FAILURE MODE EFFECT ANALYSIS FOR AVERTING RISK DUE TO MEDICATION ERROR

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Roll no:1328

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INDEX

TITLE OF THE STUDY

FAILURE MODE EFFECT ANALYSIS FOR AVERTING RISK DUE TO MEDICATION ERROR

INTRODUCTION

- Adverse medical events, as injuries to patients that arise from mistakes and accidents during medical treatment, can be result of human errors, technological errors, or a system that failed to detect these mishaps and prevent them .
- Achieving patient safety is a foremost goal among healthcare workers.

MEDICATION MANAGEMENT PROCESS (MMP)

Medication management is an important component to symptomatic, preventive, curative and palliative treatment and management of disease and condition. Processes essential to the medication management are selecting, procuring, storing, ordering/prescribing, transcribing, distributing, preparing, dispensing, administering, documenting & monitoring of medication therapies. This is accomplished through coordinated efforts of various members of hospital care team working collaboratively.

MEDICATION ERROR

According to National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) “A 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 healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing, order communication, product labelling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

INTERNATIONAL GOALS OF PATIENT SAFETY

- Goal 1 : Identify Patients Correctly
- Goal 2: Improve Effective Communication
- **Goal 3: Improve the Safety of Medication**
- Goal 4: Ensure Correct-Site, Correct-Procedure & Correct-Patient Surgery
- Goal 5: Reduce the risk of Healthcare Associated Infection
- Goal 6: Reduce the risk of Patient harm resulting from fall

PROBLEM STATEMENT

- When studying the medication management system of the hospital it was noticeable that the steps were non-identifiable and not delineated accordingly.
- There were errors in medication process that increased the risk for patients. It had serious economic consequences to the hospital in form of extended/prolonged hospital stays, returning of medicines, additional treatment and malpractice litigation.

LITERATURE REVIEW

- FMEA was first heard, when JCAHO released its Leadership Standards and Elements of Performance Guidelines in July 2002.
- ASHRM published a white paper/monograph titled “Strategies and Tips for Maximizing Failure Mode & Effect Analysis in Your Organization.”
- Two landmark studies was conducted, one in New York and the other in Utah and Colorado (Brennan et al., 1991;Thomas et al, 2000), estimated that 44,000 to 98,000 Americans die every year as a result of adverse medical events.

Contd..

- Adverse medical events and patient safety refers to:

a. Active Failures
b. Latent Failures

- The per capita rate of adverse events in Canada is probably similar to the U.S., so researchers estimate adverse events claim 5,000 to 10,000 lives every year in this country.

CONCEPTUAL FRAMEWORK

FMEA is a team-based, systematic and proactive approach for identifying the ways that a process or design can fail, why it might fail, and how it can be made safer.

CONCEPTUAL FRAMEWORK

- The purpose and intent of using such technologies (FMEA) in health care is to assess the failure mode in the system and analyses each mode
- To determine how likely it is that an error or a failure could occur, the seriousness of the consequences if it does occur & how likely it is that the problem would be discovered before the patient is harmed.

RESEARCH QUESTION

- How can the process related risks in medication error be minimized?

OBJECTIVE

- To review the medication management process from the time of prescribing medicine till monitoring, to identify and prioritize the risks so as to propose recommendations for ensuring patient safety.

METHODOLOGY

- **Type of study**: Cross sectional descriptive study
- **Type of sampling**: Convenient Purposive sampling
- **Sample size** : 25 doctors + 25 Nurses
- **Study Location**: SDMH, Jaipur
- **Study Duration**: February 2014- April 2014
- **Sources of Data**
- **Secondary data**: Collected through previous records
- **Primary data**: Data was collected with the help of:
  - Observation, Review of prescription & Interview
  - Questionnaire: Nurses & Doctors for calculating RPN

To conduct FMEA, Joint Commission on Accreditation of Healthcare Organizations (JCAHO) gave six-steps as mentioned below:

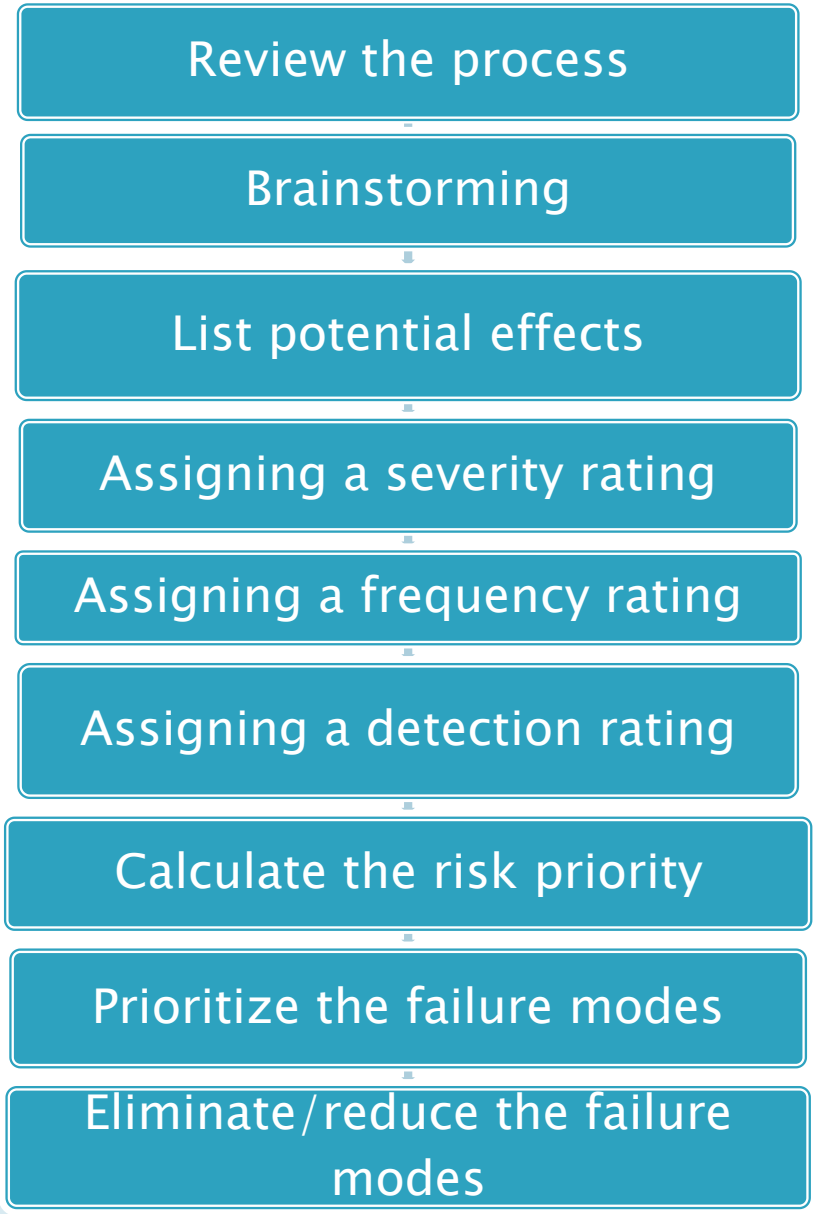
- Identification of the process
- Multi disciplinary team selection
- Description of the process
- Listing and ranking of failure modes
- Identification of root causes
- Determination of an action plan

RESULTS

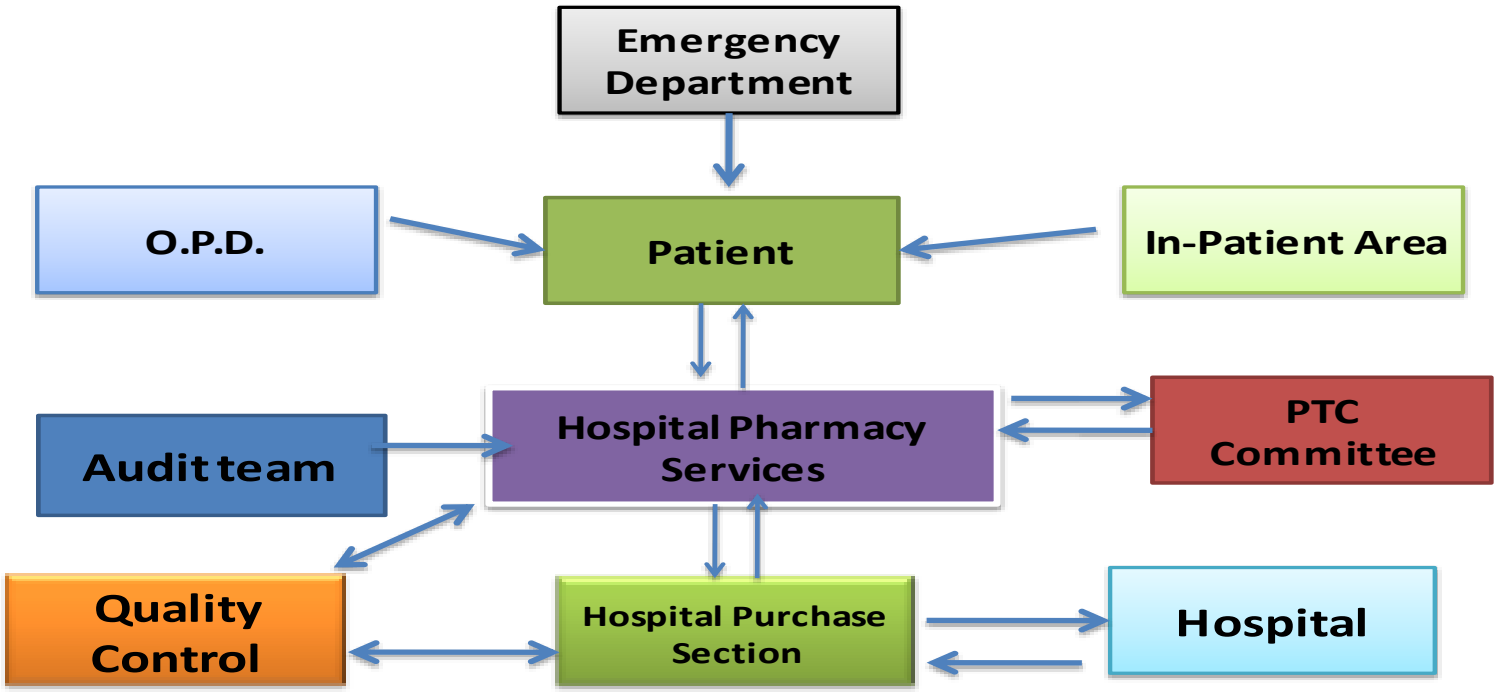
The whole study was conducted in 4 phases as follows:

1. Identified the process of the tool, diagrammatic representation of process flow of MMP, Multidisciplinary team selection.
2. Identifying failure modes.
3. Prioritizing failure modes by calculating Risk Priority Number based on its severity, frequency and detection.
4. Identify ways to minimize the risk associated with medication management process.

