International Journal of Science and Research (IJSR)
ISSN: 2319-7064
SJIF (2020): 7.803

Failure Mode Effect Analysis on Clinical Alarms

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1. Introduction

The aim of Clinical Risk management is mainly to improve the quality of care that is to be provided by the healthcare organizations to assure the safety of patients. Failure Mode Effect Analysis (FMEA) is a process used to identify all potential failures and their causes before any further service is provided. It is an analytical method which is used for risk assessment which seeks to identify all the possible risks as well as the causes and effects that are associated with it.

Clinical Alarms are routinely used in the hospitals to alert the healthcare givers regarding the deterioration of the patient condition. The process of clinical alarms identification and interventions followed are crucial for the patient's clinical outcomes.

Clinical alarm management system is essential to patient safety and any organization that aims to achieve that must have a robust clinical alarm management system in place. Given the advent of technology in healthcare, the number and kinds of alarms we now use have increased. Hence the risks that come with them has increased as well.

The clinical alarms are set on the devices so as to grab the attention of caregivers towards the patients when the condition of the patient is deviated from his/her normal status. The clinical alarms are considered as a key tool to improve the patient's safety.

The Joint Commission is also developing a proposed National Patient Safety Goal for 2013, that addresses clinical alarm systems. The purpose for the use of alarm systems is mainly related to "communicating the information that requires awareness of responses by the caretaker". The parameters set in the monitors are usually present in the device, while in some cases it requires manually setting the parameter limits.

The purpose of FMEA is to take actions to eliminate the failures, starting with the ones identified as high risk will be given highest-priority. It is a proactive tool Quality method and technique that enables us to identify and prevent possible errors from occurring before the event has occurred. Within healthcare, the goal is to avoid any adverse events that would cause any potential harm to the patients.

Failure Mode Effect Analysis (FMEA): It is a structured way to address and identify all potential failures or problems and their resulting effects on the process before any adverse events occurs. In comparison, we came up with RCA (Root Cause Analysis) and recommendations to address problems that have already occurred. Failure mode effect analysis involves identifying and eliminating process failures with the purpose of preventing an undesirable event.

The FMEA is initiated with the purpose of identifying the potential aspects of improvement in the process and to proactively evaluate the limitations of Clinical Alarm Management process and also to identify the risks and implement actions to strengthen Clinical Alarm Process.

Failure Mode Effect Analysis was done on clinical alarms to ensure and identify all the possible failures, identify the causes and effects of the same so as to ensure reduced the risk to the patients in critical units.

Each failure mode gets a numeric scoring that will quantify the likelihood of the occurrence of failure or likelihood of failure not being detected or the amount of damage or harm the failure mode can cause to the patient. The product of these 3 score is RPN (Risk Priority Number) of that failure mode. Once the failure mode was analyzed occurrence, severity and detectability scores were allocated according to the possible causes and effects and how it could harm the patients. Once the scores were allocated, the RPN (Risk Priority Number), and came up with action plans for those failure modes with higher RPN as to how the occurrence, severity and detectability can be lowered so that there is no/minimum harm to the patients in the critical areas.

Once the steps were determined and the process was observed, the possible failures were identified. Once the failures were determined, all possible causes along with all possible effects were also determined.

Depending on the failures, causes, and effects, we scored the probability of occurrence of the failure mode, detectability of the failure mode and severity of the failure mode.

The score for Probability of occurrence was given from 1 to 5, 1 being the Lowest to 5 being the highest. The score for detectability was given from 1 to 5.1 being easily detected to 5 being almost certain not to be detected. The severity was scored from 1 to 5, 1 being minor to 5 being severe or terminal outcome.

Once the scores were fixed the Risk Priority Number (RPN) was calculated and after brainstorming, we gathered corrective measures so as to prevent the failure mode from causing patient harm.

2. Literature Review

The Joint Commission International is an independent not-for-profit organization. The JCI accredits and certifies health

care organizations and programs across the globe. The accreditation and certification of JCI is recognized as a global leader for health care quality of care and patient safety [1].

In June 2013, The Joint Commission International (JCI) announced the approval of new National Patient Safety Goal (NPSG) NPSG06.01.01 on clinical alarm safety for hospital and critical access hospitals, to improve the safety of clinical alarm systems. [2]

Definition of Clinical Alarm: It is a component of some medical devices that are designed to notify the caregivers on an important change in the patient's physiologic status. A clinical alarm typically provides audible and/or visible notification of the changed status of the patient. (JCI, 7th Edition.)

