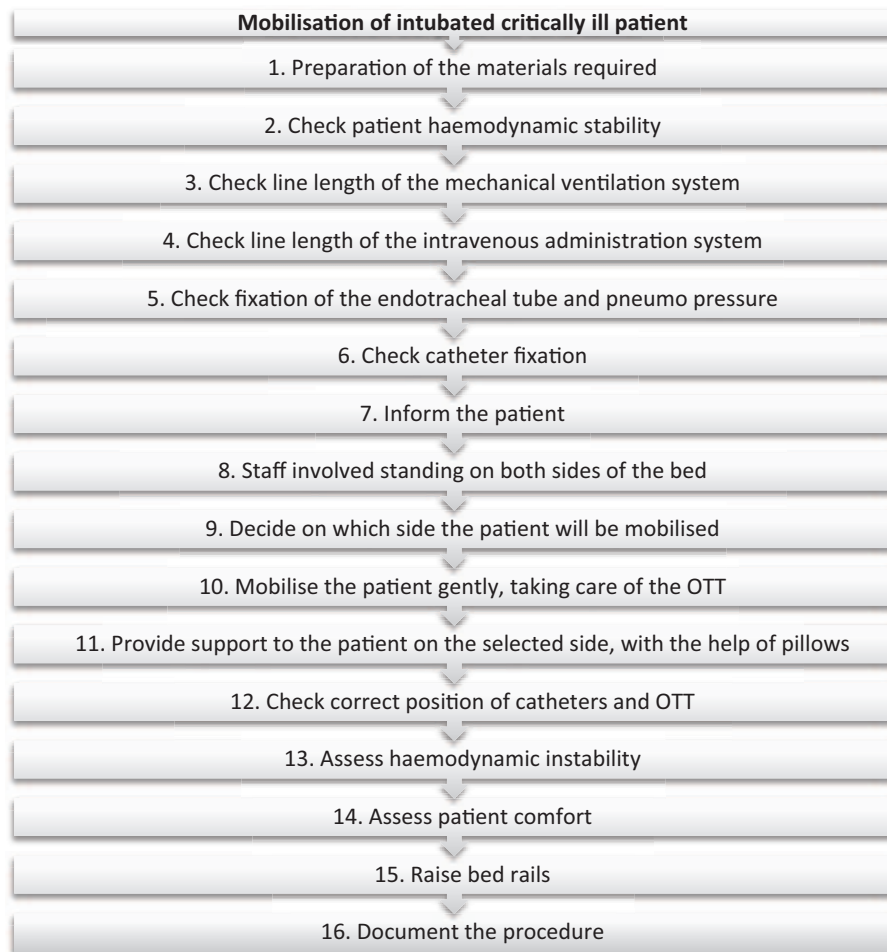
### Objective

The overall objective is to “use FMEA for identifying potential failures in the selected process,” and the specific objectives are as follows:

To identify the points at which care for the critically ill patient may fail (failure modes) and to enable the necessary means and procedures for detection.

To make the quantitative assessment of each failure mode.

To recommend actions aimed at reducing failure probability in the care process of the critically ill patient for those failures with a Risk Priority Number (RPN) higher

**Table 1. Mobilization of intubated critically ill patient**

Source: Authors.

than 300. The choice of that number was determined by the complexity of critically ill patients.

The FMEA tool was used in the ICU of the Gregorio Marañón General University Hospital (HGUGM). The design was based on the different phases of the FMEA.

### Selection of the team

The team consisted of 4 physicians, 9 registered nurses (RNs), and 3 ICU licensed practical nurses (LPNs). The majority have more than 5 years of experience working in the unit. Three 1-hour meetings were held.

### Process analysis

The phases of the process<sup>12</sup> are summarized in Table 1.

### Risk assessment

A brainstorming session was conducted with the ICU staff (physician, RNs, and LPNs), with the aim of gathering

information and reaching an agreement regarding potential failures and effects that may occur during the process and give them a numerical score: RPN (Table 2).

We discarded the ones that were not related to patient safety and, for the remaining ones, we asked the following:

- (1) Failure: What may go wrong?
- (2) Failure modes: How can it fail?
- (3) Causes: Why can it fail?
- (4) Effects: What may the consequences of the failure be?
- (5) Seriousness: What may be the repercussion of the failure for the patient?
- (6) Occurrence: What is the probability that the failure may happen?
- (7) Probability of detection: What is the probability of detecting it?