PROCESS FOR PERFORMING FMEA



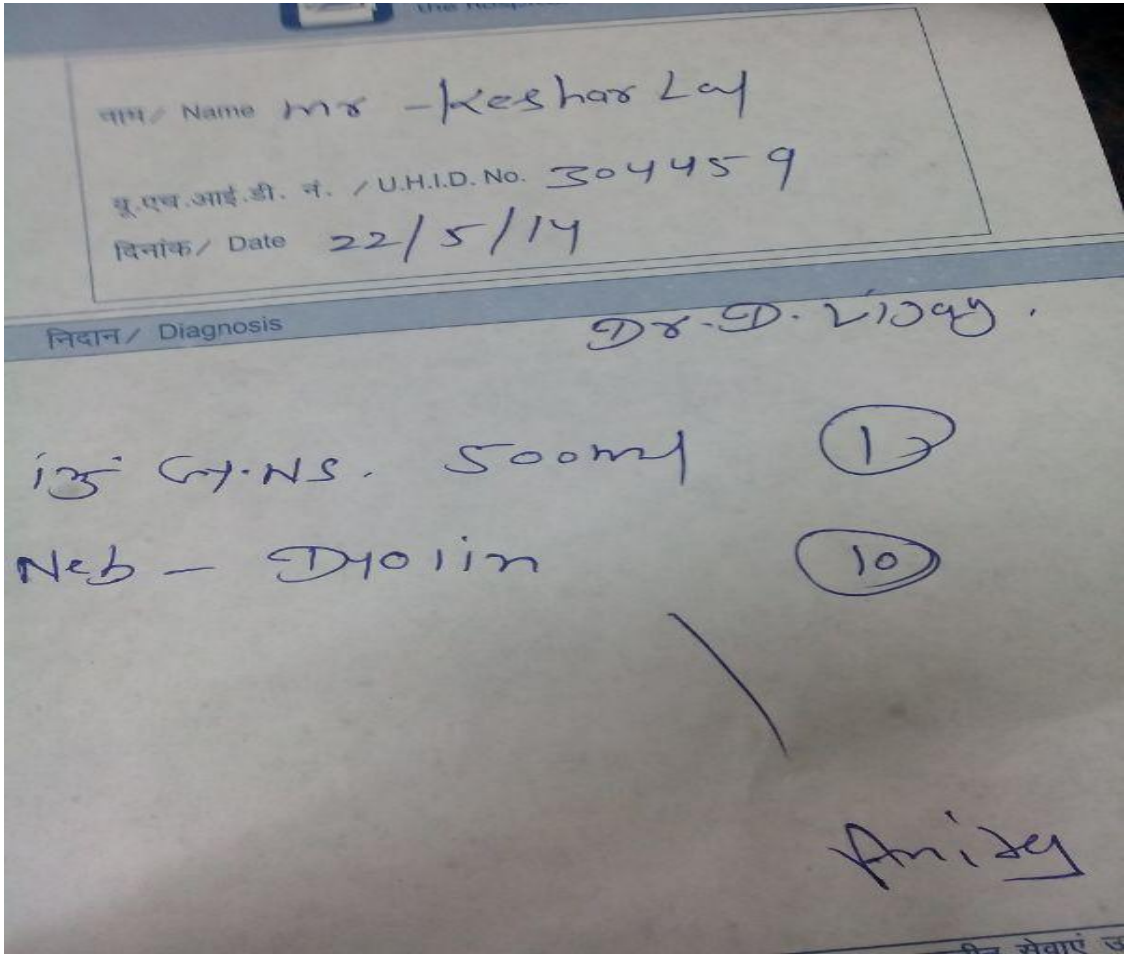
1. PROCESS FLOW OF MMP



TYPES OF ERROR IN MMP

1. **Prescription error**: The error that originates from written medication order. It includes the following:

- No route specified
- Order without indication
- Drug is indicated but the dose is inappropriate
- Writing is illegible
- Order is incomplete in specifying doses & frequency


