FAILURE MODE EFFECT ANALYSIS OF MEDICATION MANAGEMENT PROCESS at Medanta

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INTRODUCTION

- The use of medications is an integral part of medical care in hospitals.

- Failure Modes and Effects Analysis (FMEA) is a systematic, proactive method for evaluating a process to identify where and how it might fail and to assess the relative impact of different failures, in order to identify the parts of the process that are most in need of change. *(Institute of Healthcare Improvement, 2004)*

- Developed in the U.S. Military 1949, titled Procedures for Performing a Failure Mode, Effects and Criticality Analysis. Failures were classified according to their impact on mission success and personnel/equipment safety .
- Formally developed and applied by NASA in the 1960's to improve and verify reliability of space program hardware during the Apollo program.

Aim and objectives

AIM: To assess various risk points existing in the medication management process of the hospital and analyse the causes and effect of the failure modes with the help of Failure mode effect analysis (FMEA) tool.

OBJECTIVES:

- To review the medication management process that is the process mapping.
- To identify the possible failure modes in the process along with their severity and frequency.
- To analyse the causes and effects of various failure modes.
- To propose recommendations to eliminate the failures in the process so as to minimize medication errors.

Methodology

- Type of study: Observational analytical study
- Location of study: In-patient department, Medanta hospital, Gurgaon
- Study subjects: In-patient records studied for 2 months.
- sample size- 300 inpatient records
- Sources of data collection: through study of In-patient records and direct observation.

