

Study on Medication Management Process

By

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*Dissertation submitted for the partial fulfillment of the
MBA Hospital and Health Management*

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TO WHOMSOEVER MAY CONCERN

This is to certify that **Gunjan Gulia** student of MBA Hospital and Health Management from The IIHMR University, Jaipur has undergone internship training at Rockland Hospitals, Dwarka, New Delhi, from February 1st 2016 to April 26th 2016.

The Candidate has successfully carried out the study designated to her during internship training and her approach to the study has been sincere, scientific and analytical.

The Internship is in fulfillment of the course requirements.

I wish her all success in all future endeavors.

Dr. Ashok Kaushik
Dean, Academics and Student Affairs
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Dr. Tanjul Saxena
Associate Professor
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TO WHOM SO EVER IT MAY CONCERN

This is to certify that Ms Gunjan Gulia, student of The IIHMR University, Jaipur has successfully completed internship & dissertation, which is a part of her course curriculum in M.B.A. (Hospital & Health Management) program, from February 01, 2016 to April 26, 2016 at **Rockland Hospital, Dwarka**. During this period, she has worked in HR department and was mentored by Ms Rashma Nathani (Unit Head – HR) and Dr. P.K. Baliar Singh (Medical Advisor). She has successfully completed her dissertation study on the topic 'Medication Management Process' in the Hospital apart from being involved in all aspects of hospital operations. She has shown keen interest in understanding the functioning of the department and has successfully completed her training with the Hospital.

We wish her good luck for her future assignments.

For Rockland Hospital, Dwarka



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CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled Medication Management Process
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the supervision of Dr. Tanjul Saxena for award
of Postgraduate Diploma in Hospital and Health/ Pharmaceutical / Rural Management of the
University carried out during the period from 01 Feb, 2016 to
26 April, 2016 embodies my original work and has not formed the basis for the
award of any degree, diploma associate ship, fellowship, titles in this or any other Institute or
other similar institution of higher learning.



Signature

ACKNOWLEDGEMENT

I take this opportunity to express my profound sense of gratitude and indebtedness to all those who helped me throughout the duration of the project.

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ACCRONYMS/ABBREVIATIONS

ADE-Adverse Drug Event AMS-Assistant Medical Superintendent CT- Computed Tomography CMO- Chief Medical Officer CPOE-Computerized physician order entry system COW- Computer on wheels CQI-Continuous Quality Improvement CSSD-Central sterile & supply department	MAE-Medication Administration Error MAR-Medicine Administration Record ME- Medication Error MO- Medical Officer MLC-Medico Legal Cases MTP-Medical termination of pregnancy NCR-National capital Region NABH-National Accreditation Board for Hospitals and Healthcare
EMR- Electronic Medical Record FMEA- Failure Mode Effect Analysis FIFO- First In First Out FM- Failure Mode	OPD- Out Patient Department OT-Operation Theatre
HIS- Hospital Information System HOD- Head of Department	RCA- Root Cause Analysis RHL-Rockland Hospital Limited RMO- Resident Medical Officer RPN- Risk Priority Number
IPD- Inpatient Department IV-Intravenous JR-Junior Resident	UHID No.- Unique Hospital Identification Number

INTRODUCTION-

The reality that medical treatment can harm patients is one that the healthcare community has come to terms with over recent years . Medications are involved in 80 percent of all treatments and impact every aspect of a patient's life. In particular, adverse events associated with medication appear among the chief causes of this. Prescribing and drug administration appear to be associated with the greatest number of medication errors (MEs), whether harm is caused or not . Recent systematic reviews of medication administration error (MAE) prevalence in healthcare settings found that they were common, with one reporting an estimated median of 19.1 % of 'total opportunities for error' in hospitals . A significant proportion of MAEs are associated with actual or potentially harmful effects

MEDICATION ERROR- The Council defines a "medication error" as follows: "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 health care professional, patient, or consumer.

Types of Medication Error

Prescription Errors- The error that originates from written medication orders. It includes the following:

- ✓ No routes specified
- ✓ As needed order without an indication
- ✓ Drug is indicated but the dose is inappropriate
- ✓ As needed order without a time interval
- ✓ Dose change ordered without discontinuation of previous order
- ✓ Order is illegible
- ✓ Order is incomplete without specifying doses or frequency

Administration Errors- An error originating during the process directly associated with the medication administration at the nursing unit. It includes the following:

- ✓ Scheduled dose is not documented as administered.
- ✓ Drug is administered without a physician order
- ✓ Dose missed because of late transcription.
- ✓ Order is incorrectly entered in the pharmacy computer

Transcription Errors- The errors which originate during transcription of original physician's order into Medicine Administration Record by the MO/JR. It includes-

- ✓ Order not transcribed at all.
- ✓ Order transcribed incorrectly.
- ✓ Allergy not documented
- ✓ Medicine stop date and site not mentioned.
- ✓ The current medications are not mentioned(to be continued or not) in the Medical administration record

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

- ✓ Wrong drug or dilution dispensed
- ✓ Wrong preparation dispensed

Monitoring Errors- An error originating from lack of necessary monitoring or interpretation/appropriate action for selected drugs(e.g. Drug level monitoring for certain antibiotics, anticoagulants, anticonvulsants etc.

The Intercepted errors (the error which has not reached the patient) are documented by preserving a copy of the indent. The actual errors or an "error of omission", which does reach the patient in spite of auditing, are reported on a proper format called quality variance report. There are many factors that are associated with drug errors including inadequate knowledge and skills, failure to comply with policies, and failure in communication. The safest work environment address these issues by designing systems to prevent errors, make errors visible, and mitigate the effects of errors.

REVIEW OF LITERATURE-

Research estimates up to 440,000 Americans are dying annually from preventable hospital errors. This puts medical errors as the third leading cause of death in the United States, underscoring the need for patients to protect themselves and their families from harm, and for hospitals to make patient safety a priority. A medication error was defined in general as a dose administered differently than as ordered on the patient's medical record. Such medication errors were viewed as system defects (ie, outcomes different from those the system was designed to deliver and administer to the patients). Prescription medication use is widespread, complex, and increasingly risky. Clinicians have access to an armamentarium of more than 10,000 prescription medications, and nearly one-third of adults in the United States take five or more medications. Advances in clinical therapeutics have undoubtedly resulted in major improvements in health for patients with many diseases, but these benefits have also been accompanied by increased risks. An adverse drug event (ADE) is defined as harm experienced by a patient as a result of exposure to a medication, and ADEs account for nearly 700,000 emergency department visits and 100,000 hospitalizations each year. ADEs affect

nearly 5% of hospitalized patients, making them one of the most common types of inpatient errors; ambulatory patients may experience ADEs at even higher rates. Transitions in care are also a well-documented source of preventable harm related to medications.

