COMPLIANCE EVALUATION AGAINST THE PREDEFINED STANDARDS FOR THE HANDLING AND USE OF CONCENTRATED ELECTROLYTES

PRESENTED BY-

DR. URVASHI KAPOOR

ENROLLMENT NO- 1230

MBA HOSPITAL MANAGEMENT

GUIDED BY-

DR. P R SODANI

PRESIDENT, IIHMR UNIVERSITY

TABLE OF CONTENTS

INTRODUCTION

Concentrated electrolytes can be fatal if administered inappropriately. One of the frequently cited medication issues is the unintentional or incorrect administration of concentrated electrolytes

Several incidents of deaths have been identified in the literature as a consequence of inadvertent administration of concentrated electrolytes without dilution

It has been demonstrated that the standardization and simplification of the processes of medication use can reduce adverse drug events with the help of system analysis of medication use, especially medication errors

Tariq RA, Vashisht R, Sinha A, Scherbak Y. (2018). Medication dispensing errors and prevention., Ofek F, Magnezi R, Kurzweil Y, Gazit I, Berkovitch S, Tal O. Introducing a change in hospital policy using FMEA methodology as a tool to reduce patient hazards. Israel Journal of Health Policy Research. 2016;5(1), Barras M, Moore D, Pocock D, Sweedman M, Wilkinson C, Taylor K et al. Reducing the risk of harm from intravenous potassium: A multi-factorial approach in the haematology setting. Journal of Oncology Pharmacy Practice. 2013;20(5):323-331.

JOINT COMMISSION INTERNATIONAL(1/2)

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- 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"

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JOINT COMMISSION INTERNATIONAL (2/2)

Goal 3: To 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 MEs

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

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

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RESEARCH QUESTION

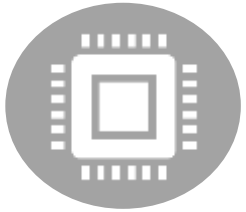
- What could be the possible gaps in compliance with the standard operating procedures (SOPs) for storage, handling, administration, and monitoring of concentrated electrolytes in ICUs and wards?
- What could be the potential failures and consequences associated with the non-compliance of SOPs of storage,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

RESEARCH OBJECTIVES

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

METHODOLOGY (1/2)

An observational cross-sectional study with simple random sampling technique



The study was conducted in the In-patient (IP) departments of Medanta-The Medicity, Gurugram, from the month of April to June.

The sample size is 30 patients who were on concentrated electrolytes infusion during the study period in the ICUs and wards. Patients not in need of concentrated electrolytes were excluded.

A total of 8 ICUs out of 12 and 2 wards were audited randomly to check their compliance with predefined standards.

METHODOLOGY (2/2)