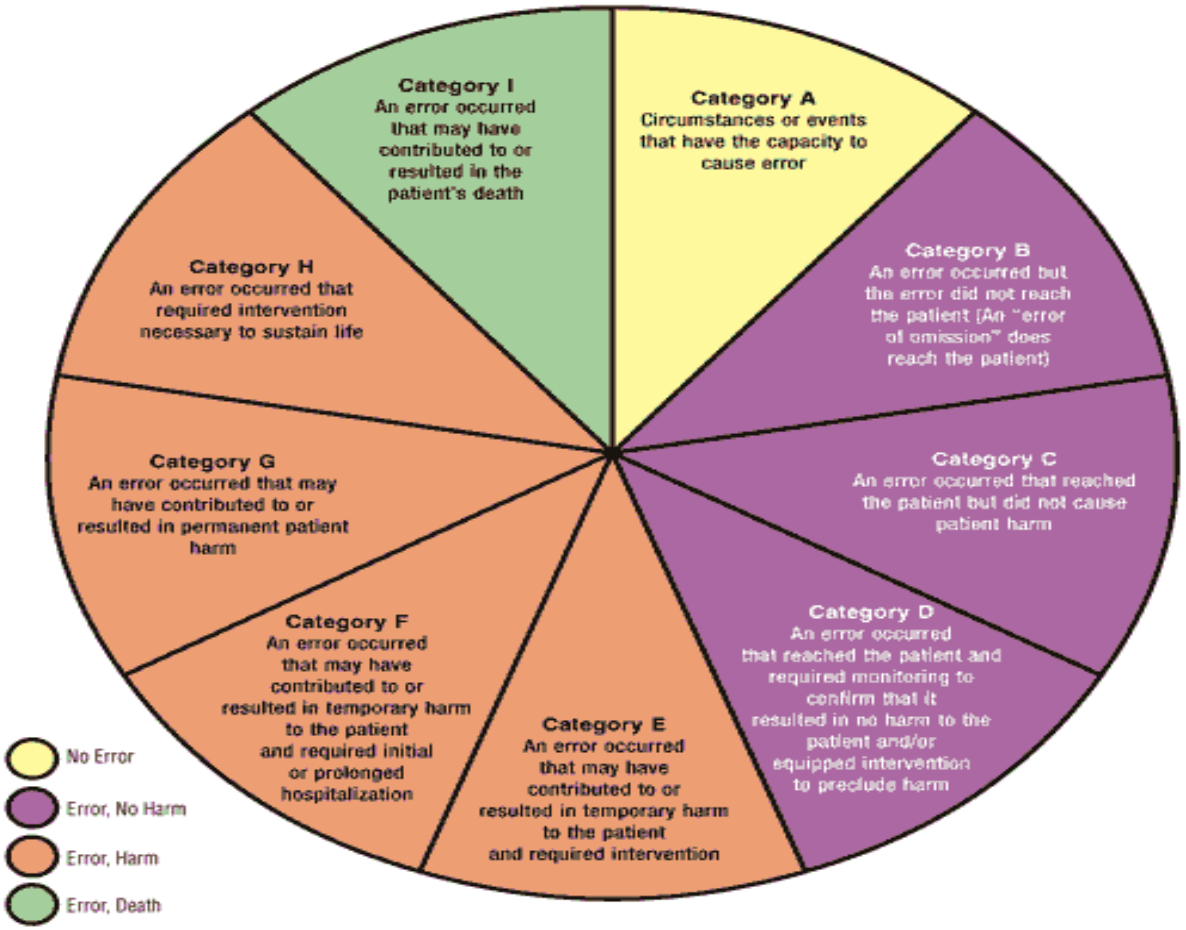
Medication Error

Medication error is “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labelling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use" (NCCMERP)

Types of Medication Errors:

- Prescription Errors
- Transcription errors
- Administration errors
- Dispensing/Indenting errors
- Monitoring errors

Figure 1. NCC MERP Index for Categorizing Medication Errors



DEFINITIONS

Harm
Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

Monitoring
To observe or record relevant physiological or psychological signs.

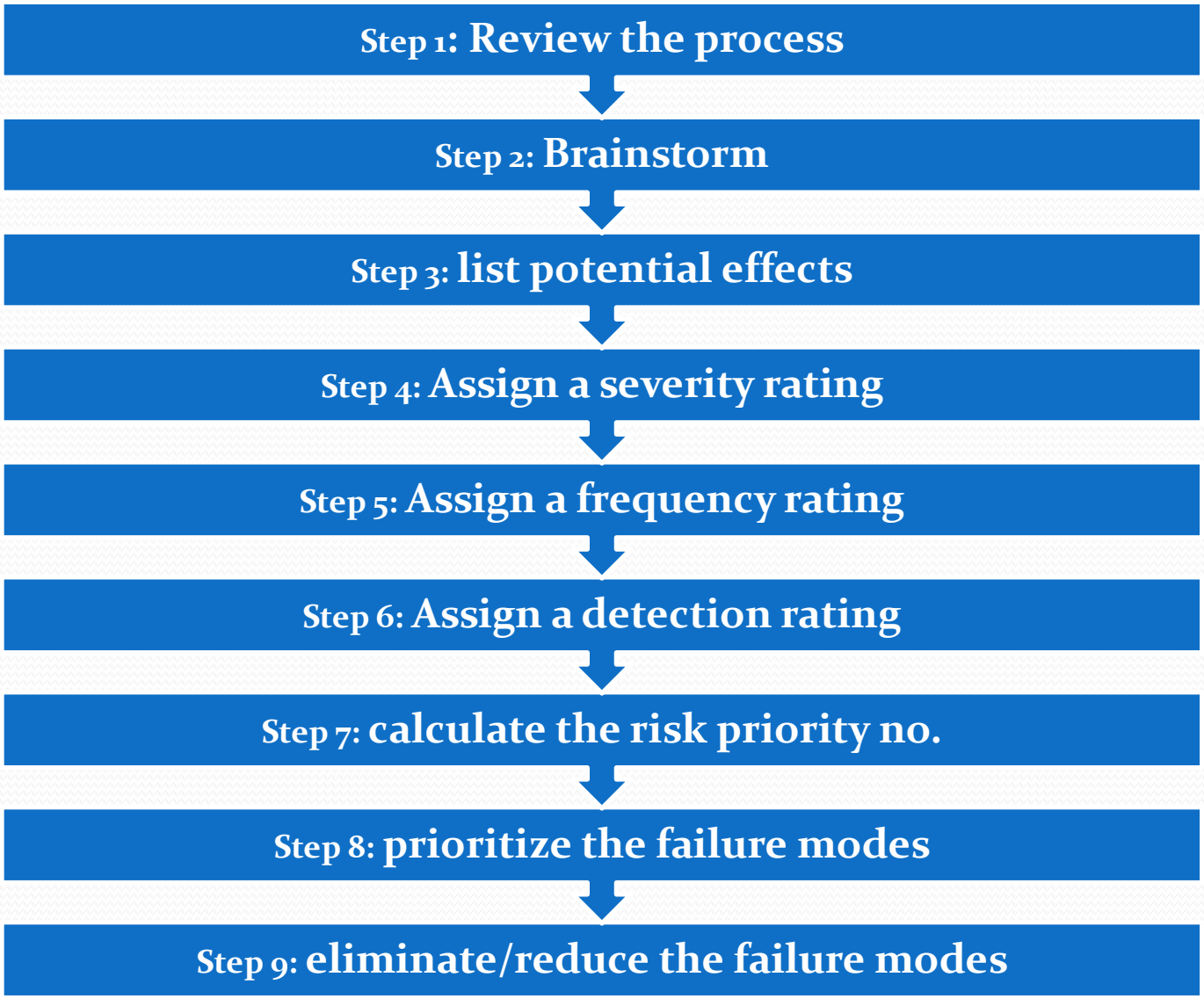
Intervention
May include change in therapy or active medical/surgical treatment.