As the clinical alarm systems are intended to alert caregivers of potential patient problems, but if they are not properly managed, they can compromise patient safety. This is a multifaceted problem. This NPSG focuses on managing clinical alarm systems that have the most direct relationship to patient safety.

Clinical alarms are vital to patient safety. They are placed at the bedside of the patients to provide optimal care to patients. The over usage and at times inconsistencies of clinical alarms have led to alarm fatigue. Alarm fatigue is the overstimulation of sensory system due to continuous alarms, resulting in desensitization of the environment.

The continuous overpowering beeps may cause the staff to become exhausted, leading to ignore or silence the alarms, and this action will further lead to having a negative impact on the safety of patients. [3]

Alarm desensitization or alarm fatigue from frequent, unnecessary, or false alarm has the possibility to lead to serious patient harm. Hence a failure mode and effect analysis process were planned to help reduce the risk of patients. [4]

Failure Mode and Effect analysis is a structured way of identifying and addressing most of the potential problems/ failures and the resulting effects on the process before the event have occurred.

We have taken up FMEA in clinical alarms as it is effective in evaluating the new and the existing processes. For all the new processes, it identifies potential bottlenecks prior to its implementation. Also, it helps in evaluating an existing process to understand as to how we can propose a change that will make an impact in the ongoing system.

When we started the process of FMEA, it was observed that there were multiple alarms beeping at the same time. And according to The World Health Organization in the section of Guidelines for community noise wherein they advised sound levels in these places as per 100mts. It was suggested that, at daytime the sound be 50dB and during the night the alarms be kept at 35dB to 40dB. But these sound levels are not followed constantly throughout the hospital. Since there are multiple alarms beeping at the same time it can lead to alarm fatigue, or in some cases the volume of the alarms is reduced which can lead to patient harm.

By starting the process of FMEA, we created steps to identify all possible failure modes in the respective critical care units and listed out how it can be identified and how it could potentially harm the patient. Accordingly, we rated the severity, occurrence and detection of the same and calculated the risk priority number and developed action plan and recommendations for the same.

3. Research Methodology

The objective of this study:

- To proactively evaluate the limitations of Clinical Alarm Management process.
- Identify the risks to implement actions to strengthen the Clinical Alarm Management Process.

Study Type: Observational Study.

Inclusion Criteria: For this study, we have included all Critical Care Units in the hospital such as, Intensive Care Unit, Pediatric Intensive Care Unit, Surgical Intensive Care Unit, Operation Theater and Medical Intensive Care Unit.

Exclusion Criteria: For this study, we have not included some departments such as Emergency Department, Outpatient Department and Day Care.

Initiation:
This project was initiated by the Corporate Quality Department and was continued by the Unit Quality Department of Multispecialty Cancer Care Centre.

