

**Failure Mode Effect Analysis for Averting Risk Due to  
Medication Error**

**Internship Training  
at  
Santokba Durlabhji Memorial Hospital cum Research Centre  
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## INDEX

| <b><u>S.NO</u></b> | <b><u>CONTENT</u></b>     | <b><u>PAGE NO.</u></b> |
|--------------------|---------------------------|------------------------|
| 1                  | List of Abbreviations     | i                      |
| 2                  | List of Graphs            | ii                     |
| 3                  | List of Table             | iii                    |
| 4                  | Executive Summary         |                        |
| 5                  | Background Overview       | 10                     |
| 6                  | Problem Statement         | 14                     |
| 7                  | Literature Overview       | 15                     |
| 8                  | Conceptual Framework      | 16                     |
| 9                  | Research question         | 18                     |
| 10                 | Objectives                | 19                     |
| 11                 | Methodology               | 19                     |
| 12                 | Results                   | 21                     |
| 13                 | Recommendation            | 28                     |
| 14                 | Limitation                | 34                     |
| 15                 | Conclusion                | 34                     |
|                    | References                |                        |
|                    | Annexure                  |                        |
|                    | Questionnaire             |                        |
|                    | Medication Reporting Form |                        |

## **ABBREVIATIONS**

|                        |   |                                                 |
|------------------------|---|-------------------------------------------------|
| FMEA                   | - | Failure Mode Effect Analysis                    |
| RCA                    | - | Root Cause Analysis                             |
| MMP                    | - | Medication Management Process                   |
| CPOE                   | - | Computerised Physician Order Entry              |
| LASA                   | - | Look Alike Sound Alike                          |
| FM                     | - | Failure Mode                                    |
| ADR                    | - | Adverse Drug Reaction                           |
| JCAHO<br>Organizations | - | Joint Commission on Accreditation of Healthcare |

| <b><u>S.NO</u></b> | <b><u>LIST OF GRAPHS</u></b>               | <b><u>PAGE NO</u></b> |
|--------------------|--------------------------------------------|-----------------------|
| 1.                 | RPN of Failure Modes                       | 24                    |
| 2.                 | Rating of Failure Modes on Severity scale  | 25                    |
| 3.                 | Rating of Failure Modes on Frequency scale | 26                    |
| 4.                 | Rating of Failure Modes on Detection Scale | 27                    |

| <b>S.NO</b> | <b>LIST OF TABLES</b>                          | <b>PAGE NO.</b> |
|-------------|------------------------------------------------|-----------------|
| 1.          | Depicting the failure modes, its effects & RPN | 23              |
| 2.          | Severity Rating Scale                          | 24              |
| 3.          | Frequency Rating Scale                         | 25              |
| 4.          | Detection Rating Scale                         | 26              |
| 5.          | List of Abbreviations & Dose expression        | 31              |

**DISSERTATION REPORT**

**FAILURE MODE EFFECT ANALYSIS FOR AVERTING RISK DUE  
TO MEDICATION ERROR**

## **EXECUTIVE SUMMARY**

Over the past decade, mismanaged health care that actually makes patients sicker has increasingly drawn the attention of the public, the media, and those involved in health care. Drug use is a complex process and there are many drug related challenges at various levels, involving prescriber, pharmacists and patients.

The FMEA tool was used to review the process and find out failure modes. 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.

The study assesses various risk points existing in the medication management process of the hospital and analyses the causes & effects of these failure modes. Attention has focussed on medication error because it represents the largest single components of all medical error and many are life threatening. Most medication errors are not caused by individual carelessness, but rather by faulty process that lead to make mistakes or fail to prevent the mistakes from occurring. FMEA includes review of the following:

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

It will comprise of the six-steps by Joint Commission on Accreditation of Healthcare Organizations (JCAHO) as mentioned below:

1. Identification of the process (Failure Modes)
2. Multi disciplinary team selection
3. Description of the process (Failure Causes)
4. Listing and ranking of failure modes (Failure Effects)
5. Identification of root causes
6. Determination of an action plan

The goal of FMEA is to predict how and where system designed to detect error fail and how processes can be improved to reduce the chances of failure.

On reviewing the medication process in detail for all the category of medication, it was been observed that 17 failure modes were been identified. Then the causes and its effects of thee failure modes were analysed and scoring was done. Out of these five failure modes 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.

Assessment of the medication system would enable the hospital to systematically identify the risk points that increase the potential for medication error and make improvement that reduces the potential for error to occur. Improvement in process is achieved through taking action that eliminates or minimises the possibility of the error occurring, stop an error before it causes harm, or minimises the consequences of the error when potential error can be eliminated.

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.

## **1.0 BACKGROUND**

The issue of human errors in complex systems has been a topic of debate for decades. Making mistakes is human nature and cannot be eradicated. What can be changed, however, are the conditions under which humans work (Reason, 2000). Adverse medical events, as injuries to patients that arise from mistakes and accidents during medical treatment are called, can be result of human errors, technological errors, or a system that failed to detect these mishaps and prevent them (Bernstein, et al., 2003). Achieving patient safety is a foremost goal among healthcare workers.

### **1.1 Medication Management Process**

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 health care team working collaboratively.

Thus the process essential to the medication management system are:

- a) Selection & procurement
- b) Storage
- c) Ordering and transcribing
- d) Preparation & dispensing
- e) Administration
- f) Clinical monitoring of effects

An effective medication process includes a viable process for reporting potential errors and near misses as well as actual errors. A consistent approach to perform improvement throughout the organization through reporting of medication error to transform the collected data into information.

### **1.2 MEDICATION ERROR**

As defined by the 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”.

### **1.3 INTERNATIONAL GOALS OF PATIENT SAFETY:**

#### **Goal 1 : Identify Patients Correctly**

Use 2 patient identifiers – Patient's name and UHID No. The patient's room number/ location are not to be used as an identifier.

