ANALYSIS OF INCIDENT REPORTING IN PATIENT CARE: A STUDY OF A MULTISPECIALTY HOSPITAL

Dissertation Submitted To

The IIHMR University, Jaipur

for the partial fulfillment for the award of the degree of

Master of Business Administration (MBA)

in

Hospital and Health Management

by

Dr. Anjali

Under the Supervision and Guidance of

Dr. Seema Mehta

2022

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DECLARATION BY STUDENT

I hereby declare that this dissertation titled … **"Analysis of Incident Reporting in Patient Care: A Study of a Multispecialty 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 Information derived from the published or unpublished work of others has been duly acknowledged in the text.

Anjali

(Signature)

Name of the Student: Dr. Anjali

Date: 1st July 2022

JAYPEE HOSPITAL
LIFE FIRST

Dated: 25 June 2022

TO WHOMSOEVER IT MAY CONCERN

This is to certify that **Ms. Anjali** from **IIHMR University, Jaipur, Rajasthan**, has successfully completed Internship in **Quality & System** with Jaypee Healthcare Limited from **29 March 2022** to **25 June 2022**. She was found sincere & hard working during this tenure.

We wish her all the best for her future endeavours.

For Jaypee Healthcare Limited

Authorized Signatory
Human Resources

JAYPEE HOSPITAL Sector-128 Noida-201304 (U.P.) (An Unit of Jaypee Healthcare Ltd.)

CERTIFICATE

This is to certify that dissertation titled **"Analysis of Incident Reporting in Patient Care: A Study of a Multispecialty Hospital**" is a record of the research work undertaken by (Name of Student) 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 his/her approach to the research study has been sincere, scientific, and analytical.

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Date 1st July 2022

ABSTRACT

Background- To keep track of adverse events and other patient safety concerns, hospitals use incident reporting systems. Adverse occurrences, near-misses, and circumstances with the potential to harm patients are all examples of reported patient safety events. Incident Reporting System can play a significant role in incident reporting and patient safety improvement. It can provide healthcare providers with timely information regarding the causes of incidents and useful insight into the processes that prevent their recurrence. It can identify and address issues with incident reporting, hence minimizing the risk to patient safety.

Methodology- The study was conducted in Jaypee hospital for a period of 3 months. The Incident Management database of the Hospital was retrospectively examined. Data about each incident that were logged between May 2021 and April 2022 including Root Cause Analysis and CAPA were reviewed and analysed through MS Excel. The incidents were segregated based on their category, type and severity and risks were identified.

Results- Out of the total incidents reported, nearly three-fourth of the incidents were closed and less than half of them were closed within the stipulated time. Half of the incident reports were reverted with satisfactory RCA and with satisfactory CAPA. Also, almost half of the incidents were raised within time and nearly three-fourth of them were given by Quality to department within time. Most of the incidents belonged to category C and D. According to type, medication errors remained on top of all.

Risks identified with highest risk scores were Patient falls, Pressure ulcers, Device associated pressure injury and other patient injuries.

FMEA of medication errors revealed Wrong dose, Wrong patient, Missed dose, Wrong medication and Wrong frequency as the failure modes. Negligence, knowledge deficit, lack of awareness, improper handover, LASA drug identification error, fatigue, shortage of staff, incorrect documentation were significant contributing factors that led to medication errors.

Conclusion- Incident reporting system serves as a useful tool when it comes to improving patient safety. The analysis produced significant findings that may be useful in the future. Reporting of incidents needs to be encouraged and quality of incident reports should be enhanced to have an in-depth analysis.

Keywords: Patient Safety**,** Incident Reporting System, FMEA, Risk Register, RCA

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ABBREVIATIONS

Abbreviation	Meaning
AE	Adverse Events
CA	Carcinoma
CAPA	Corrective Action Preventive Action
CSL	Clinical Safety Leaders
CT	Computerized Tomography
DAMA	Discharge Against Medical Advice
FMEA	Failure Mode and Effect Analysis
GDA	General Duty Assistant
GIM	General Internal Medicine
HAPI	Hospital Acquired Pressure Injury
HIS	Hospital Information System
ICU	Intensive Care Unit
IPD	Inpatient Department
IRS	Incident Reporting System
LASA	Look Alike Sound Alike
MAR	Medication Administration Record
MS	Medical Superintendent
OT	Operation Theatre
PSI	Patient Safety Incident
Q&S	Quality & Systems
RCA	Root Cause Analysis
RPN	Risk Priority Number
US	United States
WHO	World Health Organization

Analysis of Incident Reporting in Patient Care: A Study of a Multispecialty Hospital

Chapter 1: INTRODUCTION

Patient safety has long been a source of concern in health-care systems around the world, and it continues to be so. In a variety of high-risk organisations, incident reporting systems have proven a crucial instrument for improving safety and enhancing organisational learning from occurrences (commercial aviation, rail industry, and others).

To keep track of adverse events and other patient safety concerns, hospitals use incident reporting systems. Incident reporting systems, which vary in form and functionality, gather and store reports of patient-safety-related occurrences that are documented by physicians, nursing staff, or other hospital personnel. Adverse occurrences, near-misses, and circumstances with the potential to harm patients are all examples of reported patient safety events. First-person narratives and other descriptive details about the events are usually included in completed reports. Incident reports may also include details regarding the event's impact on the patient and, if known, the events' causes. Depending on the reporting system, hospital workers can submit reports in writing or electronically.

There are both challenges and advantages in Incident reporting systems-

First, due of the variety in reporting rates and consistency, determining incidence rates solely on reported data can be problematic. Hospitals can evaluate these data in order to determine the causes of occurrences and devise ways to prevent recurrence.

Second, studies show that incident reporting systems only capture a tiny number of unfavourable events, and that specific types of events are underrepresented. Furthermore, the frequency and regularity with which hospital workers report events vary widely.

Despite these drawbacks, stakeholders point to the benefits of incident reporting systems. The advantages of including frontline workers in identifying safety hazards for the organisation include system knowledge among hospital staff and the advantages obtained from involving frontline personnel in identifying safety concerns for the organisation.

Incident Reporting System can play a significant role in incident reporting and patient safety improvement. It can provide healthcare providers with timely information regarding the causes of incidents and useful insight into the processes that prevent their recurrence. It can identify and address issues with incident reporting, hence minimizing the risk to patient safety. This will help the healthcare providers to improve patients' faith and confidence (including privacy concerns) and enhance their satisfaction with technology solutions.

Chapter 2: REVIEW OF LITERATURE

Author	Objective	Methodology	Findings
Pfeiffer Y, Manser T, Wehner T (2010)	To identify the barriers and drivers of incident reporting, and to suggest a psychological framework of causes for staff members' motivation (or lack thereof) to report incidents.	In psychology literature, ideas that are important for physicians' motivation to report occurrences were found. In order to identify and categorise the obstacles to event reporting, a literature review was also carried out. Clinicians' readiness to report was influenced by a combination of incentives and barriers, and this willingness was used as a predictor of actual reporting behaviour.	Individual (Identity of the job, Error direction, Individual attitudes, and Subjective norm), Organisational (Psychological Security, Opposition Tolerance, and Managerial Support), and IRS related (e.g., unclear what an incident is and how to report it) influences on reporting behaviour can all be categorised into these three categories. When the concept of reasoned action is applied to incident reporting, obstacles resulting from the conviction that the reporter's clinical competence will probably be questioned following a report can be summed up under personal attitudes. The overall role identity of a clinician as a doctor or nurse could encourage reporting, but that clinician may choose not to

			report because that clinician is devoted to and worried about the effects on his or her team.
Thomas MJ, Schultz TJ, Hannaford N, Runciman WB (2011)	To evaluate the effectiveness of Australian health care event reporting systems and ascertain the depth of evidence that can be found in a typical system	Using a manual search tool, a sample of incidents involving patient misidentification that occurred from 2004 to 2008 was taken from several Australian health services' incident reporting systems.	The most frequent occurrence categories comprised conducting a procedure on the incorrect patient (26%) and giving medication to the wrong patient (16%). Another common occurrence type included mislabelling a pathology or medical imaging order (7%), misattributing the findings of a diagnostic test (often medical imaging) to the wrong patient (6%), and incorrectly labelling a specimen with the patient's information (6%).
Khorsandi M, Skouras C, Beatson K, Alijani A (2012)	To assess the effectiveness of the event reporting procedure in the UK's Ninewells Hospital Department of Surgery	Retrospective analysis was done on the Adverse Incident Management database of the Department of Surgery at Ninewells Hospital. Details of all serious (red, sentinel) incidents reported from May 2004 to December 2009 were evaluated, together with any relevant RCA reports and outcomes. The participating staff members were questioned	3 percent of instances were classified as red or sentinel, 23 percent were incorrectly classified as red, 38 percent of reports lacked crucial information about the specifics of adverse incidents, and 15 percent of incident descriptions were of low quality. Only 15% of reports underwent RCA, and those that did received recommendations meant to advance clinical practise. RCA effectiveness varied depending on the circumstances of the incident. A more thorough examination was conducted on adverse events

		in order to learn more relevant details.	that were believed to be more likely to cause harm to patients, costs involved, or bad press.
Pham JC, Girard T, Pronovost PJ (2013)	To find out the use of Incident Reporting System in healthcare	A review of the literature was done and described, outlining the benefits and drawbacks of incident reporting.	The IRS offers both drawbacks and benefits. The drawbacks consist of: IRS cannot be used to compare organisations, IRS cannot be used to measure changes over time, IRS cannot be used to quantify safety (error rates), IRS generate too many reports, IRS frequently do not result in in-depth analyses or strong interventions to reduce risk, and IRS are associated with costs. They are valuable because of the following: I) Local system dangers can be found using IRS; II) Experiences for rare conditions can be gathered using IRS; III) Lessons may be shared within and between organisations; and IV) Patient safety culture can be improved using IRS.
Hewitt T, Chreim S, Forster A (2016)	To evaluate the incident processes in two hospital divisions and determine the contributing elements	More than 80 semi-structured interviews with medical professionals working in neonatology, general internal medicine and obstetrics, made up the data set. The interviews' transcriptions underwent thematic	The majority of Medicine reporters were nurses, and the instances they reported were outcome-focused in terms of detection. Obstetrics reporters came from a variety of backgrounds, and the majority of the stories they covered included near-misses. In Medicine, nursing

		analysis. There were alleged inductive and deductive motifs.	and doctor analysis were carried out separately. Only the initial stage of analysis in obstetrics was carried out independently by a nursing staff leader. Through educational experiences, nurses in internal medicine frequently got individualised feedback on their performance. Obstetrics and Neonatology, on the other hand, had numerous instances of learning that came directly from the IRS. The significance of interprofessional education, variety, and feedback were the primary themes that emerged.
Ramírez E et al (2018)	To determine which improvement measures that were put into place after an examination of the reported incidents were successful in reducing near-misses or adverse outcomes	University Hospital in Spain was the site of the investigation. Local clinical safety leaders, who suggest and carry out improvement activities, examined patient safety incidents (PSIs), near misses, and adverse events that were reported to the IRS. Training sessions in patient safety and analytical tools were provided to the local CSLs. Following the IRS's notification of a PSI, prospective real-time	About 82 percent of reports were incomplete. The PSI rate climbed from 0.4 in 2014 to 3.5 in 2017/1000 stays throughout the analysis period. The number of reports each month and the patient safety seminars also had a strong association. The investigation revealed that 63 percent of the implemented modifications had statistically reduced the number of near-misses or adverse incidents. The drop in near misses or adverse events following the execution of the improvement actions was linked in the multivariate analyses to adverse