As with the more general term adverse event, the occurrence of an ADE does not necessarily indicate an error or poor quality care. A *medication error* refers to an error (of commission or omission) at any step along the pathway that begins when a clinician prescribes a medication and ends when the patient actually receives the medication. *Preventable adverse drug events* result from a medication error that reaches the patient and causes any degree of harm. It is generally estimated that about half of ADEs are preventable. Medication errors that do not cause any harm—either because they are intercepted before reaching the patient, or by luck—are often called *potential ADEs*. An *ameliorable ADE* is one in which the patient experienced harm from a medication that, while not completely preventable, could have been mitigated. Finally, a certain percentage of patients will experience ADEs even when medications are prescribed and administered appropriately; these are considered *adverse drug reactions* or *non-preventable ADEs* (and are popularly known as *side effects*). Categories of medication errors were defined as follows.

1. Unauthorized drug: the administration of a dose of medication that had never been ordered for that patient.
2. Extra dose: any dose given in excess of the total number of times ordered by the physician.
3. Wrong dose: any dose of preformed dosage units (such as tablets) that contained the wrong strength or number
4. Omission: failure to give an ordered dose
5. Wrong route: medication administered to a patient using a different route than ordered (eg, oral administration of a drug ordered intramuscularly)
6. Wrong form: the administration of a dose in a different form than ordered by the physician.
7. Wrong technique: exclusion, or incorrect performance, of a procedure ordered by the prescriber immediately before administration of each dose of medication.
8. Wrong time: administration of a dose more than 60 minutes before or after the scheduled administration

RESEARCH QUESTION

How to improve patient safety by reviewing medication management process of the hospital by eliminating failure modes from the process?

AIM

To assess various risk points existing in the medication management process of the hospital and to assess the cause and effect of failure modes.

OBJECTIVES

To review the medication management process through process mapping.

To identify the various failure modes in the process with their severity and frequency.

To analyze the causes and effects of various failure modes.

To propose recommendations to eliminate the failures from the process in order to minimize medication errors.

METHODOLOGY-

TYPE OF STUDY- Observation analytical study

STUDY LOCATION- Rockland Hospital, Dwarka

SOURCE OF DATA COLLECTION

Primary Data- Direct observation of prescriptions and interaction with nurses.

Secondary Data- Previous patient records

STUDY SAMPLE- IPD January,2016-643

IPD Feb,2016- 683

IPD March,2016- 651

Total study population 1977

$$\text{Sample Size} = \frac{Z^2 * (p) * (1-p)}{c^2}$$

Where:

Z = Z value (e.g. 1.96 for 95% confidence level)

p = percentage picking a choice, expressed as decimal

(.5 used for sample size needed)

c = confidence interval, expressed as decimal

(e.g., .05)

$$= \frac{(1.96)^2 * (.196) * (.804)}{.0025}$$

=242(approx)

Adding 10% non reporting's/errors

Sample size =266

STUDY DURATION- THREE MONTHS

STUDY TOOL- FMEA(Failure Mode Effect Analysis)

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. FMEA includes review of the following:

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

It seeks to improve patient safety by minimizing risk potential in high risk processes

By failure of a process, we refer to any malfunction, error, or defect that results in a process not performing as intended or not meeting desired requirements or standards. By failure mode we refer to anything that could go wrong during the completion of a step in a process. Causes of failure include all possible mechanisms or means that result in the failure mode, and the effects of a failure typically include the customers experience that results from the failure mode.

FMEA is used to evaluate processes for possible failures and to prevent them by correcting the processes proactively rather than reacting to adverse events after failures have occurred. This emphasis on prevention may reduce risk of harm to both patients and staff. FMEA is particularly useful in evaluating a new process prior to implementation and in assessing the impact of a proposed change to an existing process.

Types of FMEA

1. System FMEA- Used to analyze complete systems and/or sub systems during the concept of design stage
2. Design FMEA- Used to analyze a product design before it is released to manufacturing
3. Process FMEA- Used to analyze manufacturing and/or assembly process.

Process FMEA is probably the most commonly used .It is a prospective and systematic approach to identify and understand contributing factors, causes, and effects of potential failures on a process, system, or practice..FMEA has been successfully applied in the healthcare setting to improve the safety of drug administration and blood transfusion.

Steps of FMEA

- Develop a process map
 - Track process from beginning to end
 - A process flow diagram is a helpful tool
- Risk Analysis
 - Identify what “could” go wrong at each of the process steps on the flow chart
 - Identify “why it might happen”—causes of those failures
 - Identify the” effects” of each potential failure.
 - Identify any “check/controls” that increase likelihood of detection.
- Risk Analysis
 - Three factors: Severity, Probability of Occurrence, and Detection Capability.
 - The “**Severity**” is the consequence of the failure should it occur.
 - The “**probability of occurrence**” is the likelihood of a failure mode occurring.
 - The “**Detection rating**” is the ability to catch the error before causing patient harm.
- Prioritize failure modes by estimating
 - Probability of each failure occurring
 - Severity of effects of each failure
 - Probability of each failure being detected.
- Calculate Risk Priority Number(RPN) for each failure mode

$$\text{RPN}=\text{O}*\text{S}*\text{D}$$

Where:

O=frequency of occurrence ranking score

S= severity of effects ranking score

D=Probability of detection rating score

- Assign priority ranking for each failure mode in decreasing order of RPN
 - Also may want to assign priority to those with high severity scores even though RPN is low
- Identify root causes of potential failure modes
 - Critical to identify all root causes

- Develop & Implement an Action Plan
- Identify Strategies for Improvement
- Implement Strategies for Improvement
- Monitor, Sustain, Share & Re-evaluate'

Hospital Policy for medication administration

POLICY

Medications shall be administered only by qualified nurse or a doctor. Self administration of medicines is not allowed in the hospital.

PURPOSE

Medication administration is required to avoid the medication errors in the Hospital.

SCOPE

This policy applies to the pharmacy and nursing department of the Hospital.

RESPONSIBILITY

It is the responsibility of Pharmacy Department.

DISTRIBUTION

Pharmacy and Wards

PROCEDURE

- All medicine requirement of Inpatients shall be fulfilled through hospital pharmacy store. Outside medicine if required shall be purchased by the patient/relatives under the advise of concerned physician.