#### **Goal 2: Improve Effective Communication**

All telephonic / verbal / critical test result reporting.

The complete order or test result(s) is written down as received and verbally read-back to the person communicating the information & verified

#### **Goal 3: Improve the Safety of Medication**

Medication that bears a heightened risk of causing significant patient harm when used should only be permitted with prescription & proper dosage. High alert medication is only permitted in pharmacy, ICU's and Emergency department.

#### **Goal 4: Ensure Correct-Site, Correct-Procedure & Correct-Patient Surgery**

Universal Protocol to be followed:

- a. Marking the Surgical Site
- b. Pre-operative verification process
- c. Out immediately before start of a procedure.

#### **Goal 5: Reduce the risk of Healthcare Associated Infection**

The Hospital complies with WHO hand hygiene guidelines. Hand washing is the single most important factor for Infection Control.

Five moments of Hand Hygiene by WHO:

1. Before touching a patient
2. Before clean/aseptic procedure of patient
3. After patient body fluid exposure risk
4. After touching a patient
5. After touching patient surroundings

Follow “**Standard Precautions**” in the hospital.

#### **Goal 6: Reduce the risk of Patient harm resulting from fall**

All patients will be assessed for risk of fall on admission and reassessed routinely to determine ongoing need for fall prevention precautions. Interventions to protect patients at risk for falling and harming self will be initiated using the least restrictive alternative available.

## **2.0 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.

### **3.0 LITERATURE REVIEW**

Many risk managers first heard about FMEA and RCA when JCAHO released its Leadership Standards and Elements of Performance Guidelines in July 2002. Also 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.

Literature on adverse medical events and patient safety refers to ‘active’ and ‘latent’ failures. Active failures are unsafe acts committed by people who are in direct contact with the patient or the system, and thus these failures present immediate risk to patients. They include mechanical failures such as picking up the wrong syringe, cognitive failures such as memory lapses or misreading instructions and violations — deviations from standards and protocols (Vincent et al.,1998). Latent conditions are failures of a system to detect and intercept adverse events before they cause harm, or error-provoking conditions in the workplace that create long-lasting weaknesses in the system (Reason, 2000). Examples of latent failures include heavy workloads, inadequate supervision, stressful environments, rapid change within an organization, and inadequate communication.

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. A review of hospital data compiled by the Canadian Institute for Health Information shows that 3.3 to 5 percent of patients admitted to Ontario hospitals from 1992 to 1997 experienced adverse events related to their treatments (Hunter et al., 1999; Wanzel et al., 2000).

#### **4.0 CONCEPTUAL FRAMEWORK**

“Failure Mode and Effect Analysis” (FMEA) and “Root Cause Analysis” (RCA) are becoming common place terms in work environments and in the literature. The purpose and intent of using such technologies in health care. The desire for regulatory compliance overshadows the primary objective of increasing patient safety. Relatively new to the health care world, FMEA and RCA are well established in other industries. This technique examines the individual components of a system to determine the ways in which each component could fail and the effect of that failure on the stability of the entire system. It is a risk-assessment guideline, done in advance to estimate the potential for mishaps.

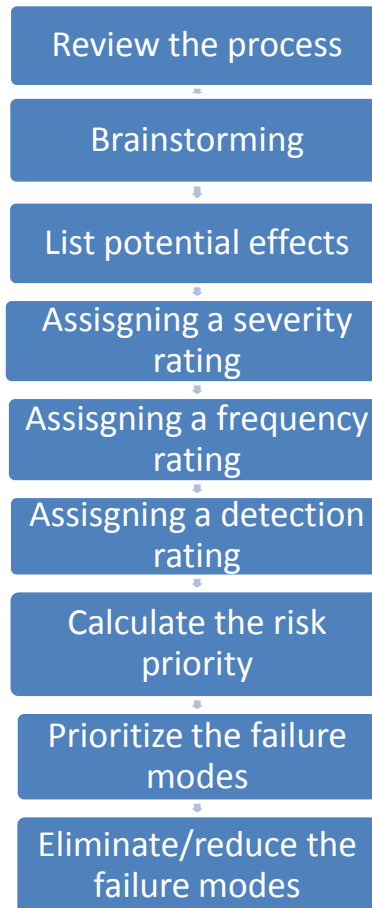
The purpose and intent of using such technologies (FMEA) in health care is to assess the failure mode in the system and analyses each mod to determine how likely it is that an error or a failure could occur, the seriousness of the consequences if it does occur & how likely it is that the problem would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

#### **4.1 FAILURE MODE & EFFECT ANALYSIS**

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.

The purpose of performing an FMEA for JCAHO was to identify where and when possible system failures could occur and to prevent those problems before they happen. If a particular failure could not be prevented, then the goal would be to prevent the issue from affecting health care organizations in the accreditation process.

## PROCESS OF FMEA



### **4.2 ROOT CAUSE ANALYSIS**

RCA is a process, usually reactive, for identifying the basic or causal factors that underlie variation in performance and which can produce unexpected and undesired adverse outcomes. Usually, a combination of root causes sets the stage for failure.

### **4.3 PATIENT SAFETY**

The degree to which the risk of an intervention/procedure, in the care environment is reduced for a patient, visitors and healthcare providers.

### **4.4 SENTINEL EVENT**

A relatively infrequent, unexpected incident, related to system or process deficiencies, which leads to death or major and enduring loss of function for a recipient of healthcare services

### **4.5 NEAR MISS**

A near-miss is an unplanned event that did not result in injury, illness, or damage--but had the potential to do so.

Errors that did not result in patient harm, but could have, can be categorised as near-misses.

Multi disciplinary team: A generic term which includes representatives from various disciplines, professions or service areas.

#### **4.6 ADVERSE EVENT**

Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have causal relationship with this treatment.