Intervention Necessary to Sustain Life
Includes cardiovascular and respiratory support (eg, CPR, defibrillation, intubation, etc).

FMEA includes review of the following:

- Steps in the process
- Failure modes (What could go wrong?)
- Failure causes (Why would the failure happen?)
- Failure effects (What would be the consequences of each failure?)

Steps For Conducting FMEA



Process flow

The doctor/consultant prescribes medicines in the progress notes

The junior resident/medical officer in IPD transcribes in the Medication administration record, including the current medications to be continued in the hospital

The staff nurse copies the medicines in the medicine indent register

The medication nurse indents the medicines in HIS

Registration of the indent by the IP pharmacy in HIS

Dispensing and dispatch of drugs from the pharmacy

Receive of drugs in the respective IPD area by the medication nurse

Administration of drugs by the respective staff nurse after verification by the medication nurse

Identification of failure modes

The following failure modes were identified after reviewing the medication management process:

- FM 1- incomplete prescription in terms of dose/ route/ frequency
- FM 2- allergies of the patient are not known/ not mentioned
- FM 3- the medicine is transcribed wrongly in the MAR.
- FM 4- the medicine is copied wrongly in the medicine indent register.
- FM 5- medicine not indented properly in HIS
- FM 6- wrong medicine/dose/form is dispensed by the pharmacy

- FM 7- medicines are not cross checked against the order as indented.
- FM 8- administration time not properly listed in the MAR.
- FM 9- the new/changed medicines are not added after the consultants round and the stopped drugs are not signed.
- FM 10- Delay in indenting of medicines from IPD/ dispensing of medicines from pharmacy
- FM 11- The drugs are not returned back to the pharmacy
- FM 12- the current medications are not mentioned in the initial assessment form and/or if mentioned not marked as ‘to be continued or not in the hospital’.

FMEA Scoring

- Severity scale (S) - can range from a slight annoyance within the system, which may rank as a 1, to terminal injury or death, which would rank as a 10.
- Frequency/occurrence scale(F/O) - addresses the likelihood and probability of the failure mode's occurrence. The likelihood should range from remote/none, with a score of 1 to dangerously high, with a score of 10.
- The detection scale (D)- rates the likelihood of the failure being detected, from very high, with a score of 1, to remote, with a score of 10.
- Risk Priority Number (RPN)- Severity rating * Frequency Rating * Detection Rating (S * F * D).

