Internship Training
at
Shri Balaji Action Hospital

Study/Project Title-

FAILURE MODE EFFECT ANALYSIS (FMEA) OF MEDICATION MANAGEMENT PROCESS IN A CORPORATE HOSPITAL

By

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TO WHOMSOEVER IT MAY CONCERN

This is to certify that **Vaishali Anand** student of Post Graduate Diploma in Hospital and Health Management (PGDHM) from International Institute of Health Management Research, New Delhi has undergone internship training at Shri Balaji Action Medical Institute from 9 April to 17 may.
The Candidate has successfully carried out the study designated to him during internship training and his approach to the study has been sincere, scientific and analytical.
The Internship is in fulfilment of the course requirements.
I wish him all success in all his future endeavours.

Dr. A.K. Agarwal
Dean, Academics and Student Affairs
IIHMR, New Delhi

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Certificate Of Approval

The following dissertation titled **"**Failure Mode Effect Analysis (Fmea) of Medication Management Process In A Corporate Hospital" at **"Shri Balaji action Medical Institute** is hereby approved as a certified study in management carried out and presented in a manner satisfactorily to warrant its acceptance as a prerequisite for the award of **Post Graduate Diploma in Health and Hospital Management** for which it has been submitted. It is understood that by this approval the undersigned do not necessarily endorse or approve any statement made, opinion expressed or conclusion drawn therein but approve the dissertation only for the purpose it is submitted.

Dissertation Examination Committee for evaluation of dissertation.

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CERTIFICATE BY SCHOLAR

This is to certify that the dissertation title" Failure Mode Effect Analysis (Fmea) of Medication Management Process In A Corporate Hospital" and submitted by Vaishali Anand Enrolment No. PG/14/063 under the supervision of Ms. Divya Agarawal for award of Postgraduate Diploma in Hospital and Health Management of the Institute carried out during the period from 9 April to 14 May 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.

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ABSTRACT

Medications play a primary role in increasing life expectancy and improving quality of life. Thus, it is a big challenge for the hospitals to utilize services efficiently to serve maximum patients with the present infrastructure. This study will help the stakeholders of medication management process in taking proper measures in strengthening the medication prescription, indenting, and dispensing and administration process by ruling out the causes of medication errors. In this study the data collected have been analyzed to identify the present trend, find out root causes, identified causes for errors in all sub stages and proposed recommendations for improvement. It is examined that lack of effective communication between pharmacist, nurses, doctors, and ward boys is the reason for most of the medication errors. This study has sought to contribute to the improvement of the medication management system and alert health care professionals to its potential and problems. The study also focused on various sub process of medication management system through FMEA (Failure Mode Effect Analysis), which includes prescription, order entry, dispensing, storage, administration of medication to patient and documentation.

Acknowledgement

I have taken efforts in this project. However, it would not have been possible without the kind support and help of many individuals in organization. I would like to extend my sincere thanks to all of them.

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Organization Overview

Sri Balaji Action Medical Institute has been established with a mission to provide world class integrated healthcare facilities to all sections of the society with a humanitarian touch, while maintaining a high standard of ethical practice and professional competency with emphasis on training and education leading to research. "The Institute will impart free Medicare to the poor and needy people with an aim to run the institute on no profit no loss basis ".

"The Institute has been promoted by Lala Munni Lal Mange Ram Charitable Trust of Action Group of Companies. The chairman of the trust Lala Mange Ram Aggarwal, a great philanthropist had a strong desire to build a hospital for the service of mankind.

Equipment, facilities and nursing standards are all structured keeping patient welfare as the ultimate goal. The core catalyst of the hospital functions is patient welfare and recovery. For us, freedom from pain, restoration of perfect health and resumption of normal life with respect to the patient is of paramount importance and throughout the treatment process the mental and physical well being of the patient is the main priority. We have thus encapsulated these work ethics in our motto “healing with a human touch” and strive to always uphold it.

The Logo of the Institute portrays its philosophy; it consists of a hand embracing the flame of life with a sphere in the background. The Human Hand represents the healing touch and health care our dedicated teams of professional provide to brighten the lives of those who come to us. The Flame denotes the traditional values of honesty and selfless service towards our patients. The Sphere in the background reflects our commitment to maintain international standards of excellence.

Vision

To become the largest healthcare provider NGO in the country with a human touch.

Mission

Sri Balaji Action Medical Institute has been established with a mission to provide world class affordable health care facilities to all sections of the society with a humanitarian touch, whilst maintaining high standards of ethical practices and professional competency with emphasis on training and education leading to research

INTRODUCTION

INTRODUCTION OF STUDY:

Medication management is one of the major components of health care in which many people are prescribed/administered medications to support and improve their health conditions. Various health care workers like physicians, nurses, pharmacist, quality managers and health care administrators have a major role to play in the medication management process. Medication errors in hospitals are common. Medication errors are those preventable acts that may cause or lead to inappropriate medication use or patient harm. Such events may be related to professional practice, health care products, procedures and systems. Therefore, controlling of medication errors is an important function for patient safety interventions. Implementing safety norms, organized and efficient medication management system is essential for controlling errors and assuring that the medical prescription is safely followed.

RESEARCH PROBLEM:

This is the Project for

- Studying the Tall Man Lettering system for Look Alike and Sound Alike (LASA) drugs of Shri Balaji action medical institute hospital and also to suggest implementation of Alert Notes to all high-risk medications of the hospital.
- To identify failure modes, their potential causes, resultant problems during the process of prescription, ordering, dispensing and administration of high-risk medications to the patient.

NEED FOR STUDY:

To address the risks associated with the prescribing, dispensing and administration of high-risk medicines managing the high-risk groups is necessary. Although most medicines have a wide margin of safety, a few drug groups have a high risk of causing patient injury or death if they are inadvertently misused or administered incorrectly. Errors with these medicines may not be more common than those from other groups but their consequences can be more devastating.

It is one of the most important areas where hospitals need to focus their improvement efforts in order to make the process error free because any mistake in the process may result in harm or damage or serious injury to the patient sometimes even causing death. An in efficient process not only causes damage to the patient but also to the organization endangering organization reputation and its future growth.

Medication error is a consequence; hence it is required to reach out to root cause for the same. A step by step analysis is required to efficiently resolve the problem and implement the measures to avoid it in future

The NSW Ministry of Health has released Policy Directive PD2012_003.High-Risk Medicines Management-which requires facilities to review medicines used within their facilities and to identify those that are high risk. Action must then be taken to improve the use of these medicines. The National Safety and Quality Health Service Standards also require health services to identify high-risk medicines used within the organization and take appropriate action to ensure that they are stored, prescribed, dispensed and administered safely.

IMPORTANCE OF STUDY:

- Evaluation of Medication management process (prescription, ordering, dispensing and administration of medications) by conducting Failure Mode Effect Analysis helps in identifying the possible failures and helps in preventing them by correcting the processes proactively rather than reacting to adverse events after failures has occurred.
- The outcome of the study helps the organization in differentiating high-risk medications from other medications in the formulary list thus strengthening indenting and dispensing process.
- Also Tall Man Lettering and Alert Notes for high-risk medications keep the organization in pace with the modern technology and both effectiveness and efficiency in the system increases with minimal chance of errors...
- This helps in preventing and reducing risk of harm to both patients and staff.

OBJECTIVES:

- To generate a tool which would help to analyze the root causes responsible for Medication error.
- To segregate the list of medications in the hospital formulary according to their category and sub category.
- To identify the high risk medications among the hospital formulary and to suggest measures for identification and handling of frequent medication errors.
- To identify Look Alike and Sound Alike (LASA) medications among the hospital formulary and to arrange them according to the Tall Man Lettering system.

- To conduct Failure Mode Effect Analysis (FMEA) analysis on medication management process (prescribing, ordering, dispensing and administration of medications)

✓ To identify potential failure modes in the process

✓ To identify potential causes of the failure

✓ To calculate the risk priority number for each process step

✓ To identify possible effects due to these failures

✓ To suggest improvement in the process steps on the basis of risk priority number

METHODOLOGY:

- Detailed analysis of the medication management (prescribing, indenting, dispensing and administering of medications) process by interviewing concerned personnel (ward secretary, nurse, sister-in-charge, and ward coordinator in wards, I.P. Pharmacist, executives, drug dispatch boy and In-patients).
- Direct observation and data collection from case sheets of In-patients and medication errors track record.
- Literature review for Failure Mode Effect Analysis (what, why, how).
- Frequency analysis for each ward was done.
- **FMEA project methodology:**

✓ Defining the FMEA topic/ process

✓ Assembling the team i.e., involving people who are involved in the process.

✓ Reviewing the process/creating a process flow chart

✓ Assigning number to each step

✓ Brainstorming potential Failure Modes, Causes And Effects

✓ Evaluating the risk of failure, or hazard score on the basis of Likelihood of Occurrence, Likelihood of Detection and Severity Rating Scale

✓ Calculating the total Risk Priority Number score

Risk priority number = Likelihood of Occurrence X Likelihood of Detection X Severity

✓ Determine the steps with high RPN scores

✓ Pareto analysis of the failure modes as regards their Risk Priority Number and identification of failure modes that require urgent intervention and designing preventive measures for these failure modes.

SCOPE:

This study is applicable to all in-patients of Shri Balaji action medical institute Hospital.

SAMPLE DESIGN:

All in-patients of Shri Balaji action medical institute Hospital from all wards are included in the study.