नाम/ Name Mr - Keshar Lal
यू.एच.आई.डी. नं. / U.H.I.D. No. 304459
दिनांक/ Date 22/5/14
निदान/ Diagnosis
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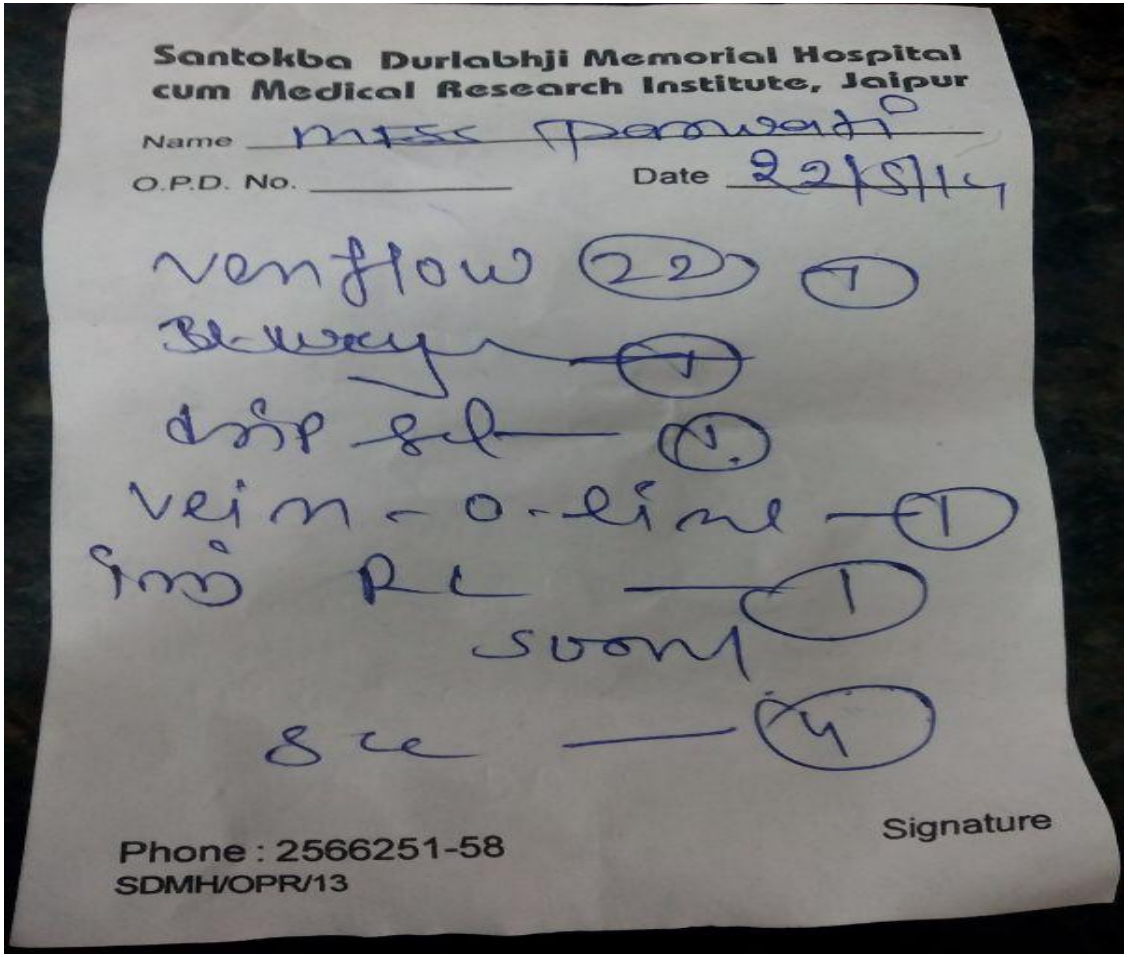

