Hospital Risk Management using Healthcare Failure Mode and Effects Analysis

A Case Study on Ventilators Whithin an Intensive Care Unit

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Abstract: The objective of this work was to analyze the potential risks associated to the use of invasive mechanical ventilators located in the intensive-care unit (ICU) of the Institute of Respiratory Diseases from Mexico. The study was addressed by applying the Healthcare Failure Mode and Effects Analysis (HFMEA), identifying possible/potential failure modes and its effects, and determining the severity and the probability of occurrence for each of these failures. We determine the risk score, and if this score was 8 or higher, we proposed a preventive action in order to develop an action plan. We identify six types of risks (electrical, mechanical, due to medical gases, biological, catastrophic and those related to human factor) and 26 potential causes related with these risks. Base on the evidence acquired by the HFMEA, we proposed a contingency plan for those potential causes.

1 INTRODUCTION

Risk is defined as the probability of harmful consequences, or expected losses (deaths, injuries, property, livelihood, economic activity disrupted or environment damaged) resulting from interactions between natural or human-induced hazards and vulnerabilities (WHO, 2007). There are hazards arise in the use of medical devices due to the inherent risk of medical treatment, from device failures (or malfunctions), and from device use. Hazards resulting from medical devices impact patients, family members, and professional healthcare providers (Kaye and Crowley, 2000).

Risk management is defined as the systematic process of identifying, evaluating and addressing potential and actual risk. Risk management has emerged as an integral element in the operational activities of hospitals. The process is a mechanism for self-protection in co-operative, self-insurance arrangements and to secure premium adjustments. Many trends have been recognized, that would suggest a predisposition toward the proliferation of risk management programs (Keddy et al., 1988).

Because of these, patient safety has become a matter of interest to healthcare professionals, governments and researchers worldwide. During the last decade, many studies have been conducted to assess the prevalence, severity and causes of a large variety of different types of adverse events in hospitals, as well as the effectiveness of various approaches to enhance safety (Wolf et al., 2001; Oliver et al., 2004; Marwick et al., 2009). The risks present in the hospital are widespread and complex. These risks are electrical, mechanical, biological, environmental and radiological, among others.

The initial steps to develop a risk management program include assessing current risk, control activities and implementing structural elements. As well, a program must address its relationship to quality assurance activities in the hospital.

The objective of this work was to analyze the potential risks of invasive mechanical ventilators (invasive ventilation is defined as mechanical ventilation via an artificial airway which can either be via endotracheal tube or tracheostomy tube), located in the intensive-care unit (ICU) of the

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National Institute of Respiratory Diseases (INER for its Spanish acronym), which is a third level public hospital in Mexico City. We address the study applying the Healthcare Failure Mode and Effects Analysis (HFMEA) (VA-NCPS, 2013) and propose a contingency plan in order to manage the risks associated with the use of this technology.

2 METHODOLOGY

Healthcare Failure Mode and Effects Analysis (HFMEA) is a prospective methodology that identifies and improves steps in a process thereby reasonably ensuring a safe and clinically desirable outcome. HFMEA has been designed by the National Center for Patient Safety (NCPS) of the Department of Veterans Affairs (VA) specifically for healthcare (VA-NCPS, 2013), and streamlines the hazard analysis steps found in the traditional failure mode and effect analysis process (IMCA, 2002). The purpose of the hazard analysis is to develop a list of hazards that are of such significance that they are reasonably likely to cause injury or illness if not effectively controlled. The steps of the HFMEA are described as follows.

2.1 Healthcare FMEA Steps

Step 1: Define the topic of the HFMEA along with a clear definition of the process to be studied.

Step 2: Assemble a Multidisciplinary Team including the subject matter expert(s) and an advisor.

Step 3: Graphically describe the Process.