#### **4.7 ADVERSE DRUG REACTION**

A response to a drug which is noxious and unintended and *which occurs at doses normally used in man* for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function.

#### **4.8 CLINICAL AUDIT**

A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. (Principles for Best Practice in Clinical Audit 2002, NICE/CHI)

#### **4.9 RISK ASSESSMENT**

Risk assessment is the determination of quantitative or qualitative value of risk related to a concrete situation and a recognised threat (also called hazard).

#### **4.10 PLAN OF CARE**

A plan that identifies patient care needs, lists the strategy to meet those needs, documents treatment goals and objectives, outlines the criteria for ending interventions, and documents the individual's progress in meeting specified goals and objectives. The format of the plan may be guided by specific policies and procedures, protocols, practice guidelines or a combination of these. It includes preventive, promotive, curative and rehabilitative aspects of care.

An Adverse Event is an injury to a patient caused by medical management rather than the Underlying disease, which prolongs the hospitalization and/or produces disability at the time of Discharge (Brennan et al., 1991).

An Adverse Drug Event (ADE), the most common type of adverse event, (Leape et al., 1993) is an injury resulting from medical intervention related to a drug (Bates et al., 1995). Examples of adverse drug events include wrong dose, wrong choice, wrong drug, wrong technique, equipment failure, etc.

#### **5.0 RESEARCH QUESTION**

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

## **6.0 OBJECTIVE**

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

## **7.0 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

This technique examines the individual components of a system to determine the ways in which each component could fail and the effect of that failure on the stability of the entire system. It is a risk-assessment guideline, done in advance to estimate the potential for mishaps.

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

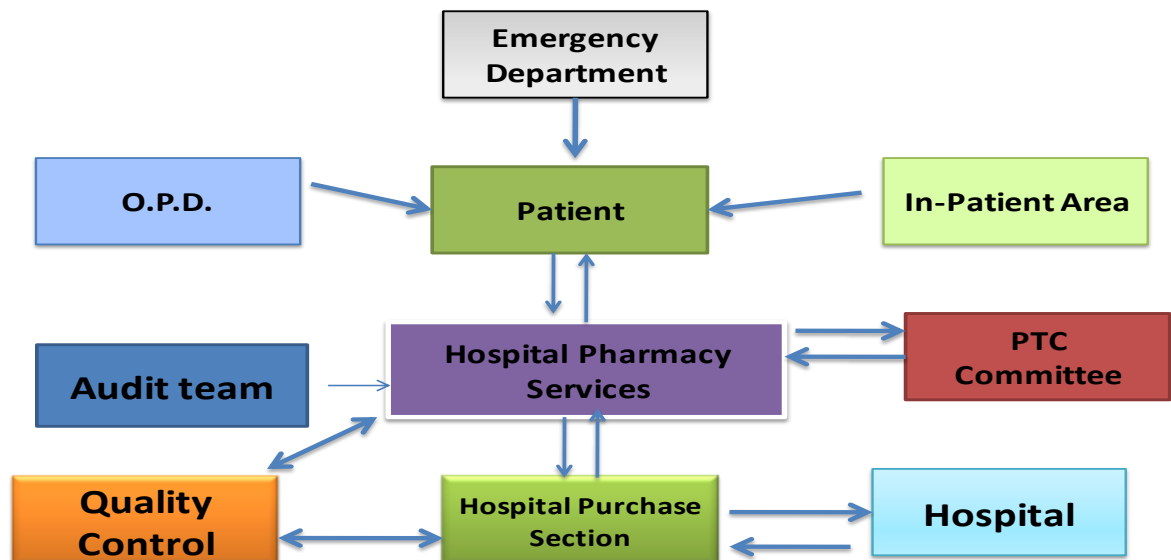
1. Identification of the process
2. Multi disciplinary team selection
3. Description of the process
4. Listing and ranking of failure modes
5. Identification of root causes
6. Determination of an action plan

### **7.1 Process adopted for FMEA**

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

### **7.1 PROCESS MAPPING OF MEDICATION MANAGEMENT PROCESS**



## **8.0 Results:**

### **8.1 IDENTIFICATION OF FAILURE MODES**

Failure modes was been analysed to evaluate the cause of medication error they are as follows

#### **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
- 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
- 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
- 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.

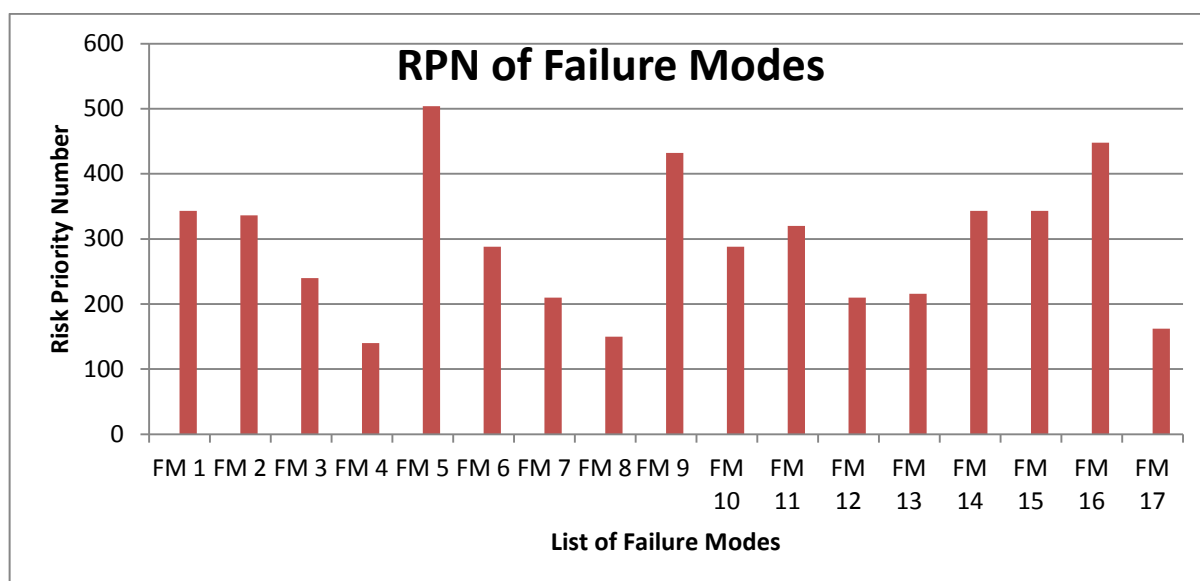
### 8.3 LISTING AND RANKING OF FAILURE MODES