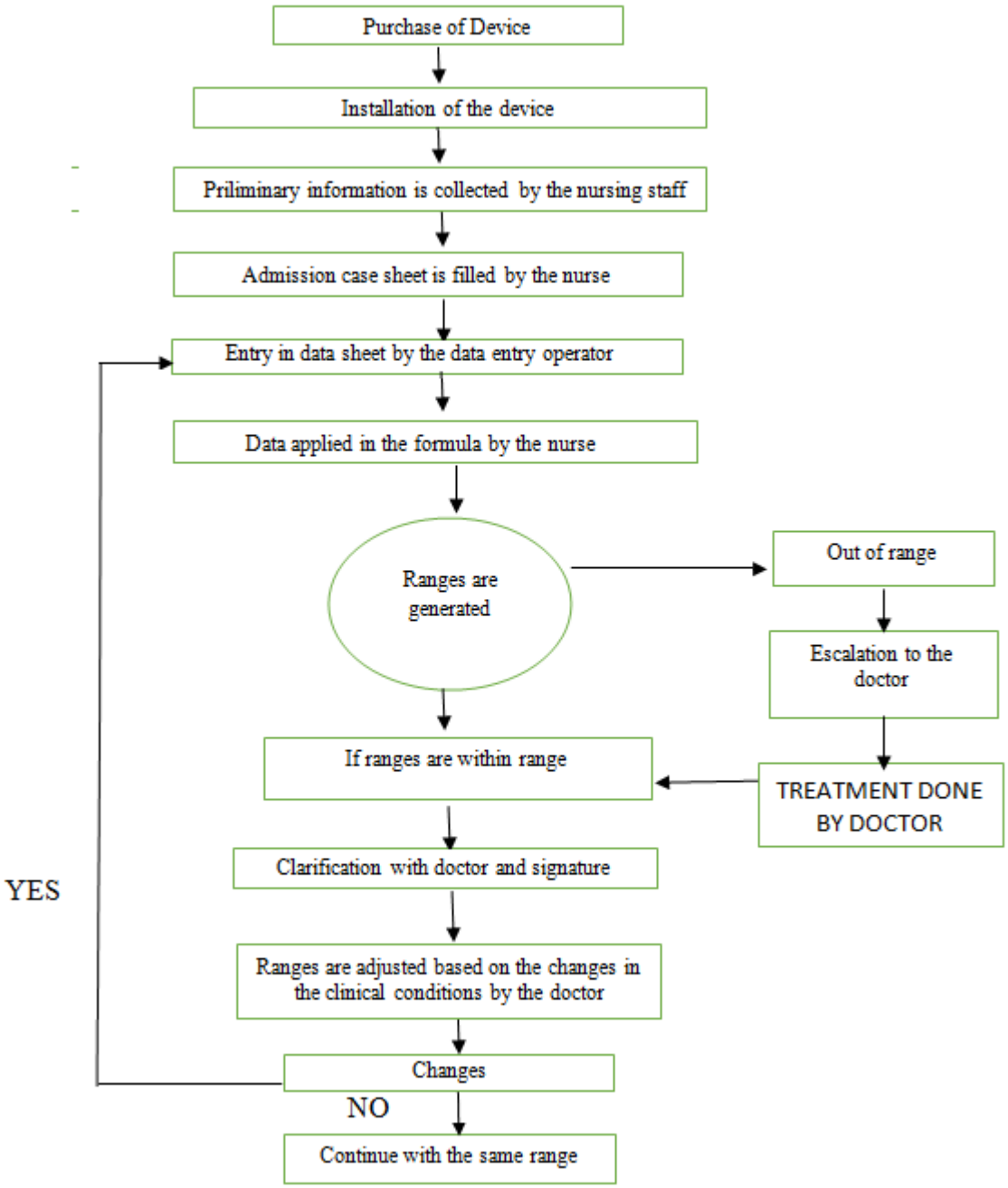
For the purpose of the study, facility rounds were done in Critical Care Units in the hospital such as, Intensive Care Unit, Pediatric Intensive Care Unit, Surgical Intensive Care Unit, Operation Theater and Medical Intensive Care Unit. The rationale for selecting these areas was that most usage of monitors with clinical alarms was seen in these areas.

A list of all the instruments which produce an alarm was made and divided area wise. The possible causes or the alarms and how it could cause potential harm was listed.