SOURCES OF INFORMATION:

Primary sources are original materials. They are from the time period involved and have not been filtered through interpretation or evaluation. Primary sources are original materials on which other research is based. They are usually the first formal appearance of results in physical, print or electronic format. They present original thinking, report a discovery, or share new information.

They are:

- Internet communications on email
- Interviews
- Records of organizations
- Web site.

Secondary sources are less easily defined than primary sources. Generally, they are accounts written after the fact with the benefit of hindsight. They are interpretations and evaluations of primary sources. Secondary sources are not evidence, but rather commentary on and discussion of evidence. However, what some define as a secondary source, others define as a tertiary source. Context is everything.

They are:

- Bibliographies
- Textbooks
- Journal articles
- Dictionaries

TOOLS AND TECHNIQUES OF ANALYSIS:

For analysis of the collected data the following quality tools are used. They are

1. Process mapping
2. Failure Mode Effect Analysis
3. Pareto Analysis

Medication errors can occur in hospitals, at the pharmacy, in the doctor's office, and even due to patient. Problems can include adverse reactions and interactions with other medications, and also basic administrative errors such as patient being given the wrong medication or wrong dosage medication.

Process mapping:

- A process is a series of steps or actions performed to achieve a specific purpose
- A process can describe the ways things get done
- A work involves many processes
- Process mapping is a pictorial representation of the sequence of actions that comprise a process.
- It provides an opportunity to learn about work that is being performed.
- ***Dr. Myron Tribus*** said
- You don't learn to Process Map, You Process Map to learn.
- Most processes today are undocumented.

Process maps are used to:

- Document processes.
- ✓ Provide a reference to discuss how things get done.
- ✓ Describe and understand the work we do.
- Analyze and improve on processes.
- ✓ Identify of areas of complexity and re-work.
- ✓ To generate ideas for improvement.
- ✓ Illustrate process improvements.

Failure mode effect analysis:

FMEA is an analytical methodology used to ensure that potential problems have been considered and addressed throughout service and process development cycle. FMEA helps to:

- Discover the potential failures, their potential cause mechanisms and the risks designed into a process
    - Develop actions that reduce the risk of failure
    - Follow-up and evaluate the results of actions on the risks that were discovered

Failure modes and effect analysis (FMEA) is used in healthcare to assess risk of failure and harm in processes and to identify the most important areas for process improvements. The primary reason for performing a FMEA is taking action to prevent a failure, improve a process control through testing or evaluation

Pareto analysis:

A Pareto analysis is the method of looking at all the root causes of a problem and trying to determine which ones have the greatest frequency. The idea behind the analysis is that an entire collection of potential causes can be broken down into those that seldom happen and those that happen on a more frequent basis.

The technique is called a Pareto analysis because it is based on the Pareto principle, also known as the 80/20 rule.

Pareto principle: Named after ***Vilfredo Pareto*** -an Italian economist

- He conducted a study in Europe in the early 1900s on wealth and poverty. He found that wealth was concentrated in the hands of the few and poverty in the hands of the many (20% of the Italian population owned 80% of Italy's wealth). “The Pareto Principle is a rule-of-thumb, which states that: “20 percent of the problems have 80 percent of the impact.”
- A small number of causes are responsible for a large percentage of the effect-usually a 20-percent to 80-percent ratio.
- This basic principle translates well into quality problems - most quality problems result from a small number of causes.
- This ratio can be applied to almost anything, from the science of management to the physical world.

Pareto diagram helps teams focus on the small number of really important problems or causes of problems. This tool is useful in establishing priorities by showing which are the most critical problems to be tackled or causes to be addressed. Comparing Pareto diagram of a given situation over time can also determine whether an implemented solution reduced the relative frequency or cost of that problem or cause. If one is trying to take action based upon causes of accidents or events, it is generally most helpful to focus efforts on the most frequent causes.

A Pareto diagram puts data in a hierarchical order, which allows the most significant problems to be corrected first. The Pareto analysis technique is used primarily to identify and evaluate nonconformities, although it can summarize all types of data.

Pareto Diagram is a combined **bar chart** and **line diagram** based on cumulative percentages. 80% improvement in quality or performance can reasonably be expected by eliminating 20% of the causes of unacceptable quality or performance.

The chart is similar to the histogram or bar chart, except that the bars are arranged in decreasing order from left to right along the abscissa. Each bar represents only a category of faults, arranged in a decreasing way, from left to the right, according to their importance.

- Pareto analysis provides the mechanism to control and direct effort by fact, not by emotion.
- It helps to clearly establish top priorities and to identify both profitable and unprofitable targets.

OF LITERATURE

DEFINITIONS:

Formulary: A continually updated list of medications and related information, representing the clinical judgment of physicians, pharmacists, and other experts in the diagnosis and/or treatment of disease and promotion of health.

Formulary is a continually revised compilation of pharmaceuticals (plus important ancillary information) that reflects the current clinical judgment of medical staff.

High Risk Medicines are those that have a high risk of causing injury or harm if they are misused or used in error. Error rates with these medications are not necessarily higher than with any other medicines, but when problems occur, the consequences can be severe.

Adverse drug event is "an injury resulting from the use of a drug. Under this definition, the term ADE includes harm caused by the drug (adverse drug reactions and overdoses) and harm from the use of the drug (including dose reductions and discontinuations of drug therapy)." Adverse Drug Events may results from medication errors but most do not.

Adverse drug reaction is 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."

Medication errors are mishaps that occur during prescribing, transcribing, dispensing, administering, adherence, or monitoring a drug. Examples of medication errors include misreading or miswriting a prescription. Medication errors that are stopped before harm can occur are sometimes called "near misses" or "close calls" or more formally, a *potential adverse drug event.* Not all prescribing errors lead to adverse outcomes. Some do not cause harm, while others are caught before harm can occur ("near misses").

Medication errors types:

Medication errors can be classified into *intercepted* and *actual errors*. Prescription errors that are corrected and prevented by **Prescription Audit Team** are called as **intercepted errors**. (On the basis whether drug reaches the patient or not) Both types of errors are further divided as:

1. **Prescription Error Orders** that is not legible, without specified route, without indication, inappropriate dose, and without/incomplete frequency.

2. **Transcribing Error Orders** that transcribed incorrectly and with no allergy documentation.

3. **Dispensing Error** Dispensing of wrong drug/dilution with wrong method of preparation.

4. **Administration Error** Missed dose, administration without physicians order, and non-documentation of the medication administration.

MEDICATION MANAGEMENT:

Introduction:

Medications are the most common intervention in health care and are also most commonly associated with adverse events in hospitalized patients.

- Older hospitalized patients are at higher risk of adverse drug events. In part due to there increased use of medications and co-morbid conditions such as kidney and liver disease.
- An increase in the number of medications increases the likelihood of drug-drug and drug-disease interactions.

Not all medications in clinical use are of equal risk to patients. Serious adverse events appear to be caused by relatively small number of medications.

The Institute of Medication Practice has identified a number of medications that they consider to be **"high-alert medications."**

The Joint Commission defines these as those medications, which are more likely to be associated with harm than other medications—they cause harm more commonly, the harm they produce is likely to be more serious, and they "have the highest risk of causing injury when misused."

Each organization must identify the **high-risk** or **high-alert medications** used within its facility, if any. As part of the identification of an organization's high-alert medications, a critical step is the development of a policy to define the medications and measures to prevent medication errors. The high-alert medication policy should include the following:

- Definition of a high-alert medication
- Purpose of the policy

    - Committee responsible for enforcing the policy
    - List of specific high-alert medications on the organization's formulary
- Recommended or implemented measures to reduce the likelihood of medication error with high-alert medications

History:

Arun D. Butt examined that adverse drug reactions are the most common cause of death in US, accounting for more than 1, and 00,000 deaths per year. For India the extrapolated figures are more than 4, 00,000 per year and incidence of serious Adverse Drug Reactions is 6.7% and fatal ADR's are 0.3%. ***León Villar J et al*** conducted a prospective, descriptive and cross-sectional study for a period of three-year duration on total number of errors reported. The nursing staff reported the largest number of errors with 54.08% followed by the pharmacist with 39.55%and the doctor 4.47%. Prescription errors were the most frequent, followed by validation and preparation errors. There was an increase in errors year after year during that study period.

Burnett, Franklin et AL have conducted a study on prescribing errors in hospital inpatients. The results showed that the error rates on medical admissions wards were significantly higher than that on surgical wards. The contributing factors for medical errors are lack of feedback on errors, poor documentation and communication of prescribing decisions and lack of information about patients' medication histories from primary care. They have concluded that there were variations among wards, organizations and specialties in error rates and how quickly they were rectified.

Burman conducted an exploratory study on reducing medication errors through naming, labeling and packaging. The results showed that up to 25% of all medication errors are attributed to name confusion and 33% to packaging and or labeling confusion.

The study recommends developing systems that may reduce the occurrence of such errors. Westbrook, ***Wood et al*** conducted an observational study on association of interruptions on medication administration errors. They found the association between interruptions and clinical errors was independent of hospital and nurse characteristics.

Error severity increased with interruption frequency. Approximately 7,000 deaths occur each year and medication errors occur in just about 1 of every 5 doses given in hospitals. The food and drug administration FDA states that there is at least one death per day and 1.3 million people are injured each year due to medication errors. Philips J.et al did a retrospective analysis of medication errors between 1993-1998 and found that the most common types of adverse medication event were from administering improper dose (40.9%; 36.4% being overdose), wrong drug (19%) and wrong route of administration (9.5%). The investigators also found that the most common cause of errors were performance and knowledge deficits (44%) and communication errors (15.8%). the study findings highlight the need to revamp the medication delivery and administration systems of US hospitals. The problem of defective medication administration systems, although varied, is widespread. While the study did not investigate possible ways to improve the delivery of medication, robotics and bar code systems could help reduce errors according to researchers. These results support the proposition that the problems lie with medication systems and thus systems research is called for.