**Table 11: Depicting the failure modes, its effects & RPN**

| Steps in the process        | Code for failure mode | Failure Mode                                 | Failure Causes                              | Potential likelihood of occurrence (1-10) | Potential Failure Effect               | Potential likelihood of Detection (1-10) | Severity (1-10) | RPN (O*D*S) |
|-----------------------------|-----------------------|----------------------------------------------|---------------------------------------------|-------------------------------------------|----------------------------------------|------------------------------------------|-----------------|-------------|
| Prescribing                 | FM 1                  | Incorrect Route                              | Lack of time devotion                       | 7                                         | Life Threatening condition             | 7                                        | 7               | 343         |
|                             | FM 2                  | Incorrect Dose (Over / under/duplicate dose) | Miscommunication, Mutual understanding      | 8                                         | Potential side effects                 | 6                                        | 7               | 336         |
|                             | FM 3                  | Incorrect Frequency                          | Miscommunication                            | 8                                         | No effect                              | 5                                        | 6               | 240         |
|                             | FM 4                  | Incorrect Time                               | Lack understanding of                       | 7                                         | Ineffective drug                       | 4                                        | 5               | 140         |
| Transcribing/ Documentation | FM 5                  | Allergy (Not documented)                     | Previous medical History not taken properly | 8                                         | Patient Develops Adverse drug reaction | 7                                        | 9               | 504         |
|                             | FM 6                  | Order not transcribed                        | Long queue at Pharmacy counter              | 8                                         | Wrong drug transcribed                 | 6                                        | 6               | 288         |
|                             | FM 7                  | Drug/drug – Drug/ Food interaction           | No counseling done                          | 7                                         | Side effect or No effect of Drug       | 5                                        | 6               | 210         |
| Storage/ Dispensing         | FM 8                  | Incorrect Rate                               | Long queue at The counter                   | 5                                         | Less/ adverse Effect of drug           | 5                                        | 6               | 150         |
|                             | FM 9                  | Incorrect labeling/ instruction (LASA)       | Drugs not kept separately                   | 6                                         | Adverse drug reaction                  | 8                                        | 9               | 432         |

|               |       |                                       |                                                             |   |                                                                |    |   |     |
|---------------|-------|---------------------------------------|-------------------------------------------------------------|---|----------------------------------------------------------------|----|---|-----|
|               | FM 10 | Expired drug                          | Not practicing FIFO                                         | 4 | Life threatening<br>For patient                                | 8  | 9 | 288 |
|               | FM 11 | Incorrect Drug                        | Illegible writing &<br>Practicing drugs<br>From formulary   | 5 | Potential side<br>Effect can<br>Develop                        | 8  | 8 | 320 |
| Administering | FM 12 | Incorrect Duration                    | Standard abbreviation<br>Not practiced                      | 6 | Over/under<br>Dose taken                                       | 5  | 7 | 210 |
|               | FM 13 | Incorrect Formulation                 | Not mentioned<br>In prescription                            | 6 | Ineffective<br>Dosage                                          | 6  | 6 | 216 |
|               | FM 14 | Incorrect Dilution /<br>Calculation   | Not mentioned<br>In prescription                            | 7 | Ineffective<br>Dosage                                          | 7  | 7 | 343 |
|               | FM 15 | Incorrect Strength /<br>Concentration | Not mentioned<br>In prescription                            | 7 | Ineffective<br>Dosage                                          | 7  | 7 | 343 |
|               | FM 16 | Omitted/ Missed Drug/<br>Dose         | Nursing staff<br>Overload with work                         | 7 | Ineffective<br>Treatment<br>Protocol,<br>Develop<br>resistance | 8  | 8 | 448 |
|               | FM 17 | Incorrect Patient                     | Miscommunication,<br>Overloaded with<br>Work, lack of staff | 2 | Endangers<br>Patients life                                     | 10 | 9 | 180 |