Santokba Durlabhji Memorial Hospital
cum Medical Research Institute, Jaipur

Name Mrs Parwati

O.P.D. No. _____ Date 22/8/14

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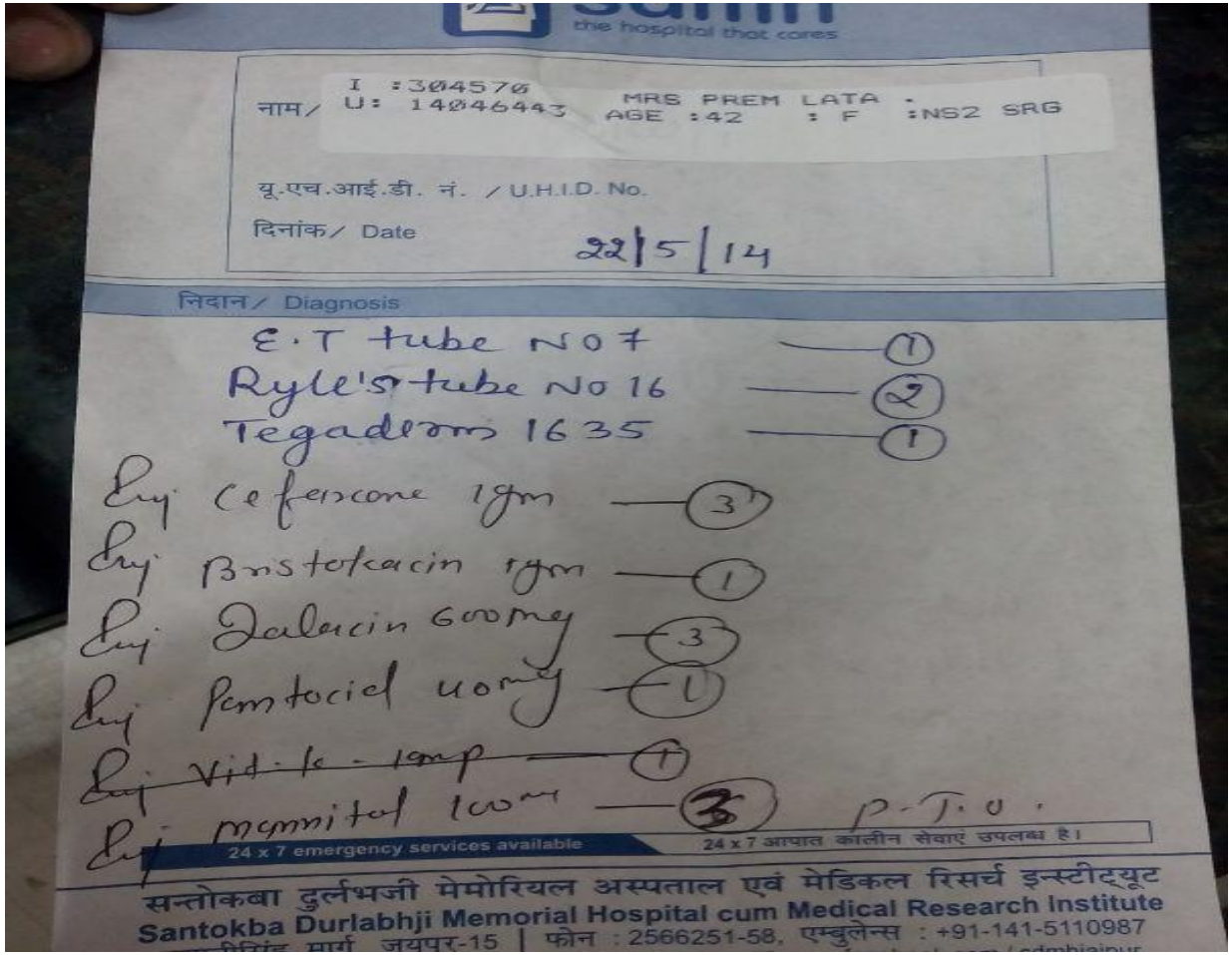


the hospital that cares

I :304570
नाम/ U: 14046443 MRS PREM LATA . AGE :42 : F :NS2 SRG

यू.एच.आई.डी. नं. / U.H.I.D. No.

दिनांक/ Date 22/5/14

निदान/ Diagnosis

E.T tube NO 7 — (1)
Ryle's tube NO 16 — (2)
Tegaderm 1635 — (1)

Inj Ceftriaxone 1gm — (3)
Inj Brustofcacin 1gm — (1)
Inj Dalacin 600mg — (3)
Inj Pantocid 40mg — (1)
~~Inj Vit-K - 10mg — (1)~~
Inj mannitol 100ml — (3) P.T.O.

24 x 7 emergency services available
24 x 7 आपात कालीन सेवाएं उपलब्ध है।

सन्तोकबा दुर्लभजी मेमोरियल अस्पताल एवं मेडिकल रिसर्च इन्स्टीट्यूट
Santokba Durlabhji Memorial Hospital cum Medical Research Institute
जयपुर-15 | फोन : 2566251-58, एम्बुलेन्स : +91-141-5110987

TYPES OF ERROR IN MMP

2. **Transcription error:** An error that originates during transcription of original physician order or transmission of the physician order to the pharmacy or nursing staff. It includes the following:

- Drug-Drug/ Drug- Food Interaction
- Order transcribed incorrectly
- Any specific finding e.g. Allergy is not specified & neither documented

TYPES OF ERROR IN MMP

3. **Administration errors**: An error originating during the process directly associated with the medication administration at the nursing unit. It includes:

- Schedule dose is not documented as administered
- Drug is administered without a physician order
- Incorrect formulation/ strength/ dilution
- Dose missed because of late transcription
- Order is incorrectly entered in the pharmacy computer
- Incorrect patient