		assessments with outside personnel were scheduled in order to document and assess the PSI's frequency. Following the execution of the improvement actions, this technique was repeated. Four areas were used to group the improvement measures: communication, medication, organisation, and technology. Univariate logistic regression was used to identify the variables linked to the improvement activities statistically significant in lowering the incidence of near-misses or adverse events.	outcome, discussion group type analysis, and root cause analysis.
Carlfjord S, Öhrn A, Gunnarsson A (2018)	To investigate the Incident Reporting coordinators' and department heads' experiences in a Swedish healthcare environment	Data was gathered in Sweden, where an electronic IR system was put in place in 2004 and the government has openly supported IR ever since. Interviews with nine department heads from three hospitals were conducted on a	After ten years, the setting chosen has a high level of acceptance for the practise of IR. Patient safety has become a priority because to IR, and there has been a noticeable shift in the culture away from placing blame. The informants advise putting more emphasis on taking action and advancing the incident reporting

		purposeful sample, and IR coordinators participated in two focus groups. Utilizing qualitative content analysis, data were examined.	and handling tools.
Fukami T, Uemura M, Nagao Y (2020)	To reassess the significance of incident reports submitted by doctors in order to understand the significant hospital incidents and promote organisational openness.	A review of reported incidents between April, 2015 and March 2019, classified according to eight variables put forth by the Hospital of Japan (Level 0-1 are Near Misses, and Level 2-5 are Adverse Events), to identify the incidents' types and the potential harm they could cause to patients.	Approximately 10% of all reports are generated annually by physicians working in clinical departments. Doctors are reporting incidents at a much higher rate now that they have a greater impact on patients. Overall, medication-related mishaps were reported the most frequently, then cure, infusion lines, inspection, drainage-tube devices, and treatment outside the operation room. Operation-related occurrences, followed by cure, inspection, care outside the operating room, and drugs, were reported by doctors the most frequently.
Raddi D et al (2020)	To identify the underlying causes of the timeline variation revealed in the Serious Adverse Events report, and to create remedial and proactive measures to reduce the rate of	A retrospective analysis was carried out at a Hospital in Belagavi. Data were gathered from Serious Adverse Events trial research files that were documented. 25 Serious Adverse Events	Even though there was no departure in the timeline for the initial report, the study found that there was a reporting gap between the start of serious adverse events and the initial report. The biggest contributing reasons were subjects being admitted to other hospitals

	variation.	that happened during clinical trials between August 2016 2019 have been included in the study using comprehensive enumeration and purposive sampling.	without understanding and subjects' or their relatives' lack of knowledge, which highlights the need for knowledge about proper safety reporting.
Mulac A, Taxis K, Hagesaether E, Granas AG (2021)	To outline the pharmaceutical errors by stage, type, and frequency that occur in hospitals of Norway, with a focus on the grave and fatal errors	Based on reports from 65 hospitals in 2016 and 54 hospitals in 2017, the Incident Reporting System provided data on drug errors. Reports included category information (such as the patient's age and the incident time) and written information outlining the incident. The errors were categorised according to the type of inaccuracy, drug process stage, therapeutic area, and severity of harm.	3372 reports in all were considered in the study. The majority of drug mistakes happened during administration and prescription. Dosing errors, omissions, and incorrect medicine were the most common forms of errors. The most often included treatment areas were antithrombotic, analgesics and antibacterial. More than half of all errors, of which five percent caused severe injury and one percent were fatal.

Chapter 3: METHODOLOGY

3.1 RESEARCH QUESTIONS

1. How are incidents reported in a hospital?
2. What are the most common risks identified through Incident Reporting System (IRS) and how can they be minimised?

3.2 RESEARCH OBJECTIVES

1. To understand the process of incident reporting in a multispecialty hospital
2. To develop a Risk Register according to the risks identified through incident report analysis
3. To do Root Cause Analysis (RCA) and create an Failure Mode and Effect Analysis (FMEA) on the highest reported incident/error

3.3 METHODOLOGY

Study Design: Retrospective Descriptive Study

Setting: Study is conducted in Jaypee Hospital, Noida

Duration of Study: Over the period of 3 months w.e.f. 28th March to 25th June 2022

Sampling Technique: Convenience Sampling

Data Collection and Analysis: Retrospective analysis is done on the hospital's incident management database. MS Excel is used to study and analyse the details of every incident that was recorded between May 2021 and April 2022, including RCA and CAPA. At every stage of this investigation, patient privacy was strictly respected.

Inclusion Criteria: All the incidents irrespective of the type and severity reported between May 2021 and April 2022 are included

Exclusion Criteria: The incidents that are not reported in the Incident database are not included

3.4 Operational Definitions:

Adverse event- A harm connected to medical treatment, as compared to a disease's complications. Medical management covers every facet of care, such as diagnosis, care, not able to evaluate or treat, and the tools and systems used to provide it.

Adverse drug reaction- a toxic and unwanted pharmacological reaction that happens at levels typically employed in humans for the prevention, diagnosis, treatment, or correction of disease or physiologic function.

Corrective Action Preventive Action (CAPA)- Corrective Action Preventive Action (CAPA) is a procedure that looks into issues, resolves them, pinpoints their causes, implements fixes, and guards against reoccurrence of the underlying issues.

Failure Mode and Effects Analysis (FMEA)- FMEA is a methodical, proactive strategy for reviewing a process to pinpoint potential failure points and evaluate the relative consequences of specific failures in order to pinpoint the process elements that require the greatest improvement.

Incident Report- It is described as the verbal or written documentation of any patient care-related event that is at odds with the expected patient outcome or standard procedures at the healthcare facility.

Medication error- A medication error is any avoidable occurrence that could result in improper drug use or patient injury while the medication is under the care of the patient, consumer, or healthcare professional.

These occurrences might have anything to do with medical practise, healthcare materials, methods, and systems, such as prescription writing, order communication, product labelling, packaging, and terminology, dispensing, administration, distribution, teaching, monitoring, and use.

Near miss- A near miss is an unanticipated occurrence that had the potential to cause harm, disease, or damage but did not.

Near misses are mistakes that potentially may have hurt patients but didn't.

No Harm Event- The patient experienced the event, but there was no harm at the time, and there is no realistic chance that there will be any harm in the future. However, occasionally an incident has the risk of harm, which means that harm could develop in the future. Incidents causing no harm demand disclosure.

Risk Register- A risk register is an instrument that informs an organization about its risk level and serves as a central repository for risk data from all areas of operation. A risk register gives the organisation the ability to oversee all internal hazards across all practise areas and track their progress.

Root Cause Analysis (RCA) - A methodical iterative procedure wherein the causes of an occurrence are determined by retracing the course of the incident and asking why again until the true root causes are understood.

Sentinel events- A systemic or procedural failure that results in a patient receiving healthcare services dying or suffering a significant and long-lasting loss of function.

A sensory, motor, physiological, or psychological impairment that wasn't there when services were requested or started is referred to as a significant and long-lasting loss of function. The impairment is unrelated to any underlying conditions and lasts for at least two weeks.

Chapter 4: RESULTS

4.1 INCIDENT REPORTING

4.1.1 INCIDENTS AND TYPES

Incident Reporting- An incident report is a document that is used to record details about an unprecedented event that takes place at the setting, like patient harm. The goal of the report is to accurately describe what happened while it is still recent in the thoughts of people who were present. As liability issues resulting from the occurrence arise in the future, this knowledge might be helpful. Health care recommendations state that the report should typically be completed as quickly as feasible after the event (but after the condition has been controlled). In this manner, the report's information is as precise as possible. If a patient is involved in an incident, they are frequently watched over for a while thereafter (because it could happen again), which may involve taking their vital signs on a regular basis.

Incident Report: - **Definition**: - It is described as the verbal or written documentation of any patient care-related event that is at odds with the expected patient outcome or standard procedures at the healthcare facility.

Example of Incident Report: -

- Adverse Effects
- Unexpected disability or death
- Mishaps or falls while a patient
- Burns that were acquired in a facility
- Pressure ulcers acquired in institutions
- Procedural Defects
- Mistakes made during the delivery of medication or blood transfusions, or unanticipated complications
- DAMA
- Prolonged delays in diagnostic testing or diagnosis

Catastrophic Events

- Performance of a procedure on the body part where it was not supposed to be done
- Performance of a procedure on the wrong patient
- Baby abduction or placement with the incorrect family
- Hospitalized patients have been raped or
- Hospitalized patients have committed suicide

According to severity, incidents are broadly categorised into-

1. **Near miss events**
2. **No harm events**
3. **Sentinel/Harmful events**

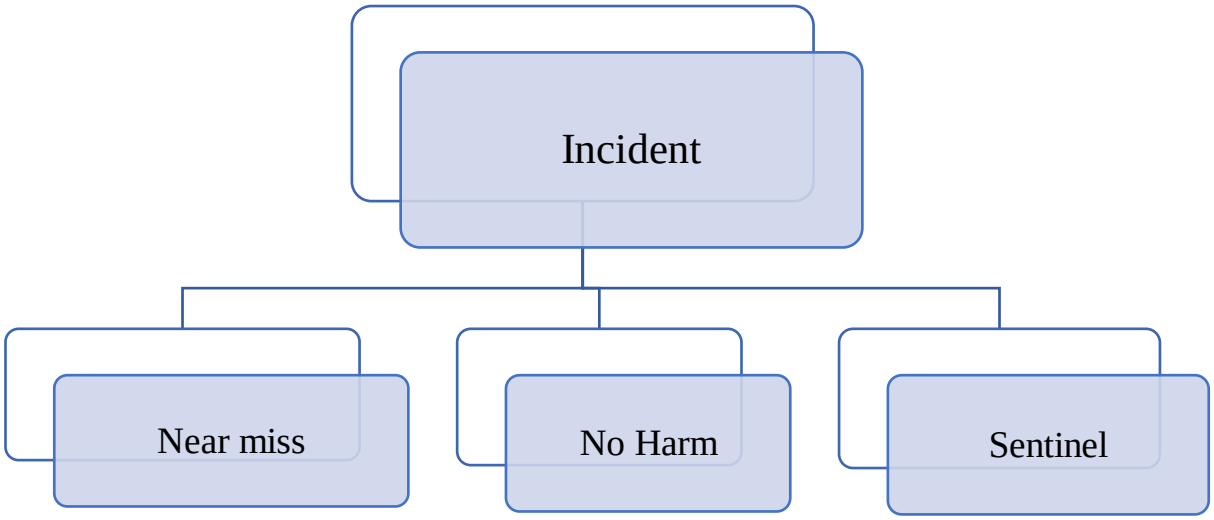


Figure 4.1: Classification of Incidents according to severity

Near Miss Event: - **Definition**: - A near miss is an unanticipated occurrence that had the potential to cause harm, disease, or damage but did not.

Near misses are mistakes that potentially may have hurt patients but didn't.

E.g.: the patient was given a contraindicated medication but had no adverse drug reactions, were prevented from receiving a potentially fatal overdose because the mistake was caught by the nurse before the medication was given, or were mitigated (A fatal overdose was given, but it was averted by an antidote.).

Examples of Near Miss Events: -

- Unclear lines of authority with consultants, nurses and administrative staff can result in near misses.
- Chances of administration of look-alike and sound-alike medicines if not kept at designated places.
- Reliance on automated system to prevent error.
- Environment and design factors like rush hour traffic in corridor, waiting area and diagnostic area.
- Medical Equipment Failure.

No Harm Event: - **Definition**: - The patient experienced the event, but there was no harm at the time, and there is no realistic chance that there will be any harm in the future. However, occasionally an incident has the risk of harm, which means that harm could develop in the future. Incidents causing no harm demand disclosure.