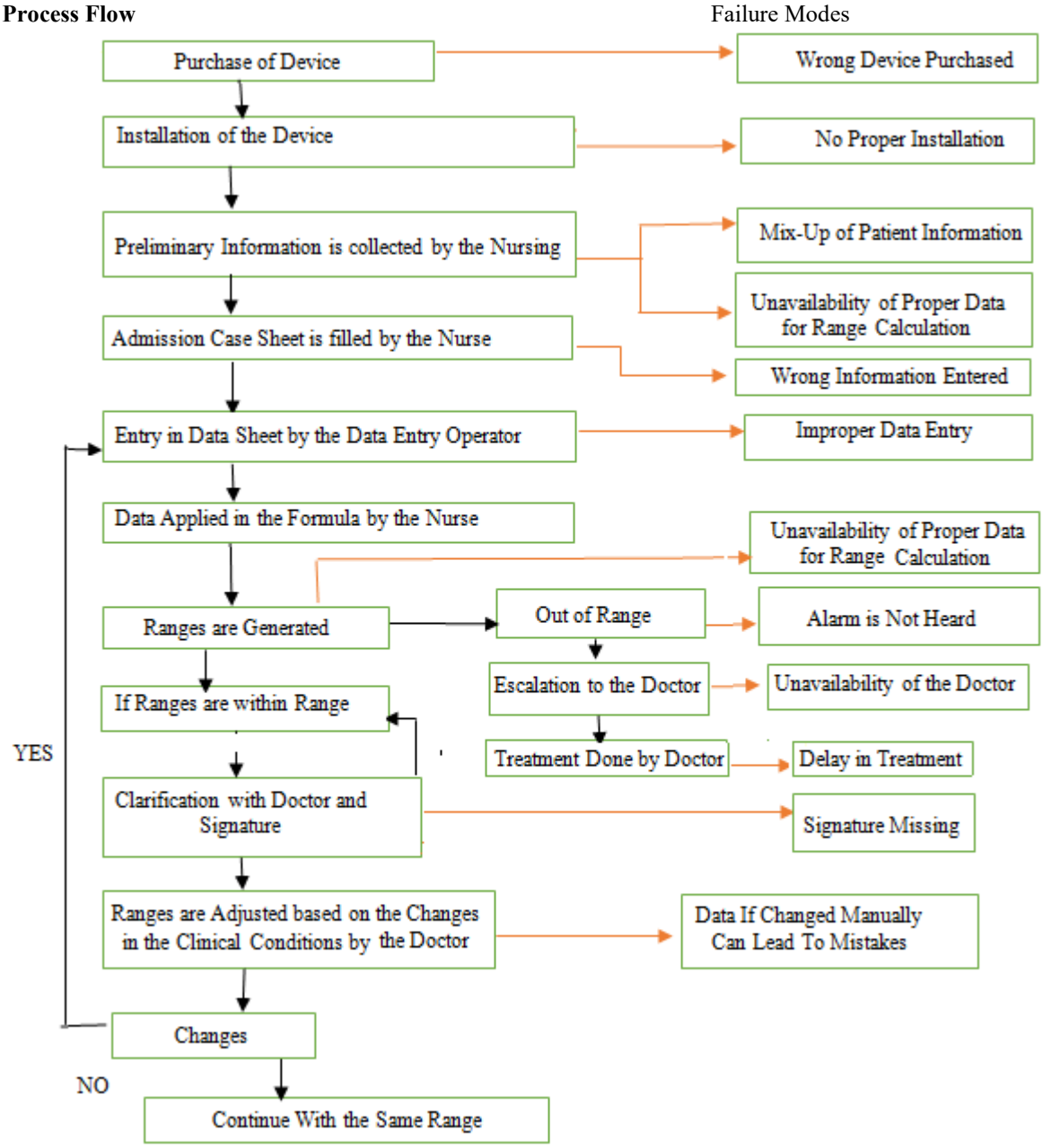
A process flow chart was created, and potential failure areas were identified. The effects of each potential failure were also identified. The severity and occurrence rating for each effect was assigned based on the Severity Rating Scale and Occurrence Rating Scale, respectively. Detection score was also assigned. Risk Priority Number was calculated and prioritized for each failure mode.

Root cause analysis was done for the failure modes with high RPN Scores. Based on the root cause analysis the action plan and recommendations were given.

Process Flow:



Process Flow



Process-Explained

For this project, we observed the whole process of the alarms so as to find the failure mode effect analysis in clinical alarms in the Medical Intensive Care unit, Surgical Intensive Care Unit and Pediatric Intensive Care Unit.

For the initiation of the FMEA in clinical alarms, we interviewed the nurses in charge regarding the whole process starting from the arrival of the patient from the OT to the MICU till their transfer to the ward.

The ICU nurses are given the list of the patients that are to be admitted in the ICU's one day prior to the operation. This ensures the beds are empty or the other patient is shifter to the ward on time.

The nurses fill the admission case sheet once the patient is received from the OT to ICU. When the patient arrives from the OT, monitors are already attached to the patient. Only the OT Technicians and the Bio Medical team have the authority to set the parameters in the monitors while the data for the parameter is given by the clinician.

The nurse identifies the patient by the MRN and name and age of the patient. The nurses in charge of the patient will have the list of parameter variation which is patient specific in case of pediatric patient and neonates. The nurse-patient ratio in the ICU varies by 2 ways, for patients on ventilators, the nurse-patient ration is 1: 1 and for non-ventilated patients, the nurse-patient ration is 1: 2.

In the ICU, continuous alarm sounds are observed, but in any given conditions the nurses are not allowed to disable the alarm, although they might reduce the volume of the alarms. The only condition where the alarms can be disabled is if the patient is no more connected to the monitors. The nurses will continuously monitor the patient's vital signs in accordance with the condition of the patient.

In case the condition of the patient deteriorates, the machine produces alarms as the vitals of the patients is low/higher than the set parameters. The nurse immediately attends to the patient and checks the vitals, if the vitals are normal all the other parameters are also checked, if it is observed to be normal the machine is check for faulty alarms. If the patient's vitals or low/higher than the set parameter, the doctor in-charge is informed immediately, and action is taken.

In some cases, the parameters of the alarms can be changed for particular patients depending on their condition in the ICU. The changing of the parameters can be done only when ordered by the doctor-in-charge.

When the patient's condition is stable and the doctor advises the transfer of the patient to the ward for observation, all the connections from the monitors are disabled by the nurse and the patient is shifted to the ward.