Severity Rating	Criteria/ Risk	Description (Severity of Failure)
10	Dangerously high	Failure could cause terminal injury or death of the patient
9	Extremely high	Failure involves regulatory noncompliance and could cause long term disability.
8	Very high	Failure causes patient's health to be seriously affected and patient has to return for major correction.
7	High	Failure seriously affects patient's health leading to high patient dissatisfaction.
6	Moderate	Failure causes disruption of patient activities of daily living leading to dissatisfaction

5	**Low**	**Inconvenience for patient and provider with failure being detected.**
4	Very Low	Inconvenience at subsequent function; minor rework. Failure detected and corrected at subsequent steps of the process.
3	Minor	Slight inconvenience at next function; minor rework. Failure detected and corrected at next step of the process.
2	Very Minor	Slight inconvenience at delivery; minor rework. Failure detected and corrected at delivery.
1	None	No noticeable effects

Frequency Criteria/ risk	Rating	Description (Probability of failure)
Dangerously high	**10**	Failure is almost inevitable. More than one occurrence per day
Extremely high	**9**	One occurrence every three to four days
Very high	**8**	High: repeated failures, one occurrence per week
High	**7**	One occurrence every month
moderate	**6**	Moderate: occasional failures, one occurrence every three months

	5	**One occurrence every six months to one year**
	4	One occurrence per year
low	**3**	Low: relatively few failures, one occurrence every one to three years
Very low	**2**	One occurrence every three to five years
none	**1**	Remote: failure is unlikely, one occurrence in greater than five years

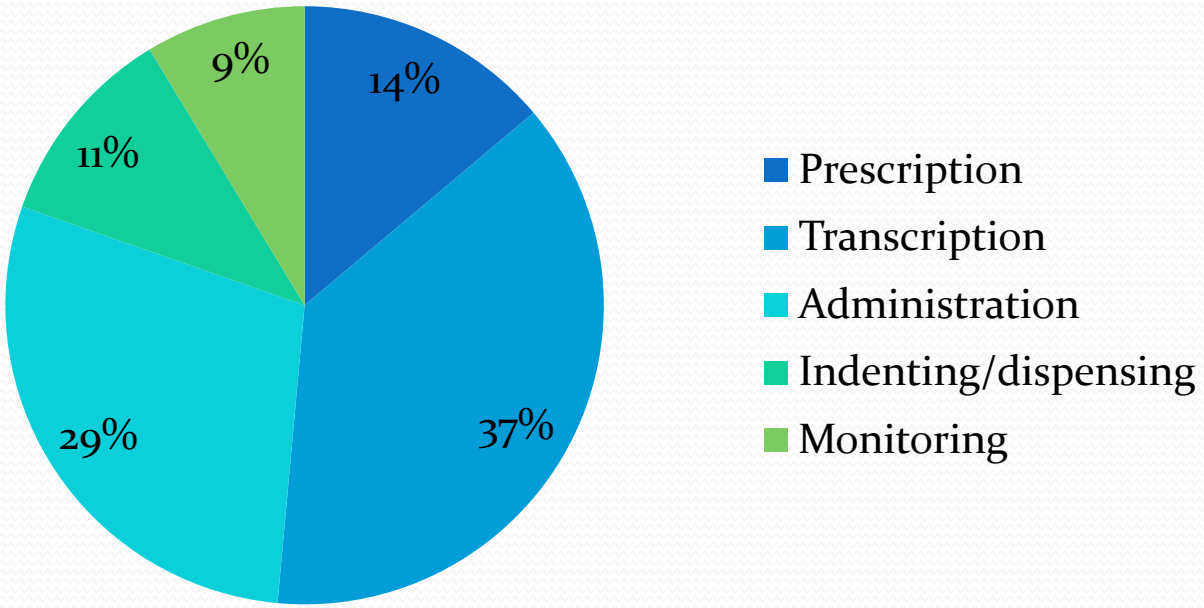
Detection Rating	Criteria/risk	Description (Detection of failure)
10	Absolute Uncertainty	Controls will not or cannot detect the existence of a failure. No known controls available to detect failure mode.
9	Very Remote	Controls probably will not detect the existence of failure mode. Control achieved with indirect or random checks only.
8	Remote	Controls have a poor chance of detecting the existence of failure mode.
7	Very Low	Controls have a low chance of detecting the existence of failure.