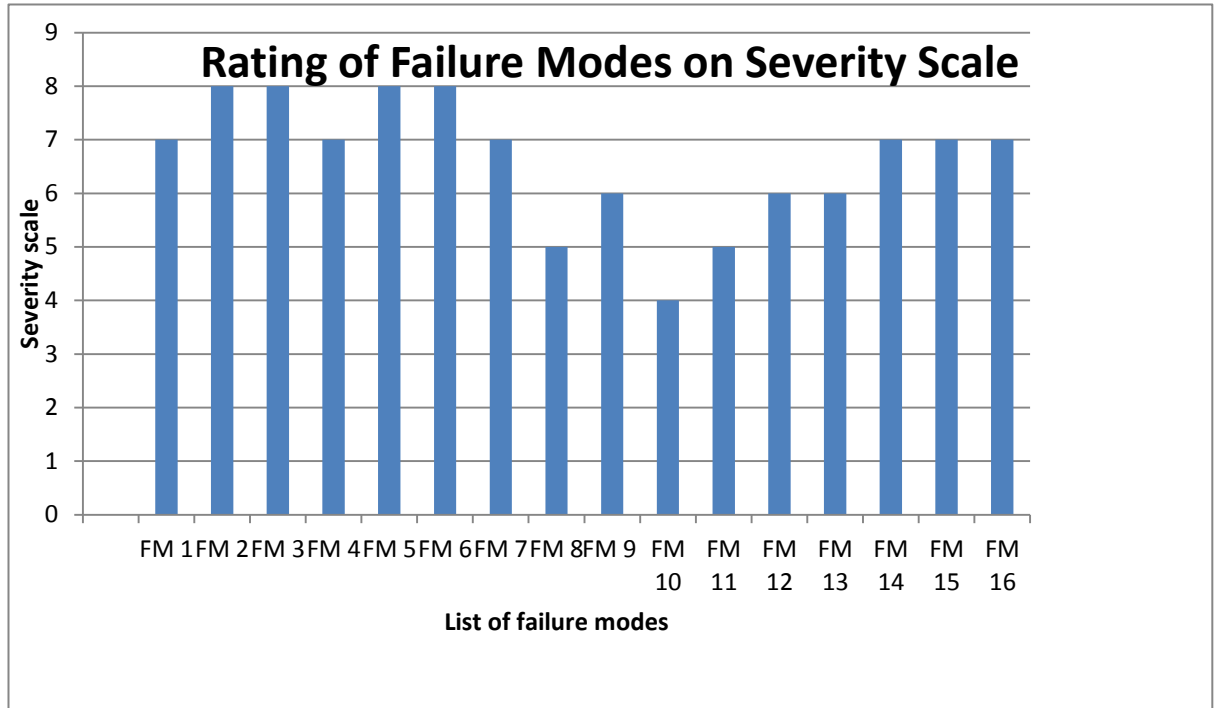
**Graph1: Depicts Risk Priority Number of Failure Modes**



The above graph 1 depicts the medication process in detail, 17 failure modes were identified. For all the identified failure modes failure cause along with its effect was been identified. After the Risk Priority Number was been calculated, out of these five failure modes were prioritized on the bases of 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.

**Table 12: Severity Rating Scale (Quality Associates International, US)**

|         |    |                                                   |
|---------|----|---------------------------------------------------|
| Extreme | 10 | Failure may seriously endanger the patient        |
| High    | 9  | Failure involves regulatory non-compliance        |
|         | 8  | Failure causes patient high dissatisfaction       |
| Moderat | 7  | Failure causes patient dissatisfaction            |
|         | 6  | Failure causes disruption of patient ADL          |
|         | 5  | Inconvience for patient                           |
| Low     | 4  | Inconvience 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.      |



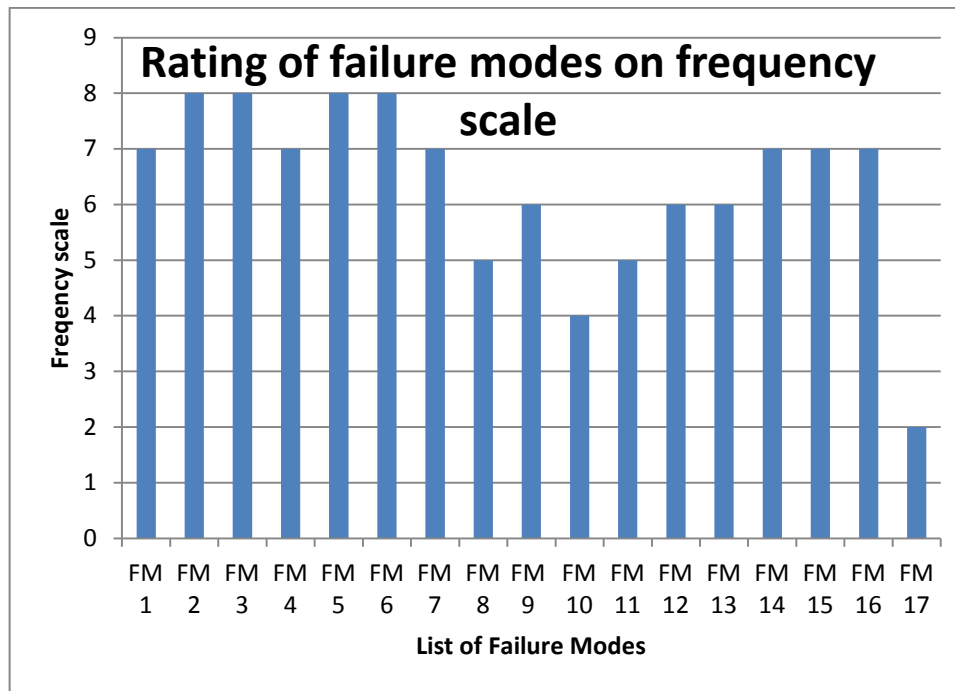
**Graph 2: Rating of Failure Modes on Severity Scale**

The graph 2 depicts the rating of failure modes on severity scale of the above mentioned list of failure modes. It shows that the severity index for FM 2, 3, 5 & 6 is maximum i.e. approximately 8 while for FM 10 it is lowest i.e. approx 4.

