EVALUATION OF COMPLIANCE AGAINST THE PREDEFINED STANDARDS FOR THE HANDLING AND USE OF CONCENTRATED ELECTROLYTES USING FMEA METHODOLOGY IN A TERTIARY CARE HOSPITAL

Dissertation submitted to

The IIHMR University

For the partial fulfillment for the award of a degree of

Master of Business Administration (MBA)

In

Hospital and Health Management

By

Dr. Urvashi Kapoor

Under the Supervision and Guidance of

Dr. P.R. Sodani

MBA-HM Batch 2020-2022

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DECLARATION BY STUDENT

I hereby declare that this dissertation titled **EVALUATION OF COMPLIANCE AGAINST THE PREDEFINED STANDARDS FOR THE HANDLING AND USE OF CONCENTRATED ELECTROLYTES USING FMEA METHODOLOGY IN A TERTIARY CARE HOSPITAL** is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

(Signature)

Name of Student- Dr. Urvashi Kapoor

Date- 01/07/22

CERTIFICATE

This is to certify that Urvashi Kapoor in partial fulfillment of the requirements for the award of the degree of MBA in Hospital and Health Management from the IIHMR University, Jaipur has successfully completed her internship at Medanta-The Medicity, Gurugram from April 11, 2022, to July 04, 2022.

Place: Gurugram

Date: 01/07/22

Preceptor/Head of the Organization

Name of the organization- Medanta-The Medicity

CERTIFICATE

This is to certify that dissertation titled **EVALUATION OF COMPLIANCE AGAINST THE PREDEFINED STANDARDS FOR THE HANDLING AND USE OF CONCENTRATED ELECTROLYTES USING FMEA METHODOLOGY IN A TERTIARY CARE HOSPITAL** is a record of the research work undertaken by Dr. Urvashi Kapoor in partial fulfillment of the requirements for the award of the degree of MBA (Hospital and Health Management from the IIHMR University, Jaipur under my guidance and supervision and her approach to the research study has been sincere, scientific, and analytical.

Faculty Guide- Dr. P R Sodani

IIHMR University, Jaipur
Date- 01/07/22

School Dean- Dr. (Col) Mahendra Sir

IIHMR University, Jaipur
Date- 01/07/22

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Table of Contents

ABSTRACT **7**

LIST OF FIGURES **8**

LIST OF TABLES **9**

ABBREVIATION **10**

CHAPTER 1. BACKGROUND **11**

RESEARCH QUESTIONS 12

OBJECTIVES 12

JOINT COMMISSION INTERNATIONAL (JCI) 13

ABOUT THE ORGANIZATION ..... **ERROR! BOOKMARK NOT DEFINED.**

CHAPTER 2. REVIEW OF LITERATURE **17**

CHAPTER 3. RESEARCH METHODOLOGY **19**

CHAPTER 4. RESULTS **28**

CHAPTER 5. DISCUSSION **35**

CHAPTER 6. RECOMMENDATIONS **37**

CHAPTER 7. REFERENCES **38**

ANNEXURE **39**

ABSTRACT

Introduction: Concentrated electrolytes can be fatal if administered inappropriately. It has been reported that prescription, preparation, or administration errors of concentrated electrolytes such as IV potassium can cause significant patient harm. The objective of this study is to present an assessment that will aid in reducing medication errors and managing the risk to ensure a safe hospital policy. FMEA methodology is used to undertake this study as it focuses on a systematic identification of postulated component failures associated with the storage, handling, administration, and monitoring process of concentrated electrolytes, identification of the resultant effects on system operation, and interventions to improve the process and mitigate failures.

Methodology: This was an observational cross-sectional study that was conducted in the In-patient (IP) units of a tertiary care hospital in Gurugram, from the month of April to June. The sampling technique was simple random sampling, and the sample size was 30 patients who were on concentrated electrolyte infusion during the study period in the ICUs and wards. A total of 8 ICUs and 2 wards were audited on a random basis to check their compliance with predefined standards.

Results: A 100% conformance was observed in the identification and verification of high-risk medication prior to the administration of concentrated electrolytes. There is a lack of compliance found at the physician's end while prescribing the concentrated electrolytes. Only 30% compliance was found for writing the date and time of starting the concentrated electrolytes. Subsequently followed by which only 33.3% compliance was found for writing the complete instructions (dose, dilution, rate, frequency) for the administration of concentrated electrolytes.

Conclusion: The results indicated good practice and adherence to the predefined standards and recommended guidelines in 68.75% of the cases. Recommendations for the improvement in the low compliance rate will further help in sustaining adherence to the defined protocols.

Keywords

Concentrated electrolytes, High-alert, FMEA, Quality, Standards

LIST OF FIGURES

Figure 3.1- Mapping the process of concentrated electrolyte administration

Figure 3.2- FMEA Process

Figure 4.1- Compliance Rate for concentrated electrolytes

LIST OF TABLES

Table 3.1- Checklist for Audit

Table 3.2- Severity Scale Scoring

Table 3.3- Occurrence Scale Scoring

Table 3.4- Detection Scale Scoring

Table 3.5- Failure Modes, Effects, and Causes of the Process

Table 4.1- RPN Calculation

ABBREVIATION

BCMA	Barcoded Medication Administration
IP	In-Patient
ISMP	Institute for Safe Medicine Practices
IV	Intravenous
JCI	Joint Commission International
KCL	Potassium Chloride
ME	Medication Errors
MgSO4	Magnesium Sulphate
RPN	Risk Priority Number

CHAPTER 1. BACKGROUND

Medication errors (MEs) are a common occurrence because of the five complex stages of the process of medication: (a) prescription, (b) transcription, (c) preparation, (d) administration, and (e) monitoring (1,2). Reportedly, one-third of all the MEs that harm the patients usually occur in the preparation and administration stage (2). Concentrated electrolytes can be fatal if administered inappropriately (3,4). It has been reported that prescription, preparation, or administration errors of concentrated electrolytes such as IV potassium can cause significant patient harm.

Types of Medication Errors for concentrated electrolytes

1. Prescription Errors

- Incorrect dosage, rate, dilution, frequency, route recommended by Doctor
- The wrong patient was given the wrong medication
- Patients' medical conditions, such as drug allergies, are not considered while prescribing
- Not considering the patient's clinical data, such as their weight, height, or body surface area, while deciding on a medication regimen
- An unsigned, undated, or untimed prescription (Wrongly documented)
- Administration of concentrated electrolytes without a sound medical basis

2. Transcription errors

- Incorrect transcribing from a doctor's prescription (dose, rate, frequency, dilution) on the medication administration record

3. Dispensing Errors

- The patient was given an inappropriate solution
- The prepared solution was inappropriately labelled

4. Administration Errors

- The wrong patient was given the wrong medication
- Inappropriate dilution or incorrect preparation of the solution
- Insufficient infusion
- Late or early doses of medication

5. Monitoring Errors

- Mismanagement of therapeutic concentrations
- Not monitoring the vitals of the patients every four hours
- Adverse events including adverse drug reactions and drug allergies might occur if a patient does not respond to them

The objective of this study is to present an assessment that will aid in reducing medication errors and managing the risk to ensure a safe hospital policy. FMEA methodology is used to undertake this study as it focuses on a systematic identification of postulated component failures associated with the storage, handling, and administration process of concentrated electrolytes, identification of the resultant effects on system operation, and interventions to improve the process and mitigate failures.