The methodology used for the study of FMEA was observational study, and on observation in the study, we tried to evaluate all possible potential failure modes for all steps in the process flow of Clinical alarm management.

4. Analysis

The failures that were identified were:

- Wrong device is purchased.
- Installation was not done properly.
- Patient misidentification.
- Mix-up of patient data.
- Unavailability of proper data for range calculation.
- Improper data entry by the operator.
- Alarm limits is changed and not communicated to the caretaker.
- Alarm conditions not detected by the staff.
- Alarm ignored due to alarm fatigue.
- Detection of an alarm conditions delayed.
- Delayed response to alarms by the nurse.
- Malfunctioning of equipment.
- Nurses initiate cardiac monitoring without the physician's order.
- Lack of communication to the allocated nurse about new patient connected to the cardiac monitor.

The below table contains the possible failure modes:

S. No	Failure Modes
1	Purchasing wrong device
2	Patient misidentification
3	Unavailability of proper range for data calculation
4	Improper data entry by the staff in the sheet
5	Manual adjustments
6	Alarm limits changed but not communicated
7	Alarm condition not detected by the staff
8	Alarm ignored due to alarm fatigue
9	Detection of an alarm condition delayed
10	Malfunctioning of equipment.
11	Nurses delayed response to the alarms
12	Other departments nursing staffs assigned to ICU who are unfamiliar with the equipment's of the ICU.
13	ICU nurse fails to plug in the monitoring equipment.
14	Nurses initiating cardiac monitoring within physicians order or with a physician's order that does not specify vital sign parameters.
15	No communication to the allocated nurse about a new patient admitted in the ICU and attached to the monitors.

Failure Modes

After the failures were identified, we listed what potentially could be the causes of the failures.

- Unavailability of device.
- Emergency requirement for the device.
- Failure in the usage of identifiers for patient identification either due to lack of awareness or negligence.
- Wrong data on patient age, weight, etc.
- Lack of proper history of the patient.
- Improper entry due to Human error.
- Data is mis-read or mis-heard by the data entry operator.
- Leakage of gas or variation in SpO2 levels leading to manual changes.
- Patient may be changed during a shift change of the nurse due to the patient condition but not informed to the nurse.
- Nurse was not present to receive Nurse Handover on patient's arrival.
- Alarm volumes turned down or are off.
- Multiple alarming devices leading to patient harm, due to lack of knowledge of the device.
- Staff members may be occupied with the needs of another patient.
- Equipment not used as per the manufacture's guidelines.
- Inadequate corrective maintenance.
- Lack of preventive maintenance.
- New nurses with minimum training time posted in critical areas due to attrition.
- Shortage of staffs and lack of verification of competencies before placed in critical areas.

- Lack of verification of competencies.
- Due to knowledge deficit, leading to failure in plugging in of monitoring equipment.
- Nurses initiating cardiac monitors without physician orders.
- No clarification from the physicians regarding the vital parameters of the patient.
- In-patient nurses did not have training on cardiac monitors.

Below table contains the possible failure modes and the potential causes of the failures.

S. No	Failure Modes	Potential Causes
1	Purchasing wrong device	Lack of knowledge on use of equipment
2	Patient misidentification	Failure to use identifiers so as to identify patients.
		Due to negligence or lack of awareness
3	Unavailability of proper range for data calculation	Improper data regarding the personal information such as age, weight or any medical history of the patient.
		Lack of proper patient history
4	Improper data entry by the staff in the sheet	Data entry staff may not hear the data clearly when the data is shared by the allocated staff
		Improper entry could result due to human error
5	Manual adjustments	Changes in the SpO2 levels leads to manual adjustments being made which might at times be out of range
6	Alarm limits changed but not communicated	Clinical alarm limits for particular patientsmay be changed in between shifts due to the patient's condition and that information is not communicated during the shift handover.
7	Alarm condition not detected by the staff	Staff is distracted / not within the hearing range of the alarm. Or in some cases the volume is turned down or off.
8	Alarm ignored due to alarm fatigue	Failure to acknowledge alarms due to multiple alarming devices.
		Lack of knowledge on each device and the alarm sounds.
9	Detection of an alarm condition delayed	Staff members may be occupied with the needs of other patient and no back up plan present for alarm coverage.
10	Malfunctioning of equipment.	Equipment not used as per manufacturer's guidelines
		Inadequate corrective maintenance
		Lack of preventive maintenance.
11	Nurses delayed response to the alarms	New staffs with lesser training due to attrition allocated in ICU. Hence do not know the appropriate response to alarms.
12	Other departments nursing staffs assigned to ICU who are unfamiliar with the equipment's of the ICU.	Shortage of nurses in the ICU's
		Lack of verification of competencies for staffs pulled from other areas of the hospital.
13	ICU nurse fails to plug in the monitoring equipment.	The knowledge deficit of the nurses.
		Negligence of nurses.
14	Nurses initiating cardiac monitoring withing physicians order or with a physician's order that does not specify vital sign parameters.	Nurses initiating cardiac monitors without physician's orders.
		Nurses not obtaining clarification from physician for vital sign parameters.
		All inpatient nurses do not have cardiac monitor training.
15	No communication to the allocated nurse about a new patient admitted in the ICU and attached to the monitors.	Nurse may not be present to receive nurse handover on the patient's arrival.