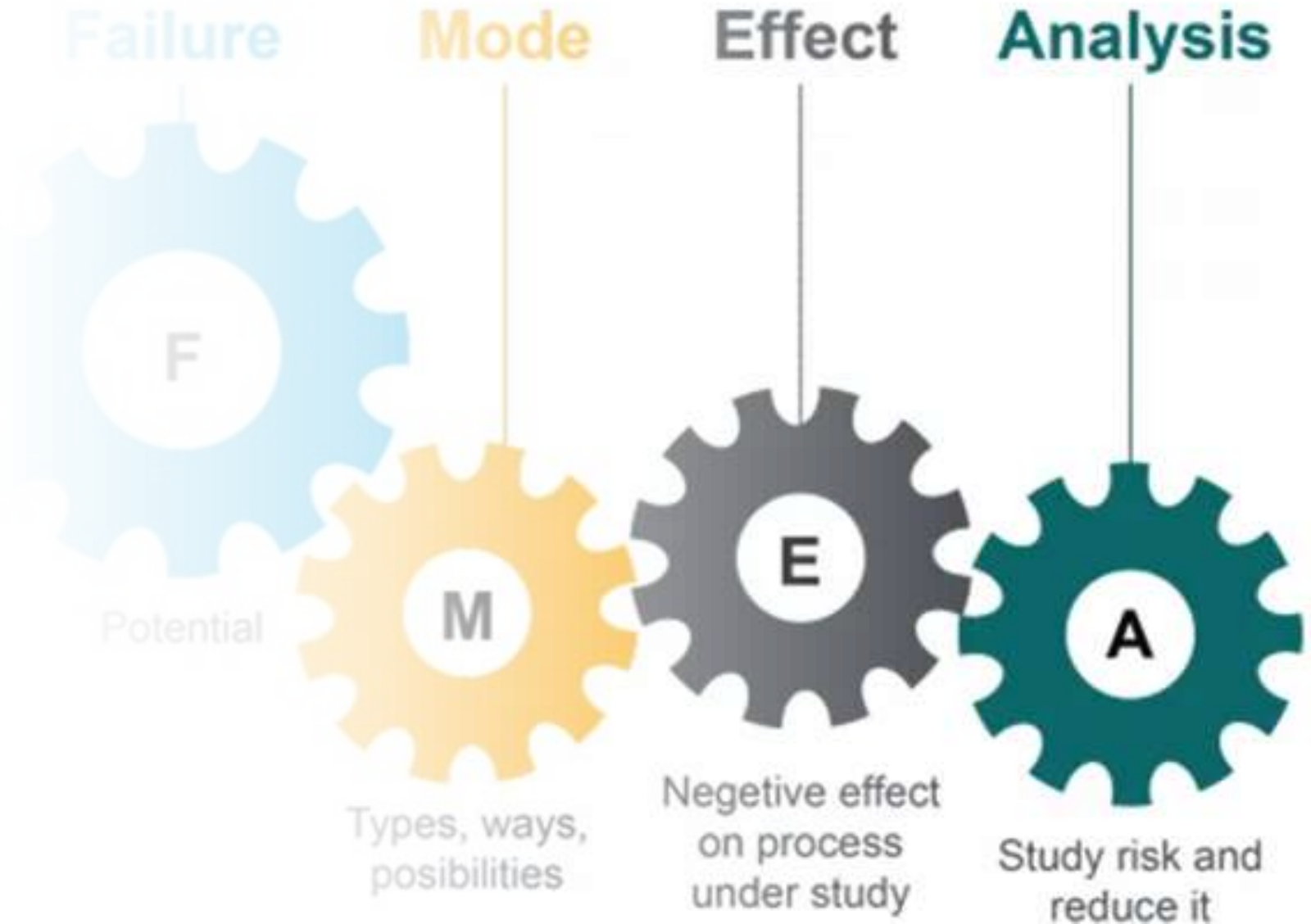
A checklist was prepared to assess the compliance against predefined protocols for the usage of concentrated electrolytes

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 ANALYSIS AND INTERPRETATION

- A systematic technique known as the Failure Mode and Effects Analysis (FMEA) was used for this study.



- A specific FMEA worksheet was 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) was then attributed to each component of the process under investigation.

Process/Product - FMEA
Failure Modes and Effects Analysis

Process or Product Name:		Prepared by:		Page ____ of ____
Responsible:		FMEA Date (Orig) _____		(Rev) _____

Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	DET	RPN
What is the process step	What is the Key Process Input?	In what ways does the Key Input go wrong?	What is the impact on the Key Output Variables (Customer Requirements) or internal requirements?	How Severe is the effect to the customer?	What causes the Key Input to go wrong?	How often does cause or FM occur?	What are the existing controls and procedures (inspection and test) that prevent either the cause or the Failure Mode? **Should include an SOP number.**	How well can you detect cause or FM?	Sev x Occ x Det
									0
									0

Factors of Risk Assessment for FMEA

- 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
- = no effect……10= maximum severity

Severity (S)

Occurrence (O)

- Based on the likelihood of occurrence, a number from 1 to 10 is used for the categorization of each cause of failure
- = very likely to occur……10= almost certain to occur

- Likelihood of detection for each cause of failure (before it reaches the end-user or customer. Based on the likelihood of the detection of the 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

Probability of Detection (D)

RISK PRIORITY NUMBER

- 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.