Step 4: Conduct a hazard Analysis:

a. List all possible/potential failure modes for the process. Failure modes include anything that could go wrong that would prevent the process from being carried out. Consecutively number these failure modes.
b. List all possible/potential effects of the failure mode. Effects include anything that could happen if the failure actually occurs.
c. Determine the severity (S) of each effect by using the severity rating (Table 1).
d. Determine the potential causes of each failure mode. Each failure mode may have multiple failure mode causes. Document the causes.
e. Determine the probability of occurrence (O) for each of the potential causes by using the probability rating (PR) as follows:
   Frequent (PR=4). Likely to occur immediately or within a short period (may happen several times in one year).

Table 1: Severity rating.

Event	Severity rating
Catastrophic (4)	**Patient Outcome:** Death or major permanent loss of function (sensory, motor, physiologic, or intellectual). **Visitor Outcome:** Death; or hospitalization of three or more visitors. **Staff Outcome:** A death or hospitalization of three or more staff. **Equipment or Facility:** Damage equal to or more than $250,000. **Fire:** Any fire that grows larger than incipient/beginning stage cannot be controlled with portable fire extinguisher or small hose.
Major (3)	**Patient Outcome:** Permanent lessening of bodily function (sensory, motor, physiologic, or intellectual), increased length of stay or increased level of care, for three or more patients. **Visitor Outcome:** Hospitalization of two or more visitors. **Staff Outcome:** Hospitalization of one or two staff or three or more staff experiencing lost time or restricted duty injuries or illnesses. **Equipment or Facility:** Damage equal to or more than $100,000.
Moderate (2)	**Patient Outcome:** Increased length of stay or increased level of care for one or two patients. **Visitor Outcome:** Evaluation and treatment for one or two visitors (less than hospitalization). **Staff Outcome:** Medical expenses lost time or restricted duty injuries or illness for one or two staff. **Equipment or Facility:** Damage between $10,000 -$100,000. **Fire:** Incipient/beginning stage or smaller can be controlled with portable fire extinguisher or small hose.
Minor (1)	**Visitor Outcome:** Evaluation and no treatment required or refused treatment. **Staff Outcome:** First aid treatment only with no lost time, nor restricted duty injuries or illnesses. **Equipment or Facility:** Damage less than $10,000 or loss of any utility without adverse patient outcome.

   Occasional (PR=3). Probably will occur (may happen several times in 1 to 2 years).
   Uncommon (PR=2). Possible to occur (may happen sometime in 1 or 2 years).
   Remote (PR=1). Unlikely to occur (may happen sometime in 5 to 30 year years).
f. Determine the risk score (RS) by multiplying the probability score by the severity score.

g. Use the hazard decision matrix (Table 2) to determine if the failure mode warrants further action. If the score is 8 or higher, strong consideration should be given to developing an action plan.

Step 5: Actions and outcome Measures:

a. Identify an action for each failure mode that will be corrected. Place the corrective actions in the process at the earliest feasible point. Multiple actions can be placed in the process to control a single hazard. An action can be used more than one time in the process.
b. Identify outcome measures that will be used to analyze and test the redesigned process.
c. Identify a single, responsible individual by title to complete the recommended action.
d. Indicate whether top management has concurred with the recommended action.
e. Record the recommended action, responsibility and target date.

Step 6: Follow-up on Actions Taken

a. After the target date for the recommended actions, follow-up to make sure the actions were implemented and on what date.
b. Now that the recommended actions have been implemented, the hazard score should be lower. So, revisit the probability of that failure mode cause using the probability rating table (Table 2) and document the new rating.
c. Obtain the new hazard score by multiplying the severity times the probability and document the result. The new hazard score should now be <8. If not, revisit the recommended actions.

Table 2: Risk decision matrix.