After the failures and the potential causes were listed, the list of all possible effects of how it could harm the patient was made.

- No clear data of patients condition due to unavailability of device.
- Setting wrong parameter ranges which could lead to life threatening situations.
- Lack of proper data leading to effects in the ranges further generated.
- Due to lack of patient history, Wrong diagnosis can be given with further will lead to complications.
- Improper data entry would lead to wrong range calculation which would lead to patient harm.
- Manal adjustments may lead to complications and major errors.
- If the alarm is not detected by the staff, it can cause major harm to the patient (Can even result in death.)
- Delay in detecting alarm may cause the patient's condition to deteriorate and could be life threatening.
- Due to incorrect usage of the equipment, the monitors may not raise alarms, which can be harmful to the patient.
- As nurses are not aware of the patient's condition the patient's condition may deteriorate without the staff noticing.
- The new staffs may not recognize the alarms, causing the patient's condition to deteriorate.
- When the monitoring equipment's are not plugged in properly, the battery dies, hence leading to loss of records.
- When the monitoring equipment's are not plugged in properly, the patient's condition my deteriorate without the notice of the staff.
- Delay in response to alarms in some cases can be fatal.
- When the nurses are over-using or under-using the cardiac monitors, it can lead to alarm fatigue which can harm the patients.

- Due to lack of knowledge on when to notify the doctor or do not know what action is to be taken, could be fatal to the patient.

The below table contains failure mode, potential causes and its effects.

SL. No	Failure Modes	Potential Causes	Potential Effects
1	Purchasing wrong device	Lack of knowledge on use of equipment	Delay in process
2	Patient misidentification	Failure to use identifiers so as to identify patients.	Possibility of setting wrong parameter ranges which in turn could contribute to life threatening situations.
		Due to negligence or lack of awareness	
3	Unavailability of proper range for data calculation	Improper data regarding the personal information such as age, weight or any medical history of the patient.	Effects the ranges generated for the parameters.
		Lack of proper patient history	Leads to wrong diagnosis and hence various complications.
4	Improper data entry by the staff in the sheet	Data entry staff may not hear the data clearly when the data is shared by the allocated staff	Leads to wrong range calculation which could lead to complications.
		Improper entry could result due to human error	
5	Manual adjustments	Changes in the SpO2 levels leads to manual adjustments being made which might at times be out of range	Leads to confusion and major errors.
6	Alarm limits changed but not communicated	Clinical alarm limits for particular patients may be changed in between shifts due to the patient's condition and that information is not communicated during the shift handover.	Potential patient harm.
7	Alarm condition not detected by the staff	Staff is distracted / not within the hearing range of the alarm. Or in some cases the volume is turned down or off.	Potential patient harm.
8	Alarm ignored due to alarm fatigue	Failure to acknowledge alarms due to multiple alarming devices.	Due to lack of awareness patient can be at harm.
		Lack of knowledge on each device and the alarm sounds.	
9	Detection of an alarm condition delayed	Staff members may be occupied with the needs of other patient and no back up plan present for alarm coverage.	Delay in required intervention for deteriorating patient could be life threatening.
10	Malfunctioning of equipment.	Equipment not used as per manufacturer's guidelines	Faulty equipment may not raise the alarm, due to which the staff may not be able to intervene in time.
		Inadequate corrective maintenance	
		Lack of preventive maintenance.	
11	Nurses delayed response to the alarms	New staffs with lesser training due to attrition allocated in ICU. Hence do not know the appropriate response to alarms.	Due to lack of awareness patient can be at harm.
12	Other departments nursing staffs assigned to ICU who are unfamiliar with the equipment's of the ICU.	Shortage of nurses in the ICU's	Omission or delay in vital signs.
			Patient condition might deteriorate without identification.
		Lack of verification of competencies for staffs pulled from other areas of the hospital.	No alarms/audible signals to alert staff.
			Alarms not recognized by staff pulled from other areas of hospital.
13	ICU nurse fails to plug in the monitoring equipment.	The knowledge deficit of the nurses.	Omission or delay in vital signs monitoring.
		Negligence of nurses.	Patient condition might deteriorate without identification.
14	Nurses initiating cardiac monitoring withing physicians order or with a physician's order that does not specify vital sign parameters.	Nurses initiating cardiac monitors without physician's orders.	Over-use or under-use of cardiac monitors.
		Nurses not obtaining clarification from physician for vital sign parameters.	Contributes to alarm fatigue.
		All inpatient nurses do not have cardiac monitor training.	Nurses have no guidance on when to notify physician. Or what action is to be taken when parameters are high/low from the expected parameters.
15	No communication to the allocated nurse about a new patient admitted in the ICU and attached to the monitors.	Nurse may not be present to receive nurse handover on the patient's arrival.	Increase in patient safety risk with potential for adverse/Sentinel event.