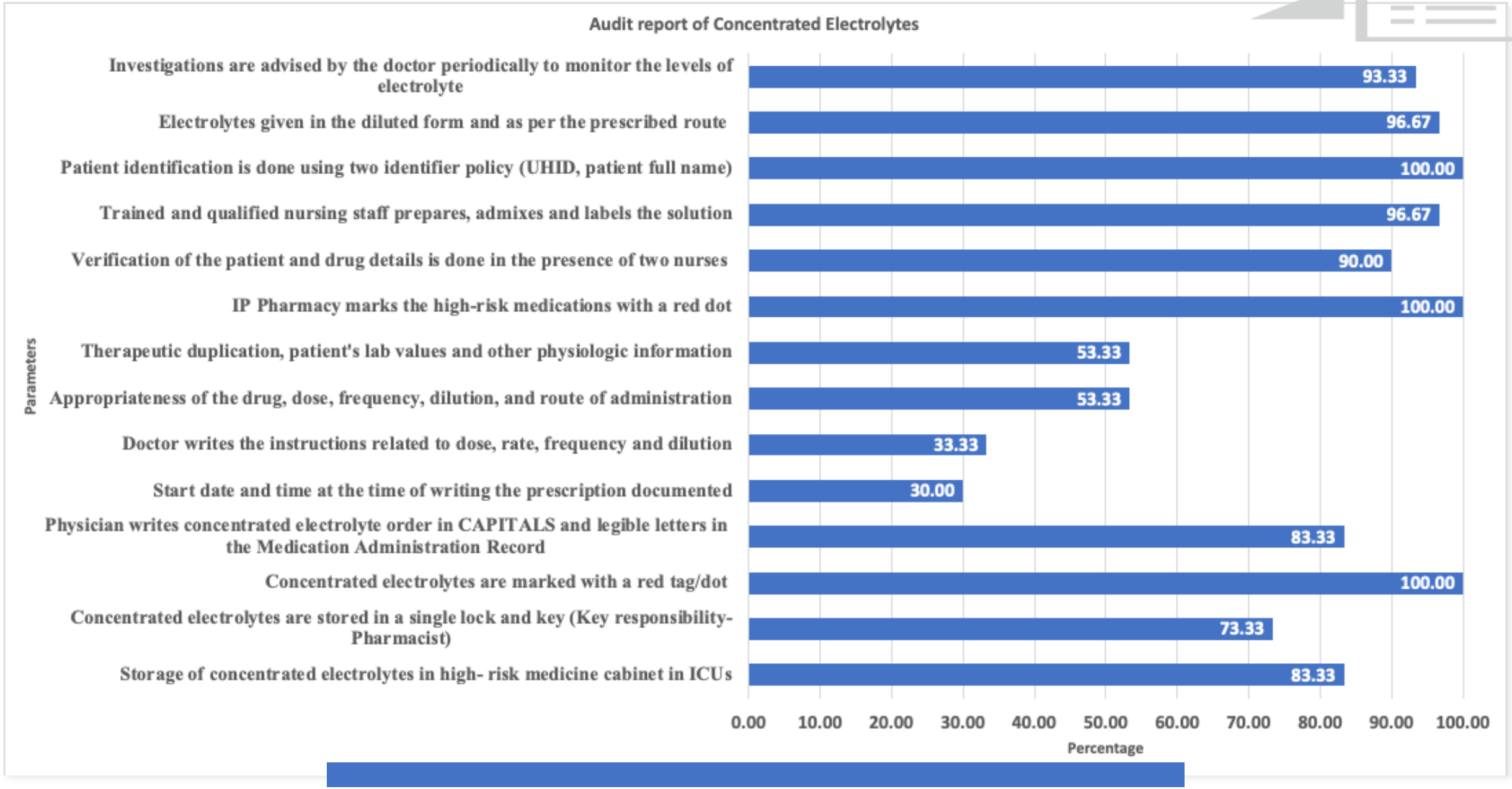
RESULTS AND DISCUSSION

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.