-Prepared medication shall be labeled prior to preparation of second drug. The label shall include patient identification detail, drug name, dose and frequency of administration.

-Following parameters shall be verified before administration of the drugs by the person administering the drug

- Written medication order(For Verbal orders refer verbal medication orders policy)
- General appearance(Physical Incompatibility) of the medicine for administration
- Dosage of medication
- Route of administration

- Time of administration

-The documentation of medication administration shall be done by person administering the drugs in medication administration sheet. Confirm the administration before documenting. All fields of medication administration sheet should be appropriately filled.

-For the administration of high risk medications follow the document of high risk medication.

-At the time of administration, nurse shall note down the following patient details-

- ✓ Allergies to particular food or medicine(Allergies must be highlighted by red ink in medication administration sheet)
- ✓ Type of Reaction
- ✓ Previous hospitalization history
- ✓ Current medication(s) with its name, dosage, frequency and time of last dose in Nursing Admission Assessment sheet.

Adverse drug Reaction

Adverse Drug Reaction is a part of adverse healthcare event. An adverse drug reaction is any noxious, unintended, undesirable or unexpected response to a drug that occurs at doses used in human for prophylaxis, diagnosis or therapy, excluding therapeutic failure(Suspected adverse drug reaction form should be filled in case of adverse drug reaction)

Act of Commission

E.g. Prescribing a medication that has a potentially fatal interaction with another drug the patient is taking

Act of Omission

Eg. Failing to prescribe a medication from which the patient would likely have benefitted.

Sentinel Adverse events

These events should be immediately reported to AMS/VP Operations/MS. These include:

Care Management Events

Patient Death or severe Disability:

- ✓ Associated with a medication error
- ✓ An individual fall that results in death or major permanent loss of function as a result of direct injuries sustained in the fall.

Environmental Events

Patient death or serious disability associated with-

- ✓ An electric shock

- ✓ A burn incurred while being cared for in the facility
- ✓ A fall while being cared for in the facility
- ✓ The use of or lack of restraint bedrails while being cared for in a facility
- ✓ An incident in which a line for oxygen or other gas to be delivered to patient contains has wrong gas or is contaminated by toxic substances.

Criminal Events

- ✓ Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist or other healthcare staff
- ✓ Abduction of any patient of any age.
- ✓ Sexual Assault on any patient within or on the grounds of facility
- ✓ Death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of facility
- ✓ Rape

List of other incidents, Events and Near Miss

Non Clinical:

- Chemical Spillage
- Equipment failure(critical equipment failure in OT,ICU or in inpatient area)
- Fire
- Security Incident
- Sharps incident
- Needle stick injuries
- Slip/trip/fall
- Theft

Clinical:

- Medication Errors
 - Wrong Dose
 - Wrong Drug
 - Wrong infusion rate
 - Extra Dose
 - Over Dose
 - Missed Dose
 - IV infiltration
 - Wrong patient
- Any other kind of Patient Identification problems
- Radiological errors
 - Wrong radiological investigation been carried out
 - Wrong amount of exposure to X-rays been used
 - Wrong Patient
 - Overdose of X-rays been used to carry out an investigation.

- Wrong or missing documents(eg. Notes) with direct consequences of care.
- Prescribing errors
 - Dose
 - Drug
 - Route
 - Patient

Adverse drug Reporting- Adverse event will be reported by the Rockland Hospital Staff as and when the adverse events occur in there area of work or department.

What is Reportable Adverse Drug Reaction(ADE)?

-Adverse Drug Event includes all medication errors and adverse drug reactions

-A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm

-A reportable adverse drug reaction (ADR) is an unintended drug reaction that:

- ✓ Prolongs hospital stay
- ✓ Results in admission or an emergency department visit
- ✓ Causes the postponement or cancellation of surgery
- ✓ Is unlabeled or rarely seen
- ✓ Results in death or permanent disability
- ✓ Is potentially life threatening

Procedures and Responsibilities

1. Identifying an ADE

- The staffs who suspect an ADE should notify prescriber and resident doctor immediately
- Assess the patient
- Implement adjustments in patient's treatment as ordered.
- Document the description of the ADE in incident form ,categorize subsequently and monitor in the progress record

2. Reporting an ADE

- Staff completes the incident reporting for immediately or not later than 24 hours of the ADE identification
- Forms are sent, confidentially to the Director Quality in hard copy
- Security of Information: No copies are made of the incident forms.
- Reports to include:
 - ✓ Describe the error or preventable adverse drug reaction. What went wrong?
 - ✓ Was this an actual medication accident or are you expressing concern about a potential error or writing about an error that was discovered before it reached the patient?

- ✓ Patient outcome
- ✓ Where in hospital did this occur?
- ✓ Generic name of all products involved
- ✓ Brand name of all products involved
- ✓ Dosage form, concentration or strength etc
- ✓ Where error was based on communication problem, is a sample of the order available? Are samples or pictures available if requested?
- ✓ Please state your recommendations for error prevention
- ✓ Please include the name and contact info of reported

3. Reviewing ADE'S

- Supervisor/manager completes timely evaluation of the circumstances surrounding the event
- Root cause Analysis
- In the case of significant ADE's or medication related sentinel events, reviewers inform department director or manager, as well as compliance with sentinel event policy
- ADE reports are categorized by: location, severity, product information and therapeutic classification ,type, causes and contributing factors.
- ADR's are further evaluated to determine:
 - ✓ Appropriateness of medication for patient's condition
 - ✓ Any contradictions to medication
 - ✓ Appropriate documentation of Allergies
 - ✓ Appropriate management and monitoring of ADR

Levels of Adverse Drug Events:

Level 1-ADE occurred but required no change in treatment with suspected drug.
Level 2- Drug held, discontinued or changed but no antidote or additional treatment needed.
Level 3-Drug held, discontinued or changed and/or antidote or other treatment required
Level 4-ADE required patient transfer to an intensive care setting.
Level 5-ADE caused permanent to the patient 4.
Level 6- ADE either directly or indirectly led to patient's death.