Probability	Severity of Effect			
	Catastrophic (4)	Major (3)	Moderate (2)	Minor (1)
Frequent (4)	16	12	8	4
Occasional (3)	12	9	6	3
Uncommon (2)	8	6	4	2
Remote (1)	4	3	2	1

3 RESULTS

This work was developed by a multidisciplinary team of biomedical engineers, respiratory therapists and nurses. The knowledge acquisition (the process of extracting, structuring and organizing knowledge from one source, usually human experts), was made through interviews to technology users and by studying the procedures of handling and use of the ventilators, and management of medical technology.

Six risk-types associated with mechanical ventilators in the ICU were identified: electrical, mechanical, due to medical gases, biological, catastrophic and those related to human factor. Its failure modes and effects, and potential causes were analyzed for every case. The results shown in this work are only those with a risk score greater or equal to 8, because according to the hazard decision matrix (Table 2) these need further corrective actions. Therefore some operative actions were proposed and related with the hospital service responsible for its implementation.

3.1 Electrical Risk

Electrical risk is defined as a dangerous condition such that contact or equipment failure can result in electric shock, arc-flash burn, thermal burn, or blast. (NFPA, 2004).

For this risk one failure mode and effect was identified and associated to four potential causes, that got RS=8 (Table 3). This failure means that the ventilator has discharged battery. For all cases the potential causes have catastrophic severity (S=4), because if the ventilator stops working the patient's life is threatened, although the probability is uncommon (P=2).

3.2 Mechanical Risk

Mechanical devices are necessary for many treatments in the modern hospital. These devices include mobility aids, transfer devices, prosthetic devices, mechanical-assist devices, and patient-support equipment. Each of these devices embodies numerous life and limb threats to patients as well to hospital staff. These devices must be subject to careful design review, failure indication, and the establishment of complete specifications for safe use (Freeman, 1979).

For this risk two failure modes and effects were identified and associated to three potential causes (Table 3). Note that the potential cause 5 got a RS=12, because it is related to the localization of the electrical outlets, hence an infrastructure issue. The other two potential causes got a minor RS (RS=9), because these problems are related to the distribution of the ventilators into the ICU cubicle.

Table 3: HFMEA for the risks associated to the ventilators in the Intensive Care Unit.

Risk	Failure mode	Failure effect	Potential cause	S	O	RS
Electrical	Discharged batteries	The ventilator does not work	1. The ventilator is unplugged to the electrical system.	4	2	**8**
			2. The ventilator is plugged to an electrical outlet that doesn't work.	4	2	**8**
			3. The ventilator is stored for a long time without being plugged to the electrical system.	4	2	**8**
			4. There is not an area for plugging the ventilators in order to charge the batteries.	4	2	**8**
Mechanical	No free access to the electrical outlets.	By plugging the ventilator, other device may be unplugged (e.g., infusion pumps).	5. The electrical outlets may be in a high position and the staff may require a bench to plug the ventilator.	3	4	**12**
	The ventilator blocks the free staff's circulation.	The staff cannot access to the patient for emergency procedures.	6. Lack of space in the patient cubicle.	3	3	**9**
			7. Crossed hoses and wires block the access of the staff to the patient.	3	3	**9**
Medical Gases	Insufficient medical gases supply pressure.	The ventilator does not work.	8. Insufficient gas compressor power.	4	3	**12**
			9. Leaking hoses.	4	2	**8**
			10. Drop of the medical gases supply pressure.	4	3	**12**
			11. Leaking medical gases outlets or ventilator connectors.	4	2	**8**
			12. Bad medical gases supply connection.	4	2	**8**
	The ventilator cannot be connected to the medical gases outlets.	The patient could not receive ventilatory support.	13. Incompatibility between the medical gases outlets and the ventilator's connectors.	4	3	**12**
Biological	Contaminated ventilators not identified.	Use of contaminated ventilators.	14. Clean and contaminated ventilators are stored in the same place (transfer).	3	3	**9**
			15. No label for contaminated ventilators.	3	3	**9**

3.3 Risks by Medical Gases

Medical gases are widely used around the hospital and are supplied in cylinders or piped into wards and clinical areas. They are safe if handled correctly, however, misuse or mishandling can have catastrophic consequences (NHS, 2012).