**Table 13: Frequency Rating Scale (Quality Associates International, US)**

|          |    |                              |
|----------|----|------------------------------|
| 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 |

**Graph 3: Depicts Rating of failure modes on Frequency Scale**

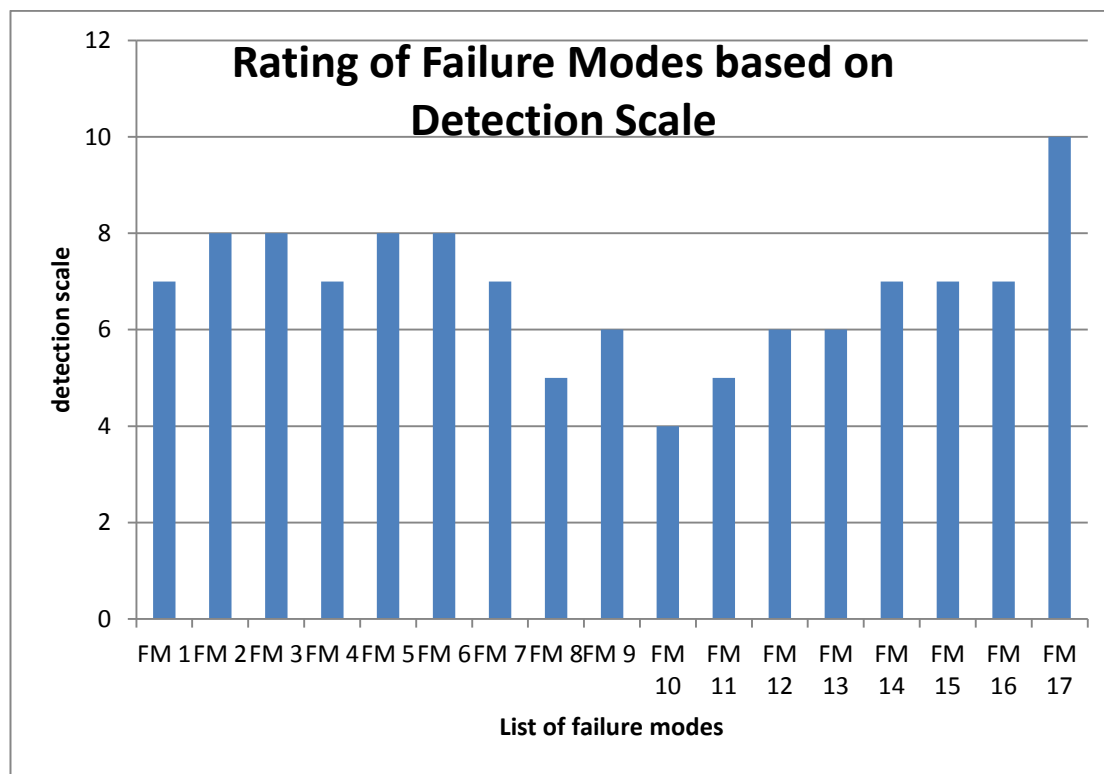


The graph 3 depicts the rating of failure modes on the frequency scale. The failure modes 2, 3, 5, & 6 shows maximum chances of occurrences while failure mode 17 i.e. incorrect patient shows least chances of occurrence.

**Table 14: Detection Rating Scale (Quality Associates International, US)**

|         |    |                                                   |
|---------|----|---------------------------------------------------|
| Extreme | 10 | Failure may seriously endanger the patient        |
| High    | 9  | Failure involves regulatory non-compliance        |
|         | 8  | Failure causes patient high dissatisfaction       |
| Moderat | 7  | Failure causes patient dissatisfaction            |
|         | 6  | Failure causes disruption of patient ADL          |
|         | 5  | Inconvience for patient                           |
| Low     | 4  | Inconvience 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.      |

**Graph 4: Depicts Rating of Failure Modes bases on Detection Scale**



The graph 4 depicts the rating of failure modes based on detection scale. The chances of detection are high in case of drug administered to incorrect patient followed by FM 2, 3, 5 & 6 while it is lowest in case of FM 10.

## **9.0 RECOMMENDATION**

### **DETERMINATION OF AN PREVENTION & CORRECTIVE ACTION PLAN**

**9.1** Nurses should be provided with continuous education

**9.2** Computerised Physician Order Entry (CPOE) system should be used for prescribing & administering drugs to prevent error.

The advantage of CPOE is:

- Standardized order of prescription
- Order are legible (transcribed)
- Information can be assessed any time
- All the order are checked for no of problem like: Allergy, drug interaction, high doses etc.

### **9.3 Medication Management and Use**

Hospital has a medication policy in place to reduce medication errors.

1. Medication orders are to be written clearly in the drug chart.
2. Start and discontinuation order of any drug has to be signed, dated and timed. (Doctors need to cancel the medication administration orders in the medication chart to discontinue the medicine usage)
3. Any wrong entry has to be crossed out with a single line and signature.
4. Effect of medication is to be documented in the progress notes.
5. Medications are administrated at standard times other than stat orders
6. Self medication and medication from outside are not encouraged in the hospital.
7. Never leave medicines unattended in the open. Keep them safe in bedside cabinets.
8. Label all open in use vials and re-filled syringes.
9. All medication error to be reported (Medication error form).
10. All ADR (Adverse Drug Reactions) need to be reported in ADR form for clinical audit.
11. All orders (including diet and nursing stands cancelled when patient undergo surgery or is transferred out of ICU's. All order including dietary order need to be written a fresh in the situation.
12. Seven Rights that everyone should remember
  1. Right patient
  2. Right Drug
  3. Right Dose
  4. Right Time
  5. Right route
  6. Right Purpose

## 7. Right Documentation

### 9.4 Required elements of a complete prescription order

- Patient identification details (Patient Name & UHID Number)
- Patient Age
- Patient sex
- Prescribing Doctor Name, Signature & “Hospital” Employment code
- Prescription date
- Provisional diagnosis / Final Diagnosis
- All the medications prescribed in clear handwriting preferably by using CAPITAL LETTERS, avoid using abbreviations or use only approved abbreviations
- Dose, Route & Frequency (standardized times are followed unless otherwise specified)
- Formulation & Medications Name
- SOS orders with indications that in which conditions medication is to be administered.
- Look-alike / Sound alike medications are to be prescribed by mentioning both Generic & Brand name.
- Preferably medications to be prescribed by using both Generic name & Brand name. For Eg..INJ FOSOLIN
- Special Dilution for required IV Infusions or preparation instructions with Infusion rate
- Un-approved & unauthorized abbreviations shall not be used.
- Abbreviation for Medication names shall not be used.
- Special instructions to be used whenever required.
- Hold Dose or Order
- Status STAT or NOW otherwise the order is assumed to be routine
- ASK before administration (with physician name)
- Medication to be given for specified durations only.