Drug and Therapeutic committee

Purpose: To formulate and review policies regarding the selection, regulation compliance, distribution, storage, safe use, and administration of drugs

Members:

Unit Director- Chairperson

HOD(Orthopedic)- Member

HOD(Gastroenterology)- Member

HOD(Microbiology)- Member

HOD(Pulmonology & critical care)-Member

Surgeon-Member

Nursing Superintendent-Member

GM(Paul Pharmacy)- Co-opted Member

HOD- Medicine-Member Secretary

HOD(General and Laparoscopic)-Member

AMS-Member

Frequency- Half Yearly

Objectives-

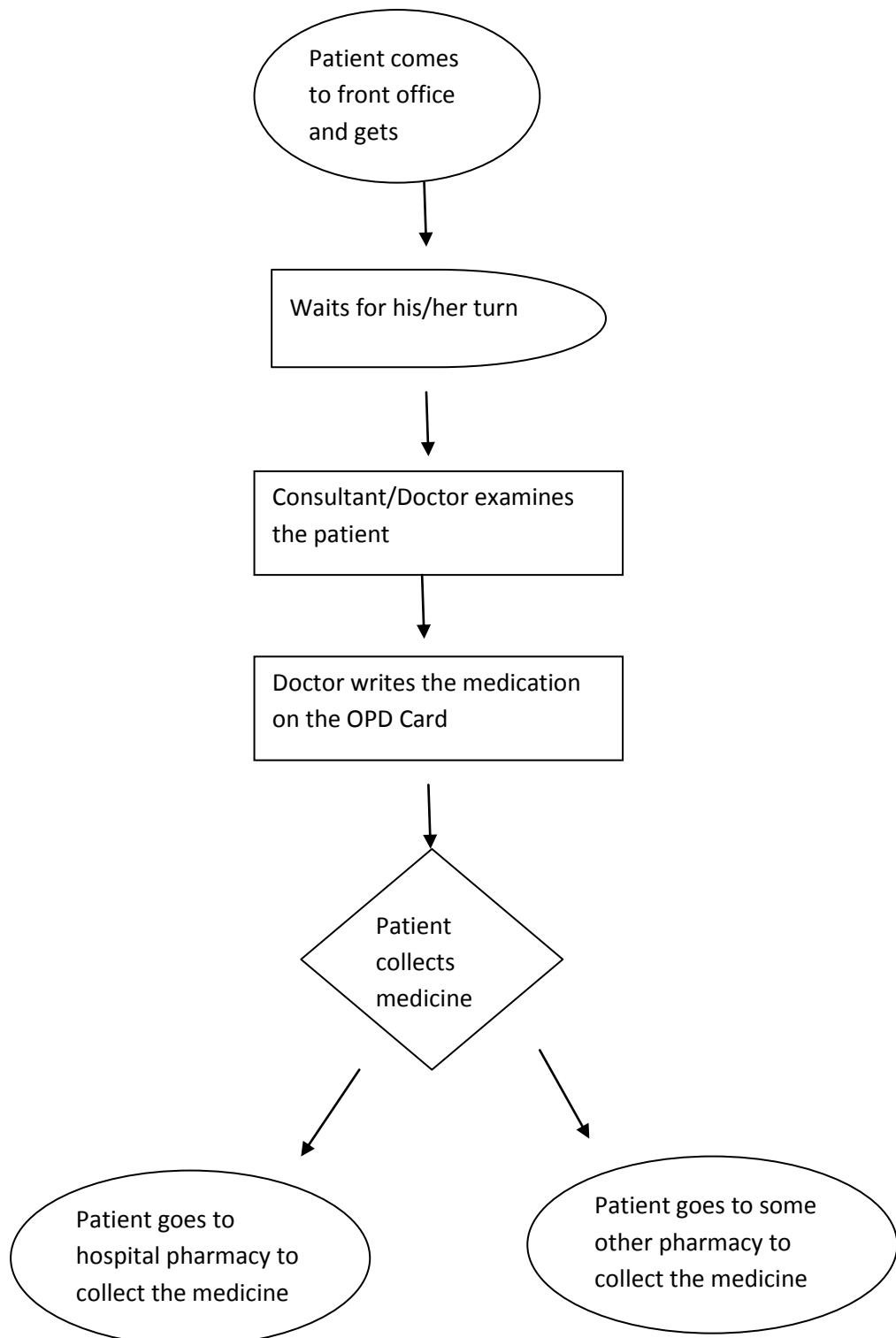
- ✓ To suggest the brand names to be used
- ✓ To enlist various companies & the drugs that may be prescribed to the patient keeping in view the Quality of product.
- ✓ To issue guidelines to Doctors and Nurses regarding needs of testing particular drugs on the patient before administration
- ✓ To implement the process of labeling on the files of patients who are allergic to particular drugs.
- ✓ To shortlist and motivate the companies whose products are commonly used is Rockland Hospital for participation in charitable activities of the hospital and sponsoring the Academic Conferences for the Doctors.
- ✓ To develop a mechanism at nursing level on the uses of the drugs which are prescribed so that the menace of substitution at chemist level can be eliminated.
- ✓ To visit the chemist shop for checking if any substandard drugs are being stored there.
- ✓ To circulate the hospital formulary to all the doctors working in the hospital.
- ✓ Monitoring of Adverse drug incident and ensuring that expiry drugs are not given to patients

