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FAILURE MODE AND EFFECT ANALYSIS (FMEA) WITH SPECIAL REFERENCE TO ICU, EMERGENCY DEPARTMENT AND BIO-MEDICAL ENGINEERING DEPARTMENT IN ONE OF THE LEADING HOSPITALS IN COIMBATORE

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Abstract- *Intensive care unit and emergency department within the hospital sector are considered as the vital part, that aids in patient care with advanced life support. The bio-medical department is considered a non-clinical department that aids in patient care. The bio-medical department is responsible for the proper supply of medical devices throughout the hospital without any errors. Any errors from these three departments can cause life-threatening issues to patients. FMEA (failure mode and effect analysis) considered as an effective method for identifying potential threats in the process or design, allowing hospital to take measure to overcome failure. This paper helps to identify failure occurring within the ICU by reducing the problems from radiology, laboratory, pharmacy, store and dietary department. FMEA helps to reduce the risk priority number (RPN) while shifting the patient from emergency department to cath lab with 20 minutes of patient arrival. The FMEA in bio-medical engineering department focuses to reduce the RPN by reducing the error in issuing the job order to the staffs.*

Keyword: Failure mode and effect analysis, FMEA, Intensive care unit, Emergency department, Bio-medical engineering department, Hospital.

1. INTRODUCTION

Failure Modes and Effects Analysis (FMEA) is an efficient and practical method used for evaluating a process or design to identify potential failure that could occur in the current process or newly developed one. This helps the hospital to make changes to prevent any confusion and havoc. The current and upcoming problems in ICU, ER, Bio-medical engineering departments can be identified and solved by applying FMEA and making few recommendations. The FMEA team includes Bio-medical engineering manager, Quality Co-ordinator, ICU and emergency Doctors and nurses etc.,

1.1. FMEA (failure mode and effect analysis)

Failure Mode and Effects Analysis (FMEA) is an organized method to discover potential causes and failures that may occur with the design or process. Failure modes signify in which a process can fail and effects signify failures that can lead to waste, defects, or harmful outcomes for the customer/patients. Failure Mode and Effects Analysis is designed to recognize, prioritize and set a perimeter to those failure modes.

To improve the process or design, the following steps are necessary,

The 10 Steps in FMEA:

- STEP 1 & 2: Assess the process/Design and brainstorm for possible failures.
- STEP 3: List potential effects to each failure mode.
- STEP 4, 5 &6: Assign a severity (SEV), occurrence (OCC), detection (DET) rating for each failure mode.
- STEP 7: Estimate the risk priority number (RPN).
- STEP 8: Develop an action plan for each failure and take necessary action.
- STEP 10: Re-evaluate each failure mode using RPN.

OBJECTIVES OF THE STUDY

1. To study process within Intensive care unit, emergency department and bio-medical engineering department.

2. To identify potential problems and implement FMEA in ICU with concerning issues with pharmacy, store, dietary, laboratory and radiology departments.

3. To identify reasons behind the delay in shifting the STEMI patient from ER to Cath lab within 20 minutes and to implement FMEA to reduce the delay.

4. To study and implement FMEA to resolve the issues in job order process at bio-medical engineering department.

5. To suggest some measure to resolve the identifies problems in ICU, emergency, and bio-medical engineering department.

2. LITERATURE REVIEW

According to Abbassi A, Ben Cheikh Brahim A, Ouahchi Z (2022) this FMEA study, focuses on the medication management process in a teaching pharmacy using traditional FMEA rating system. The anticipated risk scoring allows a better concordance with the classic method. Total of 24 failure modes were recognized for the medication management in a pharmacy with overall criticality of 2607 in the study.

According to Wenyan Song, Jing Li, Hao Li, Xinguo Ming (2020) this study, develops a risk assessment model for the identification and estimation of failure which may occur using medical devices in the clinical area. First, the "Swiss cheese" model and the SHEL model are combined along with FMEA to identify potential failures in using medical devices. Finally, this method is applied in the clinical use of respirators or to prove its competence and usefulness.

According to Leila Moradi, Abdolhossein Emami Sigaroudi, Majid Pourshaikhian, Mahmoud Heidari (2020) this study, assessed the emergency department for clinical errors by using the HFMEA method. The important reasons that inclined all clinical errors were lack of knowledge, high workload, and fatigue among the staff. The suggested solutions to decrease these errors are to educate staff and raise awareness about principles and ethics.

3. METHODOLOGY

This is a descriptive research study that uses FMEA method to describe and evaluate the potential failures that could occur in ICU, Emergency, and Bio-medical engineering department's process or design positively. Moreover, this study is qualitative through which the FMEA team members are selected based on their area of expertise.

3.1 Data Collection Tools

Through a qualitative approach, data were collected through observation, interviews, and brainstorming sessions with FMEA team members. The FMEA team members include the Bio-medical engineering manager and staff, the Quality Coordinator head, ICU and emergency doctors and nurses, the dietary manager, the radiology manager, the pharmacy and store manager, and the head of the laboratory department.

4. ANALYSIS

Data were quantitively analysed and risk priority numbers (RPN) are obtained, which are 1<RPN<1000. All failure modes are prioritized based on the RPN score.