Universal high-risk medications:

NSW health provides information about high-risk medications. These medications have been identified via IIMS, published literature and other local agencies. The acronym A PINCH is used to identify these high-risk drugs.

Sections of A PINCH

- A: Anti-infective
- P: Potassium and other electrolytes
- I: Insulin
- N: Narcotics and other sedatives
- C: Chemotherapeutic agents
- H: Heparin and other anticoagulants

In addition to the preceding list, the Institute has identified the following medications for Safe Medication Practices as high alert medications for all patients. Care should be exercised when prescribing them, and consultation with a specialist and pharmacist is recommended.

- Anesthetics
- Antiarrythimics-IV
- Antithrombotic/anticoagulants
- Beta-blockers-IV
- Chemotherapeutic agents- IV, IM, SC, IT, or oral
- Dialysis solutions
- Epidural medications
- Hypertonic/ hypotonic fluids

- Hypoglycemic-oral
- Inotropes
- Intrathecals
- Narcotics- IV, oral, transdermal, subcutaneous
- Neuromuscular blocking agents
- Radio contrast agents-IV
- Sedatives-IV, buccal, intranasal, inhaled, or oral
- Parenteral nutrition (PN) solutions

Circumstances Increasing Risk Errors in High Risk Medications:

- Poorly handwritten medication orders
- Verbal directions/orders
- Similar product packaging
- Similar medication name
- Improper packaging leading to improper route of administration
- Storage of products with similar names in the same location
- Similar abbreviations
- Improper storage of concentrated electrolytes

Strategies that can be developed to Avoid Errors Involving High Risk Medications:

- **Medication arrangement**

✓ Avoid storing look-alike, sound-alike drugs next to each other (example: instead of storing by generic name (e.g. vincristine and vinblastine) store drugs by brand name (e.g. Oncovin and Velban)

- **Formulary selection**

✓ Minimize look-alike, sound-alike formulary combinations

- **Tallman lettering**

✓ Is a combination of lower and upper case letters to highlight the differences between look-alike drug names, helping to make them more easily distinguishable e.g. hydromorphONE.

- **Computerized Prescriber Order Entry (CPOE)**

✓ Eliminates illegible handwriting

✓ Reduces opportunities for misinterpretation of verbal orders

✓ Look-alike, sound-alike drugs could still be confused by physicians

  - System alerts are in place to safeguard selection

- **Bar coding**

✓ Can serve as a double check system during medication selection, preparation, and prior to administration

✓ Scanning a bar coded medication just prior to administration can detect many types of medication errors before they occur.

- **Alert notes**

✓Highlighted stickers on packaging

✓ Pop-up messages attached to look-alike, sound-alike drugs

✓ Highlighted drug storage areas

STUDY INCLUDES:

This study includes two things:

- Conducting Failure Mode Effect analysis on Medication Management process
- Giving Tall Man Letters to Look alike and Sound alike (LASA) drugs

FMEA ANALYSIS:

This tool contains:

I. Background

II. General instructions

I. BACKGROUND:

Failure Mode Effect Analysis:

- One of the DMAIC Six Sigma quality tools to anticipate problems, and design processes and products to reduce costly and embarrassing risks.
- A proactive approach to risk reduction that seeks to improve patient safety by minimizing risk potential in high-risk processes.
- Rather than focus on a problem-after occurrence, FMEA looks at what "could" go wrong at each process step.
- The so called "failure modes", assigns a risk score to each of these possibilities, and provides for a team-oriented approach to focus resources on priority issues

- Since 1960's they have been used in the nuclear, military, aviation, food and automotive industries, now they are being used in Healthcare and other service industries.
- 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 happens?)
- Failure effects (What would be the consequences of each failure?)

Hospitals use FMEA:

- To evaluate processes for possible failures and to prevent them by correcting the processes proactively rather than reacting to adverse events after failures has occurred.
  - To prevent and 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.

Why use FMEAs in Healthcare:

Recently, **JCAHO** (Joint Commission on the Accreditation of Healthcare Organizations) added a new requirement for the use of FMEA

- To reduce risks.
- Improve patient safety, and
- To enhance patient satisfaction in high-risk processes.

"JCAHO Standard LD.5.2 requires facilities to select at least one high-risk process for proactive risk assessment each year. This selection is to be based, in part, on information published periodically by the JCAHO that identifies the most frequently occurring types of sentinel events. The National Centre for Patient Safety will also identify patient safety events and high risk processes that may be selected for this annual risk assessment."

Furthermore, the 1999 Institute of Medicine (IOM) report, "To Err is Human: Building a safer Health System," urged health organization to reduce medical errors by 50% over the following 5 years through changes to healthcare systems. The report stated that most medical errors do not result from "individual recklessness", but instead from "basic flaws" in the way the healthcare system is organized.

Choosing a process for an FMEA Project:

Many different processes occur within a hospital setting, each with varying degrees of risk. So how do you choose a process to work on? The possibilities include considering the following:

- Sentinel Events Alerts (past alerts have covered medication abbreviations, wrong-site surgery, delay in treatment, etc.)
- JCAHO's Patient Safety Goals.
- Other identified high-risk processes within the hospital.

FMEA has been conducted on Admission process, Discharge process and Medication procedure in many hospitals in and outside India as an approach to Quality Improvement.

Medication management process:

To address the risks associated with the prescribing, dispensing and administration of

high-risk medicines managing these processes is necessary. Although most medicines have a wide margin of safety, a few drug groups have a high risk of causing patient injury or death if they are inadvertently misused or administered incorrectly. Errors with these medicines may not be more common than those from other groups but their consequences can be more devastating.

As the critical step in the hospital experience, the medication management process is likely to be well remembered by the patient. Even if everything else went satisfactorily, an inefficient medication management process can result in utmost harm or injury or even may cause death to the patient resulting in great damage to the organization reputation if patient Sue’s organization.

II.GENERAL INSTRUCTIONS:

Step 1: Select a process or define topic to evaluate with FMEA

Evaluation using FMEA works best on processes that do not have too many sub processes instead of doing an FMEA on a large and complex process, doing an FMEA on sub processes or variants will be more effective. Medication Management process in hospitals can be well analyzed by using FMEA.

Step 2: Recruit a multidisciplinary team

This we can do by involving every person who is a part of the process or associated with it. Some people may not need to be part of the team throughout the entire analysis, but they should certainly be included in discussions of those steps in the process in which they are involved.

For example: A hospital may utilize couriers to transport medications from the pharmacy to nursing units. It would be important to include the couriers in the FMEA analysis of the steps that occur during the transport itself, which may not be known to personnel in the pharmacy or on the nursing unit.

Step 3: List all the steps in the process

Number every step of the process, and be as specific as possible. It must be ensured that the steps in the FMEA accurately describe process.

Step 4: Have the team list failure modes and causes

For each step in the process, list all possible “failure modes”- that is, anything that could go wrong, including minor and rare problems. Then, for each failure mode listed, identify all possible causes.

Step 5: For each failure mode, have the team assign a numeric value (known as The Risk Priority Number, or RPN) for likelihood of occurrence, likelihood of detection, and severity.

Assigning RPNs helps to prioritize areas to focus on and can also help in assessing opportunities for improvement.

For every failure mode identified, the team should answer the following questions and assign the appropriate score (the team should do this as a group and have consensus on all values assigned:

Likelihood of occurrence: How likely is it that this failure mode will occur?

Assign a score between 1 and 10, with 1 meaning "very unlikely to occur" and 10 meaning "very likely to occur."

Likelihood of detection: If this failure mode occurs, how likely is that the failure will be detected?

Assign a score between 1 and 10, with 1 meaning "very likely to be detected" and 10 meaning "very unlikely to be detected."

Severity: If this failure mode occurs, how likely is it that harm will occur?

Assign a score between 1 and 10, with 1 meaning "very unlikely that harm will occur" and 10 meaning, "very likely that severe harm will occur."

In patient care examples, a score of 10 for harm often denotes death.

Steps in process	Failure modes	Failure Causes	Failure effects	Severity rating scale (1-10)	Occurrence rating scale (1-10)	Detection rating scale (1-10)	Risk Priority number (RPN)	Actions to reduce occurrence of failure

Step 6: Evaluate the results

To calculate the Risk Priority Number (RPN) for each failure mode, multiply the three scores obtained (the 1 to 10 score for each of likelihood of occurrence, detection, and severity).

For example: The failure mode “Wrong medication selected” has a 3 for likelihood of occurrence, a 5 for likelihood of detection, and a 5 for severity, for an overall RPN of 75. The lowest possible 5 Failure Modes and Effect Analysis (FMEA) score will be 1 and the highest 1000.

Identify the failure modes with the top 10 highest RPNs.

These are the ones that should be considered first as improvement opportunities.

To calculate the RPN for the entire process, simply add up all of the individual RPNs for each failure mode.

Step 7: Use RPNs to plan improvement efforts

Failure modes with high RPNs are probably the most important parts of the process on which to focus improvement efforts.

Failure modes with low RPNs are not likely to affect the overall process very much, even if eliminated completely, and should therefore be at the bottom of the list of priorities.