For this risk two failure modes and effects were identified and associated to six potential causes (Table 3). Those related with the gas supply pressure got the mayor risk score (RS=12), because the correct operation of the ventilators depends on this; and the last three, related with the ventilator's connection to the gas outlet, got RS=8.

3.4 Biological Risk

Biological health risks are linked to the exposure to bacteria, viruses, fungi, other micro-organisms and associated toxins. These micro-organisms are widespread in nature and represent a potential danger for public health (EC, 2013).

The main biological risk arises when the staff cannot identify the contaminated ventilators, as it may cause a nosocomial infection if one of these devices is used in another patient. For this case two potential causes with a RS=9 related to the lack of a label to identify between contaminated ventilators that need cleanup and those clean ready for usage were determined.

Once the risks were analyzed, with the RS obtained a plot was made to see how the potential causes cluster and to define the priority in order to develop its prevention actions (Figure 1). Note that the risk by medical gases has the set of potential causes with mayor RS. It means that the first actions

to develop in the contingency plan will be for the potential causes of this risk. Then those for mechanical, biological and electrical risk would follow.

3.5 Catastrophic Risk (Seismic)

Catastrophic risks are those that can result in substantial loss of life or livelihood, call an organization's existence into question or cause significant environmental damage. These risks include a diverse range of events such as floods, pandemic infections, nuclear accidents, wars, seismic, economic collapse, etc. (World Economic Forum, 2012). In this sense, seismic activity occurs in many areas of Mexico, and Mexico City is particularly at risk due to unique geological characteristics coupled with an extraordinarily high concentration of exposure (USGS, 2012). This is the reason why we consider the analysis of seismic risk in this study.

For this risk one failure mode, two effects and three potential causes related with the infrastructure and movement of the ventilator in the ICU were identified (Table 4) and got a RS=8 for the three cases.

3.6 Risks by Human Factors

Hazards associated with device use are a common and serious problem. Evidence suggests that the frequency and consequence of hazards resulting from medical device use might far exceed those arising from device failures. Therefore, it is essential to ensure safe and effective device use if all hazards are to be controlled effectively (Kaye and Crowley, 2000).

Here we addressed hazards resulting from interactions between users and the mechanical ventilators in the ICU. We identify three failure modes and effects, associated to eight potential causes (Table 4). The ones with the mayor risk score (RS=12) were those related with the out-of-order ventilators and with the lack of staff capacitation in the correct use and handle of the equipment.

For these two last risks (biological and catastrophic) a plot with the gotten RS also was made (Figure 2), in which it's clearly seen that the first prevention actions to be developed are those for the risk related to human factor.

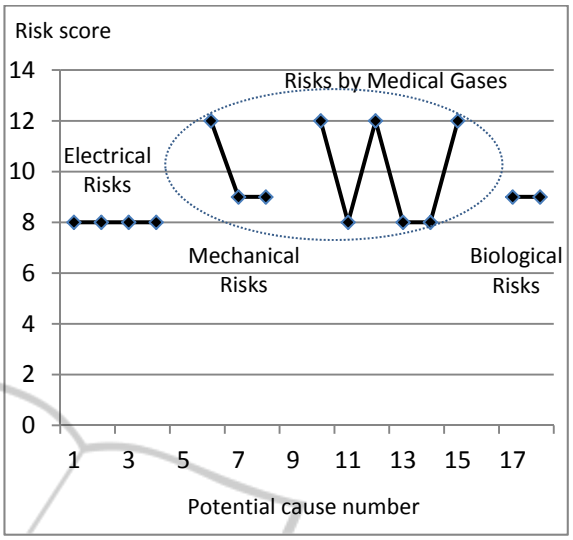

Figure 1: Graphic of the risk scores of the electrical, mechanical, by medical gases and biological risks.