Policy on verbal or Telephonic drug orders

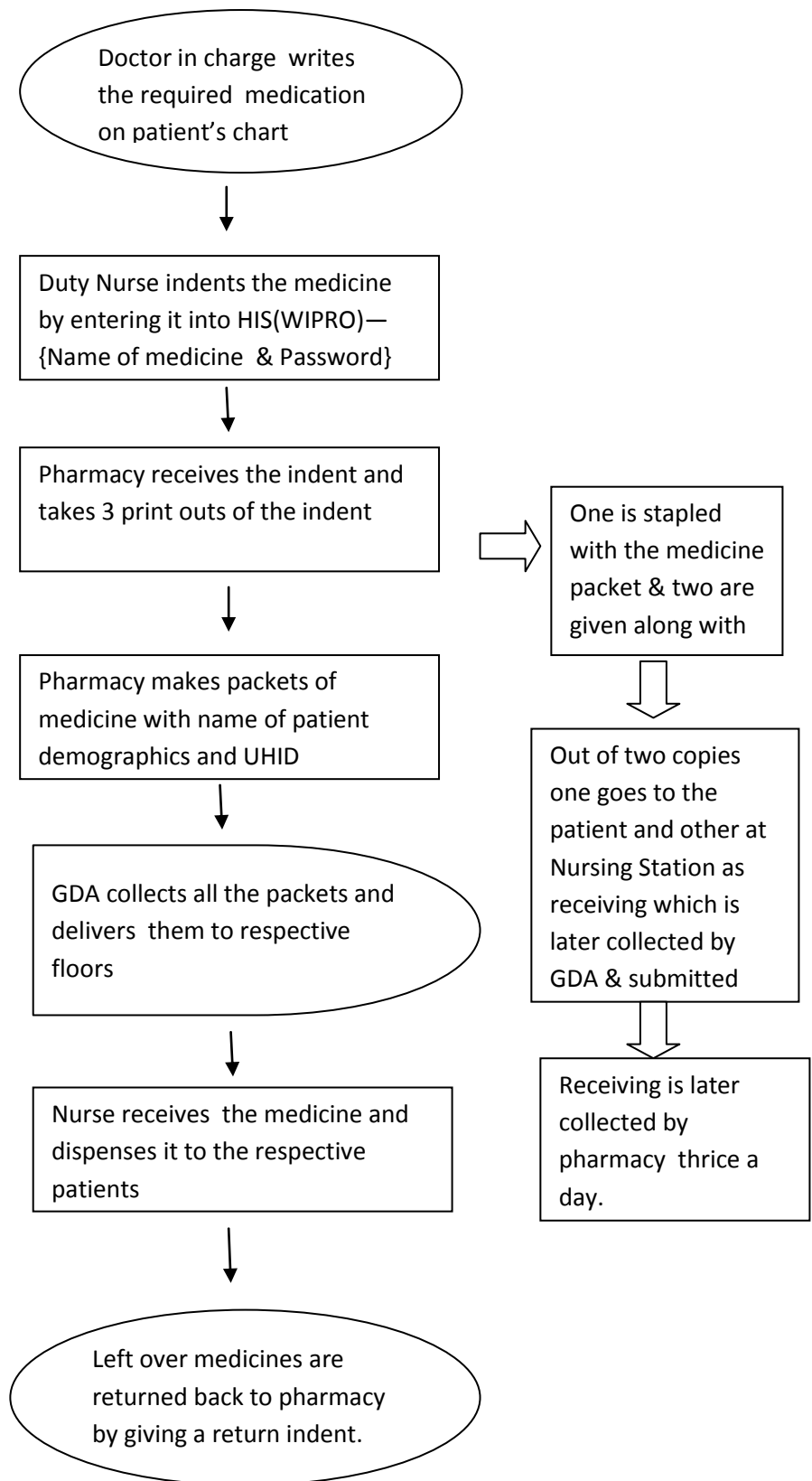
Verbal orders are not taken/considered as an option for primary treatment of patient. Verbal orders were only be taken as secondary protocol, in case the treating consultant is not available, which is to be documented in the patient's file by the RMO/CMO on duty. Further the verbal orders are to be verified by the treating consultant within 24 hrs.

Step 1-(Process Mapping)

OPD Process



IPD Process



Step 2-(Potential Failure Points)

FM 1- Incomplete prescription in terms of dose/route/frequency

FM 2- Allergies of the patient are not known/not mentioned

FM 3- Medicine is transcribed wrongly in the MAR

FM 4- The medicine is copied wrongly in HIS and indented wrongly

FM 5- Wrong medicine/dose/form is dispensed by pharmacy

FM 6- Medicines are not cross checked against the indented order

FM 7- Administration time was not proper

FM 8- After administration of medicine nurse did not sign the record.

FM 9- The new/changed medicine are not added after the physician's round and the stopped drugs are not signed.

FM 10- Delay in indenting the medicine from IPD/dispensing of medicines from pharmacy.

FM 11- The drugs are not returned back to the pharmacy.

Step 3-(Severity Rating)-(Source: NABH CQI Workshop)

Rating	Criteria/Risk	Description(Severity of Failure)
10	Dangerously High	Failure could cause terminal injury or death of patient
9	Extremely High	Failure involves regulatory non compliance and could cause long term disability
8	Very High	Failure causes patients health to be seriously affected & patient has to return for major correction.
7	High	Failure seriously affects patients health leading to high patient dissatisfaction
6	Moderate	Failure causes disruption of daily activities of patient leading to dissatisfaction
5	Low	Inconvenience to patient and provider with failure of being detected
4	Very Low	Inconvenience at subsequent functions: minor rework. Failure detected and corrected at subsequent steps of the process

3	Minor	Slight inconvenience at next function; minor rework. Failure detected and corrected at next step of the process
2	Very Minor	Slight inconvenience at delivery: minor rework. Failure detected & corrected at delivery
1	None	No noticeable effects

The severity scale used can range from a slight annoyance within the system which may rank as 1, to terminal injury or death which would rank as 10.

Step 4-(Frequency Rating/Occurrence) (Source: NABH CQI Workshop)

Rating	Criteria/Risk	Description(Probability of failure)
10	Dangerously High	Failure is almost inevitable. More than one occurrence per day
9	Extremely High	One occurrence every 3-4 days
8	Very High	High: One occurrence per week
7	High	One occurrence every month
6	Moderate	Moderate: Occasional failures, one occurrence every three months
5	Low	One occurrence every six months to one year
4	Very Low	One occurrence per year
3	Minor	Low: Relatively low failures, one occurrence every 1-3 years
2	Very Minor	One occurrence every 3-5 years
1	None	Remote: Failure is unlikely, one occurrence greater than 5 years

The frequency scale addresses the likelihood and probability of the failure mode's occurrence. The likelihood should range from remote/none with a score of 1 to dangerously high with a score of 10.

Step-5(Detection Rating) (Source: NABH CQI Workshop)

Rating	Criteria/Risk	Description(Detection of Failure)
10	Absolute Uncertainty	Controls will not or cannot detect the existence of a failure. No known controls available to detect the failure mode.
9	Very Remote	Controls probably will not detect the existence of failure mode. Controls achieved with indirect or random checks only
8	Remote	Controls have a poor chance of detecting the existence of failure modes
7	Very Low	Controls have a low chance of detecting the existence of failure
6	Low	Controls may detect the failure
5	Moderate	Controls may detect the existence of a failure mode. Error likely to be detected after service delivery.
4	Moderately High	Controls have a good chance of detecting failure mode. Error detection at service delivery
3	High	Controls have a very good chance of detecting failure mode; error detection at subsequent steps
2	Very High	Current controls almost certain to detect the failure mode. Process automatically detects failure mode
1	Almost Certain	Current controls almost certain to detect the failure mode. Reliable detection controls are known with similar processes. Process automatically prevents further processing.