Use FMEA to plan actions to reduce harm from failure modes:

<u>If the failure mode is likely to occur:</u>

- Evaluate the causes and see if any or all of them can be eliminated.
- Consider adding a forcing function (i.e., a physical constraint that makes committing an error impossible, such as medical gas outlets that are designed to accept only those gauges that match)
- Add a verification step, such as independent double-checks, bar coding on medications, or alert screens.
- Modify other processes that contribute to causes.

<u>If the failure is unlikely to be detected:</u>

- Identify other events that may occur prior to the failure mode and can serve as "flags" that the failure mode might happen.
- Add a step to the process that intervenes at the earlier event to prevent the failure mode. For example, add pharmacy rounds to remove discontinued medications from patient care units within 1 hour of discontinuation, to decrease the risk that the medications will still be available for use (the failure mode).
- Consider technological alerts such as devices with alarms to alert users when values are approaching unsafe limits.

<u>If the failure is likely to cause severe harm:</u>

- Identify early warming sights that a failure mode has occurred, and train staff to recognize them for early intervention.
- For example, use drills to train staff by simulating events that lead up to failure, to improve staff ability to recognize these early warnings
- Provide information and resources, such as reversal agents or antidotes, at points of care for events that may require immediate action.

Use FMEA to evaluate the potential impact of changes under consideration:

- Teams can use FMEA to discuss and analyze each change under consideration and calculate the change in RPN if the change were implemented.
- This allows the team to "verbally simulate" the change and evaluate its impact in a safe environment, prior to testing it in a patient care area.
- Some ideas that seem like great improvements can turn out to be changes that would actually increase the estimated RPN.

Use FMEA to monitor and track improvement over time:

- Teams should consider calculating a total RPN for the process as described above then set a goal for improvement.
- For example, a team may set a goal of decreasing the total RPN for the medication ordering process by 50% from the baseline.

Severity: 1-10, 10 = most severe effect

Risk Priority Number (RPN): Likelihood of occurrence x Likelihood of Detection x Severity

TALL MAN LETTERING:

Medication errors are still a major public safety concern for patients and consumers. Although figures published on errors caused by drug name confusion ranges from 9% to 25%, the impact of selecting the wrong drug can be catastrophic. There have been many attempts to develop safeguards and strategies to reduce errors caused by similar or look-alike drug names. One approach is to deploy a mixed-case text or tall man letters on drug names that are deemed to be orthographically similar and have the potential to cause serious patient harm if a mix-up were to occur. The tall man letter approach has been promoted and advocated by both FDA (Food and Drug Administration) and ISMP (Institute for Safe Medication Practices) in the United States for a number of years. They have recommended a standard list of tall man lettering for similar drug name pairs. A survey of a broad audience of practitioners on the use of tall man letters was conducted by ISMP in 2008. The findings showed an overwhelming support of the use of this technique. Of the 451 surveyed responses, 87% indicated that the use of tall man lettering helped to reduce drug selection errors. ISMP-Canada, engaging in a project with the Canadian Association of Provincial Cancer Agencies, also produced a list of oncology drug names with the tall man technique. This project leveraged the success from what was previously delve while more research must be conducted on the approaches used and the formatting of tall man lettering, the Spanish study is commended for taking a big step in the right direction. It is worth mentioning that changing the way a drug name looks, regardless of its degree of effectiveness, is only one strategy. It is not a panacea, but since there is not an extensive array of specific practices to minimize errors caused by confusion among already existing names, it merits application in all areas where it could be. Enhancing safer drug product packaging, both from the manufacturer and from

healthcare facility-generated labeling can play a critical role in preventing medication errors.

Tall man (uppercase) letters are used within a drug name to highlight its primary dissimilarities and help to differentiate look-alike names. Several studies have shown that highlighting sections of words using tall man lettering can make similar drug names easier to distinguish, and fewer errors are made when tall man letters are used to differentiate products with look-alike names.

The Institute for Safe Medication Practices (ISMP), the FDA, The Joint Commission, and other safety-conscious organizations such as the National Association of Boards of Pharmacy (NABP) has promoted the use of tall man letters as one means of reducing confusion between similar drug names. From a survey conducted by the ISMP in 2008, most respondents appeared to agree. Nearly all of those surveyed (87%) felt that the use of tall man letters by the medical product industry helped to reduce errors in drug selection, and two-thirds (64%) reported that tall man lettering actually prevented them from dispensing or administering the wrong medication.

Use of the tall man letters on computer-generated pharmacy labels was the most prevalent and was considered to be most effective, whereas use of the letters on preprinted order forms was among the least prevalent and was considered to be least effective.

While more research must be conducted on the approaches used and the formatting of tall man lettering, the Spanish study is commended for taking a big step in the right direction. It is worth mentioning that changing the way a drug name looks, regardless of its degree of effectiveness, is only one strategy. It is not a panacea, but since there is not an extensive array of specific practices to minimize errors caused by confusion

among already existing names, merits application in all areas where it could be. Enhancing safer drug product packaging, both from the manufacturer and from healthcare facility-generated labeling can play a critical role in preventing medication errors. In addition, there are other system safeguards that can be built into the medication use process to enhance medication safety.

One of the difficulties of using tall man letters is the lack of standardization regarding which name pairs to include as well as which letters to present in uppercase. There is some evidence to support the use of tall man letters to reduce the risk of confusion between look-alike drug names, but little evidence is available concerning which dissimilar letters in each drug name should be highlighted. To help promote standardization, the ISMP suggests that the tall man-lettering scheme provided by the FDA and the ISMP for the drug name pairs be followed consistently.

Below is the list of Look Alike and Sound Alike Drugs (LASA) of Shri Balaji action medical institute Hospital for which tall man letters are given:

SOUND ALIKE		
S.NO	**PRODUCT NAME**	**SIMILAR NAME**
1	ak**URIT**-4 tab	ak**T**-4 tab
2	a**SP**sol tab	a**PRI**sol tab
3	a**TEN D** tab	a**LERI**d **D** tab
4	b**ANOCID** forte tab	b**IDANZEN** forte tab
5	betnovate oint	betnovate **N** oint
6	card**ACE** tab	card**IVAS** tab
7	cila**NEM INJ**	cila**MIN TAB**
8	dyna**PAR INJ**	dyna**PRESS CAP**
9	dyna**SPIRIN TAB**	dyna**PRESS CAP**
10	im**ODIUM CAP**	im**MUMOD TAB**
11	flex**ILOR** tab	flex**URA D** tab
12	janu**VIA** tab	janu**MET** tab
13	lesuride **TAB**	lesuride **INJ**
14	male **CATH**	male **COT**
15	med**ROL** tab	med**LER** tab
16	metrogyl gel	metrogyl **V** gel
17	nitr**AVENT** tab	nitr**EST** tab
18	otrivin nasal drops	otrivin **S** nasal drops
19	r-ci**N** 450mg cap	r-ci**NEX** 450mg cap
20	susten inj	susten**ON** inj
21	**tEGRE**tal tab	t**REN**tal tab
22	tusq **TAB**	tusq **LOZENGES**
23	volini **SPRAY**	volini **OINT**
24	**WINOF**it cap	**ZINCOV**it cap

LOOK ALIKE		
S.NO	**PRODUCT NAME**	**SIMILAR NAME**
1	**AMINO**steril 500ml iv sol	**NEPHRO**steril**E** 500ml iv sol
2	**ATROPINE** 100ml **IV**	**NORMAL SALINE** 3% 100ml **VIAL**
3	**ATROPINE** ml amp	**GLYCOPYROLAYE** 1ml amp
4	**BETNESOL** amps	**GENTICYN 60MG** amps
5	Cele**PID** 500ml iv sol	Cele**MIN** 500ml iv sol
6	clinomel n**4** 1000ml iv sol	clinomel n**7** 1000ml iv sol
7	cp van **500MG** inj	cp van **1GM** inj
8	decadurabolin **25**mg amps	deca**M**durabolin **50**mg amps
9	depomedrol **40MG/1ML**	depomedrol **80MG/2ML**
10	**GENTA**mycin **80MG** vials	**DECA**mycin vials
11	**HESTER 6%** 450ml iv sol	**MICROSPAN** 450ml iv sol
12	**INFANT FEEDING** tube	**SUCTION CATHETER** tube
13	irnocam **100MG** inj	irnocam **40MG** inj
14	kabiven **PERIPHERAL 1440ML** iv sol	kabiven **CENTRAL 1026ML** iv sol
15	**KETROL** amps	**ISOLIN** amps
16	**LIQUID PARAFFIN**	**ORAL GLYCEROL**
17	magn**EX** 1gm inj	magn**AMYCIN** 1gm inj
18	merofit **500MG** inj	merofit **1GM** inj
19	**NELTON** catheter	**SUCTION** catheter **TUBE**
20	neu**POGEN 300MCG** inj	neu**LASTIM** inj
21	**NEUROBI**on inj	**OPTINEUR**on inj
22	otri**VIN** nasal drops	otri**NOZE** nasal drops
23	oxitan **100**mg inj	oxitan **50**mg inj
24	**OXYGEN** face mask	**NEBULIZER** face mask
25	prolution depot **250**mg amps	prolution depot **500**mg amps
26	rhoclone **150** I u inj	rhoclone **300** I u inj
27	r**OSCILL**in 500mg inj	r**EFL**in 500mg inj
28	**SUPRIDOL** inj	**BUPRIGESIC** inj
29	**TRIPLE** lumen catheter	**DOUBLE** lumen catheter
30	**TROPINE** inj	**PYROLATE** inj

ANALYSIS & INTERPRETATION

FMEA ANALYSIS:

FMEA (Failure Mode and Effects Analysis) is a proactive tool, technique and quality method that enables the identification and prevention of process or product errors before they occur. Within healthcare, the goal is to avoid adverse events that could potentially cause harm to patients; families, employees or others in the patient care setting.