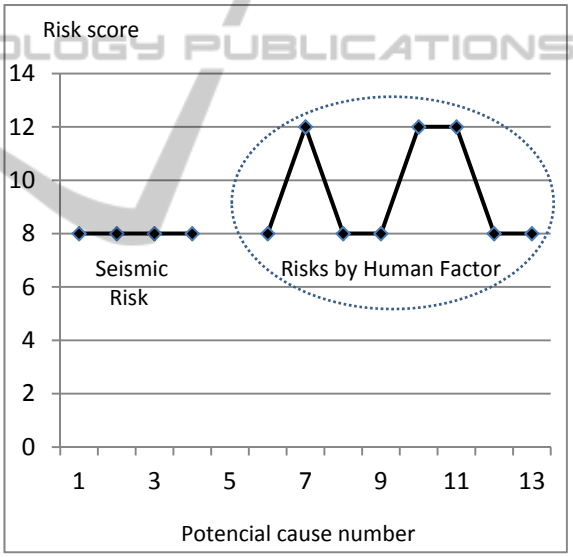

Figure 2: Graphic of the risk scores for the seismic and human factors risks.

3.7 Contingency Plan

A contingency plan is a process that prepares an organization to respond coherently to an unplanned event. The contingency plan can be also used as an alternative for action if expected results fail to materialize. The HFMEA study goes on to make recommendations on how to address the failure modes, ranging from better education, better visual displays, "time outs", bar-codes, etc.

For developing a contingency plan for the risks associated to the use of the mechanical ventilator in

the ICU, we used the risk score and the risk matrix (Table 2) to identify which critical failure modes need correction, but then is still need to make those corrections and take more action.

In this case, the Hospital would need to address 26 different potential causes. That doesn't necessarily mean that 26 separate remedial and corrective actions need to take place. A single corrective action might be able to address multiple failure modes, so a few key changes might address many failure modes at once.

Following we discuss the corrective actions for each type of risk, in order to develop the contingency plan as well as the responsible department for their implementation.

3.7.1 Electrical Risk

The proposed actions to diminish the electrical risk, in general, are of surveillance.

Inspect that the ventilator is effectively plugged to the electrical system, at least once per shift, to guarantee charged batteries. Respiratory Therapy is the area in charge for this action.

Supervise that all the electrical outlets in the ICU have electrical supply, are connected to the emergency power system and its voltage is periodically checked. Hospital maintenance is the area in charge for these actions.

To allocate an exclusive area for ventilators storage and to have a control strategy for the batteries charge process. Respiratory Therapy is the area in charge for this action.

3.7.2 Mechanical Risk

Some infrastructure modifications are proposed in order to diminish this risk, like to change the place of the electrical outlets to guarantee the staff free access to them. Hospital maintenance is the area in charge for this action.

On the other hand, it is necessary that a correct distribution of the equipment in the patient cubicles of ICU be done. The ventilators must be placed near to the medical gases and electrical outlets, and so vital signs monitors and infusion pumps must be correct placed. ICU is the area in charge of this action.

3.7.3 Risks by Medical Gases

It is important to be aware of pressures at which gases are stored and used. Therefore the medical gases supply pressure and each outlet in every cubicle must be verified, at least once a day, and so the connectors. Hospital maintenance is the area in charge of this action.

Table 4: HFMEA for the risks associated to the use of invasive ventilators in the Intensive Care Unit.