Detection rating estimates how well the controls can detect either the cause or its failure mode after they have happened but before the customer is affected. Detection is usually rated on a scale from 1 to 10, where 1 means the control is absolutely certain to detect the problem and 10 means the control is certain not to detect the problem(or no control exists)

FMEA Matrix

(ROCKLAND HOSPITAL,DWARKA)

S.No	Processes	Failure Modes (FM)	Causes	Occurrence (O)	Effects	Severity (S)	Current Control	Detection (D)	RPN= S*O*D
1	Prescription of Drugs	Incomplete prescription in terms of dose/route/frequency	Rush of patients, Illegible handwriting of doctors.	8	Wrong dosage, wrong route of administration	5	Audit of Prescriptions	5	200
2	Allergies of the patient are identified	Allergies of the patient are not known/not mentioned	Miscommunication b/w RMO & nursing staff. Negligence to put allergy sticker, Distraction	9	Wrong(allergic)drug is given to the patient	7	Allergy sticker is put on patient file/highlighted	3	189
3	RMO enters the drug name on treatment sheet	Medicine is transcribed wrongly in the MAR	Illegible handwriting, Miscommunication, Negligence, Unclear Prescription, Look alike drugs	6	Wrong drug requisition, wrong dose, wrong drug	9	Treatment sheet	4	216
4	Nurse indents the medicine through HIS	The medicine is copied wrongly in HIS and indented wrongly	Illegible handwriting, Miscommunication, Negligence, Unclear Prescription, Look alike drugs	6	Wrong drug requisition, wrong dose, wrong drug	9	HIS	5	270
5	Drugs are dispensed by pharmacy	Wrong medicine/dose/form is dispensed by pharmacy	The drug indented with other dosage form is dispensed & information not conveyed, Incomplete	8	Wrong dose is dispensed	7	Treatment sheet,HIS, Cross checking of order	4	224

			dispense of indent						
6	Drugs are verified by the nursing staff on receiving from pharmacy	Medicines are not cross checked against the indented order	Mental slip, Negligence, Non adherent to policies & procedures	7	Wrong drug is given to the patient	9	Treatment sheet, HIS	4	252
7	Nursing staff signs the treatment sheet with the time against the drug name after administration	Administration time was not proper	Not indenting on time, not available on time, time, incomplete prescription, Miscommunication b/w shifts	8	Delay in drug administration	5	Time of drug administration on treatment sheet	5	200
8	Nursing staff signs the treatment sheet with the time against the drug name after administration	After administration of medicine nurse did not sign the record	Mental slip, Negligence, Non adherent to policies & procedures	9	Re-administration /missed drug administration	5	Treatment sheet	3	135
9	After the consultants round treatment sheet is promptly updated by the RMO	The new/changed medicine are not added after the physician,s round and the stopped drugs are not signed	Miscommunication, Negligence	5	Missed drug administration	6	-	6	180
10	Pharmacy makes packets of received indent and sends them to respective floors	Delay in indenting the medicine from IPD/dispensing of medicines from pharmacy.	Negligence, Non availability of Housekeeping staff to deliver the medicines	10	Delay in drug administration	6	-	1	60
11	The drugs not used are returned back to pharmacy	The drugs are not returned back to the pharmacy.	Mental slip, Negligence	7	Overstocking of medicines on patients bedside, patient may take two or more dose of same medicine	2	-	5	170

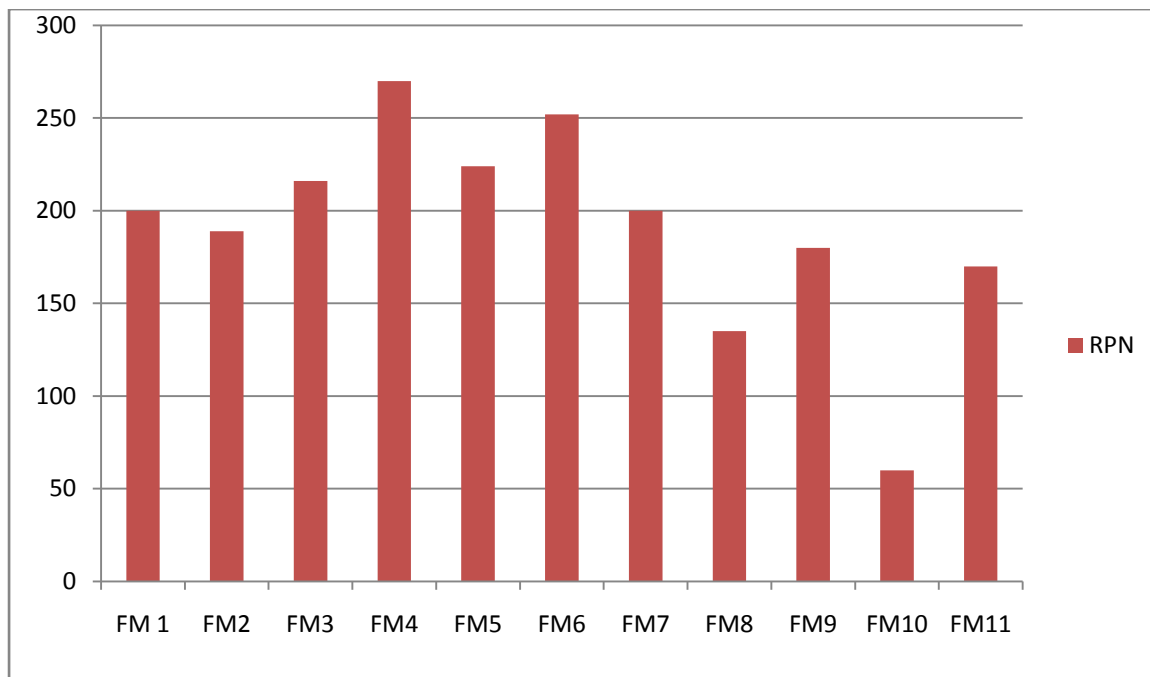


Fig 1: Graph showing RPN for the failure modes

The graph above shows the major four failure modes based on the Risk Priority Number which are as follows:

- FM 4- **The medicine is copied wrongly in HIS and indented wrongly.**(RPN=270)
- FM 6- **Medicines are not cross checked against the indented order**(RPN=250)
- FM 5- **Wrong medicine/dose/form is dispensed by pharmacy**(RPN=224)
- FM 3- **Medicine is transcribed wrongly in the MAR.**(RPN=216)

❖ *From the above matrix we can conclude that most common causes of Failure are:*