RESEARCH QUESTIONS

1. What could be the possible gaps in compliance with the standard operating procedures (SOPs) for storage, handling, administration, and monitoring of concentrated electrolytes in ICUs and wards?
2. What could be the potential failures and consequences associated with the non-compliance of SOPs of storage, handling, administration, and monitoring of concentrated electrolytes?
3. What interventions can be taken to improve compliance with SOPs for the usage of concentrated electrolytes?

OBJECTIVES

1. To find out the gaps in compliance with the SOPs for storage, handling, administration, and monitoring of concentrated electrolytes in In-patient units.
2. To identify and list the potential failure modes and consequences associated with the storage, handling administration, and monitoring of concentrated electrolytes
3. To develop action plans and give recommendations for improvement in compliance with the process at various stages of administration of concentrated electrolytes

JOINT COMMISSION INTERNATIONAL (JCI)

Joint Commission International is known to be the world's largest healthcare accreditor. The Gold seal of JCI approval is a benchmark for an exhaustive evaluation process that is recognized worldwide.

JCI standards are designed to do the following:

- "Ensure a safe environment that reduces the risk for care recipients and caregivers"
- "Offer quantifiable benchmarks for quality and patient safety"
- "Stimulate and demonstrate continuous, sustained improvement through a reliable process"
- "Improve outcomes and patient experience"
- "Enhance efficiency"
- "Reduce costs through standardized care"

Accreditation by the JCI can benefit an organization in the following ways:

- *"Guides the management of a health care organization*": The standards of JCI are designed to help the leaders to manage their organizations and ensure safety and quality care while delivering patient services effectively and efficiently.
- *"Enhances staff education":* The process of JCI accreditation is designed to be educational for the organization. The best-practice approaches and strategies shared by the JCI surveyor may help the hospital to improve the performance of day-to-day operations.
- *"Helps organize and strengthen your improvement efforts":* The concepts of performance improvement in the accreditation help in continuously improving quality and standardizing the processes of treatment, care, and services.
- *"Gives you a competitive advantage":* Achieving accreditation not only sets the hospital apart from others that offer a similar type of treatment, care, and services but also are a visible demonstration to the community and patients that the hospital is committed to providing the safest care and highest-quality services.

Goal 3: Improve the safety of high-alert medications

Standard IPSG 3.2- The hospital develops and implements a process to manage the safe use of concentrated electrolytes

New Measurable Elements-

ME1- Only qualified and trained individuals have access to concentrated electrolytes and they are clearly labelled with appropriate warnings and segregated from other medications.

ME3- Standard protocols are followed for adult, pediatric, and/or neonatal electrolyte replacement therapy to treat hypokalaemia, hyponatremia, and hypophosphatemia.

ME2- The hospital only stores vials of concentrated electrolytes outside of the pharmacy in situations identified in the intent such as cardiac kits or cardiac surgery locked storage areas.

ORGANIZATIONAL PROFILE

Medanta-The Medicity, located in Gurugram, India, is an Indian chain of multi-specialty medical institutions. Medanta, Gurugram was founded in the year 2009 by Dr. Naresh Trehan, a well-renowned heart surgeon who is the Chairman and Managing Director of the hospital.

There are more than 22 super-specialty facilities on the huge 2.1 million square foot complex of Medanta, which can accommodate 1,600+ patients. In order to ensure that the floors work as autonomous hospitals within a hospital, each level is allocated to a specific specialization..

The goal of the institution is to deliver the finest levels of medical treatment, clinical research, education, and training to India. Medanta's mission is to treat patients with care, compassion, and dedication.

In total, six centers of excellence are housed within Medanta, each with a fully integrated and comprehensive information system that will give medical intelligence, cutting-edge technology, and cutting-edge infrastructure.

Medical researchers, scientists, and clinicians from around the world have gathered in Medanta – The Medicity in order to foster interdisciplinary research that will spur new ideas and discoveries, as well as more quickly translate scientific advances into better ways of diagnosing and treating patients and the prevention of disease. As the first facility in the world that combines contemporary and traditional medicine to provide inexpensive healthcare, Medanta is a pioneer.

MISSION

Medanta's vision is to deliver world-class healthcare services by creating institutes of excellence in integrated medical care, teaching, and research. We aspire to create an ethical and safe environment to treat all with respect and dignity.

VISION

The institute is governed under the guiding principles of providing affordable medical services to patients with care, compassion, and commitment.

-Leadership & excellence

An unwavering focus on doing things better than anyone else and setting an example for others to follow.

-Integrity & courage

Setting the interests of patients ahead of the institution's and showing fortitude to do just what is right in order to maintain high ethical standards.

-Compassion & service

Patients and their carers should be treated as if they were our own family members.

-Collaboration, learning & innovation

Improve our ability to attain our goals by encouraging cooperation and cooperation among team members, as well as by embracing change and creativity.

CHAPTER 2. REVIEW OF LITERATURE

Concentrated electrolytes can be fatal if administered inappropriately (3,4). One of the frequently cited medication issues is the unintentional or incorrect administration of concentrated electrolytes, for instance, potassium chloride, potassium phosphate, sodium chloride, and magnesium sulphate. Medication Safety Authorities throughout the world consider intravenous (IV) potassium chloride (KCL) as a 'high-alert medication' (5).

Several incidents of deaths have been identified in the literature as a consequence of inadvertent administration of concentrated electrolytes without dilution (6,7). The most effective means to mitigate these instances is to analyze the process of administration, identify potential failures and prepare action plans for the improvement of this process. IPSG 3.2 in the Joint Commission International standards is concerned with the development and implementation of processes that will enable the safe use of concentrated electrolytes (6).

According to Nakatani et al., 2019, there is a worldwide occurrence of severe adverse effects including arrhythmia and cardiac arrest due to rapid intravenous administration of potassium chloride at high concentrations. One of the substantial causes is the inadvertent administration of concentrated electrolytes (8).

An article by the Institute for Safe Medication Practices (ISMP) titled, 'Administration of concentrated potassium chloride for injection during a code: Still deadly!' highlighted the lack of communication and incorrect assumptions as one of the root causes of inadvertent administration of concentrated electrolytes that lead to the unfortunate demise of a 70-year-old patient (9).

ISMP Canada reported two tragedies that lead to the deaths of two paediatric patients due to IV administration of concentrated electrolytes that could be prevented. A need for sustained, worldwide vigilance was demonstrated in these cases to identify the threats to the safety of patients when injectable concentrate solutions are not stored, monitored or administered appropriately(10).

A study conducted in the Osaka City University Hospital, Japan, by Nakatani et al., 2019, reported that some of the physicians at their hospital had prescribed high doses of KCL or undilute KCL to patients without any clinical indication (8).

It has been illustrated that the standardization and simplification of the processes of medication use can mitigate adverse drug events with the help of system analysis of medication use, especially medication errors. This can be interpreted as developing and using standardized, streamlined processes and models of treatment that are clinically sound, decreasing variation and unnecessary complexity in the medication usage process (5).