### 9.5 Automatic stop Medication Orders

- Medication orders discussed below are automatically stopped after their validity
- Routine orders of In-Patient are valid for 3 days only.
- Stat orders are Valid for single dose only
- Narcotic Drugs orders are valid for time period mentioned by doctor on Drug chart & Narcotic request book (whichever fall earlier)
- High alert medications orders are valid for single day only
- Cytotoxic chemotherapy medications orders are valid for single day only

### 9.6 List of Approved Abbreviations

- OD- ONCE A DAY
- BD- TWO TIMES A DAY
- TDS- THREE TIMES A DAY
- QID- FOUR TIMES A DAY
- SOS- WHEN NECESSARY
- PRN- WHEN NECESSARY
- ML- MILLI LITRE
- MG- MILLIGRAM
- MCG- MICROGRAM
- IV- INTRAVENOUS
- IM- INTRAMUSCULAR

- HS- EVERY NIGHT
- PO- ORAL
- RT- BY RIALS TUBE
- TAB.- TABLET
- INJ.- INJECTION
- AMP.- AMPOULE

### **9.7 Multi Disciplinary Team Selection**

The case are been reported in Pharmaceutical, Therapeutic & Consumables committee.

- Medical Superintendent
- Head of Department Gastroenterology
- Head of Department Orthopaedics
- Head of Department Gynaecology
- Assistant Medical Superintendent
- Matron
- Pharmacy Manager
- Deputy Pharmacy Manager
- Pharmacy Store In charge
- Quality Manager

### **9.8 Prescription Audit Team:**

- Assistant Medical Superintendent
- Pharmacy Manager
- Deputy Pharmacy Manager
- MRD In charge
- Matron
- Floor Supervisor
- Quality Manager

**Table 15: List of Abbreviations/ Dose Expression**

| Abbreviation<br>Dose<br>Expression | Intended<br>meaning       | Misinterpretation                                                                                                                                         | Correction                                |
|------------------------------------|---------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|
| D/C                                | Discharge<br>discontinues | Premature discontinuation of medication when D/C(intend) to mean “discharge”) has been misinterpreted as “discontinued” when followed by a list of drugs. | Use “discharge” and “discontinue”         |
| AZT                                | Zidovudine<br>(RETROVIR)  | Azathioprine                                                                                                                                              | Use the complete spelling for drugs names |
| HCl                                | Hydrochloride<br>Acid     | Potassium chloride(The “H” is misinterpreted as “k”)                                                                                                      | Use the complete spelling for drugs names |
| HCT                                | Hydrocortisone            | Hydrochlorothiazide                                                                                                                                       | Use the complete spelling for drugs names |
| HCTZ                               | Hydrochloro-<br>thiazide  | Hydrocortisone (seen as HCT250mg)                                                                                                                         | Use the complete spelling for drugs names |
| MgSO <sub>4</sub>                  | Magnesium<br>sulphate     | Morphine sulphate                                                                                                                                         | Use the complete spelling for drugs names |
| MSO <sub>4</sub>                   | Morphine<br>sulfate       | Magnesium sulphate                                                                                                                                        | Use the complete spelling for drugs names |
| MTX                                | Methotrexate              | Mitoxantrone                                                                                                                                              | Use the complete spelling for drugs names |
| TAC                                | Triamcinolone             | Tetracaine, ADRENALINE, cocaine                                                                                                                           | Use the complete spelling                 |

|                   |               |                   |                                                       |
|-------------------|---------------|-------------------|-------------------------------------------------------|
|                   |               |                   | for drugs<br>names                                    |
| ZnSO <sub>4</sub> | Zinc sulphate | Morphine sulphate | Use the<br>complete<br>spelling<br>for drugs<br>names |

**Medication error form available at all nursing counters.**

Any suspected adverse drug / device event is to be reported to pharmacy department in ADR form.

**9.9 Drug Formulary**

A list of medications (Drug-formulary) approved from Pharmacy & therapeutic committee for use in “XYZ” is to be followed by all “XYZ” Physicians

Non-formulary drugs and new drugs if required in specific conditions is to be provided by pharmacy for specific patient use only after approval from management.

**9.10 Storage Practice**

- Store all the medications at secure place.
- Do not store any medications at floors.
- Store all the medications by proper labeling.
- Use scientific methods for storing Look-Alike, Sound-Alike & Spell Alike medications
- Follow manufacturer guidelines for storage. For e.g.-  
TallMAN Labeling CAPFLUNIL 10MG CAPFLUVIR 75 MG
- Store High Alert / High Risk medication with proper labeling for e.g.

CAUTION: HIGH ALERT MEDICATION

**9.11 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

**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

#### **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

#### **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/carers issues

#### **COUNSEL PATIENT/CARER ON SAFE AND APPROPRIATE USE**

## **10.0 Limitations**

Almost automatically a stereotype of the term emerges and it may include paradigms such as:

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

## **11.0 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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**Annexure:**