- Illegible Handwriting- It includes use of incorrect abbreviations, confusion between drugs with similar names, misuse of zeroes & decimal points and unclear prescriptions.
- Delay in dispensing of order from pharmacy
- Improper/Incomplete order is dispensed from pharmacy
- Miss communication of drug orders.
- Cross checking of order was not done by the nurse
- Nurse did not sign the patient sheet after dispensing the medication.
- Medication was not administered on proper time.
- Non adherent to policies and procedures
- Negligence (Performance deficit, knowledge deficit, mental slip)

%age Distribution of Medication Errors

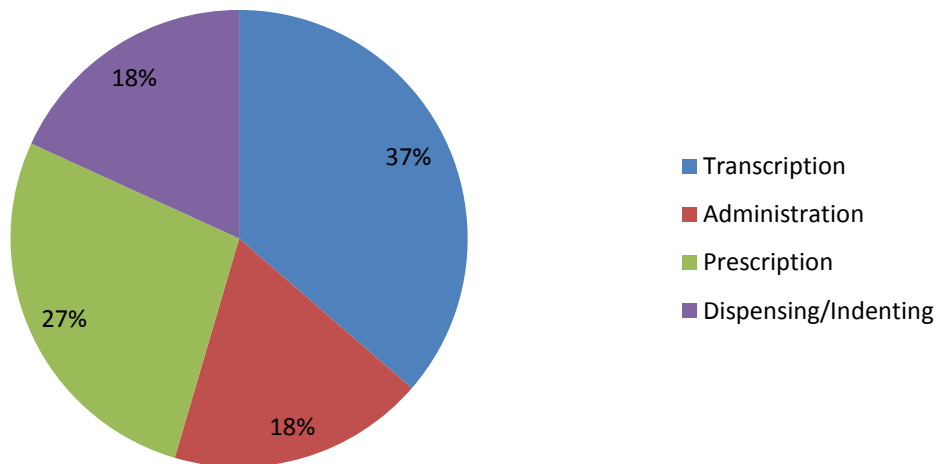
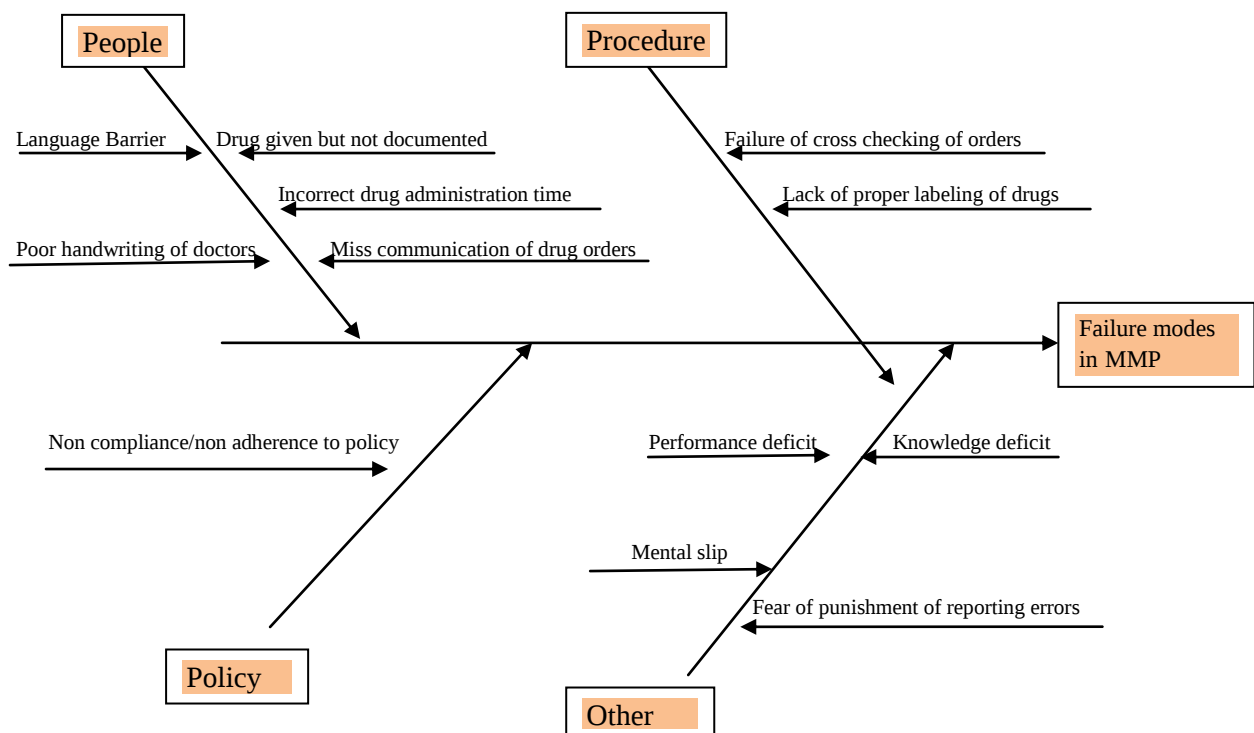


Fig 2: Distribution of Medication errors

The above graph indicates the percentage distribution of medication errors according to which the maximum percentage was found to be of transcription errors(37%) followed by Prescription errors(27%) indicating the need to identify the cause and effect of their occurrence.

Cause effect diagram of failure modes in MMP:



CONCLUSION:

- There are number of factors at each step of patient care that contribute to medication errors
- Special focus should be given to the prescription & transcriptase phases of patient care due to large number of errors tracked back to these stages of treatment
- Policies & Procedures are in place, just adherence to them is required. Training & motivation is the need of hour, should be ascribed priority and promptly addressed.
- FMEA is a continuous process and should be improved in phases
- The recommended actions are to be taken along with defined responsibilities.

RECOMMENDATIONS:

1. CPOE(Computerized physician order entry system)-

Computerized physician order entry (CPOE) is the process of a medical professional entering medication orders or other physician instructions electronically instead of on paper charts. A primary benefit of **CPOE** is that it can help reduce errors related to poor handwriting or transcription of medication orders. In theory, CPOE offers numerous advantages over traditional paper-based order-writing systems. Examples of these advantages include averting problems with handwriting, similar drug names, drug interactions, and specification errors; integration with electronic medical records, decision support systems, and adverse drug event reporting systems; faster transmission to the pharmacy; and potential economic savings.