A study by Ofek F et al., 2016, “Introducing a change in hospital policy using FMEA methodology as a tool to reduce patient hazards” was able to promote a more effective and safer process in healthcare systems. This study has demonstrated how the FMEA technique enables thorough examination to identify the causes of risks and implement a strategy to improve the safety of patients, ensure efficient pharmaceutical activity, and manage the finances. The methodology aided them to implement a change in their hospital’s policy regarding the regular usage of concentrated electrolytes (4).

A high-risk medication alert issued by the “Australian Council for Safety and Quality in Health Care” for IV KCL covers the prescription, storage, preparation, and administration of intravenous potassium chloride (11).

CHAPTER 3. RESEARCH METHODOLOGY

RESEARCH DESIGN

An observational cross-sectional study conducted to check compliance with the hospitals' predefined guidelines and JCI standards in the In-patient (IP) departments of Medanta- The Medicity, Gurugram, from the month of April to June.

SETTING OF THE STUDY

In-patient units (ICUs and wards) of Medanta- The Medicity, Gurugram.

SAMPLE SIZE AND POPULATION

The sample size is 30 patients who were undergoing concentrated electrolytes infusion during the study period in the ICUs and wards. The exclusion criteria are patients not in need of concentrated electrolytes. A total of 8 ICUs and 2 wards were audited randomly to check their compliance with predefined standards.

SAMPLING TECHNIQUE

A simple random sampling technique was used in the study.

DATA COLLECTION TOOLS AND TECHNIQUES

A checklist was prepared to assess the compliance against predefined protocols for the usage of concentrated electrolytes **Investigations- Non-Drug Orders**

Table 3. 1. This checklist comprises all the components that are necessary for the safe handling and administration of concentrated electrolytes. In reference to the JCI standard IPSG 3.2 and hospitals' policy, the process components were identified and a survey tool was developed. Random audits in the In-patient units were conducted and the process and sub-processes were identified to understand the potential failure modes in the process.

Concurrent patient medical records and the step-by-step process of concentrated electrolytes administration were audited. The concerned staff was interviewed regarding the storage, preparation, and administration-related protocols of concentrated electrolytes in their respective patient care areas.

Data source:

Prescription- Medication Administration Record

Vitals- ICU and IPD Flowsheets

Investigations- Non-Drug Orders

Table 3. 1 Checklist for Audit

PARAMETERS	**PATIENT UHID and AREA**
Concentrated electrolytes are stored in the medicine room in ICUs in a separate medicine cabinet dedicated only for high-risk medications	
Concentrated electrolytes are stored in a single lock and key, the key to high-risk medicine cabinet is with the clinical pharmacologist	
Concentrated electrolytes are marked with a red tag/dot and have a warning of dilution before use	
Physician writes concentrated electrolyte order in CAPITALS and legible letters without using any unapproved abbreviations in the Medication Administration Record	
Start date and time at the time of writing the prescription documented	
Doctor writes the instructions related to dose, rate, frequency and dilution	
Appropriateness of the drug, dose, frequency, dilution, and route of administration	
Therapeutic duplication Patient's lab values and other physiological information	
Clinical pharmacist places the indent request of concentrated electrolytes in the Hospital Information System	
IP Pharmacy marks the concentrated electrolytes with a red dot	
Clinical pharmacist verifies the received medicines and stores them in the designated areas	
Verification of the patient and drug details is done in the presence of two nurses	
Trained and qualified nursing staff prepares, admixes and labels the solution	
Patient identification is done using two identifier policy (UHID, patient full name)	
Electrolytes given in the diluted form and as per the prescribed route (central/peripheral line)	
Investigations are advised by the doctor periodically to monitor the levels of electrolyte and adjust the rate of administration accordingly	
In the event of Adverse drug reaction, solution is immediately discontinued	

DATA ANALYSIS AND INTERPRETATION

Failure Mode and Effects Analysis (FMEA) is a systematic technique that identifies the effects, evaluates, prioritizes the causes, and eliminates the potential modes of failure to improve the safety, quality, and reliability of the process (12). FMEA includes the review of as many subsystems and components as possible to identify the potential harms (causes and effects) and failure modes (4). FMEA can help change the system to a safer and more reliable condition by predicting how and where the systems might fail and preventing unacceptable failures from occurring (13).

To find failure modes and potential damage, FMEA entails examining the maximum components, and subsystems (causes and effects).

A specific FMEA worksheet is used to record the failure modes and the impact of each component on the system. A cumulative numerical value known as the Risk Priority Number (RPN) is then attributed to each component of the process under investigation. RPN is a numerical ranking of each failure mode's severity, probability, and detectability that is used to categorize the action that is to be taken on the basis of priority.

FMEA process

STEP-1 Select the Process

STEP-2 Map the process (**Figure 3. 1**)

The current situation and process of storage, handling, and administration of concentrated electrolytes were reviewed and understood. After thoroughly understanding the practice and hospital policy, the failure modes associated with the process were identified.

STEP 3 Establish a Multidisciplinary team

A multidisciplinary team that included the nursing staff, clinical pharmacist, physician, quality assurance representative, and nursing supervisor participated in the process to analyze the risks and improve the safety of medication usage.

STEP 4 Target and List the possible failure modes (**Figure 3. 2**)