The RPN score calculated through Severity X Occurrence X Detectability

Table 1. Shows the severity score for each failure modes.

SCORE	SEVERITY
10	Dangerously high
9	Extremely high
8	Very high
7	High
6	Moderate
5	Low
4	Very low
3	Minor
2	Very minor
1	None

Table 2. Shows occurrence score for each failure mode

SCORE	OCCURRENCE
10	Very likely to occur
9	Almost likely
8	Very frequent
7	Frequent
6	Highly possible
5	Possible
4	Occasional
3	Rare
2	Very rare
1	None

Table 3. Shows detectability score for each failure mode

SCORE	DETECTABILITY
10	None
9	Almost certain not to detect
8	
7	Low likelihood
6	
5	Moderate likelihood
4	
3	High likelihood
2	
1	Very likely to detect

5. RESULT

The FMEA result for each department is displayed in separate tables. Only the major findings with the highest RPN score in each department are listed along with failure mode and effect, RPN score, and recommended action to resolve those failures in the future.

5.1 FMEA On Intensive Care Unit (ICU)

5.1.1 FMEA-ICU Concerning Dietary Department

By performing FMEA in ICU concerning the overall function of the Dietary Department, 6 process steps, and 9 potential failures have been identified. Among these failure modes, Diet and feed are not prepared in time, Feed for ICU patients are not prepared on time, and Delay in the food delivery process has the highest RPN score of 189. To resolve these issues several actions have been recommended and shown in **Table 4.**

Table 4. Shows RPN calculation of each failure mode in the dietary department

Process steps	Potential Failure mode	Potential failure effect	Potential causes	RPN	Action recommended
Diet and feed preparation	Diet and feed are not prepared in time.	Delay in patient care.	Lack of supervision and language barrier between cook and dietician	189	1) To recruit a multi-linguistic supervisor 2) Constant supervision over the cooking process 3) To obtain feedback from the wards
	Feeds for ICU patients are not prepared on time	Delay in patient care due to lack of nutrition.	Patients' feed bottle is not cleaned on time by nursing technicians, lack of manpower	189	1) ICU should be made a priority 2) Feed to be made within ICU 3) Additional food preparation for emergency cases.
Diet delivery to the ICU department	Delay in food delivery process	Delay in patient's recovery	1) Decreased manpower 2) Language barrier among ICS workers and dieticians	189	1) Allocation of more resources to the kitchen 2) Surveillance of the food delivery process

5.1.2 FMEA-ICU Concerning Laboratory Department

By performing FMEA in ICU concerning laboratory department, 7 process steps and 11 potential failures have been identified. Among these failure modes, Delay in system entry, Wrong blood sample entry, and Delay in transportation has the highest RPN score of 112. To resolve these issues several actions have been recommended and shown in **Table 5.**

Table 5. Shows RPN calculation of each failure mode in the laboratory department

Process steps	Potential Failure mode	Potential failure effect	Potential causes	RPN	Action recommended
Online system entry done by float nurse	Delay in the system entry	Samples are not tested in the laboratory without system entry	Blood collection and system entry are not made by the same staff nurse	112	Assigned staff to do the system entry and avoid using float nurse to do system entry or reduce the workload of the float nurse
	Wrong blood sample entry	Sample gets mixed up with different patience and hence there could be an error	Float nurse makes system entry instead of experienced staff or assigned staff him/herself doesn't make the entry	112	1) Use laboratory form while doing system entry 2) Double check before system entry 3) Assigned staff to do the system entry 4) Label blood sample with time, date, and initials
Transportation of blood samples to the laboratory	Delay in transportation	The laboratory will not be able to receive the sample at the correct time and delays the process of sampling	The non-availability of ward attendees to send the sample, the staff nurse forgets to send the sample	112	1) Send samples without delay 2) Utilize a nursing assistant or use the pneumatic system to send sample 3) The head nurse should monitor whether samples are sent without delay

5.1.3 FMEA- ICU concerning Pharmacy Department

By performing FMEA in ICU concerning pharmacy department, 4 process steps and 7 potential failures have been identified. Among these failure modes, the wrong drug intends for a different patient, errors in system entry, and delay in receiving STAT drugs have the highest RPN score of 162. To resolve these issues several actions have been recommended and shown in **Table 6.**

Table 6. Shows RPN calculation of each failure mode in the pharmacy department

Process steps	Potential Failure mode	Potential failure effect	Potential causes	RPN	Action recommended
Online Medicine intending process	The wrong drug intends for different patient	The patient receives the wrong drug, wasting resources, delays in delivery of medicines	Not doing proper double-check before intending, using float nurse to intend for entire patients	162	1) Assigned staff should use be responsible for intending their own assigned patient's drugs 2) Double verification from fellow staff before intending the drug 3) The drug intending person should have the patent's file while intending to avoid wrong entry
	Errors in the system entry	The drug entry process will be delayed due to system failure	Total system failure	162	1) Not depend completely on the system for drug purchasing 2) Re-educate about using the manual prescription often 3) Have drug stock in ICU for emergencies

