RISK MANAGEMENT USING INCIDENT REPORTING SYSTEM- A STUDY OF SUPER-SPECIALTY HOSPITAL

Dissertation Submitted to

The IIHMR University, Jaipur

for the partial fulfilment for the award of the degree of

Master of Business Administration (MBA)

in

Hospital and Health Management

By

Dr. Madhvika Bhardwaj

Under the Supervision and Guidance of

Dr Vinod Kumar S.V

2023

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DECLARATION BY STUDENT

I hereby declare that this dissertation titled **"Risk Management Using Incident Reporting System-A Study of Super Specialty Hospital"** is the bonafide record of my original researchwork. 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 Information derived from the published or unpublished workof others has been duly acknowledged in the text.

Madhvika
(Signature)

Name of Student: Dr Madhvika Bhardwaj

Date: 3rd June 2023

AMRITA HOSPITAL
FARIDABAD

Embrace Good Health

20 May 2023

To Whomsoever It May Concern

This is to certify Dr Madhvika Bhardwaj, has successfully completed her internship with Amrita Institute of Medical Sciences and Research Centre, Faridabad under the Quality Department in Medical Administration from 20 February 2023 to 20 May 2023. This internship was part of her Masters of Business Administration, Healthcare Management from IIHMR, Jaipur and enrolment No. IIHMR – U/01/2021-23/1314. She went through an experiential learning on the job.

During her course of internship, we found her sincere and hardworking.

We wish her success in his future endeavours.

AMRITA HOSPITAL Sec-88 Faridabad

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CERTIFICATE

This is to certify that dissertation titled **"Risk Management Using Incident Reporting System-A Study of Super Specialty Hospital"** is a record of the research work undertaken by **Dr Madhvika Bhardwaj** 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.

Dr. Vinod Kumar S.V

Faculty Guide
IIHMR University, Jaipur
Date: 3rd June 2023

Dr.(Col) Mahender Kumar

School Dean
IIHMR University, Jaipur
Date: 3rd June 2023

ABSTRACT

Background- Risk Management is a process Inculcated by various healthcare organizations to reduce errors, safeguard patient safety and organizational assets, maintain brand value and most importantly prevent financial losses. Incident reporting system is one of the means employed by various organizations to bring about risk assessment, it is found to be a crucial instrument for improving safety and enhancing organizational learnings. The system provides the organization with timely information of incidents and useful insights into processes that prevents their recurrence.

Methodology-A study was conducted in Amrita Super Specialty hospital for a period of 3 months, the incident management system was retrospectively analyzed. Incidents reported between Oct'22 to March '23 were analyzed for the type of incident, corrective actions and preventive actions taken for the same, using MS-Excel. FMEA analysis was also done to determine the flaws in the incident management system of Amrita hospital, Faridabad and changes in the process are initiated for improvement of the same.

Results- The analysis of incidents over the period of six months reveals that out of the total incidents reported, nearly 63% of the incidents were closed. Further, nearly half of the incident reports i.e., somewhere around 45% of them were reverted with satisfactory RCA and with satisfactory CAPA. Almost all the incidents were raised within time and were given to the Quality department. If we talk about incidents according to their type, most of the incidents reported were medication errors i.e., 30% of the total, followed by 12 % of other care related cases, 10 % of them were bed sores and 10% were security and safety incidences. If we talk about near miss error, it is observed that there were very few near misses. The study also saw the occurrence of a few sentinel events which were 2 in number. The FMEA analysis of incident reporting system determined 11 failure modes and 32 failure causes.

Conclusion- Incident reporting system serves as a useful tool when it comes to improving patient safety. Incident reporting system is evolving over time depending upon the type of incident reported and technological advancement, the study highlights the type of incidents and measures taken up to improve the system and reinforce better risk management.

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Thank you

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ABBREVIATION

Abbreviation	Meaning
AE	Adverse Event
CAPA	Corrective Action Preventive Action
CQO	Chief Quality Officer
CT	Computerized Tomography
DAMA	Discharge Against Medical Advice
DDI	Dedicated Drug-Drug Interaction
FMEA	Failure Mode Effect Analysis
GDA	General Duty Assistant
HIS	Hospital Information System
ICU	Intensive Care Unit
IPD	Inpatient Department
IRS	Incident Reporting System
LASA	Look Alike Sound Alike
LAMA	Leave against Medical Advice
ME	Medication Error
MS	Microsoft
NHS	National Health Service
NPSD	National Patient Safety Database
NRLS	National Reporting and Learning System
OT	Operation Theatre
PSI	Patient Safety Incident
QA	Quality Assurance
QSM	Quality Steering Meeting
RCA	Root Cause Analysis
RPN	Risk Priority Number
WHO	World Health Organisation

RISK MANAGEMENT USING INCIDENT REPORTING SYSTEM- A STUDY OF SUPER-SPECIALTY HOSPITAL

Chapter 1: INTRODUCTION

Risk management is a process inculcated by various healthcare organisations in the present time to reduce errors in all the fronts of existing operational mechanisms, to ensure patient safety and improve patient delight. It also focuses on improving the efficiency and quality of services provided by the staff and ensure staff self-satisfaction and encouragement. The purpose of risk management eventually boils down to safeguarding patient safety and healthcare organisation's assets, accreditation, brand value and community standing and preventing financial stress of medical mal practices claims and anticipating the future requirements for best possible functioning of the organisation. Risk management in healthcare setting comprises of clinical and administrative systems, process and reports which are employed to detect, assess, Monitor, mitigate and prevent risk. Incident Reporting system is one of the means employed across various organisations to bring about risk assessment and it forms a cornerstone in the process of risk management.