These proposed benefits have been empirically confirmed to some extent, and recent studies have added to the evidence base supporting CPOE. CPOE appears to be quite effective at preventing prescribing errors. A meta-analysis found that the likelihood of a prescribing error was reduced by 48% when using CPOE compared with paper-based orders, which translates into more than 17 million medication errors prevented yearly in the United States. However, the effect of CPOE on clinical adverse drug event rates is less clear. Other reviews found that CPOE did not reliably prevent patient harm, and high rates of adverse drug events persist in some hospitals with entirely computerized order entry systems. One interpretation of these results is that decision support is the key intervention in reducing errors, and that CPOE by itself may prevent only clinically inconsequential errors.

Advantages-

- Direct entry of orders into EMR
- Replaces handwritten orders
- Cross reference for potential drug-interactions or allergies
- Reduces wait times for patients
- Improves compliance with best practices
- Ready access to patient data
- Improves patient safety
- Potential to improve efficiency
- Cost saving benefits by:
 - Reducing number of duplicate tests
 - Reducing errors

Disadvantages-

- Cost
- User resistance
- Personalization for individual hospitals
- Potential for integration issues with other systems
- Disruption of workflow with employee training

2. COW(Computer on wheels)-

Placing computing power at the point of care is a major thrust in the move toward greater adoption of healthcare information technology COWs' purported benefits of mobility, usability, and processor speed have enabled the job to be more efficient be it entering patient data, gaining access to patients' electronic medical records, reviewing lab results or radiology reports, checking drug compatibility, or other "charting" tasks.

As a result, most paper documentation has been eliminated, and tracking down the right chart often was time-consuming – even if they were supposed to be in *specific* storage

location. Time savings, work efficiency, improved care, and the ability to create a more accurate patient record are the main benefits of being able to pull information from multiple sources without digging through paper records, especially because the information is presented in a logical fashion.

Advantages-

- Spend more time with patients- Nurses select nursing as a profession because they are passionate about providing care for patients.
- Deliver better care-The highest satisfaction comes from direct time and care at the bedside, and patients feel the highest level of comfort and care when the nurse is with them.
- Improve data accuracy and patient safety.
- Connect with patients and to patient information at the bedside

Disadvantages-

- Cost
- User resistance
- Personalization for individual hospitals
- Bulky for small hospitals
- Raises safety issues
- Battery must be charged constantly
- Potential for integration issues with other systems
- Disruption of workflow with employee training

3. Policy for written orders-

Hospital has a written policy for medication management which has to be duly followed by the doctors and nurses. Prescriptions of doctors has to complete in all aspects. Physicians must include the following information on a prescription in neat and legible handwriting:

- ✓ Name of patient-
- ✓ Name of the drug, drug strength and quantity or duration of therapy
- ✓ Full instructions for use of the drug
- ✓ Full date (day, month and year)
- ✓ Allergy details with allergy alert label
- ✓ Avoid abbreviations
- ✓ Refill instructions, if any;

- ✓ Printed name and signature of prescriber
- ✓ Any additional information if required

4. Labeling of drugs-

All drugs must be properly labelled while dispensing from the pharmacy including the name, date of manufacturing and expiry date of drug. If the drug with same name and different dosage levels is dispensed at the same time then the information should be conveyed to the nursing station in written. Breakdown in communication system is a common cause of harm to patients and these needs are to be addressed at different levels.

5. Training & Motivation-

- ✓ Fostering motivation among staff by ensuring open & non punitive environment for
- ✓ reporting medication errors
- ✓ Organising training sessions regarding the existing medication safety policies for RMO's evidence based practices.
- ✓ Addressing the language barriers among the nursing staff.
- ✓ Vigorous training sessions for the nursing staff with strict follow up. Also a proficiency test could be conducted bimonthly or quarterly to assess the knowledge of the staff regarding the policies and procedures. This would help to evaluate the deficient areas and formulate further action plans
- ✓ Rewarding system(scoring or giving points) for those who report errors.
- ✓ RCA(Root cause analysis) of all the errors should be done to select the most reasonable cause from the myriad of competing causes. It is generally accepted that adverse events have causes and that a careful analysis of the actions of persons and the states of the system in which the event occurred will reveal the causal agents.

6. Adherence to policies & procedures-

To ensure proper medication administration the health care worker must adhere to the five rights of medication administration:

- the right patient
- the right drug
- the right dose
- the right route
- the right time

References-

- Prevalence & nature of medication administration error in health care setting: a systems review of direct observation evidence, Keers RN, Williams SD, Cooke J, Ashcroft DM *Ann Pharmacother* 2013 Feb;42(2):237-56
- Agency for Healthcare Research and Quality –Patient safety Network.
- Interactive Workshop on CQI: Tools & Techniques(National Accreditation Board for Hospitals and Healthcare providers - Course notes
- Institute of Medicine, *To Err Is Human: Building a Safer Health System*. Washington, DC National Academy Press 1999
- Barker KN; McConnell WE, *American Journal of Hospital Pharmacy*. 1970 Aug;19:361-9
- Medication Errors Observed in 36 Health Care Facilities, *Jama Internal Medicine*
- Barker KN, Harris JA, Webster DB et al. Consultant evaluation of a hospital medication system: analysis of the existing system. *Am J Hosp Pharm*. 1984;41:2009-2016
- Failure Modes and Effects Analysis (FMEA) Tool, Institute for Healthcare Improvement, Cambridge, Massachusetts, US
- Hospital Errors are the Third Leading Cause of Death in U.S., and New Hospital Safety Scores Show Improvements Are Too Slow, **Washington, D.C., October 23, 2013.**
- AHRQ(Agency for healthcare research & quality), advancing excellence in health care-US department of health & human services, PS Net.
- Oxford University of Press Journal-International Journal on medication error.
- Department of Health. Report of an Expert Group on Learning from Adverse Events in the NHS Chaired by the Chief Medical Officer. London: The Stationery Office; 2000. An Organization with a Memory
- Allan EL, Barker KN. Fundamentals of medication error research. *Am J Hosp Pharm*. 1990;47(3):555–57
- Strategies to reduce medication errors: working to reduce medication safety, www.fda.gov/medwatch/how.htm
- FMEA & RCA: the mantras of modern risk management: JW Senders, *Qual Saf health care* 2004;13:249-250
- A visual computer interface concept for making error reporting useful at the point of care, Ranjit Singh
- 2007 National Academy of science, Preventing medication errors: Quality chasms series.
- National coordinating council for medication error reporting and prevention, NCCMERP (accessed 15 February 2014)