Examples of No Harm Events: -

- Missed dose of medication
- Wrong dose administered
- Medical device failure
- Blood sample taken from wrong patient

Sentinel Events: - **Definition**: - A systemic or procedural failure that results in a patient receiving healthcare services dying or suffering a significant and long-lasting loss of function.

A sensory, motor, physiological, or psychological impairment that wasn't there when services were requested or started is referred to as a significant and long-lasting loss of function. The impairment is unrelated to any underlying conditions and lasts for at least two weeks.

Examples of Sentinel Events: -

Surgical Events

- The wrong bodily portion was operated on during surgery
- Operative procedure done on the incorrect patient
- Incorrect operative procedure done on the incorrect patient
- Objects left in patient discovered after operative procedure

- Patient passing away shortly after surgery
- Anaesthesia-related event
- Device or Product Events
- Intravascular air embolism

Patient Protection Events

- Patient death or major impairment related to escape from the healthcare facility
- Baby discharged to the wrong person
- Suicide, attempt of suicide, or intentional self-harm that results in a major handicap in the patient
- Wilful harm to a patient by a staff member, another patient, visitors and others
- An instance where a patient received treatment through a line that was intended to give oxygen but instead contained another gas or was contaminated with harmful substances
- Mortality or major disability due to hospital acquired infections or disease

Environmental Event

- A charr sustained from any source
- A slide, accident, or fall resulting in injury
- An electrocution resulting in death

Patient Care Events

- Patient death or impairment associated with a haemolytic response due to the delivery of incompatible blood or blood products
- Death of the mother or significant impairment related to the delivery process in a childbirth of less harm probability
- Drug error resulting in patient mortality or severe impairment as a result of improper drug delivery, for instance
    - Omission Mistake
    - Improper Dosage
    - Error in dose formulation
    - Incorrect timing error
    - Incorrect delivery rate
    - Error in the delivery technique
    - Incorrect Patient Error

- Patient death or significant impairment brought on by a preventable lag in care or a reaction to erroneous test results

Criminal Events

- Any case of treatment ordered by or supplied by an individualism personating a healthcare personnel
- Kidnapping of a patient
- Attempted rape on a patient that takes place in the hospital
- Death or significant harm of a patient or staff member resulting from a violent abuse or other criminal event that takes place in the hospital

Sentinel, Adverse Occurrences, Incidence that MUST be reported IMMEDIATELY:

Clinical:

1. Medication errors:

- Wrong dose
- Wrong drug
- Wrong infusion rate
- Extra dose
- Over dose
- Missed dose
- IV infiltrations
- Wrong patient

2. Any other kind of Patient Identification problems

3. Radiological errors

- Wrong radiological investigation been carried out
- Wrong amount of exposure to X-rays been used
- Wrong patient
- Overdose of X-rays been used to carry out an investigation

4. Wrong or missing documents (e.g., notes) with direct consequences of care

5. Prescribing errors

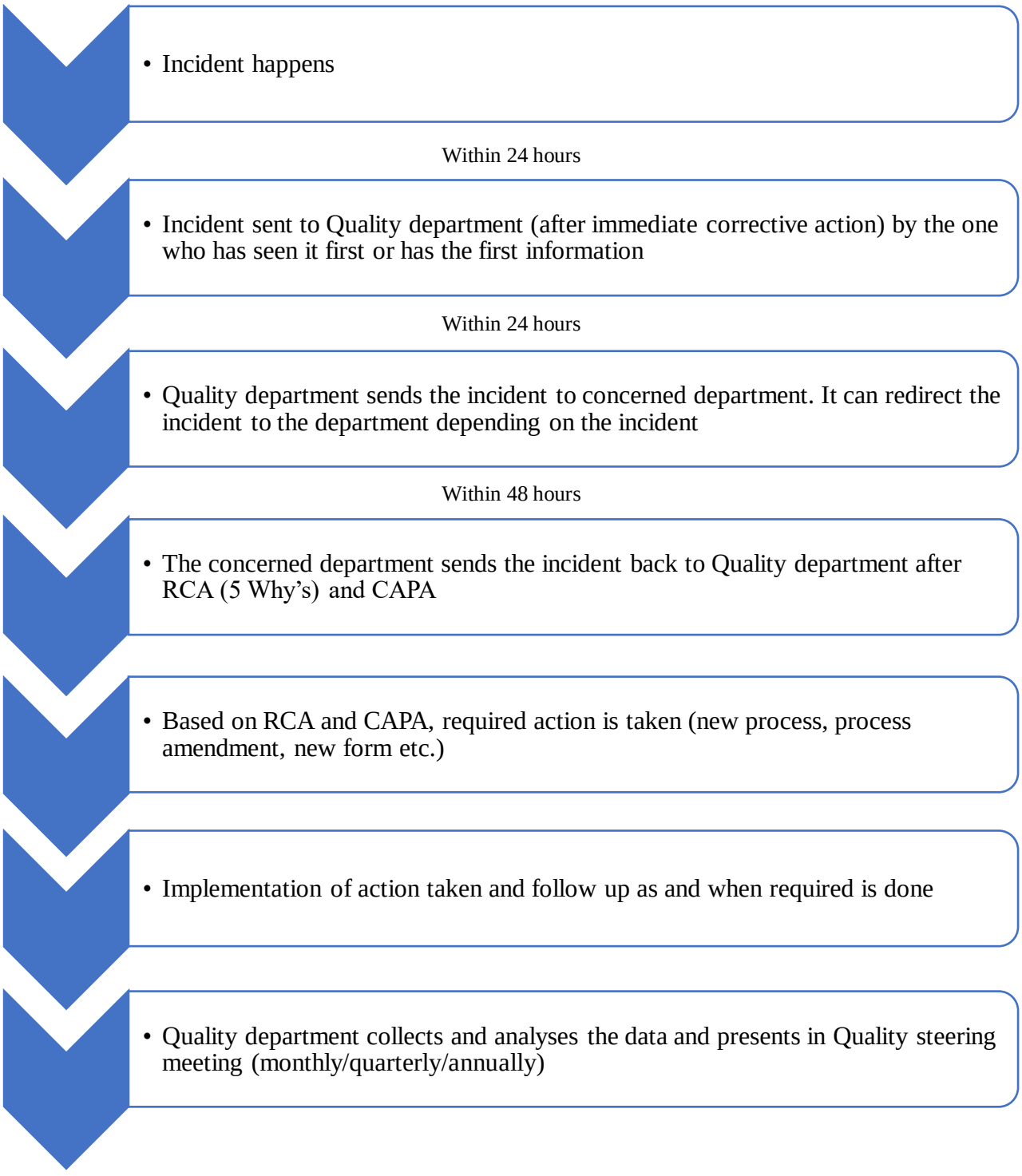
- Dose
- Drug
- Route
- Patient

Non-Clinical: Chemical Spillage Equipment failure (critical equipment failure in OT, ICU or in Inpatient area) Fire Security incident Sharps incident Needle Stick Injuries Slip/trip/fall Theft

4.1.2 REPORTING AND DOCUMENTATION

- All the above-mentioned events shall be reported in Incident document which must be recorded within a day of event. The record of the same shall be maintained with Quality Department.
- All events that fall under above category shall be assessed by performing Root Cause Analysis.
- RCA shall be done immediately following the incident. The analysis and action plan shall be completed within 45 days of the event or becoming aware of the event and redesigning of the processes shall be done to prevent or reduce the risk of sentinel events recurring.
- Inform about the events to floor coordinator / In charge / Supervisor
- Document the Adverse drug reactions, sentinel events, Incident and near miss events through incident excel format, which needs to be submitted to Q&S department within 24 hrs of incidence.
- Q&S team will send the incident to respective department.
- Q&S team will discuss RCA & CAPA with the concerned department coordinator.
- Q&S team will ensure CAPA has been implemented as and when required.
- Based on the RCA and CAPA required action to be taken e.g., new process, process amendment, new form etc
- Implementation of action taken and follow up upon the action taken as required.
- Q&S team will present all incidence reported to quality within a month in Quality Steering Committee Meeting.
- Escalation Matrix in case RCA/CAPA not done by the concerned Department or delayed RCA/CAPA.

4.1.2 (a) Process of Incident Reporting


• Incident happens
Within 24 hours
• Incident sent to Quality department (after immediate corrective action) by the one who has seen it first or has the first information
Within 24 hours
• Quality department sends the incident to concerned department. It can redirect the incident to the department depending on the incident
Within 48 hours
• The concerned department sends the incident back to Quality department after RCA (5 Why's) and CAPA
• Based on RCA and CAPA, required action is taken (new process, process amendment, new form etc.)
• Implementation of action taken and follow up as and when required is done
• Quality department collects and analyses the data and presents in Quality steering meeting (monthly/quarterly/annually)

4.1.3 ANALYSIS OF INCIDENTS

The total number of incidents raised through the 12-month period i.e., from May 2021 to April 2022 was 138. Out of which 99 were closed. An incident is considered closed when the respective departments' sends it back to Quality with appropriate RCA and CAPA. 78 incidents had satisfactory RCA and 84 incidents had satisfactory CAPA. 77 of the total incidents were reported within time. 100 incidents were given to department by Quality within time and 57 were closed within time.

According to classification of incidents, 13 near miss events and 3 sentinel events were reported.

According to types of incidents raised, 6 were fall incidences, 25 bedsore incidences and 53 medication error incidences.

Table 4.1: Month-wise segregation of incidents according to severity and type

S.NO	DATA	NUMBER											
		May-21	**Jun-21**	**Jul-21**	**Aug-21**	**Sep-21**	**Oct-21**	**Nov-21**	**Dec-21**	**Jan-22**	**Feb-22**	**Mar-22**	**Apr-22**	**Total**
1	Total number of incidents raised	7	19	23	6	16	12	7	6	1	14	12	15	**138**
2	Total number of incidents closed	3	14	13	5	13	5	6	5	1	12	11	11	**99**
3	Total number of incidents not closed	3	2	9	0	3	7	1	1	0	2	1	4	**39**
4	Near miss	0	1	2	0	4	1	0	3	0	1	1	1	**14**
5	Total number of sentinel event	0	0	0	0	1	1	1	0	0	0	0	0	**3**
6	Total number of fall incidents	0	0	0	0	2	2	1	0	0	1	0	0	**6**
7	Total number of pressure ulcer incidents	2	2	0	2	2	1	2	1	1	4	4	4	**25**

8	Total number of medication error incidents	5	6	17	3	6	1	4	1	0	4	1	5	**53**
9	Total number of satisfactory RCA	3	9	10	5	13	2	5	5	1	10	6	9	**78**
10	Total number of satisfactory CAPA	3	10	10	5	13	2	6	5	1	12	7	10	**84**
11	Total number of incidents raised within time	2	9	10	5	10	7	2	5	1	10	7	9	**77**
12	Total number of incidents given to respective department by Quality within time	3	12	12	5	15	11	6	5	1	12	9	9	**100**
13	Total number of incidents closed within time	2	7	9	1	2	3	4	2	1	10	8	8	**57**

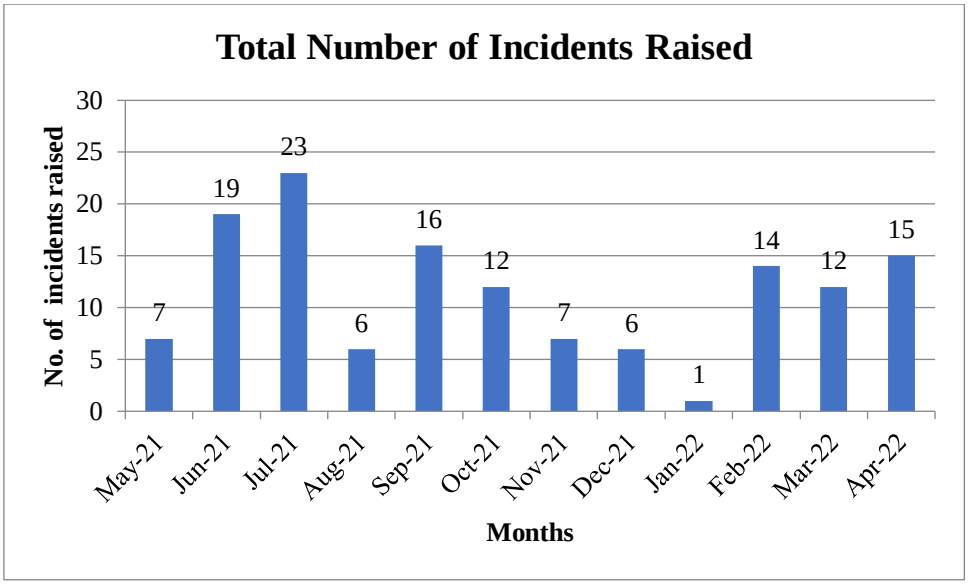


Figure 4.2: Total number of Incidents raised

Figure 4.2 shows the total number of incidents raised during the 12-month period. Out of the total 138 incidents, maximum no. of incidents were reported in July (23) followed by June (19) and September (16) while January (1) had the lowest incidents reported.