Together, seriousness, occurrence, and probability of detection provide the RPN score, which is then used to prioritize improvement actions. Each parameter is scored from 1 to 10 and then multiplied among themselves.

Table 2. Brainstorming

<ul style="list-style-type: none"> <li>• Catheter dislodgement due to absence of care, leading to an increase in morbidity and mortality</li> <li>• System disconnections</li> <li>• Extubation</li> <li>• Line kinks</li> <li>• Risk of falling</li> <li>• Ulcers</li> <li>• Lines not long enough to allow mobilization without the risk of extubation or catheter dislodgement</li> <li>• Shortage of staff</li> <li>• No regard for circadian rhythms in the patient</li> <li>• Inadequate assessment before mobilizing the patient (only routine type of assessment)</li> <li>• Respect for patient privacy</li> <li>• Acute changes in lung mechanics with the risk of barotrauma, hypoxemia, and hypercapnia</li> </ul>	<ul style="list-style-type: none"> <li>• Cables not long enough causing devices to fall or creating a risk of harm to the patient</li> <li>• Risk of increased ICP</li> <li>• Poor body alignment, increasing the risk for ICP elevation, dislocations, pain</li> <li>• Failure to mobilize the patient may result in pressure ulcers, disuse syndrome, stiffness, etc</li> <li>• Inadequate chair that may be too small for the patient or not in perfect condition</li> <li>• Problem with the lifting device used to raise the patient because of power failure or malfunction</li> <li>• Inadequate use of the lifting device</li> <li>• Kinks in the perfusion system</li> <li>• Poor placement of the diuresis bag</li> <li>• Failure to assess and treat pain adequately</li> <li>• Dragging the patient in bed. Friction may cause pressure ulcers</li> </ul>
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Source: Authors.

Seriousness may be quantified as

- (1) Low (1–2): no consequences resulting in patient injury, no prolonged length of stay, no need to increase surveillance.
- (2) Moderate (3–4): prolongs length of stay or requires greater surveillance during a limited period of time.
- (3) High (5–8): Results in injury, permanent loss of some function, need for additional treatment, longer length of stay, or need for additional care due to hemodynamic instability.
- (4) Catastrophic (9–10): Life-threatening.

Occurrence may be quantified as

- (1) Remote (1–2): Improbable, no known event.
- (2) Infrequent (3–4): Possible occurrence, some known case over the past 5 years.
- (3) Occasional (5–8): Probability of occurrence, several known cases over the past 2 years.
- (4) Very frequent (9–10): Probability of it happening right away, several known cases over the past year.

Possibility of detection may be quantified as

- (1) High (1–4): Error is detected right away and always.
- (2) Occasional (5–6): Error is detected early and always.
- (3) Moderate (7–8): Error is almost always not detected early.
- (4) Low or nil (9–10): Error always undetectable.

## Development of FMEA tables

Once everything was analyzed, FMEA tables in the form of results were prepared (Table 3).

## Results

The tables show 101 failure modes and we proposed improvement actions for subprocesses with RPN values

higher than 300. The decision was driven by the complexity of critically ill patients, in order to focus resources on those errors with the highest scores for the quantified parameter. This means they need at least to be highly serious, of occasional occurrence and/or not amenable to early detection. For example, mechanical ventilation disconnection represents a serious risk for the patient; although it occurs very frequently, failsafe mechanisms such as the ventilator alarms are activated immediately, making it possible to respond quickly and address potential effects, avoiding consequences.

These improvement actions will result in changes to the process or the addition of new barriers in order to avoid the risks identified (Table 4).

RPN values range between 576 and 20; 46 were higher than 300, accounting for 46.46% of the total.

Following our results, 63 improvement actions have been recommended.

## Discussion

These results cannot be compared with prior studies because, although FMEA has been applied in other areas of medicine,<sup>13</sup> it has never been applied to the process studied by our group.

Although there are FMEA studies in Spain,<sup>14,15</sup> improvement actions are applied to failures with an RPN above 100. In this study, improvement actions are applied to failures with an RPN greater than 300, given the complexity of the critically ill patient.

Other health care centers with different mobilization protocols might find different failures and quantify them differently, based on their own peculiarities.

RPN scores were found to range between 20 and 576.