MEDICATION MANAGEMENT PROCESS:

A process is a set of actions or steps, each of which must be accomplished properly in the proper sequence at the proper time to create value for a customer or patient. For understanding and improving patient flow, identifying the critical paths to minimize delays and resources utilization and to maximize quality of care is a must.

Step 1: Orders written for new medications by doctor which are copied into medication chart by nurse and then indents are also raised by nurse.

Step 2: Electronic indents are received in I.P. Pharmacy

Step 3: Pharmacist enters details of medications like batch number, issue, pending drugs.

Step 4: Vouchers or bills are generated; high-risk medications are identified and highlighted by I.P. Pharmacist

Step 5: Segregated vouchers are taken to packing area and medications are packed

Step 6: Packed medications are transferred to the dispensing bay where they are arranged floor-wise

Step 7: Ward boy collects the medicines and dispatches them to wards

Step 8: Nurse receives medications from pharmacy

Step 9: Nurse verifies the bill and patient details

Step 10: Identification of high-risk medications by nurse and CAUTION marking is done

Step 11: Nurse checks case sheet for doctor orders

Step 12: Nurse prepares medication for patients

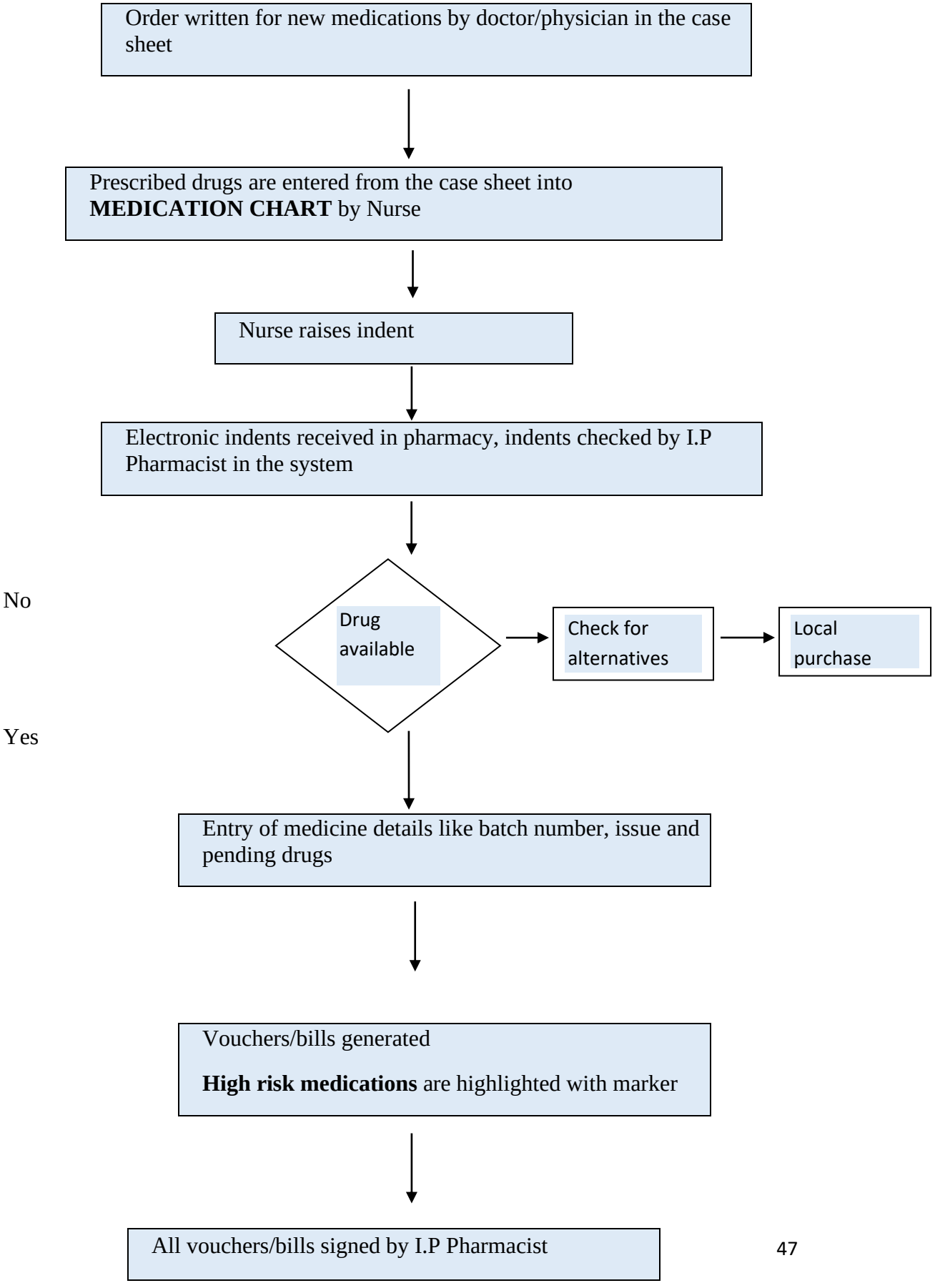
Step 13: Nurse informs her sister in charge before administering medication to the patient

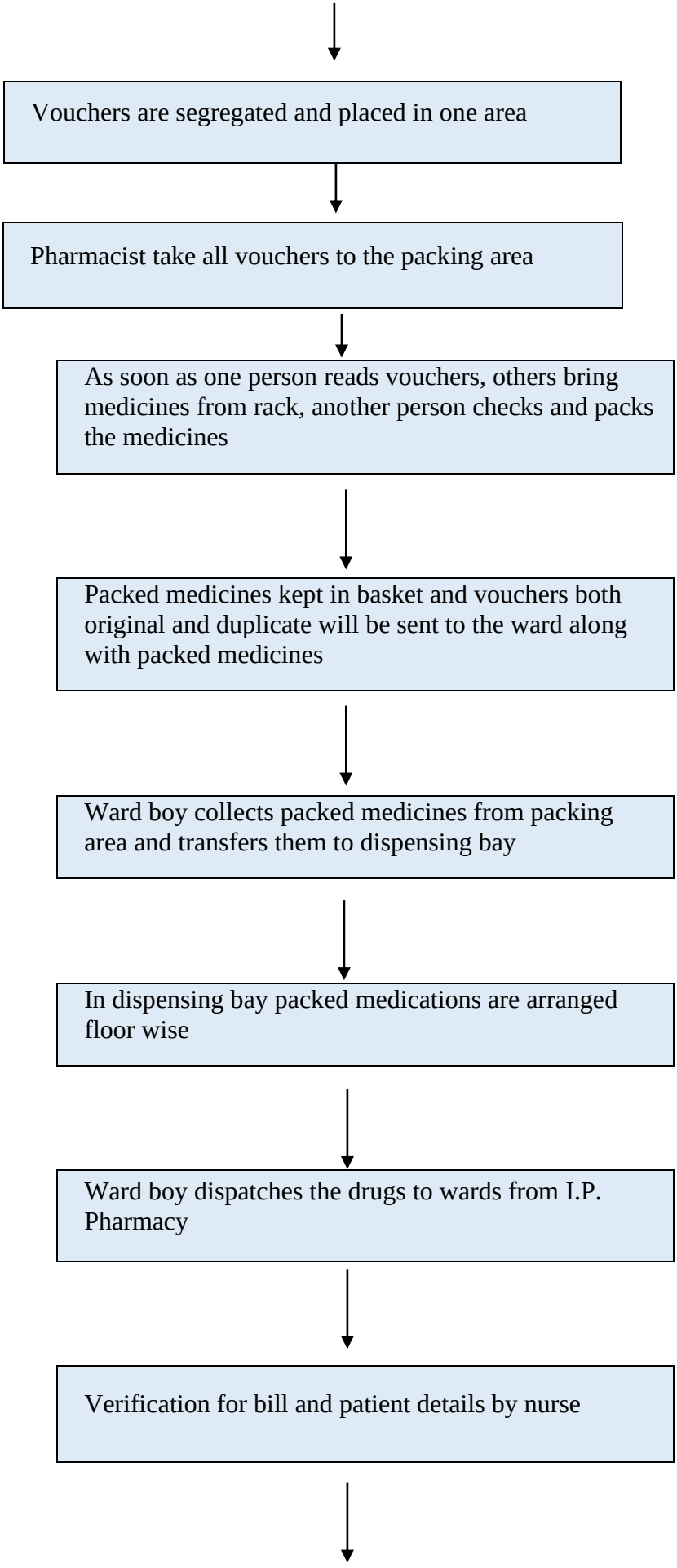
Step 14:nurse educates Patient before administering medication