Risk	Failure mode	Failure effect	Potential causes	S	O	RS
Catastrophic	Seismic	The ventilator does not work.	16. The medical gases supply is interrupted due to damage to the hospital infrastructure.	4	2	**8**
			17. The ventilator gets disconnected from the medical gases supply, electrical system or breathing circuit.	4	2	**8**
		The ventilator may hinder the evacuation of patient and staff.	18. The ventilator moves and blocks the staff's evacuation of the cubicle.	4	2	**8**
Human Factors	Lack of available ventilators.	Patient does not receive ventilatory support.	19. Contaminated ventilators.	4	2	**8**
			20. Out-of-order ventilators.	4	3	**12**
			21. Not enough accessories (breathing circuits, hoses, etc.).	4	2	**8**
			22. Cleaning verification not passed.	4	2	**8**
	Not enabled staff in the use of ventilators.	Patient does not receive ventilatory support.	23. Invasive ventilator used for patient transfer.	4	3	**12**
			24. Lack of capacitation to the user.	4	3	**12**
	The ventilator stops working during patient transfer.	Patient does not receive ventilatory support.	25. The ventilator sustains a breakdown during the patient transfer.	4	2	**8**
			26. Drop of the medical gas tank pressure.	4	2	**8**

To check the hose and breathing circuit state at least once per shift and to have a replacement strategy in accordance to the manufacturer's specifications, also the compatibility between medical gases outlets and ventilator connectors must be assured, and those that do not meet this requirement must be replaced. Respiratory Therapy is the area in charge of this action.

3.7.4 Biological Risks

In this case developing an infection control plan is fundamental; it will allow identifying contaminated ventilators in order to start effective decontamination procedures. The Respiratory Therapy is the area in charge of these actions.

3.7.5 Catastrophic Risk (Seismic)

In case of an earthquake, having the sufficient equipment and accessories to maintain the maximum technology capacity is necessary.

Also, portable oxygen tanks to keep the ventilators working until the regular gas supply is reestablished, enough transfer ventilators and compatible invasive transfer ventilators circuits to avoid patients' re-intubation are required. The Respiratory Therapy is the area in charge of these actions.

Furthermore, it is very important to verify the wheel brakes of both the ventilator and the bed to avoid displacements during an earthquake. ICU is the area in charge of this action.

3.7.6 Risks by Human Factors

For these risks the following actions are proposed:

Supervise the effective cleaning of the ventilators. Acquire enough equipment, accessories and consumables according to the demand of ventilators. Use transfer ventilators for patient mobilization. Respiratory Therapy is the area in charge of this action.

On the other hand, it is necessary to schedule daily equipment review routines to guarantee the availability of verified ventilators. Improve the ventilators' preventive and corrective maintenance response. To develop a continuous training program for the staff and a continuous ventilators' functionality test program. The Biomedical Engineering Department is in charge of these actions.

Distribute the workload of the ICU according to the staff available and to promote the recruitment of more staff.

4 CONCLUSIONS

The HFMEA application showed evidence that allowed to analyze the potential causes associated to six identified risks (electrical, mechanical, due to medical gases, biological, catastrophic and those related to human factors), in the use of mechanical ventilators in the ICU.

With the RS obtained for each one of the 26 potential causes, its priority was determined and preventive actions were proposed, aiming for a risk management contingency plan development.

Once the contingency plan in the ICU is established, the tracing and feedback actions that allow to recalculate the RS and to evaluate the effectiveness of the preventive measures implemented will be carried out, and, if so, keep or modify them. As we know, a common outcome of risk analysis is to re-emphasize the training and procedure-following by staff members.

By the other hand, an equipment control program must be implanted in the ICU, in order to enforce the contingency plan. The control program provides a structure for the clinical utilization of equipment in the hospital, and directs the effort by the entire institution to apply technical competence, management techniques, and organizational skills to the control and application of technology (Furst, 1979).

In this work is shown the usefulness of the HFMEA for the evaluation and management of risks associated with mechanical ventilators use in the ICU. However it is a tool that can be used for analyzing and evaluating risks of any medical technology in any clinical service.

As further work, an evaluation of the risk management framework is going to be conducted by a pilot program (a preliminary study) to see how part of the ICU, using the proposed contingency plan performs better than part of the ICU not using it, in order to evaluate feasibility, time, cost, adverse events, and effect size.

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