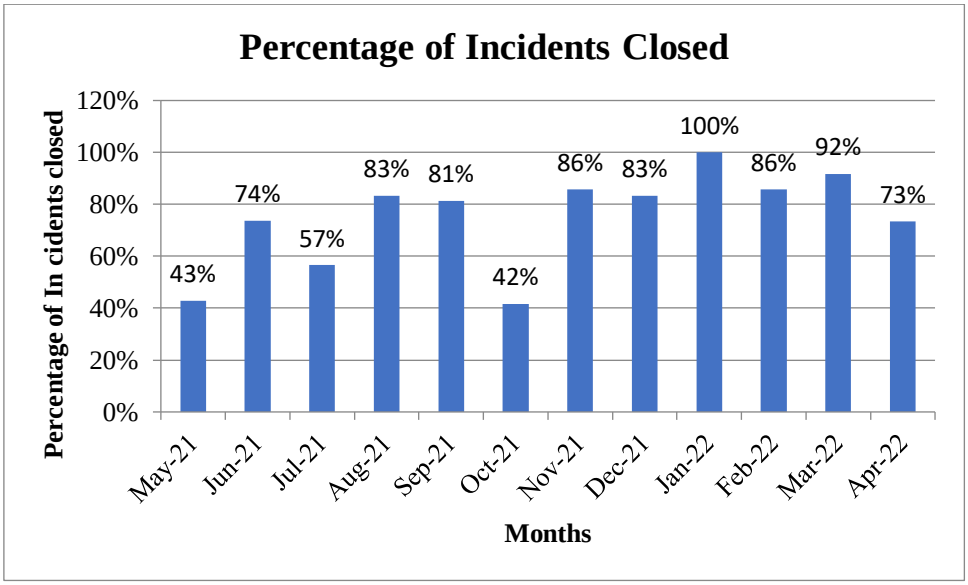


Figure 4.3: Percentage of Incidents closed

Figure 4.3 shows the percentage of incidents closed during the 12-month period. Only January had all the incidents closed, all the other months had some incidents which were not closed. After January, March had the maximum incidents closed (92%).

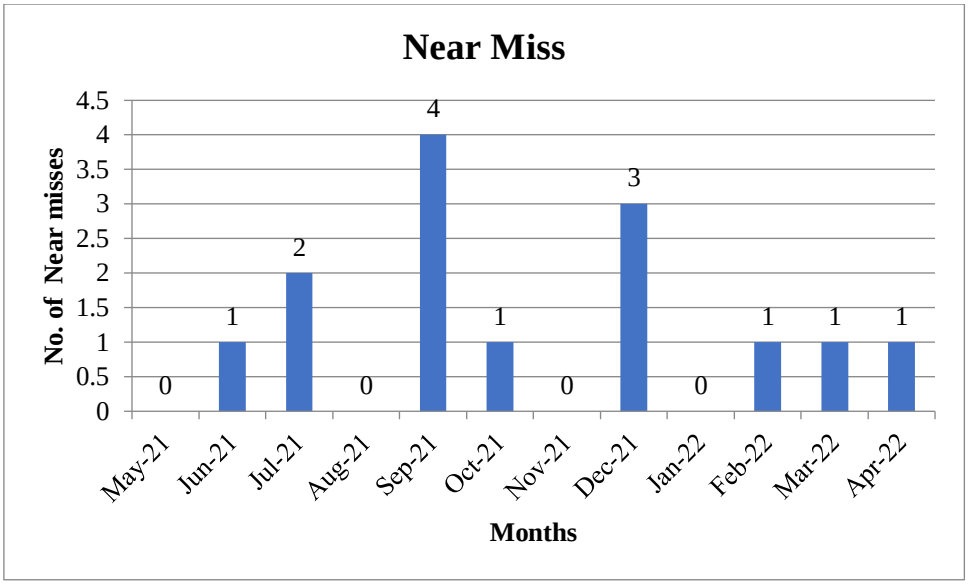


Figure 4.4: Near miss events

Figure 4.4 shows the number of near miss events reported during the 12-month period. September (4) had the maximum no. of near misses followed by December (3). There were no near miss events in May, August, November and January.

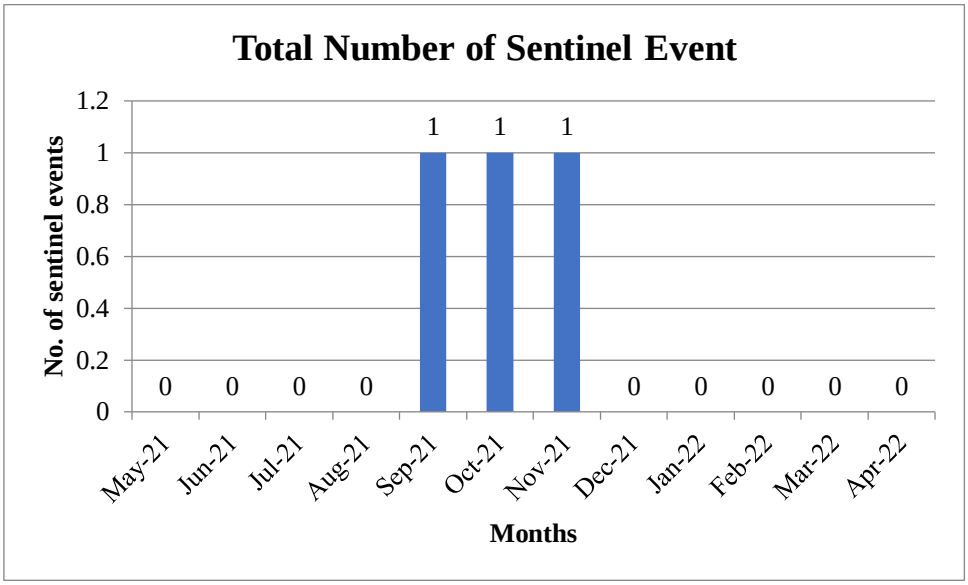


Figure 4.5: Sentinel events

Figure 4.5 shows the number of sentinel events reported during the 12-month period. September, October and November, all three of them had 1 sentinel event reported.

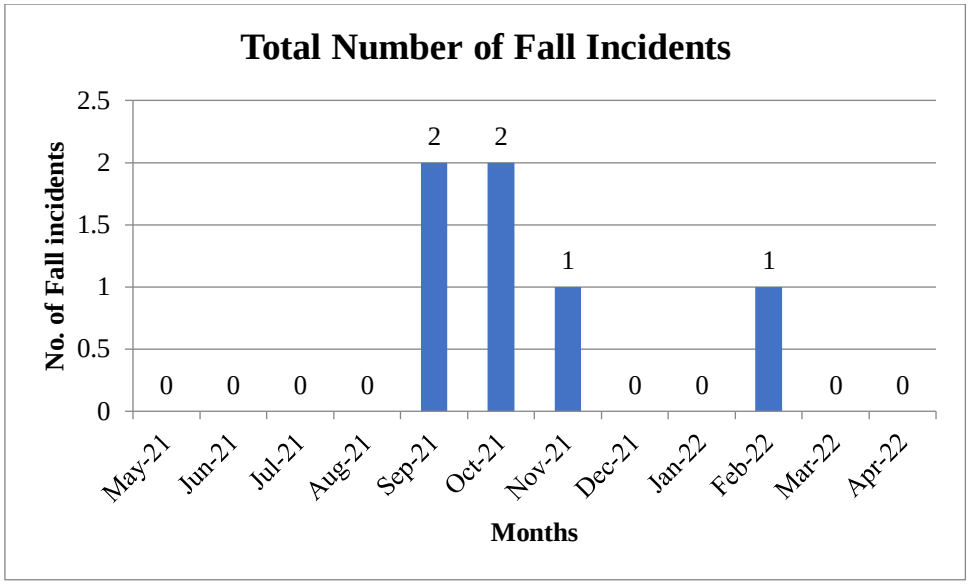


Figure 4.6: Total number of Fall incidents

Figure 4.6 shows the number of fall incidents reported during the 12-month period. September and October had 2 fall incidents reported while November and February had 1 each.

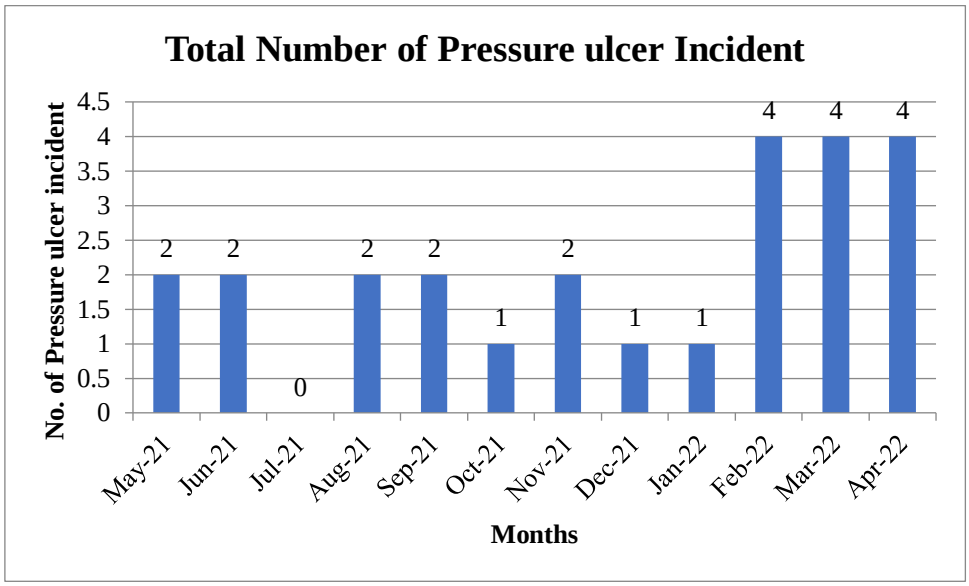


Figure 4.7: Total number of Pressure Ulcer incident

Figure 4.7 shows the total number of bedsore incidents reported during the 12-month period. February, March and April each had 4 bedsore incidents reported while July had no bedsore incident.