Table 3. FMEA tables

Process	Mobilization in bed				
Team	Score				
Seriousness (S)	Frequency (F)		Detectability (D)		
Catastrophic	9-10	Very frequent	9-10	Low or nil	9-10
High	5-8	Occasional	7-8	Moderate	7-8
Moderate	3-4	Infrequent	5-6	Occasional	5-6
Low	1-2	Remote	1-4	High	1-4

Steps in the process	Potential failures	Potential causes	Potential consequences	S	F	D	RPN
Preparation of the material	Inability to lower the head of the bed	Bed failure; bed not connected	Poor patient mobilization; patient injury; staff injury.	4	9	1	36
Check patient HD status	Failure to consider patient instability	No adequate prior assessment	Harm for the patient; HD instability	8	9	5	360
Check length of the MV system cables	Extubation	Rigid lines; short lines; poorly fixed; loose pneumo	Hypoxia; hypoxemia, vital risk; potential arrest	9	7	4	252
Check orotracheal tube (OTT)	No OTT check	Loose fixation band; deflated pneumo	Extubation; hypoxia; hypoxemia, vital risk; potential arrest	9	8	4	288
Check good length of IV perfusion systems	No catheter system check	Short lines; sudden movements	Catheter dislodgement; HD instability; do not administer VAD; bleeding	8	7	4	224
Check catheter fixation	No check	Despiste; Inexperiencia Prisas; Falta de conocimientos	HD instability; failure of VAD perfusion Bleeding	8	7	7	392
Informar al paciente	Not advising patient about mobilization	Coming to the patient unexpectedly; startling the patient; hasty movements	Inflicting pain/discomfort to the patient; startling the patient; poor mobilization; nervousness	4	7	1	28

Process	Mobilization in bed						
Team	Score						
Steps in the process	Potential failures	Potential causes	Potential consequences	S	F	D	RPN
Decide on which side to mobilize	Inadequate side	Sloppiness; lack of knowledge; haste; lack of experience	Falls; extubations; hemodynamic instability. Discomfort.	8	5	5	200
Mobilize the patient	Catheter dislodgement	Poor fixation of catheters and infusion system; short system lines	HD instability; VADs do not perfuse; bleeding; infection	8	8	4	256
	Extubation.	Poor OTT fixation; short lines; haste; pneumo not tested; sudden movements	Hypoxia; hypoxemia; vital risk; potential arrest	9	9	4	324
	Kinks in IV systems	Poor patient mobilization	HD instability; no DVA infused	8	9	5	360
	Dragging the patient	Shortage of staff; lack of expertise; lack of knowledge; haste	Pressure ulcers; pain; scrapes	5	9	4	180

Process	Mobilization in bed						
Team				Score			
Steps in the process	Potential failures	Potential causes	Potential consequences	S	F	D	RPN
Mobilize the patient	Dragging the patient	Haste; sloppiness; lack of skill; inexperience	Falls; HD alterations; pain inflicted to the patient; injuries; extubation	8	5	1	40
Support the patient on the selected side	Kinks in IV lines	Lack of knowledge; sloppiness; haste	HD instability; VADs not infused	8	9	5	360
	Falls	Failure to raise bed rails; haste; excessive lateralization; lack of experience; staff shortage	Injuries; pain; extubation; HD alterations	9	5	4	180
Assess patient comfort	Poor body alignment	Haste; lack of experience; lack of knowledge	Pain; HD alterations, injuries	8	8	8	512
	Lack of privacy	Removing the covers; lack of experience; haste	Nervousness; discomfort	2	7	5	70
	Not respecting sleep	Moving the patient while asleep	Insomnia; discomfort	3	7	5	105
Raise bed rails	Failure to do it	Haste; forgetfulness; lack of knowledge; sloppiness	Falls; injuries; trauma; extubation	8	8	8	512
	Limb entrapment	Haste; sloppiness	Injuries; pain; trauma	8	7	4	224
	Catheter dislodgement	Limbs trapped in the railings; haste	HD alterations; bleeding	8	8	4	256
	Extubation	Trapping of lines; poorly fixed OTT	Hypoxia; desaturation; vital risk	9	6	4	216

Source: Authors.