TYPES OF ERROR IN MMP

4. Dispensing Error: An error originating when medication is dispensed from the pharmacy. It includes the following:

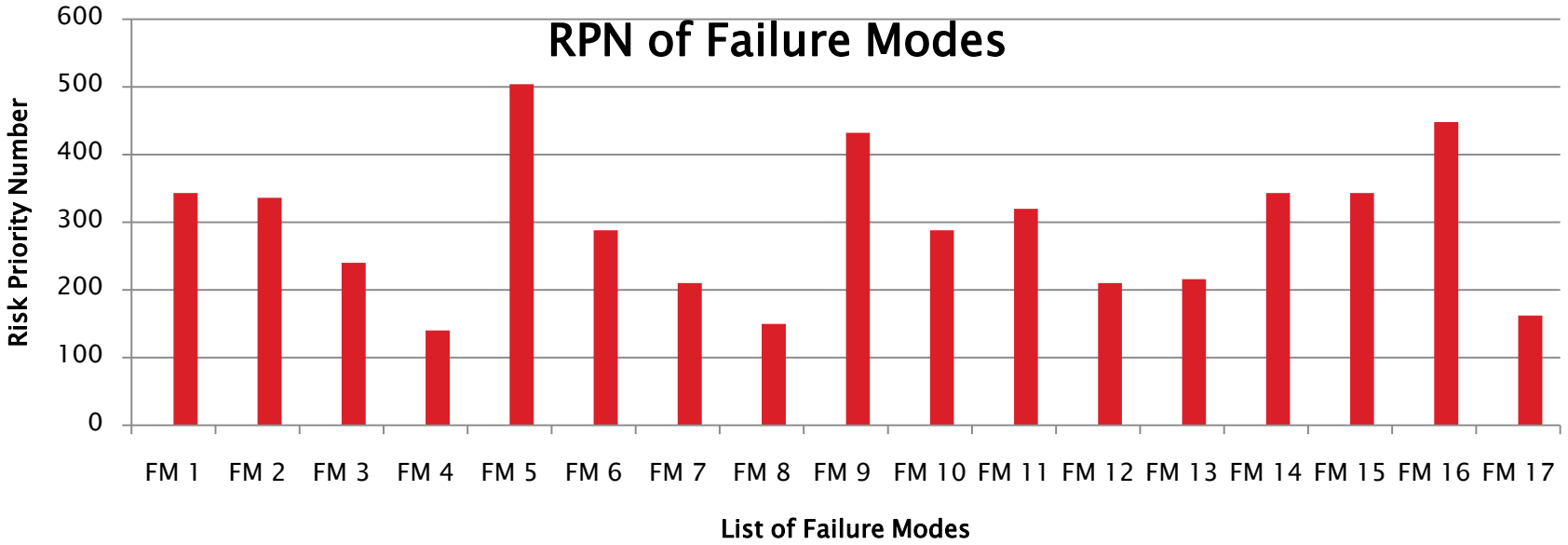
- Wrong drug or dilution dispensed
- Wrong preparation dispensed
- Incorrect labelling/ LASA Drugs

5. Monitoring Error: An error originating from lack of necessary monitoring or interpretation/ appropriate action for selected drugs.

3.LISTING AND RANKING OF FAILURE MODES

Steps in the process.docx

Risk Priority Number of Failure Modes



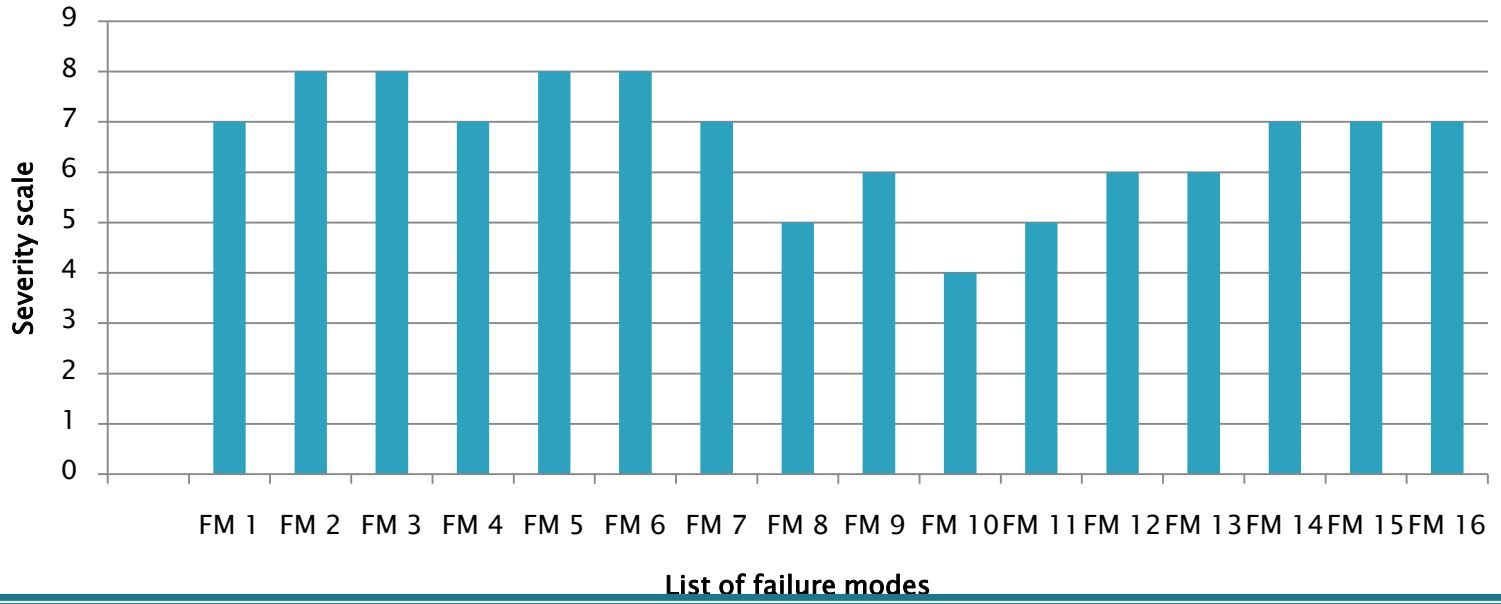
FM1: **Incorrect Route**
FM 2: Incorrect Dose (Over / under/duplicate dose)
FM 3: Incorrect Frequency
FM 4:Incorrect Time
FM5: Allergy (Not documented)
FM 6:Order not transcribed
Drug/drug – Drug/
FM7:Food interaction
FM8:Incorrect Rate
FM9:Incorrect labeling/ instruction (LASA)

FM 10 Expired drug
FM11 Incorrect Drug
FM 12 Incorrect Duration
FM 13 Incorrect Formulation
FM 14 **Incorrect Dilution / Calculation**
FM 15 **Incorrect Strength / Concentration**
FM16 **Omitted/ Missed Drug/ Dose**
FM17 Incorrect Patient

SEVERITY RATING SCALE

Extreme	10	Failure may seriously endanger the patient
High	9	Failure involves regulatory non-compliance
	8	Failure causes patient high dissatisfaction
Moderate	7	Failure causes patient dissatisfaction
	6	Failure causes disruption of patient ADL
	5	Inconvience for patient
Low	4	Inconvienece at subsequent function, minor rework
	3	Slight inconvience at next function, minor rework
None	2	Slight inconvience at delivery, minor rework
	1	Patient will probably not notice. No effect.