STEP 5 Prioritize the failure modes

STEP 6 Develop an Improvement Plan

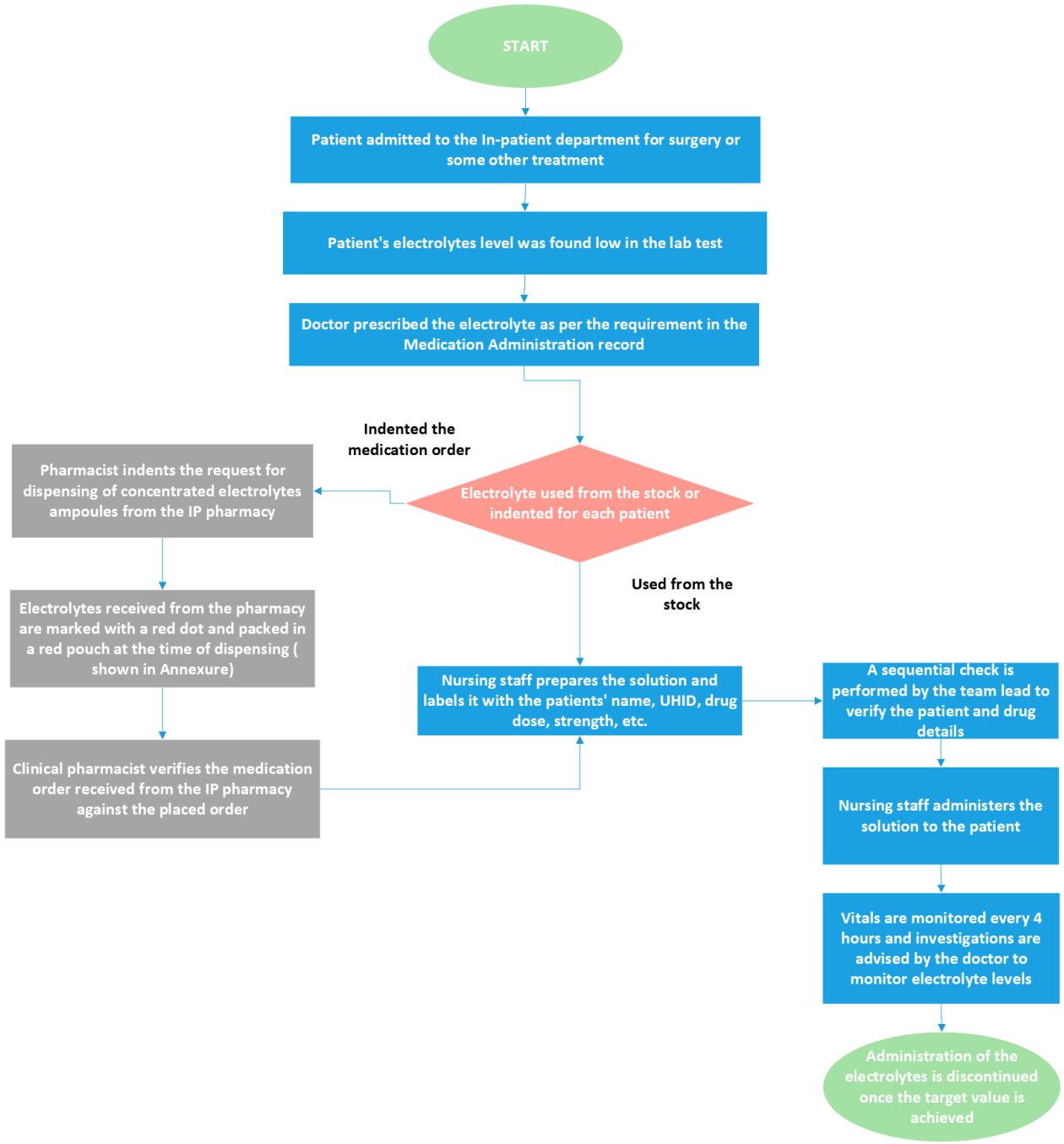

Figure 3. 1 Mapping the process of concentrated electrolyte administration

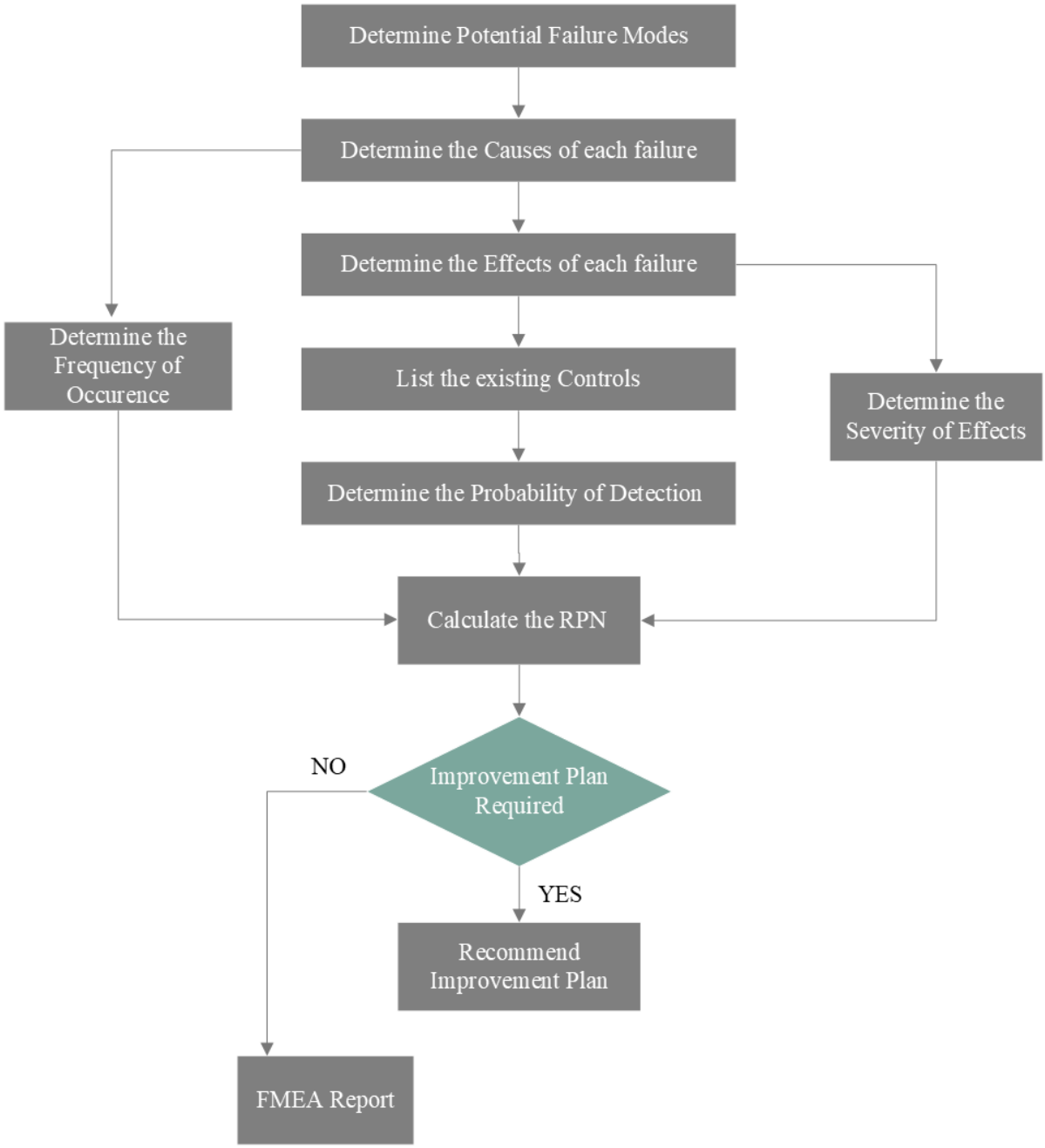

Figure 3. 2 FMEA procedure

Factors of Risk Assessment for FMEA

⇒ Severity (S)- Based on the severity of effects of potential failure modes, a number from 1 to 10 is used for the categorization of the severity of a failure mode.

1= no effect……10= maximum severity

Table 3.2 Scoring of Severity Scale

1	When there is no Effect
2	Might affect the system when there is slight annoyance
3	May affect the patients, categorized as a system problem which is moderate
5	May affect the patient, categorized as a system problem which is major
7	May cause temporary harm to the patient, Minor injury
9	Major injury: permanent lessening of body function, surgical intervention required, disfigurement
10	Terminal injury or death

⇒ Occurrence (O)- Based on the likelihood of occurrence, a number from 1 to 10 is used for categorization of each cause of failure

1= very likely to occur…….10= almost certain to occur

Table 3.3 Scoring of Occurrence Scale

1 Remote	No known occurrence or happens less than 10% of the time
3 Low	Possible, but no known data; or happens 10-30% of the time
5 Moderate	Documented but less frequent; or happens 40-60% of the time
7 High	Documented and frequent; or happens 70% of the time
10 Very High	Documented, almost certain; or happens 90-100% of the time

⇒ Probability of Detection (D)- Likelihood of detection for each cause of failure (before it reaches the end-user or customer.

