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FMEA Analysis of Medical Equipment ventilator in a72 bedded Intensive care unit setup

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ABSTRACT

Introduction: The failure Mode Effect Analysis (FMEA) is one of the tools that can be used for performing HIRA on processes involving medical equipment.. FMEA is a process improvement methodology.

The goals of FMEA are as follows:

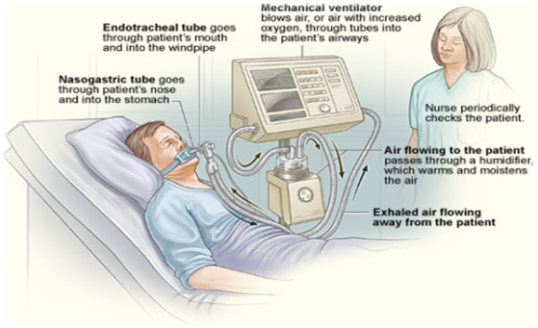
- To identify the failure modes involved in the process involving medical equipment.
- Establish the risk & consequences of these failure modes
- Identify and implement mitigation strategies for the effect.
- Access the success of mitigation strategies.
- Implement the modifications to the hospital as appropriate.

Method: Observation study of failure modes.

Results: Total Risk priority number calculated during 4 major steps of process is 63.

Conclusion: A continuous FMEA study of the process can reduce the machine downtime drastically.

KEYWORDS :



INTRODUCTION:

The Ever evolving role of technology in healthcare services now allow hospitals to diagnose faster, with accuracy than ever before and in increasingly in a least-invasive manner. It allows hospitals to treat better & helps patient to recover faster. Most of the processes in high risk clinical areas of hospital like operating room, intensive care etc… involve usage of medical equipment in a manner other than in which it was intended to may lead to serious disability or death of patient. For example wrong delivery of medicine dose through non calibrated infusion pump.

As per NABH accreditation standards, the Hazard Identification and Risk Analysis (HIRA) exercise to be conducted by and it should take all necessary steps to eliminate or reduce such hazards and associated risks. It is mandatory to monitor adverse events and near misses in the hospital.

The ***failure Mode Effect Analysis (FMEA)*** is one of the tools that can be used for performing HIRA on processes involving medical equipment. FMEA is a process improvement methodology. The goals of FMEA are as follows:

- To identify the failure modes involved in the process involving medical equipment.
- Establish the risk & consequences of these failure modes
- Identify and implement mitigation strategies for the effect.
- Access the success of mitigation strategies.
- Implement the modifications to the hospital as appropriate.

The following covers some basic FMEA terminology:

Failure mode: The specific manner or way by which a failure occurs in terms of failure of the item (being a part or (sub) system) function under investigation; it may generally describe the way the failure occurs

Failure effect: Immediate consequences of a failure on operation, function or functionality, or status of some item.

Probability*(P):*The likelihood of the failure occurring.

Severity*(S):*The consequences of a failure mode. Severity considers the worst potential consequence of a failure, determined by the degree of injury, property damage, system damage and/or time lost to repair the failure.

Detection(D): The means detection of the failure mode by maintainer, operator or built in detection system, including estimated dormancy period (if applicable)

Risk Priority Number (RPN): Severity S(of the event) * Probability P (of the event occurring) * Detection D (Probability that the event would not be detected before the user was aware of it)

AIM:

- Understanding the use of FMEA tool.
- Measuring breakdown time of Ventilator.
- Analysis of possible causes of breakdown.
- Failure mode & effect analysis of ventilators.

METHODOLOGY:

Study undertaken in 72 bedded multi super speciality hospital with a backup of 17 ventilators.

RESULTS:

Total ventilator downtime studied was 14 hrs 17 mins.

In this study reasons for failure of ventilator has been studied and according to the RPN value of each process mitigation steps have been suggested to reduce the down time and its severe effect on the

patients. Further these mitigation steps will be implemented and same FMEA analysis will be done for the same to understand the effect.

Total RPN value calculated for this downtime is 63 as per scoring effect given in Table 01

Table:1 Numerical Effect Scoring		
Severity (S)	Occurrence (O)	Detectability (D)
Major: 3	Frequent : 3	Low: 3
Moderate: 2	Occasional : 2	Medium: 2
Minor : 1	Rare: 1	High : 1

Process parameters observed in this study is shown in Chart 01

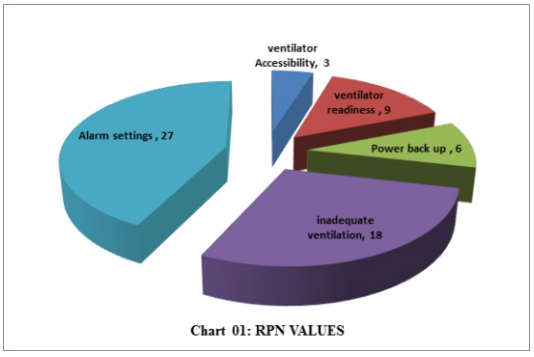


Chart 01: RPN VALUES

CONCLUSION:

In summary, FMEA permits the proactive identification of possible failures in complex processes and provides a basis for continuous improvement. With the increasing complexity of clinical services, FMEA offers tools for predicting failure and for implementing changes to prevent such failures from occurring in the future.According to Sentinel event statistics data of Joint commission (from 1995 to Dec 2002) % of Ventilator death/injury is 0.9%.

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