Rating of Failure Mode based on Severity Scale



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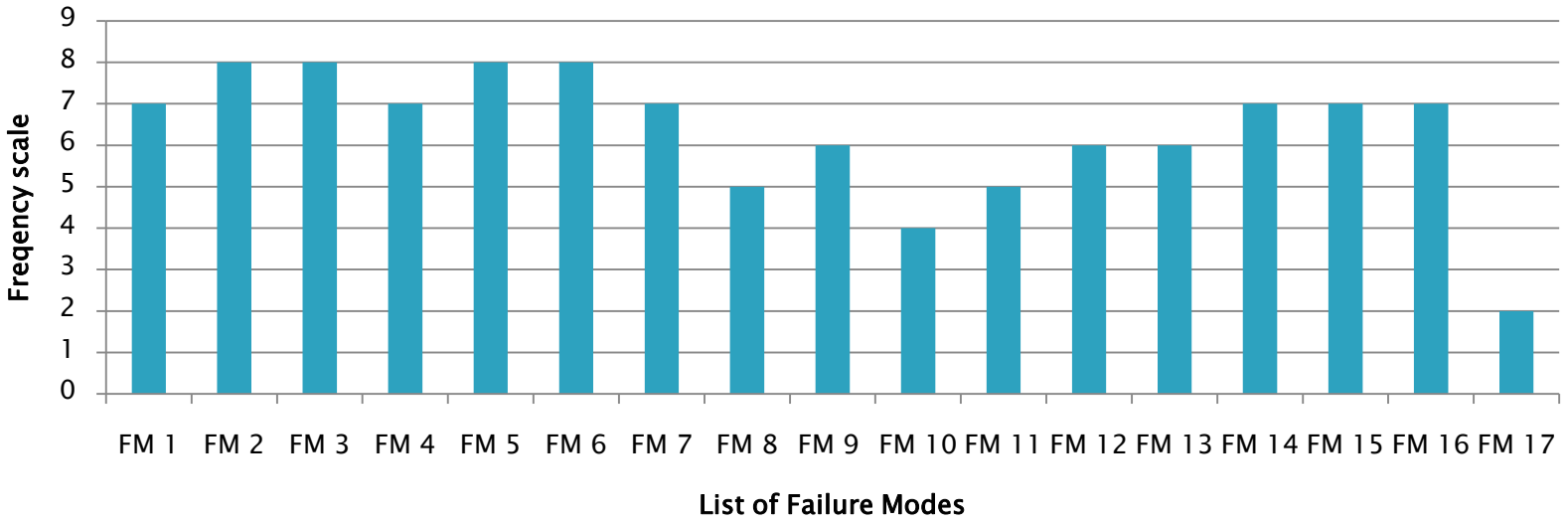
FREQUENCY RATING SCALE

None	1	Unlikely to occur
Low	2	Once in 3-5 years
	3	Relatively few failure
Moderate	4	Once in a year
	5	Once in 6 months to one year
	6	Occasional failure
High	7	Once occurrence in month
	8	Repeated failure once a week
Extreme	9	Once occurrence in 3-4 days
	10	Failure is almost inevitable