	Delay in receiving STAT drugs	Patients' life-threatening	Staff forgets to mention STAT while intending or, STAT drugs are indented along with other routine medicines	162	1) Assigned staff to be re-educated to indent the drugs with STAT 2) Utilize the clinical pharmacist for indenting 3) Make a phone call to receive STAT drugs without delay 4) Utilize a pneumatic system to receive STAT drugs

5.1.4 FMEA-ICU Concerning Store

By performing FMEA in ICU concerning store, 6 process steps and 8 potential failures have been identified. Among these failure modes, Delay in preparing the orders and Frequent cancellation and returning the item to the pharmacy has the highest RPN score of 112. To resolve these issues several actions have been recommended and shown in **Table 7.**

Table 7. Shows RPN calculation of each failure mode in store department

Process steps	Potential Failure mode	Potential failure effect	Potential causes	RPN	Action recommended
Order received in store through HIS	Delay in preparing the orders	Delay in patient care	Not enough manpower	112	1) Priority to be given to ICU 2) Reallocate available resources during busy hours
	Frequent cancellations and returning the item to the pharmacy	Inconvenience in Hospital store	Error from floater nurse	112	1) New items should be indented and the old wrong item should be returned later to avoid delay in patient care. 2) Double check should be done by the nurses' side

5.1.5 FMEA-ICU Concerning Radiology Department

By performing FMEA in ICU concerning the radiology department, 7 process steps and 17 potential failures have been identified. Among these failure modes, the Patient fails to remove metal objects and has the highest RPN score of 135. To resolve these issues several actions have been recommended and shown in **Table 8.**

Table 8. Shows RPN calculation of each failure mode in the radiology department

Process steps	Potential Failure mode	Potential failure effect	Potential causes	RPN	Action recommended
The patient is asked to remove the outer dress and metal objects	The patient fails to remove metal objects	Metal objects are attracted to MRI machines and can be life-threatening	Patient forgets/is unaware of metal objects in pocket/cloths, patient not aware of the magnetic property of certain objects.	135	1) Nurses should make sure all the metallic objects are removed from the patients 2) Pacemaker fixed patient should be assessed before the scan

5.2 FMEA On Emergency Department

By performing FMEA to reduce time delay in shifting STEMI patients from ER to Cath lab at the emergency department, 6 process steps and 12 potential failures have been identified. Among these failure modes, the time taken by the patient's family member in deciding on PCI procedure, Delay in bill payment, and Delay in part preparation has the highest RPN score of 189. To resolve these issues several actions have been recommended and shown in **Table 9.**

Table 9. Shows RPN calculation of each failure mode in the emergency department

Process steps	Potential Failure mode	Potential failure effect	Potential causes	RPN	Action recommended
Patient prepared for a PCI procedure	Time is taken by the patient's family member in deciding on the PCI procedure	Delay in patient treatment	Doctor fails to explain the PCI procedure to the patient's family members due to language barriers or family members' lack of medical knowledge	189	1) Utilize a medical interpreter or PRO to interact with the family member while the doctor explains the procedure and the nurse should document it. 2) Doctor shouldn't fail to explain the critical situation of the patient
	Delay in bill payment	Patient not taken for PCI procedure on time	The patient doesn't know where to make the payment or doesn't have proper knowledge about the CM scheme and insurance facility in the hospital	189	1) Displaying the availability of the Scheme and insurance facility in ER 2) PRO or clerk to explain the cost of procedures 3) Accepting bank checks to compensate till the insurance form is accepted
	Delay in part preparation	The patient can't be posted for a PCI procedure	Non-availability of Barber	189	1) Re-educating barbers 2) Nurses should be able to do the part preparation in case of emergency

5.3 FMEA On Bio-Medical Engineering Department

By performing FMEA to rule out the errors in job order at the Bio-medical engineering department, 5 process steps and 5 potential failures have been identified. Among these failure modes, BMD engineers fail to document the job order form in the Bio-medical engineering department has the highest RPN score of 216. To resolve these issues several actions have been recommended and shown in **Table 10.**

Table 10. Shows RPN calculation of each failure mode in the Bio-medical engineering department

Process steps	Potential Failure mode	Potential failure effect	Potential causes	RPN	Action recommended
Job completed by the BMD engineers	BMD engineers fail to document the job order form in the Bio-medical engineering department.	Time of work completion cannot be tracked correctly	BMD engineers gave another job order at the same time.	216	BMD engineers should make a phone call to BMD after the work is completed and the secretary should be responsible to enter the work completion time. This helps the BMD secretary to track the engineer's location.

6. CONCLUSION

Failure mode and effect analysis (FMEA) is considered a practical, team-based, and systemic approach, which helps to identify the potential ways for a design or process to fail. By using FMEA, failure modes can be assessed before their occurrence and can be avoided. Applying FMEA in ICU, emergency department and bio-medical engineering department helps the hospitals to assess the potential failure has a higher chance to occur being detected. This study helps to unwrap certain failure modes that can affect the current process in these departments. Certain action plan has been suggested, by applying these suggestions could help, and developed the process and design in ICU, emergency department, and bio-medical engineering department.

7. REFERENCE

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