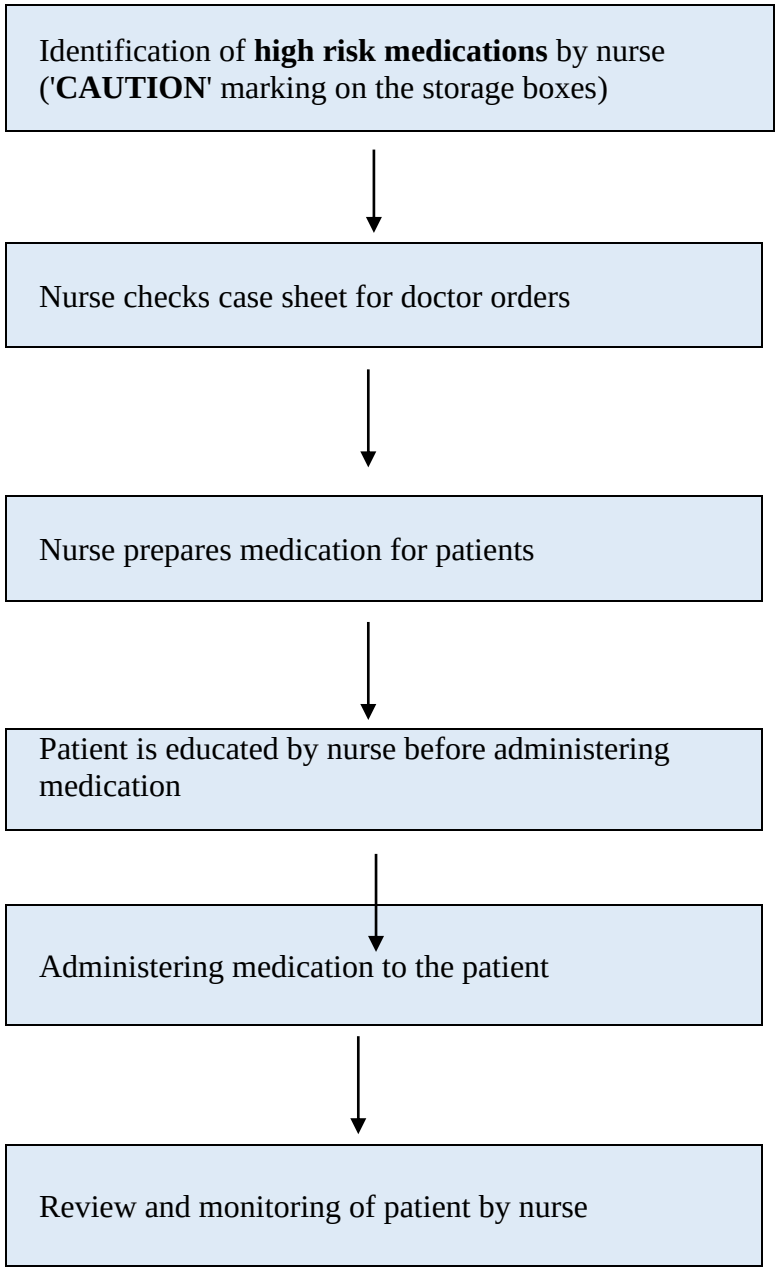
Step 15: Nurse administers medication to the patient

Step 16: Review and monitoring of patient after administering the medication.

MEDICATION MANAGEMENT FLOW CHART:




Vouchers are segregated and placed in one area
Pharmacist take all vouchers to the packing area
As soon as one person reads vouchers, others bring medicines from rack, another person checks and packs the medicines
Packed medicines kept in basket and vouchers both original and duplicate will be sent to the ward along with packed medicines
Ward boy collects packed medicines from packing area and transfers them to dispensing bay
In dispensing bay packed medications are arranged floor wise
Ward boy dispatches the drugs to wards from I.P. Pharmacy
Verification for bill and patient details by nurse


Identification of **high risk medications** by nurse ('**CAUTION**' marking on the storage boxes)
Nurse checks case sheet for doctor orders
Nurse prepares medication for patients
Patient is educated by nurse before administering medication
Administering medication to the patient
Review and monitoring of patient by nurse

FMEA RATING SCALES:

SEVERITY RATING SCALE:

Rating	Description	Definition (Severity of Effect)
10	Dangerously high	Failure could injure the customer or an employee.
9	Extremely high	Failure would create noncompliance with federal regulations.
8	Very high	Failure renders the unit inoperable or unfit for use.
7	High	Failure causes a high degree of customer dissatisfaction.
6	Moderate	Failure results in a subsystem or partial malfunction of the product.
5	Low	Failure creates enough of a performance loss to cause the customer to complain.
4	Very Low	Failure can be overcome with modifications to the customer's process or product, but there is minor performance loss.
3	Minor	Failure would create a minor annoyance to the customer, but the customer can overcome it without performance loss.
2	Very Minor	Failure may not be readily apparent to the customer, but would have minor effects on the customer's process or product.
1	None	Failure would not be noticeable to the customer and would not affect the customer's process or product.

OCCURRENCE RATING SCALE:

Rating	Description	Potential Failure Rate
10	**Very High:** Failure is almost inevitable.	More than one occurrence per day or a probability of more than three occurrences in 10 events (C_{pk}< 0.33).
9	**High:** Failures occur almost as often as not.	One occurrence every three to four days or a probability of three occurrences in 10 events (C_{pk}≈ 0.33).
8	**High**: Repeated failures.	One occurrence per week or a probability of 5 occurrences in 100 events (C_{pk}≈ 0.67).
7	**High**: Failures occur often.	One occurrence every month or one occurrence in 100 events (C_{pk}≈ 0.83).
6	**Moderately High:** Frequent failures.	One occurrence every three months or three occurrences in 1,000 events (C_{pk}≈ 1.00).
5	**Moderate:** Occasional failures.	One occurrence every six months to one year or five occurrences in 10,000 events (C_{pk}≈ 1.17).
4	**Moderately Low**: Infrequent failures.	One occurrence per year or six occurrences in 100,000 events (C_{pk}≈ 1.33).
3	**Low:** Relatively few failures.	One occurrence every one to three years or six occurrences in ten million events (C_{pk}≈ 1.67).
2	**Low:** Failures are few and far between.	One occurrence every three to five years or 2 occurrences in one billion events (C_{pk}≈ 2.00).
1	**Remote:** Failure is unlikely.	One occurrence in greater than five years or less than two occurrences in one billion events (C_{pk}> 2.00).

DETECTION RATING SCALE:

Rating	Description	Definition
10	Absolute Uncertainty	The product is not inspected or the defect caused by failure is not detectable.
9	Very Remote	Product is sampled, inspected, and released based on Acceptable Quality Level (AQL) sampling plans.
8	Remote	Product is accepted based on no defectives in a sample.
7	Very Low	Product is 100% manually inspected in the process.
6	Low	Product is 100% manually inspected using go/no-go or other mistake-proofing gauges.
5	Moderate	Some Statistical Process Control (SPC) is used in process and product is final inspected off-line.
4	Moderately High	SPC is used and there is immediate reaction to out-of-control conditions.
3	High	An effective SPC program is in place with process capabilities (C_{pk}) greater than 1.33.
2	Very High	All products are 100% automatically inspected.
1	Almost Certain	The defect is obvious or there is 100% automatic inspection with regular calibration and preventive maintenance of the inspection equipment.

CALCULATION OF RISK PRIORITY NUMBER (RPN):

Risk Priority Number = Severity X Occurrence X Detectability

ANALYSIS AND FINDINGS:

STEP 1: Orders written for new medications by doctor which are copied into medication chart by Nurse and then the nurse raises indents

FAILURE MODES	CAUSES	EFFECTS	SEVERITY RS	OCCURENCE RS	DETECTION RS	RPN
1.Physician may write incorrect order, illegible order or confusing order	Order may be misinterpreted by RMO, nurse/ pharmacist	Patient may receive incorrect medication, dose, route	10	5	5	250
2.NURSE making errors during entry of details into medication chart			7	7	5	245

Calculation:

Occurrence: Likelihood of Occurrence (1-10)

Detection: Likelihood of Detection (1-10)

NOTE: 1 = Very likely it WILL be detected

10 = Very likely it WILL NOT be detected

Severity: Severity (1-10)

RPN: Risk Priority Number (Occ × Det × Sev)

1. **10 x 5 x 5 = 250**
2. **7 x 7 x 5 = 245**

STEP 2: Electronic indents received in pharmacy

FAILURE MODES	CAUSES	EFFECTS	SEVERITY RS	OCCURENCE RS	DETECTION RS	RPN
New orders not retrieved by pharmacy	Nurse forgot to keep order due to over work load Online connectivity problems	Pharmacy will not be aware of new orders Delay in patient treatment (patient may be at risk)	7	2	6	84

Calculation:

Occurrence: Likelihood of Occurrence (1-10)

Detection: Likelihood of Detection (1-10)

NOTE: 1 = Very likely it WILL be detected

10 = Very likely it WILL NOT be detected

Severity: Severity (1-10)

RPN: Risk Priority Number (Occ × Det × Sev)

= 7 x 2 x 6 = 8

STEP 3: Entry of medication details by pharmacist

FAILURE MODES	CAUSES	EFFECTS	SEVERITY RS	OCCURENCE RS	DETECTION RS	RPN
Errors may occur during entry of details such as improper placement	Multiple medications are placed in the list Phone calls, distractions, workload	Patient may receive wrong medication or dose if not caught by nurse Delay in patient treatment	6	5	4	120

Calculation:

Occurrence: Likelihood of Occurrence (1-10)

Detection: Likelihood of Detection (1-10)

NOTE: 1 = Very likely it WILL be detected

10 = Very likely it WILL NOT be detected

Severity: Severity (1-10)

RPN: Risk Priority Number (Occ × Det × Sev)

= 6 x 5 x 4 = 120

STEP 4: Vouchers/ bills generated, **high-risk medications** are identified and highlighted by pharmacist

FAILURE MODES	CAUSES	EFFECTS	SEVERITY RS	OCCURENCE RS	DETECTION RS	RPN
Some/few high risk medications are not highlighted	Look alike drug names written after one another Label ambiguity Workload, phone calls, distractions Lack of focus	Wrong drug therapy If nurse is not aware of high risk medications, patient will be at risk Delayed therapy	10	5	6	300