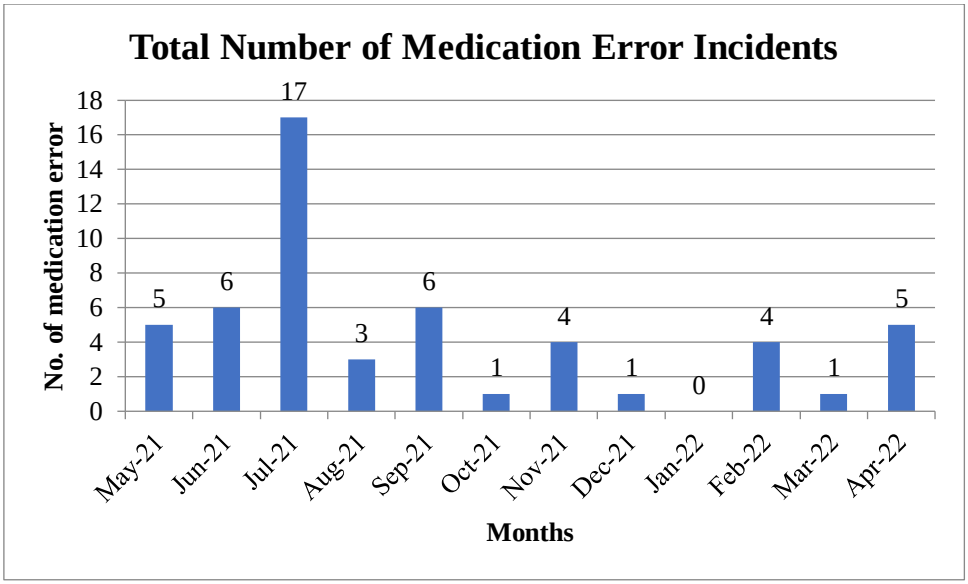


Figure 4.8: Total number of Medication error incidents

Figure 4.8 shows the total number of medication error incidents reported during the 12-month period. The maximum no. of medication error was reported in July (17). June and September each had 6 medication error incident reported while in January, no medication error were reported.

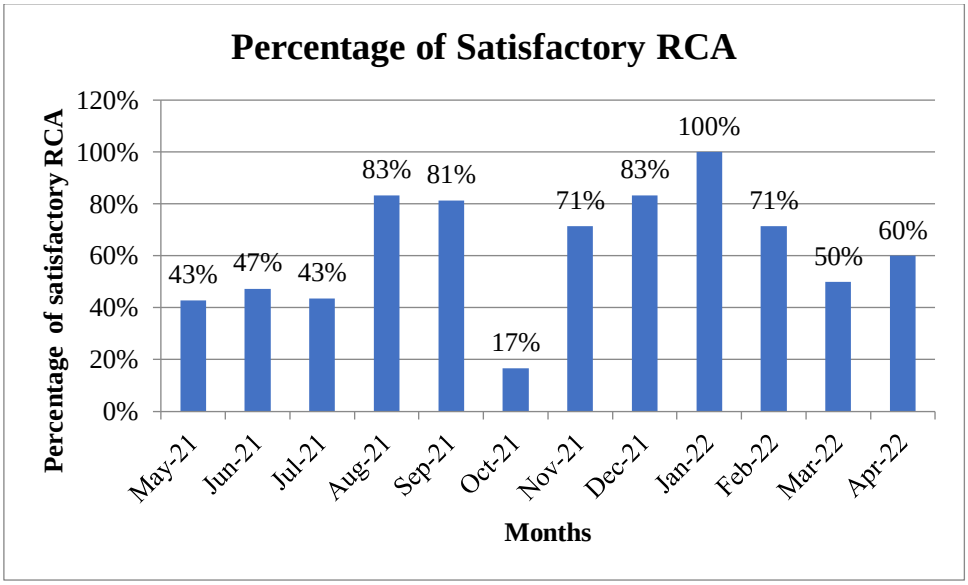


Figure 4.9: Percentage of Incidents having satisfactory RCA

Figure 4.9 shows the percentage of incidents having satisfactory RCA i.e., their root causes were appropriately mentioned in the report. Only January had satisfactory RCA of all

incidents reported. After January, August (83%) had the maximum satisfactory RCA while October (17%) had the lowest.

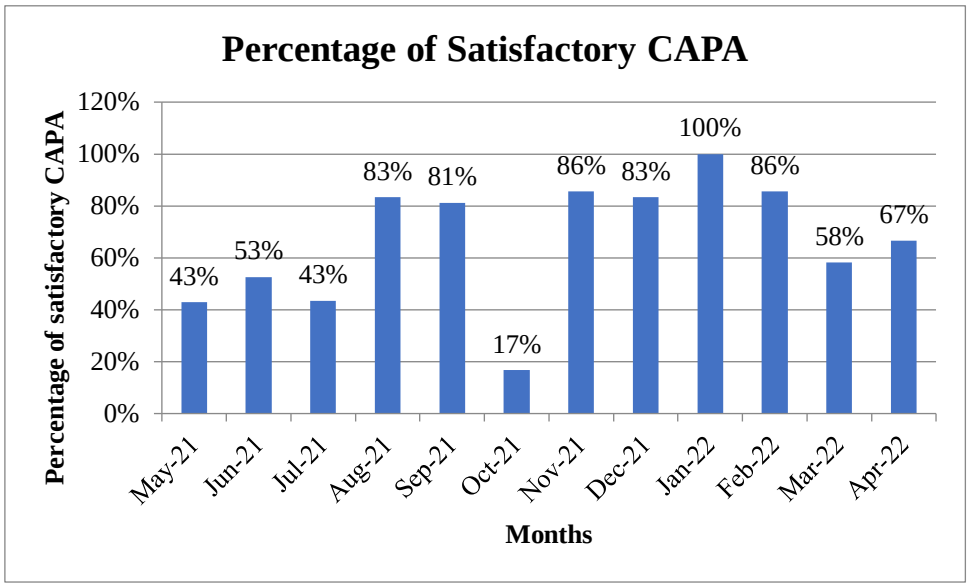


Figure 4.10: Percentage of Incidents having satisfactory CAPA

Figure 4.10 shows the percentage of incidents having satisfactory CAPA i.e., their Corrective and Preventive Action was appropriately mentioned in the report. Only January had satisfactory CAPA of all incidents reported. After January, February (86%) and November (86%) had the maximum satisfactory CAPA while October (17%) had the lowest.

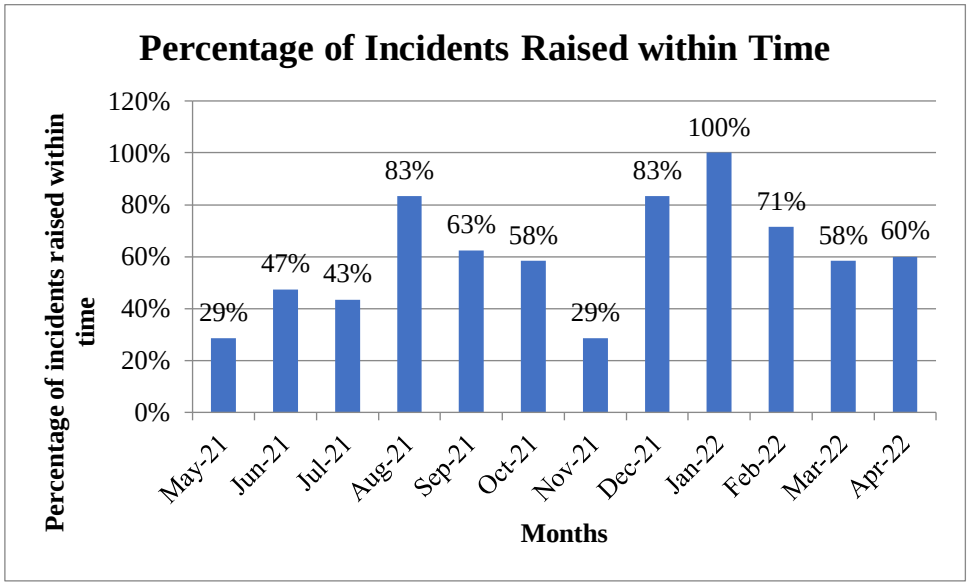


Figure 4.11: Percentage of Incidents Raised within Time

Figure 4.11 shows the percentage of incidents raised within time i.e., 24 hours. Only January had all incidents raised within time. After January, August (83%) and December (83%) had the maximum while November (29%) and May (29%) had the lowest.

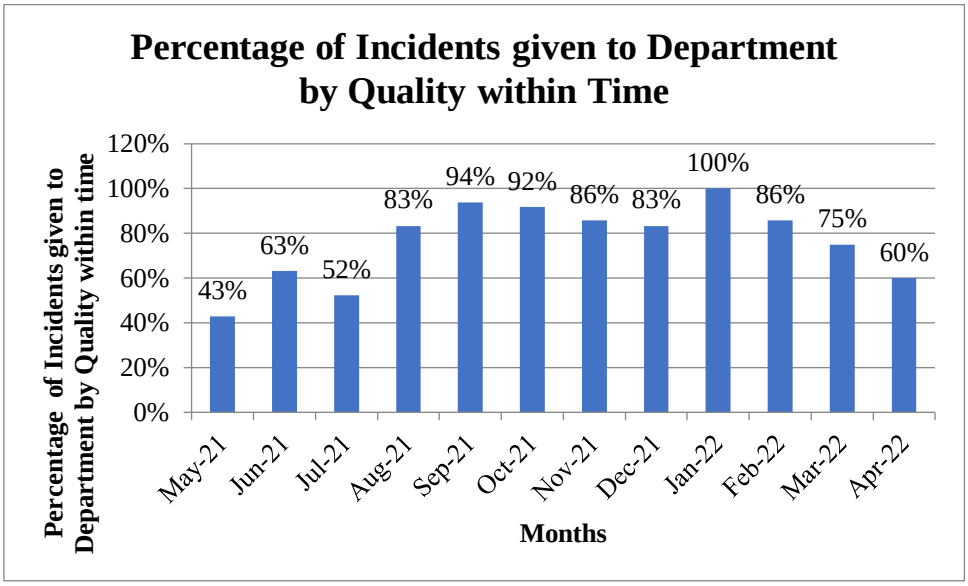


Figure 4.12: Percentage of Incidents given to Department by Quality within Time

Figure 4.12 shows the percentage of incidents given to departments by Quality within time i.e., within 24 hours after it was sent to Quality. Only January had all the incidents given to departments by Quality within time. After January, September (94%) had the maximum while May (43%) had the lowest.

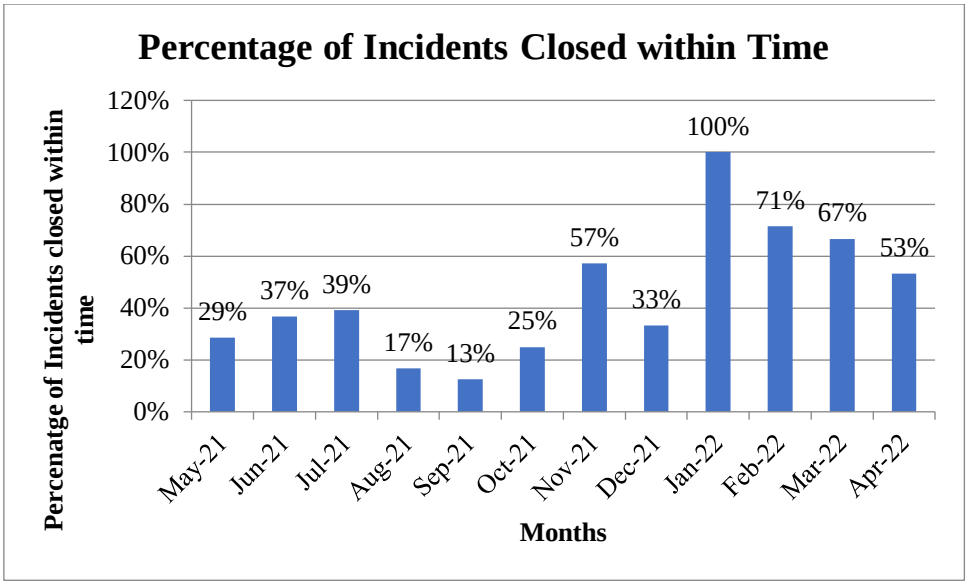


Figure 4.13: Percentage of Incidents closed within Time

Figure 4.13 shows the percentage of incidents closed within time i.e., within 48 hours after it was sent to the concerned department. Only January had all the incidents closed within time. After January, February (71%) had the maximum while September (13%) had the lowest.