**QUESTIONNAIRE FOR MEDICATION MANAGEMENT PROCESS:**

| Reason why medication error occurs         |            |           |          |
|--------------------------------------------|------------|-----------|----------|
| Analysis of failure modes                  | Occurrence | Detection | Severity |
| Allergy (Not documented)                   |            |           |          |
| Contraindication                           |            |           |          |
| Drug/drug – Drug/Food interaction          |            |           |          |
| Expired drug                               |            |           |          |
| Incorrect Rate                             |            |           |          |
| Incorrect labeling/instruction (LASA)      |            |           |          |
| Incorrect Dose (Over/under/duplicate dose) |            |           |          |
| Incorrect Drug                             |            |           |          |
| Incorrect Duration                         |            |           |          |
| Incorrect Formulation                      |            |           |          |
| Incorrect Dilution / Calculation           |            |           |          |
| Incorrect Strength /Concentration          |            |           |          |
| Incorrect Patient                          |            |           |          |
| Incorrect Frequency                        |            |           |          |
| Incorrect Time                             |            |           |          |
| Incorrect Quantity                         |            |           |          |
| Incorrect Route                            |            |           |          |
| Omitted/ Missed Drug/Dose                  |            |           |          |

## MEDICATION ERROR FORM

| 1. PATIENT DETAILS & LOCATION OF EVENT                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | DIAGNOSIS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | TIME & DATE OF EVENT                                                                                                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|
| Age _____ GENDER <input type="checkbox"/> Male <input type="checkbox"/> Female<br>Patient UHID - _____ Location _____                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Date of Event : ____ / ____ / ____<br>Time of Event : _____                                                         |
| 2. Please describe the error. Include description/ sequence of events and work environment (e.g. change of shift, short staffing, during peak hours). If more space is needed, please use back of the page or attach a separate page.                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 3. Stage(s) of the process did the error occur?<br><div style="display: flex; flex-wrap: wrap;"> <div style="width: 50%;"><input type="checkbox"/> Storage</div> <div style="width: 50%;"><input type="checkbox"/> Administration</div> <div style="width: 50%;"><input type="checkbox"/> Prescribing</div> <div style="width: 50%;"><input type="checkbox"/> Dispensing</div> <div style="width: 50%;"><input type="checkbox"/> Ordering</div> <div style="width: 50%;"><input type="checkbox"/> Monitoring</div> <div style="width: 50%;"><input type="checkbox"/> Transcribing</div> <div style="width: 50%;"><input type="checkbox"/> Other (Specify)</div> </div> |                                                                                                                     |
| 4. DETAIL OF DRUG INVOLVED                                                                                                                                                                                                                                                                                                     | Dose                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Route                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 5. INCIDENT DETAIL                                                                                                  |
| Name of Drug                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Frequency                                                                                                           |
|                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <input type="checkbox"/> Incident <input type="checkbox"/> Near Miss <input type="checkbox"/> Adverse drug Reaction |
| INCIDENT CATEGORY                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                     |
| <input type="checkbox"/> Allergy (Not documented)                                                                                                                                                                                                                                                                              | <input type="checkbox"/> Incorrect Dose (Over/under/duplicate dose)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <input type="checkbox"/> Incorrect Patient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                     |
| <input type="checkbox"/> Contraindication                                                                                                                                                                                                                                                                                      | <input type="checkbox"/> Incorrect Drug                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <input type="checkbox"/> Incorrect Frequency                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                     |
| <input type="checkbox"/> Drug/drug – Drug/Food interaction                                                                                                                                                                                                                                                                     | <input type="checkbox"/> Incorrect Duration                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <input type="checkbox"/> Incorrect Time                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                     |
| <input type="checkbox"/> Expired drug                                                                                                                                                                                                                                                                                          | <input type="checkbox"/> Incorrect Formulation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <input type="checkbox"/> Incorrect Quantity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                     |
| <input type="checkbox"/> Pump incident(detail if relevant)                                                                                                                                                                                                                                                                     | <input type="checkbox"/> Incorrect Dilution / Calculation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <input type="checkbox"/> Incorrect Route                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                     |
| <input type="checkbox"/> Incorrect Rate                                                                                                                                                                                                                                                                                        | <input type="checkbox"/> Incorrect Strength /Concentration                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <input type="checkbox"/> Omitted/ Missed Drug/Dose                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                     |
| <input type="checkbox"/> Incorrect labeling/instruction                                                                                                                                                                                                                                                                        | <input type="checkbox"/> Others                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                     |
| 7 Did the error reach the patient? <input type="checkbox"/> Yes <input type="checkbox"/> No                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                     |
| 8. PLEASE TICK THE APPROPRIATE ** ERROR OUTCOME CATEGORY (SELECT ONE)                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                     |
| <b>NO ERROR</b><br><input type="checkbox"/> A. Events have potential to cause error<br><br><b>ERROR, NO HARM</b><br><input type="checkbox"/> B. Actual Error -did not reach patient<br><input type="checkbox"/> C. Actual Error -caused no harm<br><input type="checkbox"/> D. Additional monitoring required - caused no harm |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <b>ERROR, HARM</b><br><input type="checkbox"/> E. Treatment/ intervention required -caused temporary harm<br><input type="checkbox"/> F. Initial/ prolonged hospitalization -caused temporary harm<br><input type="checkbox"/> G. Permanent harm<br><input type="checkbox"/> H. Near death event<br><br><b>ERROR, DEATH</b><br><input type="checkbox"/> I. Death                                                                                                                                                                                                                                                                                                       |                                                                                                                     |
| 9. DETAILS OF REPORTER:                                                                                                                                                                                                                                                                                                        | INTERVENTION DONE:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                     |
| (optional)<br>Name: _____<br>Designation: _____<br>Mobile No _____                                                                                                                                                                                                                                                             | <div style="display: flex; flex-wrap: wrap;"> <div style="width: 50%;"><input type="checkbox"/> Administered antidote</div> <div style="width: 50%;"><input type="checkbox"/> Changed to correct drug / dose / frequency</div> <div style="width: 50%;"><input type="checkbox"/> No action needed</div> <div style="width: 50%;"><input type="checkbox"/> Education / training provided</div> <div style="width: 50%;"><input type="checkbox"/> Communication process improved</div> <div style="width: 50%;"><input type="checkbox"/> Others (specify)</div> </div> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                     |