Calculation:

Occurrence: Likelihood of Occurrence (1-10)

Detection: Likelihood of Detection (1-10)

NOTE: 1 = Very likely it WILL be detected

10 = Very likely it WILL NOT be detected

Severity: Severity (1-10)

RPN: Risk Priority Number (Occ × Det × Sev)

= 10 x 5 x 5 = 300

STEP 5: Segregated vouchers are taken to packing area and medications are packed

FAILURE MODES	CAUSES	EFFECTS	SEVERITY RS	OCCURENCE RS	DETECTION RS	RPN
1.May select wrong medication while packing	Many medications are placed in list at one time Look alike drug names Label ambiguity Workload, distractions, phone calls	Patient may receive wrong medication Delay in patient treatment	10	6	4	240
2.Medications may be placed in incorrect bins			7	5	5	175

Calculation:

Occurrence: Likelihood of Occurrence (1-10)

Detection: Likelihood of Detection (1-10)

NOTE: 1 = Very likely it WILL be detected

10 = Very likely it WILL NOT be detected

Severity: Severity (1-10)

RPN: Risk Priority Number (Occ × Det × Sev)

1. **10 x 6 x 4 = 240**
2. **7 x 5 x 5 = 175**

STEP 6: Packed medications are transferred to the dispensing bay where they are arranged floor-wise

FAILURE MODES	CAUSES	EFFECTS	SEVERITY RS	OCCURENCE RS	DETECTION RS	RPN
Errors may occur during segregation of medicines floor wise	Number of packages are more Workload, distractions, phone calls	Delayed therapy	6	6	5	180

Calculation:

Occurrence: Likelihood of Occurrence (1-10)

Detection: Likelihood of Detection (1-10)

NOTE: 1 = Very likely it WILL be detected

10 = Very likely it WILL NOT be detected

Severity: Severity (1-10)

RPN: Risk Priority Number (Occ × Det × Sev)

= 6 x 6 x 5 = 180

STEP 7: Ward boy dispatches drugs to wards

FAILURE MODES	CAUSES	EFFECTS	SEVERITY RS	OCCURENCE RS	DETECTION RS	RPN
1.Medications delivered to the wrong area	Ward boy picks up the incorrect bag, may deliver the medication to the wrong address Workload, distractions	Could be severe if a patient receives and is administered incorrect medication	7	4	5	140

Calculation:

Occurrence: Likelihood of Occurrence (1-10)

Detection: Likelihood of Detection (1-10)

NOTE: 1 = Very likely it WILL be detected

10 = Very likely it WILL NOT be detected

Severity: Severity (1-10)

RPN: Risk Priority Number (Occ × Det × Sev)

= 7 x 4 x 5 = 140

STEP 8: Nurse receives medications from pharmacy

FAILURE MODES	CAUSES	EFFECTS	SEVERITY RS	OCCURENCE RS	DETECTION RS	RPN
1.Delay in delivery	Inadequate staffing Look alike packaging Label ambiguity	Delayed therapy Wrong dose/wrong drug may be given to patient	8	3	6	144
2.Medication delivered to the wrong area			7	5	5	175

Calculation:

Occurrence: Likelihood of Occurrence (1-10)

Detection: Likelihood of Detection (1-10)

NOTE: 1 = Very likely it WILL be detected

10 = Very likely it WILL NOT be detected

Severity: Severity (1-10)

RPN: Risk Priority Number (Occ × Det × Sev)

1. **8 x 3 x 6 = 144**
2. **7 x 5 x 5 = 175**

STEP 9: Verification for bill and patient details by nurse

FAILURE MODES	CAUSES	EFFECTS	SEVERITY RS	OCCURENCE RS	DETECTION RS	RPN
1.Verification not completed	Time constraints Nurse is too busy Inadequate staffing Ward boy delivered wrong medication	Delayed therapy Wrong medication may be given to patient	8	6	4	192
2.Received wrong medication			7	4	6	168

Calculation:

Occurrence: Likelihood of Occurrence (1-10)

Detection: Likelihood of Detection (1-10)

NOTE: 1 = Very likely it WILL be detected

10 = Very likely it WILL NOT be detected

Severity: Severity (1-10)

RPN: Risk Priority Number (Occ × Det × Sev)

1. **8 x 6 x 4 = 192**
2. **7 x 4 x 6 = 168**

STEP 10: Identification of high-risk medications by nurse ('**CAUTION**' marking)

FAILURE MODES	CAUSES	EFFECTS	SEVERITY RS	OCCURENCE RS	DETECTION RS	RPN
Improper identification of high risk medications	Look alike medications Not highlighted by the pharmacist Nurse is not aware of high risk medications	Wrong dose/ drug may be given to patient Patient will be at risk	9	6	4	216

Calculation:

Occurrence: Likelihood of Occurrence (1-10)

Detection: Likelihood of Detection (1-10)

NOTE: 1 = Very likely it WILL be detected

10 = Very likely it WILL NOT be detected

Severity: Severity (1-10)

RPN: Risk Priority Number (Occ × Det × Sev)

= 9 x 6 x 4 = 216

STEP 11: Nurse checks case sheet for doctor orders

FAILURE MODES	CAUSES	EFFECTS	SEVERITY RS	OCCURENCE RS	DETECTION RS	RPN
1.Order UN-clear/ not understood	Illegible hand writing Misread letters Sound alike drugs Unnecessary verbal orders Failure to read back	Delayed therapy Sub therapeutic dose/ over dose Wrong drug therapy	9	6	5	270
2.Verbal order misheard			7	6	5	210

Calculation:

Occurrence: Likelihood of Occurrence (1-10)

Detection: Likelihood of Detection (1-10)

NOTE: 1 = Very likely it WILL be detected

10 = Very likely it WILL NOT be detected

Severity: Severity (1-10)

RPN: Risk Priority Number (Occ × Det × Sev)

1. **9 x 6 x 5 = 270**
2. **7 x 6 x 5 = 210**

STEP 12: Nurse prepares medication for patients

FAILURE MODES	CAUSES	EFFECTS	SEVERITY RS	OCCURENCE RS	DETECTION RS	RPN
1.Incorrect medication prepared for patient	Careless errors, work load Messy work area (may pick up the wrong bottle)	Patient gets wrong medication and/ or wrong dosage. Could lead to hospitalization or possibly death.	10	5	4	200

Calculation:

Occurrence: Likelihood of Occurrence (1-10)

Detection: Likelihood of Detection (1-10)

NOTE: 1 = Very likely it WILL be detected

10 = Very likely it WILL NOT be detected

Severity: Severity (1-10)

RPN: Risk Priority Number (Occ × Det × Sev)

= 10 x 5 x 4 = 200

STEP 13: Nurse educates Patient before administering medication

FAILURE MODES	CAUSES	EFFECTS	SEVERITY RS	OCCURENCE RS	DETECTION RS	RPN
Did not check patient identification	Number of patients waiting for medications is too long	Endangerment of patient	10	6	5	300

Calculation:

Occurrence: Likelihood of Occurrence (1-10)

Detection: Likelihood of Detection (1-10)

NOTE: 1 = Very likely it WILL be detected

10 = Very likely it WILL NOT be detected

Severity: Severity (1-10)

RPN: Risk Priority Number (Occ × Det × Sev)

= 10 x 6 x 5 = 300

STEP 14: Administering medication to the patient

FAILURE MODES	CAUSES	EFFECTS	SEVERITY RS	OCCURENCE RS	DETECTION RS	RPN
1.Patient is not educated regarding medication	Nurse is too busy Language barrier Patient is sleeping Patient refusal	Contra-indications may happen	7	8	5	280

Calculation:

Occurrence: Likelihood of Occurrence (1-10)

Detection: Likelihood of Detection (1-10)

NOTE: 1 = Very likely it WILL be detected

10 = Very likely it WILL NOT be detected

Severity: Severity (1-10)

RPN: Risk Priority Number (Occ × Det × Sev)

= 7 x 8 x 5 = 280

INTERPRETATION:

PARETO ANALYSIS:

Pareto analysis is a statistical technique in decision-making that is used for selection of a limited number of tasks that produce significant overall effect.

It uses the Pareto principle – the idea that by doing 20% of work, 80% of the advantage of doing the entire job can be generated. Or in terms of quality improvement, a large majority of problems (80%) are produced by a few key causes (20%).