When all possible failures, possible causes and all possible effects were listed, in the next step we calculated the probability of occurrence, detectability and severity scores.

Probability of occurrence:

The probability of occurrence tells us the likelihood that some identified risk could occur. For the probability of

occurrence, the values ranging are from 1 to 5, 1 (Being Remote) to 5 (Being Very High).
Score 1 is when the chance of occurrence is little or when the occurrence has occurred previously till date.
Score 2 is when there is a possibility of occurrence, but the problem occurs in isolated cases.
Score 3 is when the occurrence is documented but the occurrence is infrequent, and the problem has a reasonable chance of re-occurring.
Score 4 is when the occurrence is documented and is frequent, the problem occurs regularly or within a short period of time.
Score 5 is when the occurrence is documented and is almost inevitable.

Occurrence		
Rating	Description	Definition
1	Remote to non-existent	Little or no occurrence, highly unlikely
2	Low	Possible, but problem occurs in isolated cases
3	Moderate	Documented, but infrequent: problem has a reasonable chance to occur
4	High	Documented, frequent, problem occurs regularly or within a short time period.
5	Very High	The team determines how best to change the process to reduce the risk of patients from being harmed.

Probability of Occurrence

Detectability:
The detection is a number that is associated with the best control. The detection ranking is the likelihood of detection of the failure mode or cause in accordance with the defined criteria. It is a relative ranking within the scope of FMEA and is determined irrespective of the severity or likelihood of occurrence.

Detection means detecting the issues before it causes any serious harm to the patients. It is based on the chances of the failure to be detected prior.

The Detection was scored from 1 to 5, 1 being the “always detected” to 5 being “Most certain not to be detected”.

A lower detectability score reflects a greater likelihood that the failure mode will be detected before any harm reaches the patient, and a higher score reflects a lower probability that the failure mode will be detected.

Detection		
Rating	Description	Definition
1	Certain to be detected	Almost always detected immediately
2	High	Likely to be detected
3	Moderate	Moderately likely to be detected
4	Low	Unlikely to be detected
5	Almost certain not to be detected	Detection not possible

Detectability Ranking

Severity:
For severity, the effect is related, not the failure mode. The ratings are based on the risk of injury to the patient and the significance of the injury resulting from the effect of the failure mode. Severity ratings are subjective as such.

Severity is a ranking number that is associated with the most serious effect for a given failure mode. It assesses the impact of all possible failure modes.

In most cases, processes with the score of severity exceeding 4 may require a detailed RCA and CAPA. The severity ranking is based mainly on a relative scale which ranges from 1 to 5.5 being the most effective i. e., dangerously high severity which will lead to patient harm and 1 means the severity is extremely low.

Severity		
Rating	Description	Definition
1	Minor of no effect	Would not be noticeable to the patient, would not affect the process
2	Moderate effect	May affect the patient, would not affect the process.
3	Minor injury	Would result in minor physical or psychological injury to the patient: would affect the process.
4	Major injury	Dangerous, would result in major injury to the patient (e. g., loss of limb, loss of function); would affect the process
5	Severe or terminal outcome	Very dangerous; would result in potential death; would affect the process.

Severity Rating Scale

RPN (Risk Priority Number):

It is a technique which is used to analyze the risks associated with potential problems during the FMEA. The RPN utilizes three rating scales i.e., Severity, occurrence and detection.

Formula:

Risk priority number = Severity X Occurrence X Detection.