6	Low	Controls may detect the failure.
5	Moderate	Controls may detect the existence of a failure mode. Error likely to be detected after service delivery.
4	Moderately High	Controls have a good chance of detecting failure mode. Error detection at service delivery.
3	High	Controls have a very good chance of detecting failure mode, error detection at subsequent steps.
2	Very High	Current controls almost certain to detect the failure mode. Process automatically detects failure mode.
1	Almost Certain	Current controls almost certain to detect the failure mode. Reliable detection controls are known with similar processes. Process automatically prevents further processing.

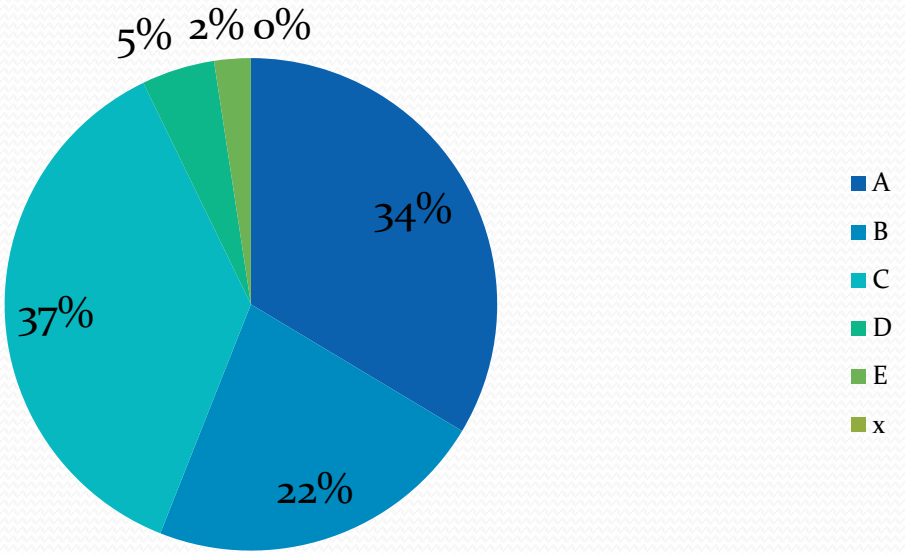
FMEA matrix

FMEA matrix.docx

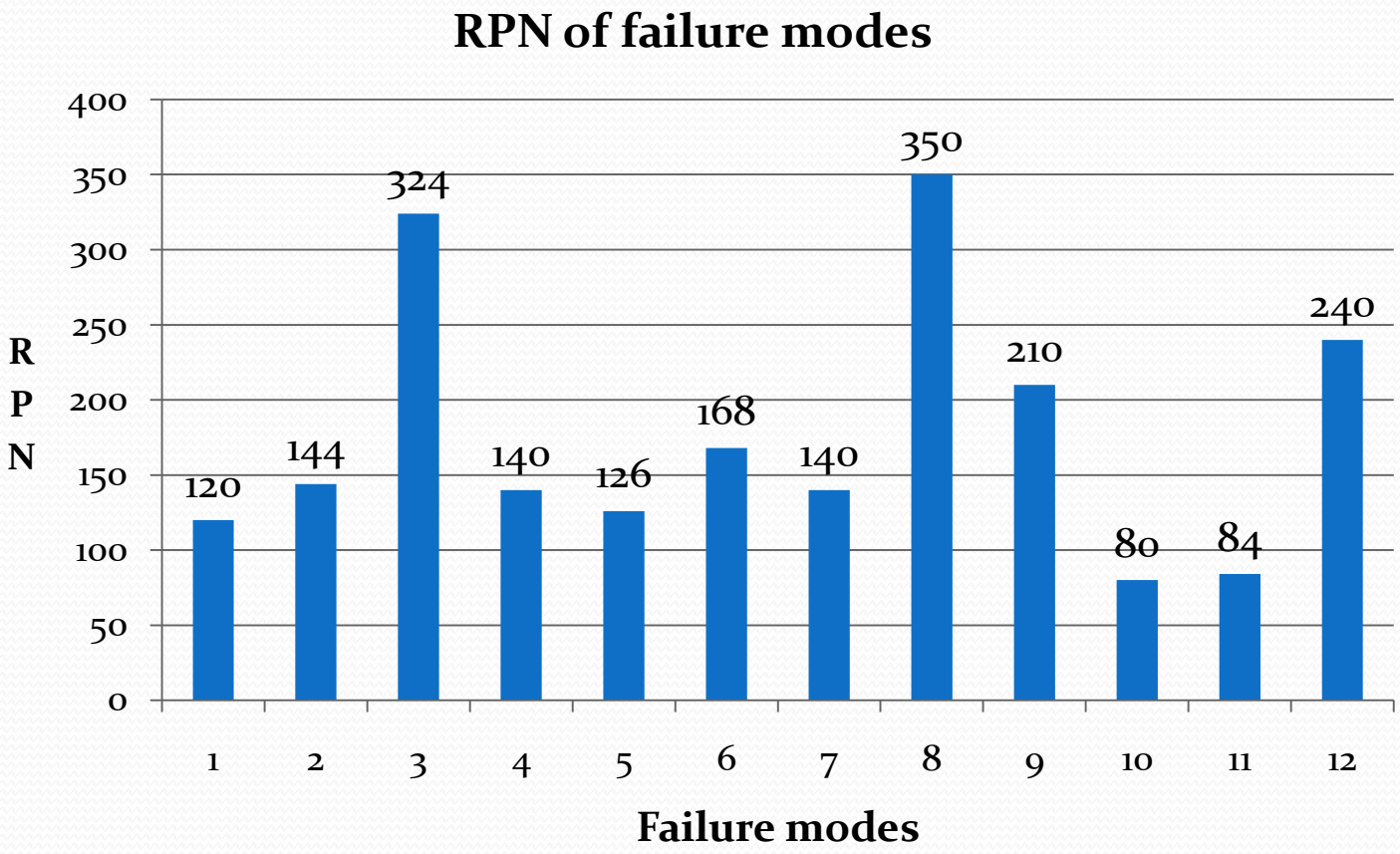
Fig.1 Percentage distribution of medication errors



Percentage distribution of medication errors according to NCCMERP Index



Category C -An error occurred that reached the patient but did not cause patient harm
Category A -Circumstances or events that have the capacity to cause error
Category B- An error occurred but it did not reached the patient
Category D-an error reached the patient and required monitoring but cause no harm
Category E-an error reached the patient and caused temporary harm


RPN of failure modes
RPN
400
350
300
250
200
150
100
50
0
120
144
324
140
126
168
140
350
210
80
84
240
1
2
3
4
5
6
7
8
9
10
11
12
Failure modes

Five major failure modes

- FM 3- the medicine is transcribed wrongly on the treatment sheet (RPN-324)
- FM 6- wrong medicine/dose/form is dispensed by the pharmacy (RPN-168)
- FM 8- incorrect administration time listed in the MAR (RPN-350)
- FM 9- the new/changed medicines are not added after the consultants round and the stopped drugs are not signed (RPN-210)
- FM 12- the current medications are not mentioned in the initial assessment form and/or if mentioned not marked as 'to be continued or not in the hospital (RPN-240)

Conclusion

- There are a number of factors at each step of the patient care process that contribute to medication errors.
- Special focus should be given to the prescription and administration phases of patient care due to the large number of errors tracked back to these stages of treatment.
- Policies and procedures are in place; just adherence to them is required. Training and motivation is the need of the hour and should be promptly addressed.

Recommendations

- Computer on Wheels (COW)
- Conversion of crash cart into a medication cart
- Policy for written orders
- Adherence to existing policies along with training and continuous reminders
- Continuing the process of FMEA in the form of a team comprising of Nursing supervisor/perceptor, resident doctor and clinical pharmacist.

Computer on wheels (COW)

Medication cart

Way ahead

- FMEA is a continuous process which can be continued in phases.
- The recommended actions to be taken along with responsibilities are defined
- The process is repeated to ascertain the effects of actions taken with the aim to reduce the risk priority number.

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Preventing problems Is cheaper and easier than cleaning them up!!!

THANK YOU