Based on the likelihood of the detection of system (design control process, quality testing, etc.) responsible for the fault, a number from 1 to 10 was used for categorization

1= nearly certain detection……10= impossible to detect

Table 3.4 Scoring of Detection Scale

1 Very high	The error can be caught 9 out of 10 times, almost always detected
3 High	The error can be caught 7 out of 10 times or likely to be detected
5 Moderate	The error can be caught 5 out of 10 times or likelihood of detection is moderate
8 Low	The error can be caught 2 out of 10 times or likelihood of detection is low
10 Remote	Detection not possible at any point; or can be caught (0 out of 10 times)

Risk Priority Number- The failure mode's risk is found by the formula:

RPN= Severity (S) x Occurrence (O) x Detection (D)

RPN will be a number between 1 (virtually no risk) and 1000 (extreme risk). Regardless of RPN high severity scores should be given special attention.

Table 3.5 Possible modes of failure associated with use of concentrated electrolytes

S.No.	Failure Mode	Causes of Failure	Effects of Failure
1	Concentrated Electrolytes stored at the patient's bedside	Nursing staff might not be aware of the protocol of storage/ was in a hurry to manage other patient/ pharmacist was not available to receive the dispensed medications	Staff can administer wrong medication, misuse
2	Concentrated electrolytes stored with normal medications in the medicine cabinet	The clinical pharmacist might not be aware of the protocol/ high alert medications received from IP pharmacy without a red coloured dot/tag making it difficult to identify as high-risk/ stored it with normal drugs in a hurry	Storage of high-risk medicines with normal medications can lead to administration of wrong medication, pilferage
3	Concentrated electrolytes stored without lock and key	The clinical pharmacist forgot to lock the cabinet of high-risk medication/ was not aware of the protocol	pilferage, access to high-risk medications can lead to administration of medicines without verification
4	Key to the high-risk medicine cabinet is with an unauthorized personnel/ anyone can access the key	The clinical pharmacist handed over the key to the nursing staff to take the medications/pharmacist misplaced the key	pilferage, access to high-risk medications can lead to administration of medicines without verification
5	Red tag/dot and warning missing from the bottle of concentrated electrolytes	IP pharmacy didn't verify and mark concentrated electrolytes medicine with a red dot before dispensing	can lead to storage of high-risk medicine in the normal medicine cabinet which can further lead to administration errors
6	Physician wrote the prescription in running handwriting/ illegible letters	Overwriting/ running handwriting in the Medication Administration Record/writing the prescription in a hurry	Ineffective communication, prescription errors can lead to preparation errors which further result in administration errors
7	Error in doctor's instruction documented in Medication Administration Record: dose or rate	Prescribed mistakenly while handling multiple records at the same time/ illegible letters	Ineffective communication, prescription errors can lead to preparation errors which further result in administration errors
8	The physician prescribed a high dose of electrolyte without any clinical indication	Lab reports were not accessible/ critical value shared with the doctor was wrong	can lead to deteriorating patient's condition, life-threatening
9	Documented an incomplete or wrong order	Got busy with some other patient/ attending an emergency situation/ mentioned in some other patient's records while handling multiple records at the same time	Ineffective communication, and prescription errors can lead to administration of an inappropriate solution

			to the patient, Deteriorating patient's condition
10	First dose appropriateness review not done	Clinical pharmacologist didn't review the medication record thoroughly/ failed to cross-check with the doctor/ handling too many patient files at the same time/ inadequate staff	Administration of an inappropriate solution to the patient
11	The clinical pharmacist failed to check any therapeutic duplications, patient's lab reports and other physiologic information	Pharmacist didn't review the medication order before preparation of the solution	Therapeutic duplications can lead to overdose of electrolyte which can lead to abnormal rhythms or adverse drug reactions
13	Clinical pharmacist indented the medication for the wrong patient	Pharmacist didn't check the patient's name and UHID before indenting/ not aware of patient identification policy/indented the request for a different patient while handling multiple records at the same time	Wrong indent can lead to medication errors or a sentinel event/Deteriorating patient's condition Administration of an inappropriate solution to the patient
14	IP Pharmacy didn't mark concentrated electrolytes with a red dot Clinical pharmacist stored the medicines in the designated area without performing a verification	IP pharmacy not aware of the policy and standards for high-alert medications	Can lead to storage of concentrated electrolytes in the normal medicine cabinet which can further lead to administration errors
15	Clinical pharmacist stored the medicines in the designated area without performing a verification	Pharmacist was not aware of the policy/ was busy/ asked the nursing staff to receive the medication	Can lead to storage of concentrated electrolytes in patient bedside, misplaced, misuse of the medication, pilferage, administration errors
16	Team lead or supervisor did not perform a sequential check	Nursing staff did not verify the dose, route, rate of administration/ Doctor's prescription was not legible/ running handwriting/ Fixation on familiar pattern of dose regimen	Dose or rate miscalculation leading to error in the administration that can lead to a life threatening condition
17	Nursing staff does not prepare the solution as per the order given	Unaware of the dilution standards, failed to see the warning on the ampoule, lack of knowledge about the dilution	Preparation of a solution inappropriate for the patient, administration errors leading to deteriorating patient's condition

18	Unsterile and cluttered drug preparation area, infection control protocols not followed	Nursing staff might not be aware of the protocol of preparation/ prepared the solution at the patient bedside in a non-sterile environment	Solution prepared in an unsterile environment can lead to hospital acquired infections
19	Proper labelling of prepared solution is not done	Unaware of the policy/standards in place, busy with other task or patient/ preparing multiple solutions at the same time	Wrong labelling can lead to administration of a solution not appropriate for the patient
20	Patient identification not done using two identifier policy	Lack of knowledge of two identifier policy/ didn't check both the identifiers	Wrong identification can lead to administration errors
21	Nurse did not administer the prepared solution as per the prescribed route	Nursing staff not aware of the standards or protocols of concentrated electrolyte administration	Administering a high dose via the peripheral line could cause phlebitis and pain
22	Doctor fails to advise the investigation to monitor patient's status after administration of concentrated electrolytes	Physician gave a verbal order/ advised in the progress sheet instead of the non-drug orders	Overdose of concentrated electrolytes, abnormal rhythm, cardiac arrest
23	Solution administration not discontinued and not informed the doctor	Nursing staff doesn't know how to handle the situation/ fails to inform the doctor/ didn't pay attention	Can lead to life threatening situation and death of the patient in case of serious ADRs

CHAPTER 4. RESULTS

FMEA methodology was used to evaluate the risk associated with each component of the process. The modes of failure were assessed for each element and graded according to the impact of risk and with the "cut-off" RPN value of 300, five primary risks were identified.

Random audits to monitor the level of compliance with the process have been conducted in several intensive care units and wards. The key failure risk modes where non-compliance was identified and that require awareness and training, as shown in Table 4.1, are listed below:

⇒ Storage of concentrated electrolytes at the patient's bedside- In the wards audited for compliance, concentrated electrolytes were found at the patient's bedside which is against the predefined protocol.