Categories of Incidents

Near misses, No harm and Sentinel events are further classified into 8 categories for the ease of reporting-

Category A- Situation or occurrences that have the potential to cause error

Category B- An occurrence that did not touch the person

Category C- An occurrence that touched the person but did not cause injury

Category D- An occurrence that reached the person and necessitated observation or involvement to ensure no harm was done

Category E- An occurrence that caused injury to the individual (lasting less than 2 weeks)

Category F- An occurrence that caused injury to the individual lasting more than 2 weeks

Category G- An occurrence that caused long lasting injury to the individual

Category H- An occurrence that require intervention to sustain life

Category I- An occurrence that resulted in death of the individual

Categories F, G, H & I are referred to as Sentinel events and are reported together.

Table 4.2: Classification of incidents according to their category

Category of Incident	Number	Percentage
Category A	21	15%
Category B	11	8%
Category C	55	40%
Category D	44	32%
Category E	4	3%
Category F, G, H, I	3	2%

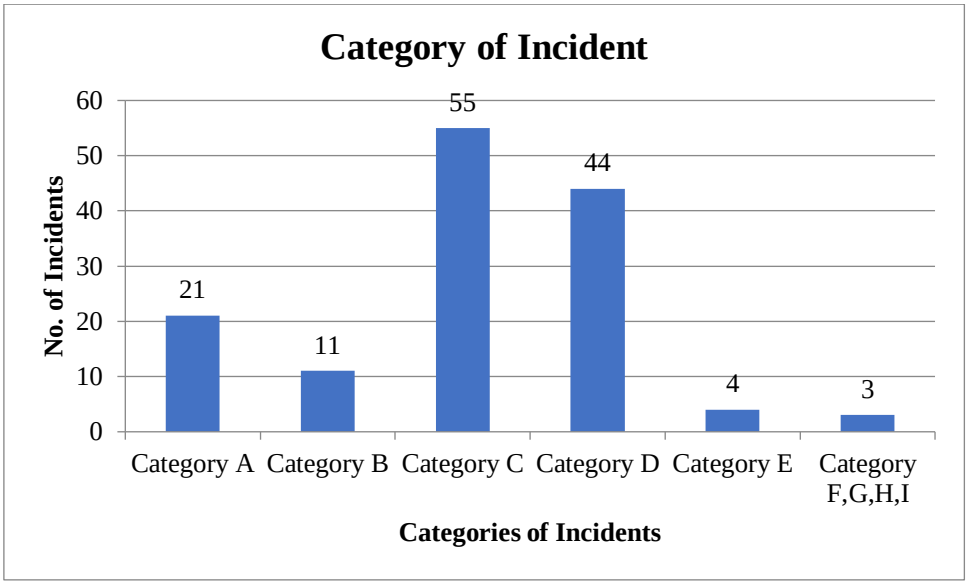


Figure 4.14: Classification of Incidents according to their category

Figure 4.14 shows the classification of incidents according to their category, reported during the 12-month period. Category C (55) had the maximum no. of incidents reported followed by category D (44). Category A had 21, Category B had 11, Category E had 4 and Category F, G, H & I had 3 incidents reported.

4.2 RISK REGISER

A Risk Register is a document that details the risks that have been discovered, the outcomes of the identified risks (impact, probability, effects), and the risk response strategy.

Major risks were identified through analysis of incident report and written along with the brief explanation of the risk description. Their probability and impact were estimated with the help of Table 4.4. and 4.5 and the Risk score (Probability*Impact) was calculated. The risks were then colour coded based on their severity with help of table 4.6. The responsible person and the response plan according to the risk that would help in their mitigation were then listed.

Table 4.3: Risk Register of Analysed Incidents

No.	Risk	Risk Description	Probability	Impact	Risk Score	Risk Severity	Responsible person	Response Plan
1	Pressure ulcer	Patient on ventilator Poor skin integrity Debilitated patient Stool incontinence Bedridden patient	4	4	16	High	Nursing Head	Training the personnel in the following: -Turning and repositioning every two hours -Soft, padded beds to relieve pressure -Good skin care by keeping the skin clean and dry -Good nourishment
2	Patient fall	No staff attendant with patient Patient on neurological medications Nurse call bell not working	4	4	16	High	Nursing Head	-Educating patients and families about fall prevention; -Training staff members in fall risk assessment; -Providing fall risk assessment training to the staff -Monitoring high-risk patients -Teaching patients and families fall prevention

								techniques -Ensuring a staff attendant is on duty anytime assistance is needed -Counselling patients on neurological drugs -Acquainting the patient with his/her hospital bed and surroundings
3	Equipment failure	Improper handling and inadequate maintenance of machine	1	2	2	Low	Biomedical Engineering Head	-Teaching the personnel how to handle machinery properly -Increase the amount of time spent physically inspecting and monitoring -Ensuring that the technology utilised adheres to the highest quality and safety standards
4	Patient dissatisfaction due to delay in allotment of room in IPD	Communication gap between nursing staff of different departments	2	1	2	Low	IPD Operations Head	-Proper bed management training -To improve communication skills, regular training and seminars to be held for in-service nurses.
5	Delayed discharge	Unplanned discharge of TPA patient	2	2	4	Low	MS	-Discharge summary to be prepared a day prior to discharge

		Improper documentation in discharge summary					Clinicians	-Information of discharge to be sent to all stakeholders -Proper documentation to be followed
6	Device associated pressure injury	Allevyn dressing not applied before giving BiPAP mask	4	4	16	High	Nursing Head	Training the staff on- -Applying dressings to cushion and protect the skin in high-risk regions (such as the nasal bridge and device rim) -Removing or moving devices to check the skin at least once a day -Teaching staff the proper way to use devices and how to prevent skin breakdown
7	Patient injury	Patient with CA Thyroid and skeleton metastasis attended without proper care	4	4	16	High	Nursing Head	-Training staff on patient initial assessment and patient safety
		Tourniquet not removed after taking blood sample						-Training the staff on safe blood sampling -Proper bedside assessment to be followed

8	Patient identification error	No identity wrist band on patient Patient identification not done before generating barcode of sample collection CT order placed in the name of other patient by the nurse Barcode of another patient attached on sample collection vial	3	3	9	Medium	Nursing Head	--Introducing training on how to properly verify a patient's identity as well as advice for the workforce on the significance and relevance of accurate identification -All inpatients must wear an ID band at all times while they are hospitalised -Before delivering any medication or performing any intervention or operation, the personnel must verify the patient's ID -To confirm the patient's ID, at least two identifiers must be utilised, such as the patient's complete name and ID number. -If it is discovered that the patient does not have an ID band, no treatment should be given and no operation or intervention should be carried out -It is the staff's duty to see that the patient's ID band is

								replaced right away if it has been damaged, rubbed off, or removed for any other reason
9	Code Red	Electrical cable not plugged in properly in the machine	1	4	4	Low	HR	-Training the staff on proper handling of machines
10	Code Violet	Room allotted without informing about the condition of the patient next to them Mistakes made by the billing staff in the registration form repeatedly	2	2	4	Low	IPD Operations Head & Front Office Head	-Proper communication to be followed between nurses and PCA staff

Table 4.4: Probability score

Probability Score	Descriptor
1	Most likely, this won't occur or happen again
2	Don't anticipate it to occur or reoccur

3	Could occur or repeat occasionally
4	Will undoubtedly occur, but it won't be a constant problem
5	Unquestionably occur, possibly repeatedly

(Source: Shaw, A., 2012. *Managing Risk in Complex Healthcare Organisations: Use of a Risk Register*. [online] HealthManagement. Available at: https://healthmanagement.org/c/it/issuearticle/managing-risk-in-complex-healthcare-organisations-use-of-a-risk-register)

Table 4.5: Impact score

Impact Score	Descriptor
1	No harm/very little harm 8-hour minimum loss of service or facility
2	Minor injuries necessitating first aid or more treatment 8 to 24 hours of service or facility disruption
3	Immediate harm, moderate procedure expansion 1-to-7-day loss of service or facility due to disruption
4	Permanent or enduring damage resulting from the occurrence >1 week of service/facility loss or disruption
5	Death directly due to the incident (not as a result of underlying illness) Irreversible loss of facility or service

(Source: Shaw, A., 2012. *Managing Risk in Complex Healthcare Organisations: Use of a Risk Register*. [online] HealthManagement. Available at: https://healthmanagement.org/c/it/issuearticle/managing-risk-in-complex-healthcare-organisations-use-of-a-risk-register)

Table 4.6: Risk Quantification Matrix

	Impact				
Probability	1	2	3	4	5
1	1	2	3	4	5

2	2	4	6	8	10
3	3	6	9	12	15
4	4	8	12	16	20
5	5	10	15	20	25

(Source: Shaw, A., 2012. *Managing Risk in Complex Healthcare Organisations: Use of a Risk Register*. [online] HealthManagement. Available at: https://healthmanagement.org/c/it/issuearticle/managing-risk-in-complex-healthcare-organisations-use-of-a-risk-register)

Table 4.3 shows the risk register with identified risks, their description, the risk score, responsible person and the response plan. The major risks identified through incident report analysis were Patient fall, Pressure ulcer, Defective machine, Patient dissatisfaction due to delay in Allotment of room in IPD, Delayed discharge, Patient identification error, Hospital acquired pressure injury, Patient injury, Code red and Code violet. Patient fall, Pressure ulcer, Hospital acquired pressure injury and Patient injury have higher risk score. Patient identification error have medium risk score while Defective machine, Patient dissatisfaction due to delay in allotment of room in IPD, Delayed discharge, Code red and Code violet have low risk score. Red areas require urgent action; yellow areas require scheduled action and green areas require monitoring.

4.3 FMEA OF MEDICATION ERRORS

4.3.1 Medication Management Process Flow

To understand the causes of medication errors, it is important to understand the process flow of medication management.

There are six stages of the medication management: Prescribing, Transcribing, Indenting, Dispensing, Administration and Monitoring. Figure 4.15 shows the process flow of medication management. Doctor prescribes the drug which is transcribed by the Pharmacist in HIS. According to the transcription, the medicines are indented by either nurse or pharmacist. Pharmacist dispenses the drug from pharmacy and GDA distributes it. The nurse, then, administers the medicine to the patient and monitors for any adverse reaction. This is how a normal medication management is followed in IPD.

Breach in any of the steps, for example; wrong dose administered, illegible writing, wrong drug indented can lead to medication error.