Rating of Failure Mode based on Frequency Scale



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DETECTION RATING SCALE

Extreme	10	Failure may seriously endanger the patient
High	9	Failure involves regulatory non-compliance
	8	Failure causes patient high dissatisfaction
Moderate	7	Failure causes patient dissatisfaction
	6	Failure causes disruption of patient ADL
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Low	4	Inconvienece at subsequent function, minor rework
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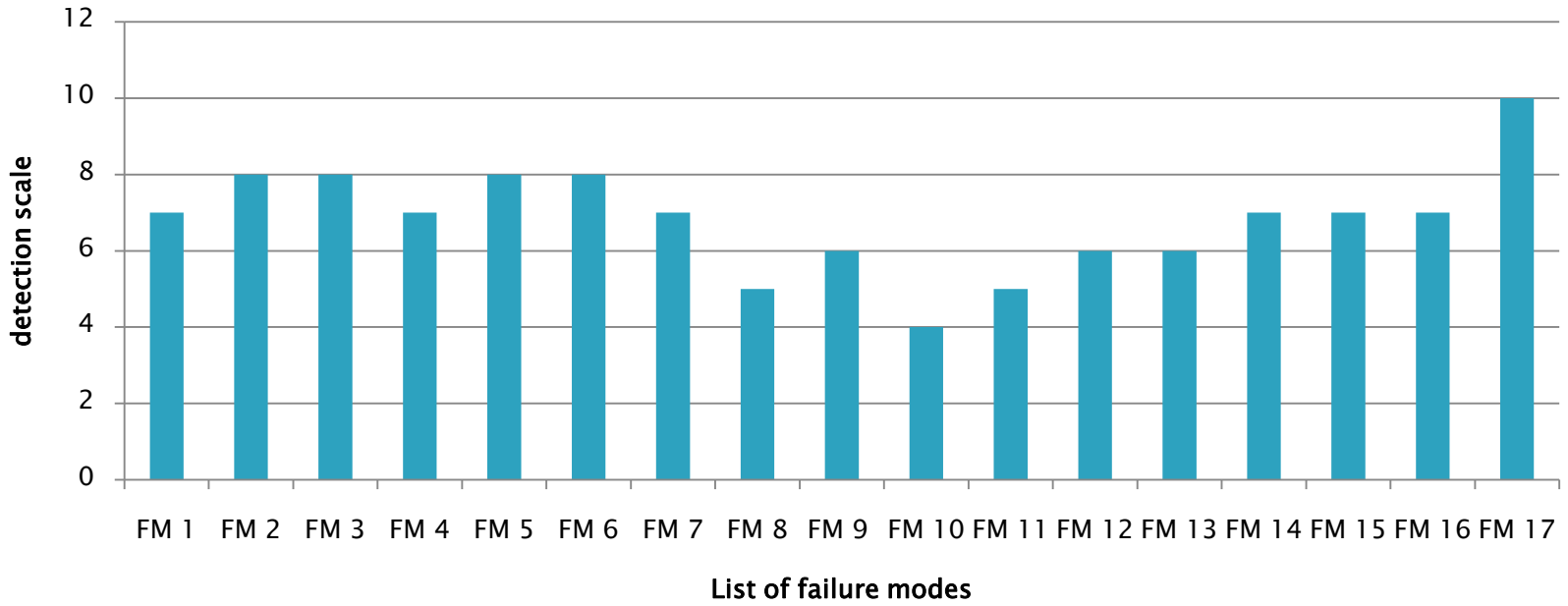
Rating of Failure Mode based on Detection Scale



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CAUSE EFFECT DIAGRAM

Cause effect diagram.docx

4. DETERMINATION OF AN PREVENTION & CORRECTIVE ACTION PLAN

After the FMEA analysis the plan of action is

- Nurses & pharmacist should be provided with continuous education.
- Computerised Physician Order Entry (CPOE) system should be used for prescribing & administering drugs to prevent error.
- Medication Management and use.
- Automatic stop Medication Order
- List of Approved Abbreviations & Dose Expression
- Multi Disciplinary Team to monitor the Medication process.
- Prescription Audit Team

MEDICINE DISPENSING PROCESS CHECKLIST

a) ACCEPT AND CHECK PRESCRIPTION DETAILS

- Prescriber details
- Patient details
- Confirm items to be dispensed

b) SAFETY AND APPROPRIATENESS

- Safe dosage
- Contra-indications (not appropriate with certain medical conditions)
- Appropriateness of prescription for age, weight etc

MEDICINE DISPENSING PROCESS CHECKLIST

c) REVIEW PATIENT'S DISPENSING HISTORY

- New or changed therapy
- Duplication
- Interactions (drug-drug, drug-disease state, drug-herb)
- Compliance issues
- Misuse/abuse issues

d) PATIENT-SPECIFIC FACTORS

- Age
- Allergies
- Diagnosis
- Pregnancy/lactation

MEDICINE DISPENSING PROCESS CHECKLIST

e) SELECT/PREPARE AND CHECK

- Appropriate drug, brand, strength, form, quantity
- Repack if needed
- Prepare where needed
-

f) DISPENSING CHECK

- Correct drug, brand, strength, form, quantity
- Correct formula/methodology for compounded products
- Confirm Pharmaceutical Benefits Scheme processing

MEDICINE DISPENSING PROCESS CHECKLIST

g) LABEL AND ASSEMBLE DISPENSED PRODUCTS

- Review expiry, instructions, cautionary labels
- Complete documentation and records
- Organise counselling aids (e.g. written materials)

h) SUPPLY PRESCRIPTION TO PATIENT

- Correct patient
- Correct medicines
- Documentation present
- Patient/Carer understands directions/advisories
- Clarify patient/carer issues

MEDICATION REPORTING ERROR FORM

1.docx

LIMITATIONS

I. Medication error reporting form was not available of previous years.
II. Fear of punishment in case of reporting error.
III. Only a few in the organization understand them.
IV. They signify yet another compliance burden placed on the managers by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

CONCLUSION

In the study conducted the failures modes due to Medication Management Process were prioritised on the basis on RPN. The major causes of error are Allergy not documented, incorrect labelling/ instruction (LASA), Omitted/ Missed Drug/ Dose, Incorrect Dilution / Calculation, Incorrect Strength / Concentration & Incorrect Route. To reduce the error preventive & correction action has to be taken. The preventive action has to be taken in form of CPOE, Prescription Audit, Medication management Checklist, List of approved abbreviation have to be implemented. Continuous training of Nurses& pharmacist has to be done along with filling up of medication error reporting form so as corrective action can be taken.

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