⇒ The key to the high-risk medicine cabinet is with unauthorized personnel- Ideally, a high-risk medicine cabinet can be accessed by pharmacists and team leaders/ supervisors. However, at the time of the audit, there was a nonconformance with this parameter, as even the nursing staff had access to the locked cabinet.

⇒ The physician prescribed running handwriting or illegible letters, as well as the start date and time of the drug and its rate of administration, were also not documented in several instances.

⇒ An appropriateness review was not performed or the pharmacist did not conduct an in-depth review and did not verify any therapeutic duplications or patients' lab reports and other physiologic information.

However, major parameters were found in compliance with the hospital policy and JCI standards. A 100% conformance was observed in the identification and verification of high-risk medication prior to the administration of concentrated electrolytes.

The percentage of compliance was found to be low during the prescription and verification stages of concentrated electrolytes, as illustrated in **Figure 4.1.** There was a lack of compliance observed when prescribing the concentrated electrolytes. Physicians failed to adhere to the protocol of prescribing the concentrate electrolytes in CAPITALs and mention the complete details of the medication orders such as date, time, dose,

dilution, frequency, and rate. Only 30% conformity was found for writing the start date and time of concentrated electrolytes. Subsequently, only 33.3% compliance was found for the writing of complete instructions (dose, dilution, flow rate, frequency) for the administration of concentrated electrolytes.

Additionally, 53.3% compliance was found for the appropriateness review conducted by the pharmacist before preparation of the solution and after administration of the same. The following parameters in accordance with hospital policy are intended to be verified by the pharmacist after every medication order, especially in the case of concentrated electrolytes: Appropriateness of the drug, dose, frequency, dilution, route of administration, therapeutic duplications, patient's lab values, and other physiologic information. Fourteen out of 30 prescription orders were not thoroughly verified by the clinical pharmacist of the designated ICUs

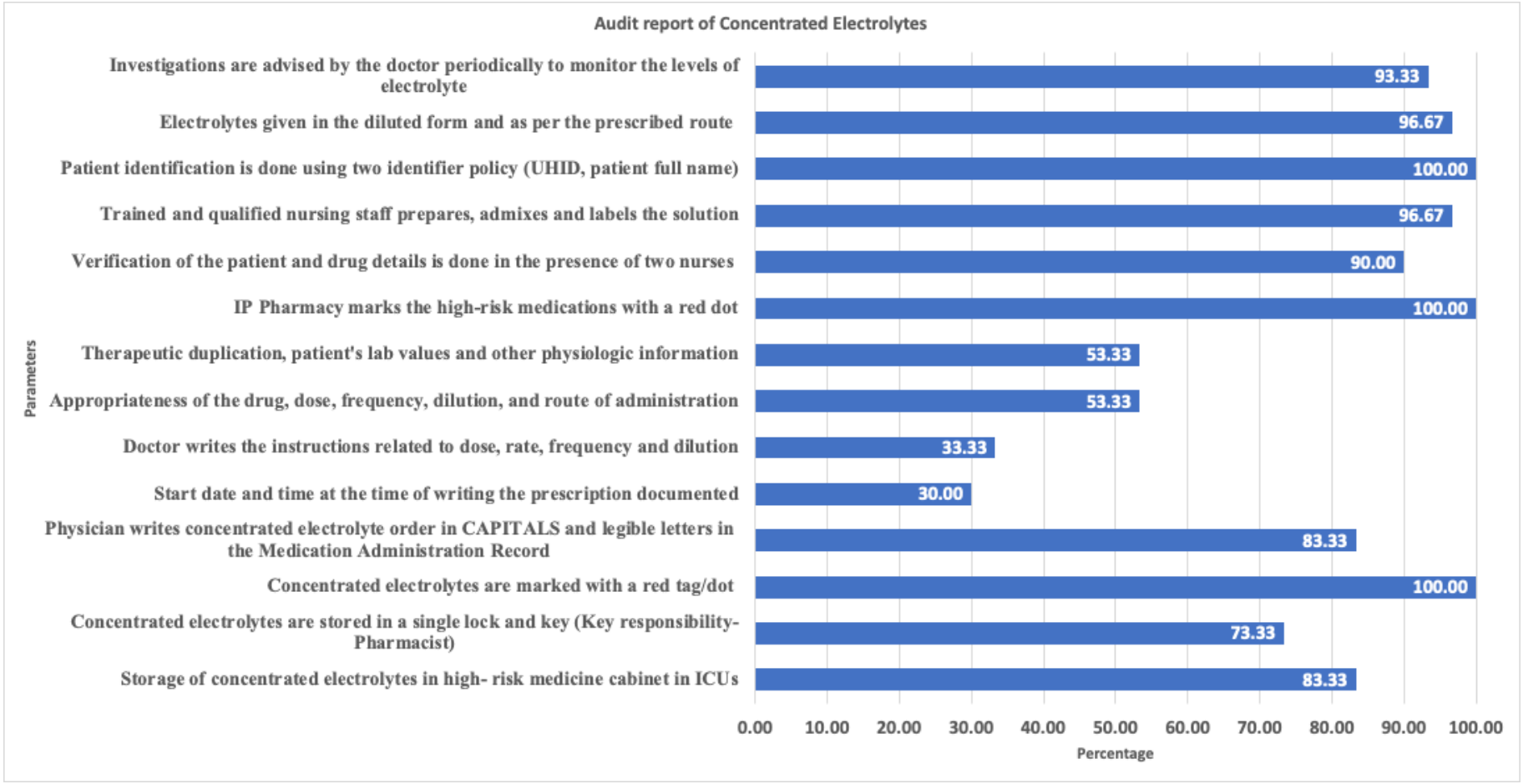

Figure 4.1 Compliance Rate of Concentrated electrolyte

Table 4.1 Failure modes scoring and RPN calculation

Failure Mode	Frequency of Occurrence (O)	Severity of Effects (S)	Probability of Detection (D)	Risk Priority Number (RPN)	Improvement Plan
Concentrated Electrolytes stored at the patient's bedside	10	7	7	490	Need for regular training and evaluation of nurisng staff on storage of high-risk medications and continuance surveillance audits by the clinical pharmacist
Concentrated electrolytes stored with normal medications in the medicine cabinet	4	6	3	72	
Concentrated electrolytes stored without lock and key	5	5	3	75	
Key to the high-risk medicine cabinet is with an unauthorized personnel/ anyone can access the key	7	5	8	320	A stock register can be maintained where the pharmacist has to document his/her signatures with the date and before the medicine is used from the stock for the preparation
Red tag/dot and warning missing from the bottle of concentrated electrolytes	2	7	3	42	
Physician wrote the prescription in running handwriting/ illegible letters	10	7	8	560	A bar-coded medication administration system can be adopted to avoid human errors Medication Order can be entered in the HIS with the help of a computer on wheels (COW)- a pilot project by doctors to avoid overwriting, running handwriting, or illegible prescription which can lead to administration errors
Dose or rate miscalculation leading to error in the administration that can lead to a life threatening condition	3	7	5	105	
The physician prescribed a high dose of electrolyte without any clinical indication	2	8	3	48	