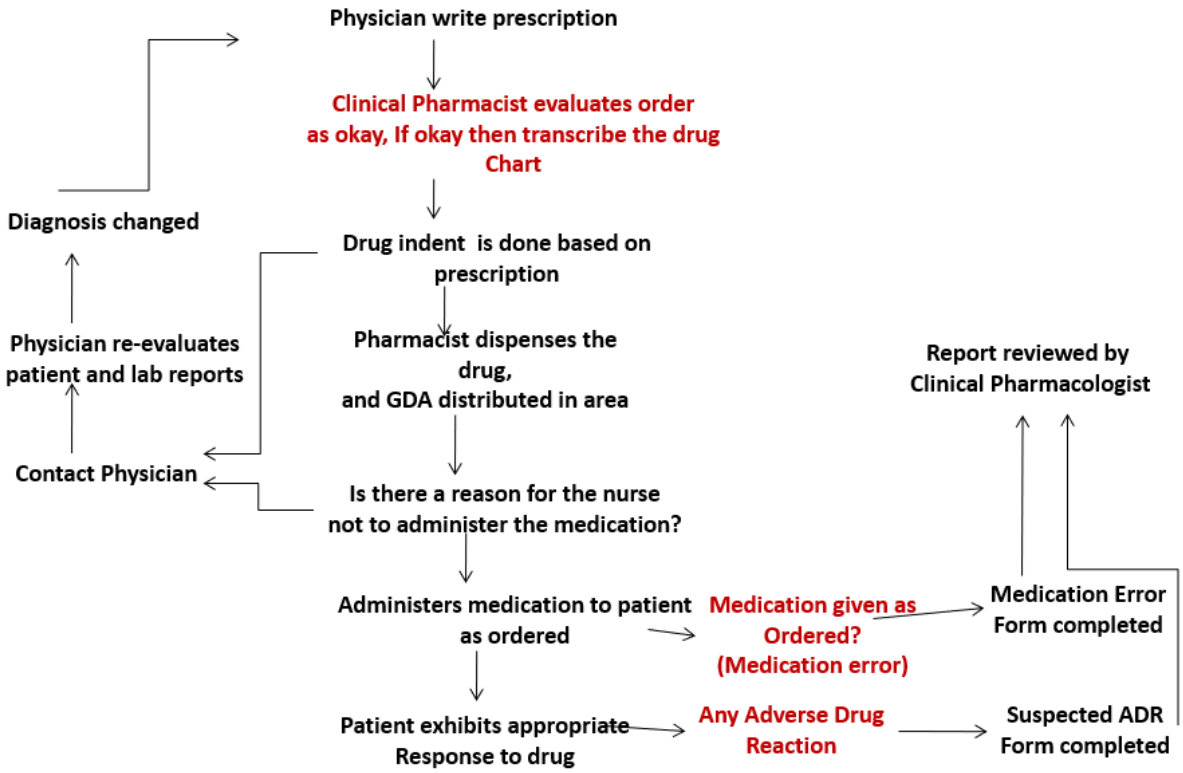


Figure 4.15: Medication Management Process Flow

(Source: Department of Clinical Pharmacology, Jaypee Hospital)

4.3.2 Medication errors

There are mainly 7 types of medication errors that can occur during medication management process, namely, Prescription error, Transcribing error, Indenting error, Dispensing error, Administration error, Monitoring error and Documentation error.

For finding out the medication errors, Incident management database of the hospital was retrospectively reviewed. Details of all incidents CAPA related to medication errors which were returned by the departments after doing RCA and recorded between May 2021 and April 2022 including RCA and CAPA were reviewed and analyzed. Medication errors were segregated based on their category and their root causes were identified.

Table 4.7: Types of Medication Error

Error	Number	Percentage

Prescription Error	2	6%
Transcription Error	2	6%
Indenting Error	4	12%
Dispensing Error	0	0%
Administration Error	18	55%
Monitoring Error	0	0%
Documentation Error	7	21%
Total	**33**	

Table 4.8: Month-wise Segregation of Medication Errors based on their Category

Months	Total No. of Medication Errors	Category A	Category B	Category C	Category D	Category E
May-21	1	0	0	Documentation-1	0	0
Jun-21	5	Administration-1	0	Administration-2, Indenting-1	0	Administration-1
Jul-21	7	0	0	Administration-2, Documentation-1, Prescription-1	Indenting-1, Administration-2	0
Aug-21	3	0	0	Administration-1	Administration-1, Transcription-1	0
Sep-21	4	0	0	Administration-2, Indenting-1	Administration-1	0
Oct-21	0	0	0	0	0	0
Nov-21	3	0	0	Administration-2	Prescription-1	0
Dec-21	1	0	Administration-1	0	0	0

Jan-22	0	0	0	0	0	0
Feb-22	3	0	0	Administration-1, Documentation-1	Documentation-1	0
Mar-22	1	0	Administration-1	0	0	0
Apr-22	5	0	0	Documentation-3, Transcription-1, Indenting-1	0	0

Table 4.7 lists the type of medication error and their percentages. Out of 53 medication error incidents reported during the 12-month period, 33 were sent back by the department to Quality with RCA and CAPA. Most of the medication error reported were Administration error (55%) followed by Documentation error (21%). Dispensing and Monitoring error were not found to be reported.

Table 4.8 shows the month-wise segregation of medication errors based on their category. Most of the medication errors were reported in July (7) followed by June (5) and April (5).

4.3.3 Root Cause Analysis of Medication Errors

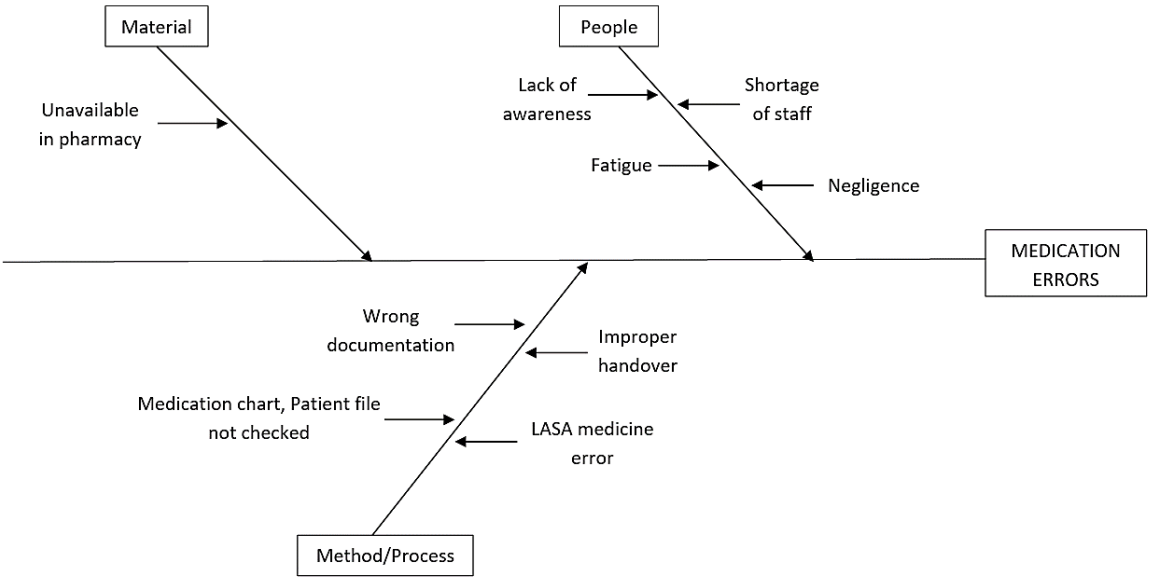


Figure 4.16: Root Cause Analysis of Medication Errors

Root causes of medication errors were divided into People, Process and Material. Most of the causes were found to be in people and process. Staff having lack of awareness, shortage of staff, fatigue and negligence were found to be most possible causes of medication errors in people. In Process, wrong documentation, improper handover, not checking medication chart and file and LASA drug not properly stored were responsible for medication errors. In material, the medicine being not available in pharmacy was found to be a root cause.

4.3.4 FMEA of Medication Errors

After analyzing the incident database of hospital, it was found that most of the incidents were related to medication errors. An FMEA was conducted as a result in order to develop an action plan to decrease errors.

It is a method for prospective risk assessment that identifies potential failures in the care process before outlining the process of care in order to promote patient safety. Their effects and causes responsible for those potential failure modes were mapped. Risk Priority Numbers (RPNs) were calculated (RPN=Severity*Probability*Detection). Further, the appropriate safety measures that are necessary to prevent potential medication errors pertaining to these failure modes were also listed.

Table 4.9: FMEA of Medication Errors

Potential Failure Mode	Potential Causes	Potential Effects	Severity	Probability	Detection	RPN	Actions to Reduce Failure Mode
Wrong Dose	• Lack of awareness • Knowledge deficit • Incorrectly mentioned in medication chart	• Overdose or under dose • Adverse drug reaction	6	6	6	**216**	• Training on 10 R's • Correct documentation to be followed • Frequent audit by clinical pharmacologist • Supervision by senior staff for newly joined staff • More frequent patient safety audits by nurse-Quality
Wrong Patient	• Similar patient name	• Patient harm	9	2	2	**36**	• Training on 10 R's • Training extended to all staff in department to be more vigilant

	• Negligence • Patient file not checked • Fatigue						while administering medication to patient
Missed Dose	• Improper handover • Medication chart not checked • Unavailable in pharmacy • Negligence	• Patient harm	6	5	6	**180**	• Training the nursing staff wrt administration of medication • Instructing nursing staff wrt handover of MAR sheet • Handover audits by quality nurse • Communication between pharmacy, nursing and doctor should be clear in case of non-availability of drug • Sound inventory control practices
Wrong medication	• Failure of double checking • Look-alike sound-alike drug • Incorrectly transcribed	• Patient harm	6	4	5	**120**	• Training staff on administration of medication • High-risk drug including LASA and different concentrations of same medication to be stored physically apart • Training the nursing staff to check the Name of medication properly before administering • Staff to be instructed to not do the transcription of medicine in the drug chart, EMO should do the transcription of medicines in the medication chart
Wrong frequency	• Improper handover • Medication chart not checked • Knowledge deficit	• Patient harm	6	7	6	**252**	• Supervision by senior staff for newly joined staff • Training the nursing staff about rights of medication

	• Incorrect documentation						

Table 4.10: FMEA Scoring

Severity Score	Probability Score	Detection Score	Rating
Catastrophic effect; death	Failure is practically a given	No acknowledged mechanism to detect failure mode	10
A serious injury that necessitated life-saving measures	Failure is almost unavoidable	There is a slim probability that mechanism may notice the failure	9
A rather serious injury necessitated an additional ICU monitoring stay	Process is not in analytical control		8
Moderate harm; further stay in high dependence was necessary	Similar procedures have encountered issues	Mechanism could identify a failure if one exists	7
Minor injury; further monitoring was needed	Analytical control is in place, although there are occasional failures		6
No patient injury occurred, however any side effects needed to be monitored	Some previous methods have occasionally failed		5
No patient damage, however treatment regimen is impacted	Previous procedures have encountered uncontrollable circumstances	The likelihood of controls spotting a failure is high	4
No patient damage, return to regular treatment schedule	Process is in analytical control		3
No patient harm	Process is in analytical control. Only a few occasional failures linked to practically identical processes	Failure is automatically detected by the process. Controls will almost definitely identify a failure if one exists	2
No impact	It's unlikely to fail. No known		1

	failures linked to the same processes		

(**Source:** 2013. *FAILURE MODE EFFECT ANALYSIS (FMEA) PROJECT ON ADMINISTRATION OF CONCENTRATED KCL INFUSION IN CICU*. [online] Available at: https://www.singaporehealthcaremanagement.sg/Abstracts/Documents/PDFs/RM0010%20-%20Lee%20Ang%20Noi.pdf)

Table 4.9 depicts the FMEA of medication errors. There were five potential failure modes identified, namely, Wrong dose, Wrong patient, Missed dose, Wrong medication and Wrong frequency. Wrong frequency had the highest RPN (252) followed by Wrong dose (216) and Wrong patient has the lowest (36). This implies that medication being administered with wrong frequency pose the highest risk and should be given utmost priority. "Wrong patient" should be given attention irrespective of the fact the lowest RPN because it has the highest severity (9). Negligence, knowledge deficit, lack of awareness, improper handover, LASA drug identification error, fatigue, shortage of staff, incorrect documentation were significant contributing factors that led to medication errors.