		Severity						
		1	2	3	4	5		
Occurrence	1	1	2	3	4	5	1	Detection
	2	4	8	12	16	20	2	
	3	9	18	27	36	45	3	
	4	16	32	48	64	80	4	
	5	25	50	75	100	125	5	

RPN Rating

Each failure mode is assigned the scores for probability of occurrence, detectability and severity, and in accordance with that we applied the formula to calculate the risk priority number i. e., RPN = O x D x S.

SL. No	Failure Modes	Occurrence	Detectability	Severity	RPN
1	Purchasing wrong device	2	4	1	**8**
2.	Patient misidentification	2	1	5	**10**
3	Unavailability of proper range for data calculation	1	3	5	**15**
		1	3	5	**15**
4	Improper data entry by the staff in the sheet	2	3	4	**24**
		2	3	4	**24**
5	Manual adjustments	1	3	4	**12**
6	Alarm limits changed but not communicated	1	3	3	**9**
7	Alarm condition not detected by the staff	2	3	4	**24**
8.	Alarm ignored due to alarm fatigue	3	2	4	**24**
9	Detection of an alarm condition delayed	3	2	4	**24**
10	Malfunctioning of equipment.	3	2	4	**24**
		2	1	4	**8**
		2	1	4	**8**
11	Nurses delayed response to the alarms	3	2	4	**24**
12	Other departments nursing staffs assigned to ICU who are unfamiliar with the equipment's of the ICU.	5	5	5	**75**
13	ICU nurse fails to plug in the monitoring equipment.	3	3	5	**45**
14	Nurses initiating cardiac monitoring withing physicians order or with a physician's order that does not specify vital sign parameters.	3	3	5	**45**
15	No communication to the allocated nurse about a new patient admitted in the ICU and attached to the monitors.	3	3	5	**45**

RPN SCORES FOR FAILURE MODES

5. Result

The main aim of the implementation of FMEA in clinical alarms in the critical units were so that we can reduce the patient risk within in the critical areas by streamlining each process and ensure it is followed by the care givers.

All possible causes and effects of the failure modes were identified in the critical area, and we scored them according to their occurrence, severity and detectability, which was different for each failure mode and the risk priority number was calculated.

For the failure modes with high RPN's, recommendations for RNP scores on the higher range to cause patient harm or in some cases where the incident has a higher chance of causing patient harm were listed, to ensure that there is a reduced chance for the occurrence, severity and detectability which in turn will help increase the patient's safety in the critical areas. But recommendations were suggested as a preventive measure.

In the below table the failure modes are listed along with the RPN and recommendations:

S. No	Failure Modes	RPN	Recommendations
1	Improper data entry by the staff in the sheet	24	Re check the data entered for conformation.
		24	
2	Alarm condition not detected by the staff	24	It is recommended to use visual aids if in case the volumes are turned down,
3	Alarm ignored due to alarm fatigue	24	It is recommended to use visual aids if in case of alarm fatigue.
4	Detection of an alarm condition delayed	24	A back up nurse recommended in case of emergencies.
5	Malfunctioning of equipment.	24	Nurses should be informed on the proper usage of equipment's.
6	Nurses delayed response to the alarms	24	Training should be given to the nurses before inter-departmental transfers.
7	Other departments nursing staffs assigned to ICU who are unfamiliar with the equipment's of the ICU.	75	Training should be given to the nurses before inter-departmental transfers.
			Training should be given to the nurses before inter-departmental transfers.
8	ICU nurse fails to plug in the monitoring equipment.	45	One member from the Biomedical department to be present when the nurse in charge is handling monitors, to ensure there is no patient harm.
9	Nurses initiating cardiac monitoring within	45	Nurses in the critical units should be educated on the protocols for

	physicians order or with a physician's order that does not specify vital sign parameters.		checking vitals.
			There should be a clear communication between the doctors and nurses.
			Nurses in the critical units should be trained for all basic equipment's and processes used in the ICU's.
10	No communication to the allocated nurse about a new patient admitted in the ICU and attached to the monitors.	45	Training to be given to all the nurses on the importance of communication in terms of important information during handovers.

6. Conclusion

There should be a significant reduction in patient risk, the recommendations are followed and a detailed RCA and CAPA is done so the preventive measures can be taken hence resulting in better patient care.

The aim for the implementation of FMEA in clinical alarms in the critical units were so that we can reduce the patient risk within those areas by streamlining each process and ensure it is followed by the care givers. By calculating the RPN, we know the problem areas and keeping that in mind we can follow a process which will in turn reduce the RPN.

Reference

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