Documented an incomplete or wrong order	2	8	10	160	A bar-coded medication administration system can be adopted to avoid humans errors Medication Order can be entered in the HIS with the help of a computer on wheels (COW)- a pilot project by doctors to avoid overwriting, running handwriting, or illegible prescription which can lead to administration errors
First dose appropriateness review not done	8	7	8	448	the use of the Clinical Decision Support Module (CIMS) tool which can be integrated with the HIS. It assists the clinical pharmacists in identifying any therapeutic duplications or drug-drug interactions and helps minimize any medication errors.
The clinical pharmacist failed to check any therapeutic duplications, patient's lab reports and other physiologic information	9	8	8	576	
Clinical pharmacist indented the medication for the wrong patient	3	8	2	48	
IP Pharmacy didn't mark the concentrated electrolytes with a red dot	2	6	3	36	
Clinical pharmacist stored the medicines in the designated area without performing a verification	4	6	3	72	
Team lead or supervisor did not perform a sequential check	3	7	4	84	
Nursing staff does not prepare the solution as per the order given	2	7	3	42	
Unsterile and cluttered drug preparation area, infection control protocols not followed	8	8	3	192	
Proper labelling of prepared solution is not done	2	7	2	28	
Patient identification not done using two identifier policy	4	7	3	84	
Nurse did not administer the prepared solution as per the prescribed route	3	8	3	72	
Doctor fails to advise the investigation to monitor patient's	6	8	3	144	

status after administration of concentrated electrolytes					
Solution administration not discontinued and not informed to the doctor	2	9	2	36	

CHAPTER 5. DISCUSSION

Medication errors are a significant problem for healthcare practitioners, pharmacists as well as medical administrators. This study describes the FMEA methodology as a systematic data collection tool to mitigate the errors associated with the handling and administration of concentrated electrolytes and increase the safe usage of this high-risk medication.

FMEA as an analytical tool allows performing a thorough analysis to pinpoint the root causes of problems and towards an approach that is an acceptable approach for balancing the safety of patients, and quality.

The various loci of intervention were clarified by ranking the distinct aspects, the severity of effects, the frequency of occurrence, and the probability of detection opening the way for desirable directives and cementing organizational policy.
Five major critical risks with the highest RPN were identified out of 8 selected potential failure modes.

FMEA methodology was undertaken to put forward the possible modes of failure and emphasize the most severe ones.

The purpose of the audits was to examine the compliance of the administration of concentrated electrolytes with the hospital policy. The results indicated good practice and adherence to the predefined standards and recommended guidelines in 68.75% of the cases. Recommendations for the improvement in the low compliance rate will further help in sustaining adherence to the defined protocols.

Concentrated electrolytes are made and given out as solutions with the idea that they will be diluted before being administered. Examples include but are not limited to Sodium Chloride 23.4%, Potassium Chloride 2mEq/ml, Hypertonic Premix Saline Solution 3%; solution; Sodium Bicarbonate 8.4%, and Magnesium Sulphate 50%. The potential of unintentional administration without dilution increases when these solutions are available in a patient care unit, especially in an emergency. In some therapeutic settings, such as crash carts in intensive care units and the emergency room, it may be important to stock concentrated electrolytes. Crash carts in intensive care units, procedural or interventional

suites, cardioplegia solutions in operating rooms for use during cardiac surgery, emergency rooms, emergency response medication boxes, drug detoxification programs, etc. are a few clinical settings where stocking concentrated electrolytes may be advised.

In order to prioritize areas for improvement based on the actual or potential impact (i.e., criticality) of care, treatment, or services provided, a proactive risk assessment (FMEA) thoroughly examines a process, including the sequencing of events, actual and potential risks, and failure or points of vulnerability.

CHAPTER 6. RECOMMENDATIONS

The hospital's policy needs some modifications to the predefined guidelines as well as to move on to the electronic medical/health records (EMR/EHR). Electronic Health Records are the first step to advanced and transformed healthcare. This helps in providing safe and higher quality care for the patients as well as creating tangible enhancement for an organization.

Commercially diluted solutions and standard dosage regimens can also be practiced to minimize the rate of potential errors happening at all preparation and administration stages.

Keeping in mind the higher attrition and indulgence of new employees in the system, there is a growing need for regular training and evaluation to sustain the adherence towards the defined protocols.

For instance, a Barcoded medication administration (BCMA) system can be used to prevent human errors. Its goal is to ensure that patients receive the correct medications at the correct time by properly documenting and validating medications. BCMA can improve patient safety.

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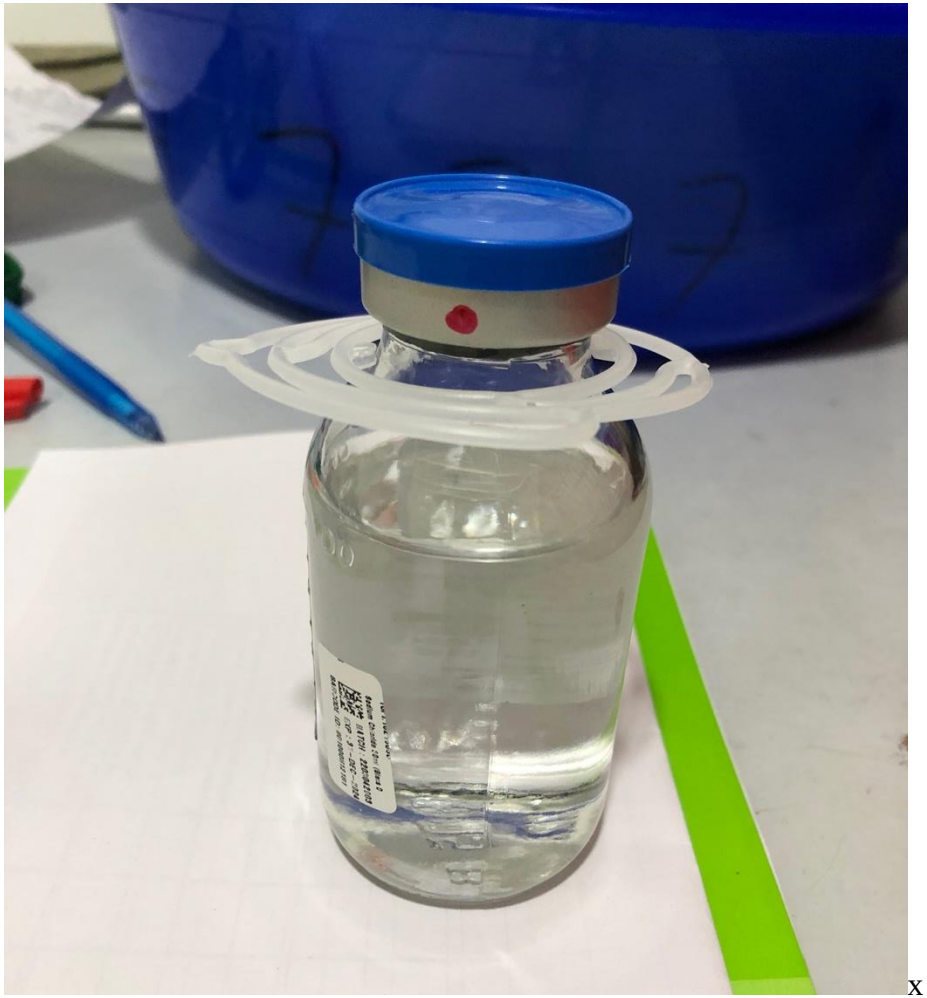
ANNEXURE