Chapter 5: DISCUSSION

The analysis was carried out to understand process of incident reporting in hospital and to analyse the incident management database of the hospital. The study had limitations since it was a cross-sectional study with retrospective data analysis, which does not show cause and effect relations but rather identifies patient safety incidents and makes it possible to understand what happened. The root cause analysis approach enables a detailed assessment of the incidents that occur, partially overcoming these limits through the identification of the numerous elements that contributed to a specific incident and the recommendation of measures to prevent recurrence. Incident reporting system serves as a useful tool when it comes to improving patient safety. The analysis produced significant findings that may be useful in the future.

5.1 Incident Reporting

The month-wise analysis of incidents reveals that out of the total incidents reported, nearly three-fourth of the incidents were closed and less than half of them were closed within the stipulated time. Not all incident reports being closed represent a risk to patient safety as, a

root cause analysis is necessary to understand the cause of the incident to prevent future incidents. Further, nearly half of the incident reports were reverted with satisfactory RCA and with satisfactory CAPA. Out of all the incidents that were reverted back, only half of them being reverted with satisfactory RCA and CAPA would make it difficult for patient safety managers to evaluate the incident and take further action. Also, almost half of the incidents were raised within time and nearly three-fourth of them were given by Quality to department within time. This was a gap in incident reporting where incidents were not reported and sent within time which causes a delay in the process and endangers patient safety.

If we talk about incidents according to their category, most of the incidents belonged to category C i.e., an event that touched the person but did not cause injury, followed by category D i.e., an event that touched the person and necessitated observation or involvement to ensure no harm was done. This shows that most of the errors reached the individual whether it resulted in no harm or required monitoring/intervention. In another study it was found that almost one in ten individuals experience adverse incidents while being admitted to the hospital. These incidents can be avoided in a large portion of cases (11).

Adverse healthcare events are generally classified into-Near miss, No harm and Sentinel events (WHO). A study conducted based on information from the Korea Patient Safety Report (12) found that 35% of incidents were for near misses, 57% were for adverse events, and 9% were for sentinel occurrences which is different from this study where near miss reported were 10% near miss events, 62% no harm incidents and 2% sentinel events. This might possible due to the under-reporting of incidents in the hospital.

5.2 Risk Register

Risk assessment, strategy development, and risk reduction employing managerial resources are all parts of the process by which risk is managed. Risk management is an organised way to managing uncertainty associated to a danger. Healthcare organisations that use risk management proactively and methodically protect patient safety as well as their assets, market share, accreditation, levels of reimbursement, brand value, and reputation in the community. One tool for performing a risk analysis to stop future adverse events is the risk register.

This study determined that Patient falls, Pressure ulcers, Device associated pressure injury and other patient injuries were the risks with the highest risk scores. Hospital acquired injuries not only cause patient dissatisfaction and endanger hospital’s reputation, but also

results in financial penalties. According to a study, a HAPI may cost an average of 10708 dollars, or more than 26.8 billion dollars in the US per year (13). Debilitated patients, patients on neurological medications and ventilator, bedridden patients, older age are some of the risk factors associated with hospital acquired injuries. Patient identification error is another severe risk identified through the analysis. Patients experience treatment delays, ineffective treatments, and repetitive lab testing, which eventually compromise patient results and put their safety at risk. On the other hand, healthcare providers face with unwelcome attention, a loss of reputation, rejected claims, and poorer ratings. Other risks identified were equipment failure, patient dissatisfaction due to delay in allotment of room in IPD, delayed discharge, code red and code violet alarm which had low risk but still needed to be monitored.

5.3 FMEA of Medication Error

Irrespective of the care setting, proper use and analysis of medication error reports offer insightful information regarding system-based issues. In this incident report analysis, it was noted that the highest reported incidents were medication errors (38%). This finding is similar to the study conducted in a US hospital by Nuckols et al, where 45% of the total incidents were medication errors (14) while another study conducted in Brazil demonstrated most of the incidents related to surgical procedures (15). The most common stage of medication-use process that was involved in reported events was found to be at the administration stage.

This study sought to increase the safety of medication administration by utilising FMEA to proactively identify failure modes, potential causes, and related corrective action. Wrong dose, Wrong patient, Missed dose, Wrong medication and Wrong frequency were identified as the potential failure modes. The most severe failure mode, choosing the incorrect patient, must always be taken care of. Negligence, knowledge deficit, lack of awareness, improper handover, LASA drug identification error, fatigue, shortage of staff, incorrect documentation were significant contributing factors that led to medication errors in this study. These results are consistent with the finding of the research conducted in a teaching hospital of Sri Lanka (16).

Chapter 6: CONCLUSION AND RECOMMENDATIONS

Any system that assists an organisation in keeping track of, investigating, and recording risky situations is known as an incident reporting system. It might be a risky situation, an accident, or simply a near miss.

Voluntary IRS is not meant to be a precise representation of the frequency or severity of PSIs that happen within a health services setting. Instead, they provide an important tool for comprehending and addressing hidden and contributory factors in a group of PSIs. This calls for established safety learning platforms that facilitate and promote event reporting from all healthcare settings where patients are present. Instead of punishing people responsible for the errors, the error incidence must motivate them to build and enhance the mechanism connected with identifying the systematic reasons of error incidence. Healthcare providers should develop a culture that encourages reporting so that prevention measures and best practices can be instituted.

After reporting and analysing incidents, actual learning and changes in daily practise to prevent incidents from happening again take place. Future research should focus on techniques for changing behaviour and reflecting on past errors. This adjustment ought to be made in light of a thorough comprehension of occurrence types and their underlying causes at the unit level. Healthcare professionals desire quick and honest feedback to retain their continuing commitment. To identify trends, maintain track of contributing factors, and allow units to monitor changes over time, a database with information on event types and root causes could be employed. Additionally, a patient safety reporting system must be established so that patients and their representatives can actively engage in patient safety activities and voluntarily report on PSIs.

Recommendations to encourage incident reporting-

- Manuals and posters detailing the kinds of situations personnel should report ought to be put up in clinical areas.
- There should be separate training sessions on the significance of incident reporting for doctors.
- The results of the incident report should be used on a regular basis for feedback.
- The personnel should be trained on what incidents to be reported along with the timeline of reporting. Also, education on RCA and CAPA should be provided.

- Instead of punishing people responsible for the errors, the error incidence must motivate them to build and enhance the mechanism connected with identifying the systematic reasons of error incidence.

Recommendations to reduce errors-

Medication errors-

- Training the nursing staff on rights of medication administration (Right drug, Right patient, Right dose, Right route, Right time & frequency, Right documentation, Right history & assessment, Drug approach & right to refuse, Right drug-drug interaction and evaluation, Right education & information)
- Correct documentation should be followed
- Frequent audit by clinical pharmacologist should be conducted
- Supervision by senior staff for newly joined staff
- More frequent patient safety audits by quality nurse
- Enforcing double- and triple-checking
- Issuing warnings when a rate or dose deviates from the norm
- Communication between pharmacy, nursing and doctor should be clear in case of non-availability of drug
- Sound inventory control practices should be followed
- High-risk drug including LASA and different concentrations of same medication to be stored physically apart

Patient falls-

- Training the staff on fall risk assessment
- Provide additional staff to help patients at risk of falling
- Set bed alerts for close monitoring of patients at high-risk
- Perform frequent safety rounds on all high-risk patients
- Identify high-risk patients with cues alerting clinicians of the fall risk
- Educate patient and family on fall prevention
- Counselling of patients on neurological medication
- Making patient familiar with the surroundings of his hospital room/bed

Pressure ulcers-

- Providing soft cushioning beds to decrease pressure
- Teaching staff to turn and reposition patients every two hours
- Providing good nutrition to patients with pressure ulcers
- Providing proper skin care by keeping the skin clean and dry

Device associated pressure injuries-

- When choosing a device, the patient's age and the type of intervention needed should be taken into account to select the appropriate shape and size
- Staff should be trained on how to cushion and protect the skin with dressings in high-risk areas (such as the nasal bridge and the rim of the device)
- Removing or moving devices to assess the skin at least once per day
- Educating on proper device use and skin breakdown management

Patient identification errors-

- Instruction on how to properly verify a patient's identity implemented, and the workforce given advice on the significance and value of accurate identification
- All inpatients must wear an ID band at all times while they are hospitalised, according to hospital staff regulations
- Before providing any medication or performing any intervention or operation, the personnel must confirm the patient's ID using at least two identifiers, such as the patient's complete name and ID number
- If it is discovered that the patient does not have an ID band, no treatment should be given and no operation or intervention should be carried out.
- It is the staff's duty to see that the patient's ID band is replaced right away if it has been damaged, rubbed off, or removed for any other reason

Equipment failure-

- Standardize the use of devices in comparable care contexts, including as infusion pumps, monitors, machines
- Being involved in establishing and assessing institutional, organisational, and governmental technology policy
- Ensuring that the technology utilised adheres to the highest quality and safety standards

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ANNEXURE

S.No	Date of Incident	Time of Incident	Location of Incident	Department of Incident	Incident raised by		Incident occured with	UHID of Patient (If Applicable)	category of Incident	Type	Description of Event or Incident	Immediate Corection done
					Name	Department						
1	13-05-2021	12:16pm	COVID ICU	Nursing	SHUBHAM	Clinical Pharmacology	Inpatient	JHN000361524	Category C: An Error tha reached the individual but did not cause harm.	Medication	The patient was admitted in Covid ICU on 9/5/2021 . For this patient Injection Remdac was indented by Clinical Pharmacist and also it was issued by IPD Pharmacy but Injection Remdac was not administered by nursing staff to the patient due to which patient missed his dose.	Informed to covid cordinator on duty & Nursing TL

Figure: Example of an Incident Report Template when an incident is raised

S.No	Date of Incident	Time of Incident	Location of Incident	Department of Incident	Incident raised by		Incident occured with	UHID of Patient (If Applic	category of Incident	Description of Event or Incident	Immediate Corection done	Incident received by		Incident given to Dept. by		NOTE: Primary department for which incident has been raised to collabrate and Primary Department - for which incident has been raised			
					Name	Department						Date	Time	Date	Time	Root Cause Analaysis		Corrective and Preventive Action	
																5 Whys	Description	CA	PA
1	13-05-2021	12:16pm	COVID ICU	Nursing	SHUBHAM	Clinical Pharmacology	Inpatient	JHN000361524	Category C: An Error tha reached the individual but did not cause harm.	The patient was admitted in Covid ICU on 9952021. For this patient Injection Remdac was indented by Clinical Pharmacist and also it was issued by IPD Pharmacy but Injection Remdac was not administered by nursing staff to the patient due to which patient missed his dose.	Informed to covid cordinator on duty & Nursing TL	26.05.2021	4:03 PM	26.05.2021	5:20 PM	Why 1	patient admitted with covid po	patient indent and empty vials counter checked its found ok	briefing given to all nursing staff regarding correct documention
																Why 2	inj Remdac administerd by the staff and not signed in the drug chart		
																Why 3	documentation done in the icu flowchart ,but not, in medication chart, so it found		
																Why 4			
																Why 5			

Figure: Example of an Incident Report Template when it is sent to Quality after doing RCA and CAPA by the concerned department