Table 4. Improvement actions mobilization in bed

Failure-RPN	Cause	Improvement	Responsibility	Implantation timeline
Step 2. Failure to consider patient instability, 360	Absence of prior adequate assessment	Training	Regular training	12 months
		Writing a protocol	FMEA team	6 months
Step 6. Not checking, 392	Oversight; lack of experience; haste; lack of knowledge	Training	Regular training	12 months
Paso 10, Extubación, 324	Poor OTT fixation; short lines; pneumo not checked; haste; sudden movements	Reminders at bedside	FMEA team	1 month
Step 10 and 11. Kinking of IV systems, 360	Lack of knowledge; sloppiness; haste	Training	Regular training	12 months
Step 14. Poor body alignment, 512	Haste; lack of experience; lack of knowledge	Training	Regular training	12 months
Step 15. Failure to raise bed rails, 512	Haste; oversight; lack of knowledge; sloppiness	Board or Bedside reminders	ICU supervisors FMEA team	3 months
		Training	Regular training	12 months

Source: Authors.

The highest RPN in our study was 576 and reflects failure to use a basic safety mechanism such as raising bed rails, increasing the risk of falling.

The lowest RPN in our study was 20, reflecting the absence of mechanical devices for mobilizing the patient. This situation poses no risk to the patient, although it does represent a risk for the health care staff in charge of mobilizing the patient.

A large number of the improvement actions proposed in this research are based on training and awareness of the health care staff. Therefore, an adequate “training plan” is imperative in order to address mistaken habits that influence daily practice. This training plan must be part of organizational strategy and highlighted as a safety objective by the committees, units, or task forces charged with patient safety and risk management in health care institutions. Recycling in known techniques will always be welcome as new published knowledge is adopted. Recycling underpinned by good training will create awareness among the senior staff, the population for which change in routine practice is the hardest. Moreover, this training plan should be mandatory for all new staff in a special or new unit, as it would improve the quality of health care, as shown in the study by Alonso Ovies et al.<sup>16</sup>

A patient mobilization protocol should be developed by the FMEA team, including requirements for getting the patient out of bed and into bed. The recommendation is to use the available mechanical lifting devices for this job, and at least three RNs or LPNs should participate. Considering that the lifting device as well as its fixtures are critical for this work, it is important to ensure that everything is operational. This requires regular checks by the staff in charge, such as the ICU supervisor or the person responsible for maintenance of all ICU devices. It is also advisable to have a set of batteries to ensure that there is always one being charged, and that the lift will always be operational. Finally, it is important to insist on the measures designed to prevent falls, including bed rails, which need to be in good condition and must be used at all times. In this regard, it is advisable to place signs in the unit to remind the staff. Although intubated patients may be under different levels of sedation, it does not mean that the risk of falling is avoided.

The brainstorming phase is critical in the FMEA model, as it brings a large number of potential failures in health care processes and subprocesses to the surface, things that might not have been considered by the staff otherwise. Different personal perspectives from people with different backgrounds may also be eye-openers for others.

Training in FMEA and a step-wise approach to analyzing routine processes in daily practice will set the basis for developing a “risk map” that will result in safer and more efficient day-to-day practice. Organizations cannot afford to cover the costs associated with unsafe practices at a time in which equity requirements do not allow budget derailing.

## Conclusion

The FMEA tool was effective for determining failure modes in the selected process. Also, FMEA allowed to identify errors in the selected process, with a finding of 101 failure modes, 46 of which exceeded a PRN of 300, and have been selected for 63 proposed improvement actions.

Many of the failures result from practices entrenched in custom that need to be changed by means of training and awareness measures, because some techniques may become routine as a result of repetition. Changes in health care staff behaviors are needed in order for FMEA to be effective. They must be made aware of the fact that FMEA offers a new possibility to work in a harm-free environment in the long run.

It is highly advisable to incorporate the FMEA tool into our education plans so that it can eventually be used in the most routine processes of our health care practice.

A new mobilization protocol may be proposed as a result of the analysis of the failure modes. It would be useful to review it and implement it rigorously, providing adequate training to the staff in the unit as well as to other staff that may join the unit in the future.

## Ethical disclosures

**Protection of human and animal subjects.** The authors declare that no experiments were performed on humans or animals for this study.

**Confidentiality of data.** The authors declare that they have followed the protocols of their work center on the publication of patient data.

**Right to privacy and informed consent.** The authors declare that no patient data appear in this article.

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## Conflicts of interest

None.

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