Sodium Chloride (3%)
Magnesium Sulphate (50%)
Potassium Chloride 10ml
Heparin 5000 units
Heparin 25000 units
Midazolam 10mg
Vecuronium Bromide
Nitrinon 10 ml


HIGH RISK MEDICINE
HIGH RISK MEDICINE
INJ. POTASSIUM CHLORIDE 10ML
Magnesium Sulphate (50%)
PATIENTS CONCENTRATED ELECTRO
Potassium chloride 10ml
Magnesium Sulphate (50%)



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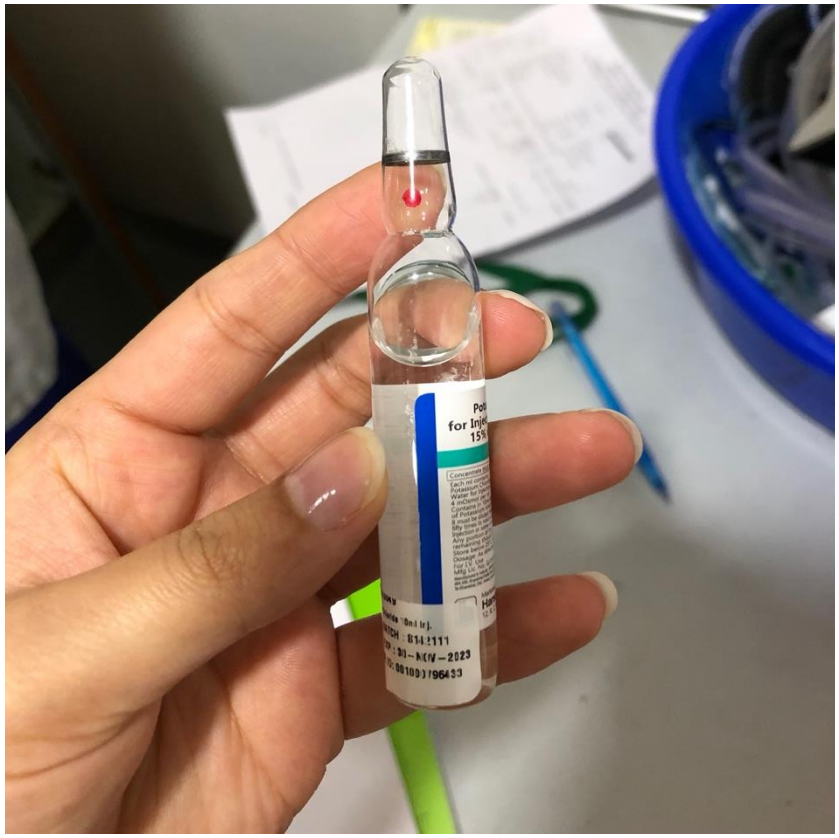
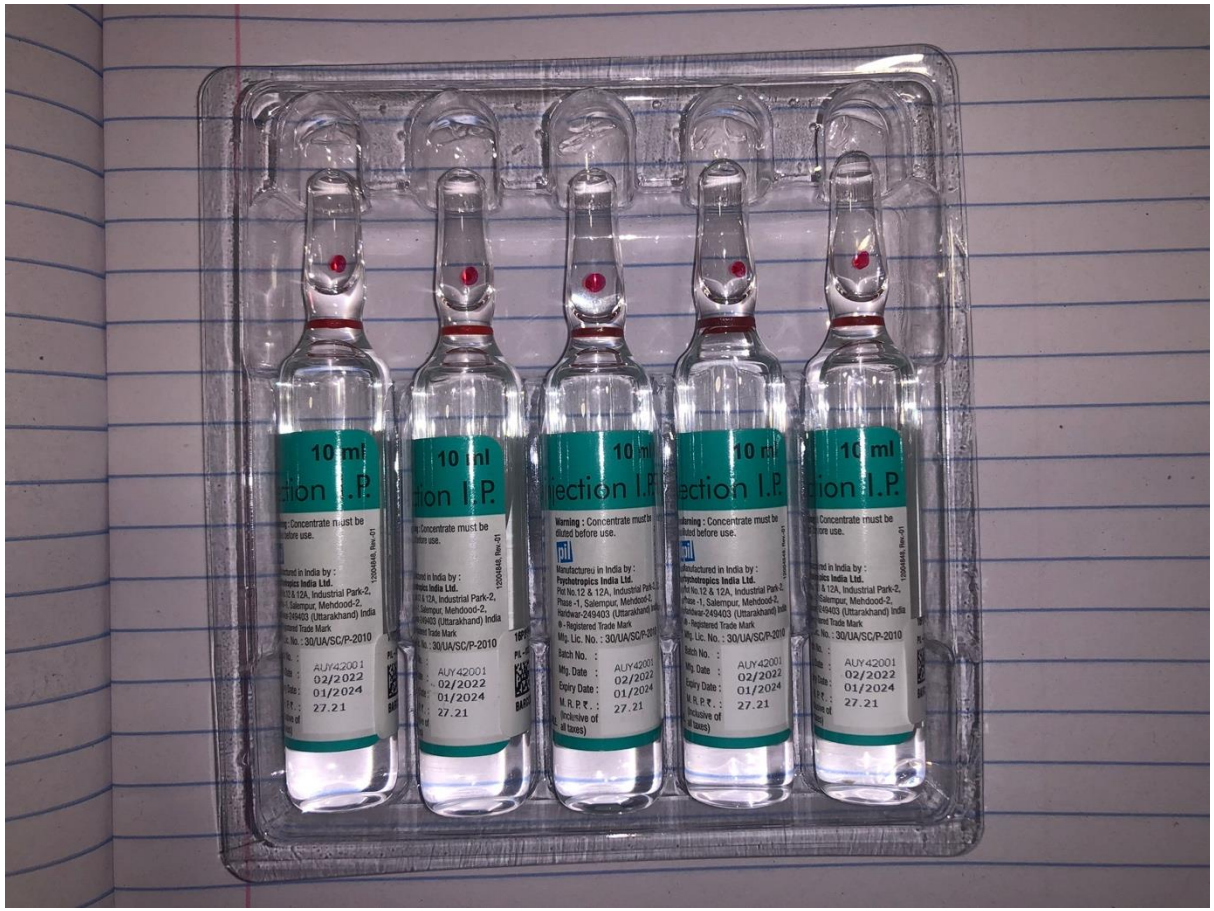



Injectomat
Agilia
KCl
2.0
ml/h
STOP
MENU
EXIT
UHID
Drug Name
Drug Strength
Injectomat
Agilia
STOP
MENU
EXIT
Battery backup > 20 minutes


10 ml
Warning : Concentrate must be diluted before use.
Manufactured in India by :
Psychotropics India Ltd.
Mfg. Lic. No. : 30/UA/SC/P-2010
Batch No. : AUY42001
Mfg. Date : 02/2022
Expiry Date : 01/2024
M. R. P. ₹. : 27.21