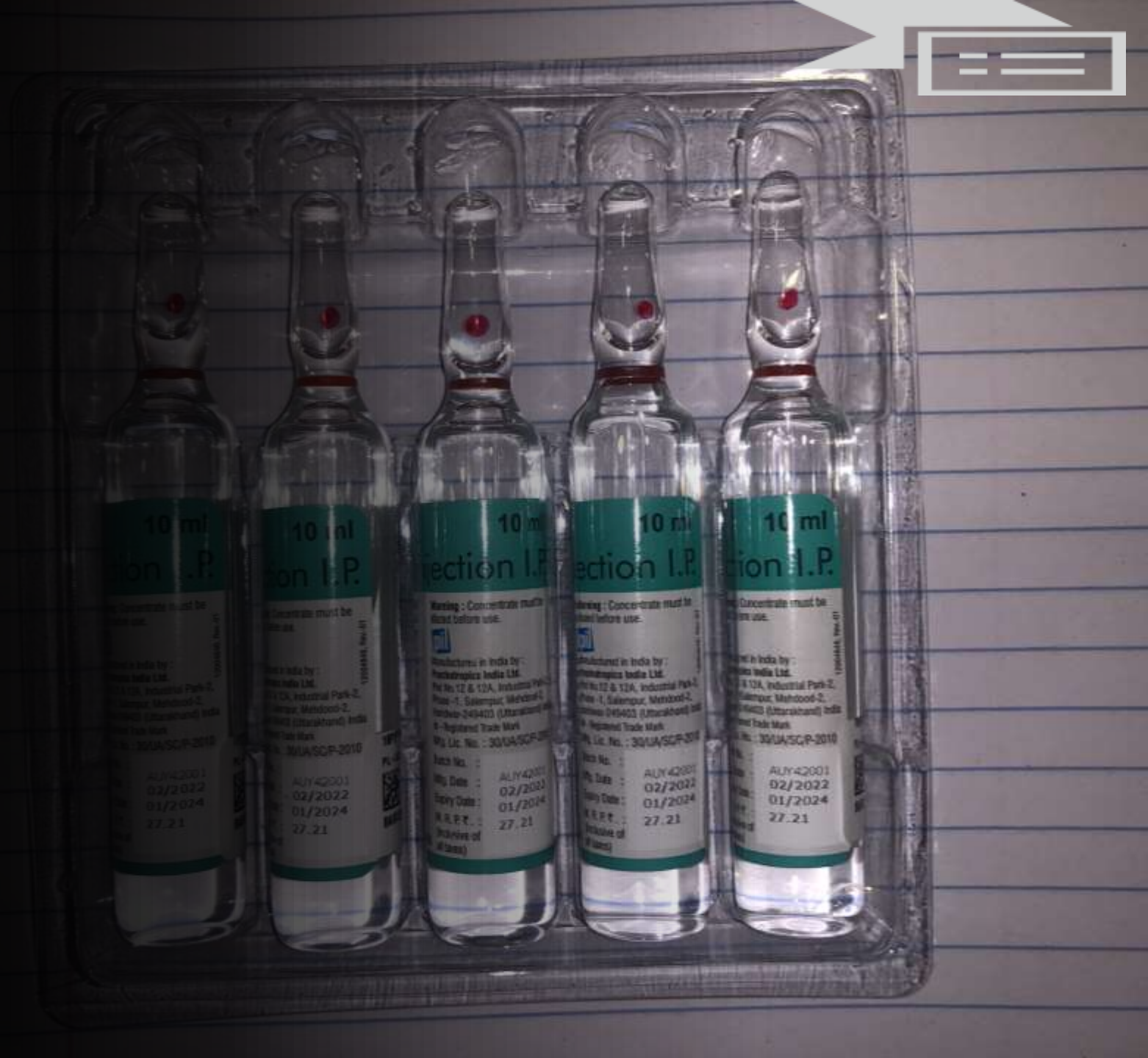
The physician prescribed running handwriting or illegible letters, as well as the start date and time of the drug and its rate of administration, were also not documented

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.


Audit report of Concentrated Electrolytes
Investigations are advised by the doctor periodically to monitor the levels of electrolyte
93.33
Electrolytes given in the diluted form and as per the prescribed route
96.67
Patient identification is done using two identifier policy (UHID, patient full name)
100.00
Trained and qualified nursing staff prepares, admixes and labels the solution
96.67
Verification of the patient and drug details is done in the presence of two nurses
90.00
IP Pharmacy marks the high-risk medications with a red dot
100.00
Therapeutic duplication, patient's lab values and other physiologic information
53.33
Appropriateness of the drug, dose, frequency, dilution, and route of administration
53.33
Doctor writes the instructions related to dose, rate, frequency and dilution
33.33
Start date and time at the time of writing the prescription documented
30.00
Physician writes concentrated electrolyte order in CAPITALS and legible letters in the Medication Administration Record
83.33
Concentrated electrolytes are marked with a red tag/dot
100.00
Concentrated electrolytes are stored in a single lock and key (Key responsibility-Pharmacist)
73.33
Storage of concentrated electrolytes in high- risk medicine cabinet in ICUs
83.33
Parameters
0.00
10.00
20.00
30.00
40.00
50.00
60.00
70.00
80.00
90.00
100.00
Percentage

RESULTS AND DISCUSSION

- The results indicated good practice and adherence to the predefined standards and recommended guidelines in 68.75% of the cases



Failure Modes	Frequency of Occurrence (O)	Severity of Effects (S)	Probability of Detection (D)	Risk Priority Number (RPN)
Concentrated Electrolytes stored at the patient's bedside	10	7	7	490
Key to the high-risk medicine cabinet is with an unauthorized personnel/ anyone can access the key	7	5	8	320
Physician wrote the prescription in running handwriting/ illegible letters	10	7	8	560
Documented an incomplete or wrong order	2	8	10	160
First dose appropriateness review not done	8	7	8	448
The clinical pharmacist failed to check any therapeutic duplications, patient’s lab reports and other physiologic information	9	8	8	576

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).
- 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.

THANK YOU