Pareto analysis helps in:

- Separating the few major problems from the many possible problems to make improvement efforts.
- Arranging data according to priority or importance.
- Determining which problems are most important using data, not percept

FAILURE MODE RPN SCORES:

SL NO	STEPS	RISK PRIORITY NUMBER
1	Orders written for new medications by doctor which are copied into medication chart by the nurse and then nurse only raises indents	250
		245
2	Electronic indents received in pharmacy	84
3	Entry of medication details by pharmacist	120
4	Vouchers/ bills generated, **high risk medications** are identified and highlighted by pharmacist	300
5	Segregated vouchers are taken to packing area and medications are packed	240
		175
6	Packed medications are transferred to the dispensing bay where they are arranged floor-wise	180
7	Ward boy dispatches drugs to wards	140
8	Nurse receives medications from pharmacy	144
		175
9	Verification for bill and patient details by nurse	192
		168
10	Identification of high risk medications by nurse ('**CAUTION**' marking)	216
11	Nurse checks case sheet for doctor orders	270
		210
12	Nurse prepares medication for patients	200
13	Patient is educated by nurse before administering medication	280
14	Administering medication to the patient	300
	TOTAL RPN	3889

PARETO CHART:

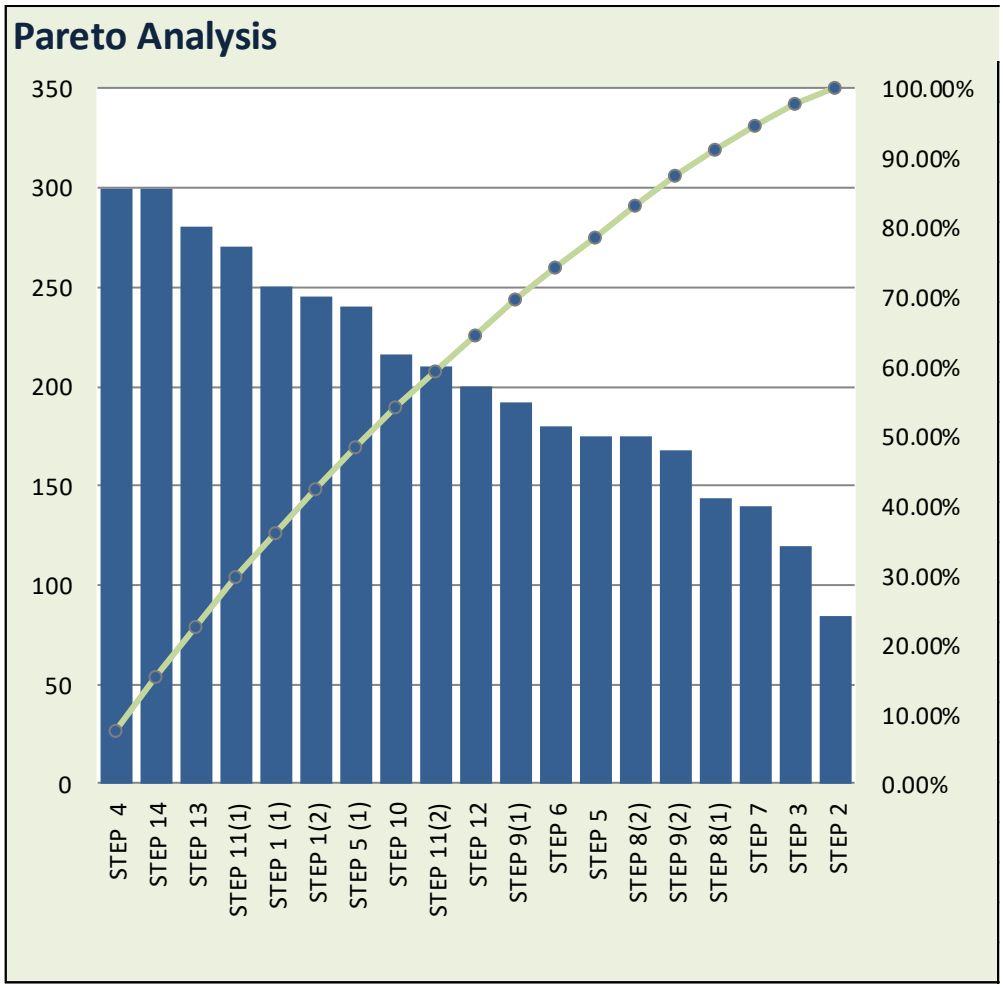
Pareto principle states“80% of medication errors arise from 20% of failure causes.”

The Pareto Chart brings immediate focus to which categories are part of the “vital few” and thus should receive attention first. By dropping a vertical line from where the horizontal line at 80% intersects the cumulative percentage line, this chart shows that first ten steps in the chart are the most critical departments that are leading to medication errors and thus patient dissatisfaction. Thus organization has to focus its improvement efforts on these areas in order to prevent medication errors and to achieve patient satisfaction.

From the above Pareto chart we can see that the first ten steps in the Pareto chart cause almost 78% of the complaints with high Risk Priority Number.

Taking into consideration that it is easier to reduce a high frequency than a low one, the diagram shows that it would be more useful that the improvement focuses on the first ten causes (few and vital) rather than on the low incidence ones (many and trivial).

Once implemented the appropriate actions to reduce these ten causes, another diagram can be drawn up in order to check the decrease of the failure mode causes at each of the ten categories


Pareto Analysis
350
300
250
200
150
100
50
0
100.00%
90.00%
80.00%
70.00%
60.00%
50.00%
40.00%
30.00%
20.00%
10.00%
0.00%
STEP 4
STEP 14
STEP 13
STEP 11(1)
STEP 1 (1)
STEP 1(2)
STEP 5 (1)
STEP 10
STEP 11(2)
STEP 12
STEP 9(1)
STEP 6
STEP 5
STEP 8(2)
STEP 9(2)
STEP 8(1)
STEP 7
STEP 3
STEP 2

total:	3889	
STEPS	RPN	Cumulative %
STEP 4	300	7.71%
STEP 14	300	15.43%
STEP 13	280	22.63%
STEP 11(1)	270	29.57%
STEP 1 (1)	250	36.00%
STEP 1(2)	245	42.30%
STEP 5 (1)	240	48.47%
STEP 10	216	54.02%
STEP 11(2)	210	59.42%
STEP 12	200	64.57%
STEP 9(1)	192	69.50%
STEP 6	180	74.13%
STEP 5	175	78.63%
STEP 8(2)	175	83.13%
STEP 9(2)	168	87.45%
STEP 8(1)	144	91.15%
STEP 7	140	94.75%
STEP 3	120	97.84%
STEP 2	84	100.00%

SUMMARY

RECOMMENDATIONS:

From the study undertaken, the following recommendations can be taken into account like

- It was observed in the hospital that there was no way to highlight the use of high risk medication, in such case the system of Alert notes was adopted which allowed the all the respective care delivers associated to the patient to know if any high risk medication was induced to the patient.
- Instead of indenting a single drug, Nurse can indent total number of particular medicine needed for complete day, so that they can reduce the indent number to the pharmacy. this measure was very helpful for the pharmacist as well as for the nurse as it reduced the risk associated.
- Nurse should verify the indented slip and case sheet after receiving packages of medicine from pharmacy to avoid wrong drug and dose.
- Double check to be done by other pharmacist before packing of medicine, so that it can reduce the incomplete and wrong medication dispensing to ward.
- System like Tall Man Lettering and Alert Notes must be implemented for high risk medications to minimize the errors due to these high risk groups (includes look alike and sound alike drugs)
- Constant supervision of the pharmacy boy has to be done by the pharmacy supervisor.
- All the nursing staff must be aware of high-risk medications.
- Ward nursing staff must know the overall process of prescribing, indenting, dispensing and administration of medications to the patients and their schedule and should have a commitment to make it happen on time.
- Prescription audit for drugs must be done by pharmacologist

- Time is not devoted for patient education, patient education is either missing or incomplete, therefore more in-service training regarding patient education must be given to ward staff and they should be advised to devote time for it.
- Patient safety rounds must be performed on a schedule by audit team to monitor the patient condition.
- Ensure that follow-up instructions are properly given to the patient by nurse/residents.
- LAMA (Leave Against Medical Advice) patients should also be given instructions regarding the given medications at the time of discharge.
- Medical audits in wards must be done on a regular basis

LIMITATIONS OF STUDY:

- Failure mode effect analysis can be well performed and will be effective on a simple process than on a complex process involving too many sub processes. Medication management is a complex process involving too many sub processes.
- Obtaining, interpreting, and applying severity, probability of failure, and detection ratings can be difficult and tedious. This is one of the limitations associated with FMEA.

Three other major limitations to the FMEA methodology are as follows:

- It only examines individual faults of system elements; the combined effects of simultaneous failures are not considered
- It takes time to complete a full analysis, especially for complex systems; and
- It is not geared to identify human frailties.

CONCLUSION

Medication management is very necessary and it is worth the factor to apply for a better living. Implementing safe, organized and efficient medication management system is essential for controlling errors. An appropriate drug ordering, dispensing, storage, administration systems are important for the prevention and reduction of medication errors in hospital.

On the basis of FMEA analysis of medication management process we can conclude that FMEA's provide the management with a tool that can assist in providing reliable, safe and patient pleasing services and process as well as improves the efficiency of process and prevents errors.

This tool worked as a benchmark and the hospital should conduct this study in every quarter so as to analyze the improvement with the time.

Since FMEA helps the management to identify the potential services or process failures, they can use it to:

- Develop service or process requirements that minimize the likelihood of those failures.
- Evaluate the requirements obtained from patients or their relatives in the design process to ensure that those requirements do not introduce potential failures.
- Track and manage potential risk in the process.
- Ensure that any failures that could occur will not injure or seriously impact the patient of the process.

SCOPE FOR FURTHER RESEARCH:

There is a scope for further research, after implementing necessary corrective measures for the prevention of the high risk failure causes, one can again conduct Failure Mode Effect Analysis and calculate the new Risk Priority Number (RPN) and compare it with the old Risk Priority Number (RPN) and check whether the implemented corrective measures reduced the risk of potential failure causes.

APPENDIX

FAILURE MODES AND EFFECT ANALYSIS (FMEA) MATRIX:

Steps in process	Failure modes	Failure Causes	Failure effects	Severity rating scale (1-10)	Occurrence rating scale (1-10)	Detection rating scale (1-10)	Risk Priority number (RPN)	Actions to reduce occurrence of failure
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
							Total RPN	

Failure mode: What could go wrong?

Failure causes: Why would the failure happen?

Failure effects: What would be the consequences to failure?

Likelihood of Occurrence: 1-10, 10 = very likely to occur

Likelihood of Detection: 1-10, 10 = very unlikely to detect

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