In variety of high-risk organisations, incident reporting systems have proven to be a crucial instrument for improving safety and enhancing organisational learning from occurrences of untoward incidents (commercial aviation, rail industry, and others). Incident reporting system is now widely used across many healthcare organisations to keep track of adverse events and other patient safety concerns, the Joint Commission now requires that all hospital have and use the incident reporting system. The recent patient safety act has resulted in creation of national data base for sharing of adverse events, known as the National Patient Safety Database (NPSD).

Incident reporting systems, vary in form and functionality depending upon the type of healthcare organisation, it gathers and store reports of various untoward events and patient-safety-related occurrences that are documented by the staff members of the hospital which could either be a physician, nursing staff, or other hospital personnel. Adverse occurrences, near-misses, sentinel events and circumstances with the potential to harm patients, staff, infrastructure etc of the organisation are documented in the Incident Reporting system. 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' cause. Depending on the Organisation, the Incident Reporting System can either be a paper-based system with various forms such as medication error reporting form, transfusion reaction form, patient fall reporting form and a general incident reporting form etc, or there could be an online incident reporting form which can be operated electronically using an online portal to register the occurring incidences.

Incident Reporting System applied in an organisation comes with both challenges as well as advantages. Few of the challenges that any incident reporting system could face includes a wide variety in reporting rates hence it cannot be used to measure safety (error rates) or measure changes over time, it cannot be ignored that a good Incident reporting system is associated with cost. studies show that incident reporting systems capture only a small 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, hence it cannot be used to compare organisations. Despite a few challenges Incident Reporting system comes with various other advantages and will continue to be of great significance to improve patient safety.

A few advantages of an Incident reporting system include its value in determining the local system hazards, it can be very useful in accumulation of experiences for uncommon conditions, it can be used to share learnings and lessons within organisation and across organisations. Incident Reporting System can play a significant role in highlighting and bringing to notice the occurring adverse events and improving patient safety. It can provide healthcare providers and other staff members of the organisation with timely information regarding the causes of adverse events and useful insight of the measures taken or can be taken to prevent their recurrence. The concept behind incident reporting system is very simple, it provides with a mechanism to identify risk so that the organisation can take appropriate measures to reduce these risks.

Chapter 2: REVIEW OF LITERATURE

Sr. No	Title	Author	Methodology	Findings
1	Significance of incident reports by medical doctors for organizational transparency and driving forces for patient safety.	Tatsuya Fu kami, Masakazu Uemura, Yoshimasa Nagao.	A backward -Looking study of Incident which were registered in the database of the National University Hospital council, Japan starting from April 1st, 2015, to March 31st, 2019, was done and the sample size taken for the same was 43,775 incidents reported. These incidents were classified based on eight variables decided by the National University Hospital Council, Japan. This classification would segregate the incidents based on their type and potential harm	It was observed in this study that approximately 8 % of the incidents are reported by medical doctors in clinic, and the rate of reporting has significantly increased, and the incident which pose potential harm and have a higher impact on patient are largely reported.
2	Experiences from ten years of incident reporting in health care: a qualitative study	Siw Carl ford, Annica Ohan, Anna Gunnarsson	This study was carried out in Sweden where an electronic online incident reporting system was implemented in 2004	This study discussed the importance of incident reporting system where the features of incident report were divided into two main themes. First

	among department managers and coordinators.		and all the other authorities have explicitly adopted this system across the country. Data was collected in Sweden itself where a purposive sample of nine head of department from three public hospital were taken and interviewed separately also two focused group discussion with incident reporting coordinator was done followed by this a qualitative content analysis was performed.	theme was that "Incident reporting has come to stay" and under this theme the importance of IR i.e., advantages, changes observed due to it and its values were acknowledged, under the second theme "Remaining challenges in Incident Reporting" such as need for action, encouraged learning, IR system development for prospects and proper use was highlighted.
3	Effectiveness and limitations of an incident reporting system analysed by local clinical safety leaders in a tertiary hospital Prospective	Elena Ramirez, Alberto Martin, Yuri Villain, Miguel Lorento	A study was conducted in University Hospital La Paz Canto Blanca III, sample size taken was 1400 public safety incidents reported on public IRS which used Australian classification to prioritize the incident, these incidents and their contributing factor are	The study suggests improvement measures like communication, medication, organization and technology and barrier to their implementation include physical, natural, human actions and administrative barriers. The study observed reduction in

	evaluation through real-time observations of patient safety incidents.		studied, and improvement measures are implemented, followed by this the barriers in the implementation of improvement measures are studied.	near miss and adverse event in 63.15% of improvement measures implemented, on assessing the public safety awareness of health professionals it was seen that awareness increased through period of study, it also emphasizes on efficiency of measures taken and showed a significant relationship between patient safety workshop and number of incidents reported.
4	Incident Report: Between the Shadows of Obligation and Formality	Savitri Citra Budi, Sunartini Hapsara, Fatwa Sari Tetra, Lutfan Lazuardi.	The study explores the roles and barrier faced by the staff in Hospital incident reporting in Nepal. Study design is exploratory quantitative and convenience sampling was used to select informants who were hospital staff (worked for a minimum period of 3 years) and recovered patients (three doctors, two recovered patients, one nurse, one	This study showed that regulations were placed on incident management by the staff to prioritize discipline, responsibility, and honesty. Most importantly this study showed requirement of supportive attitude from board of directors to create a friendly culture towards incident reporting. It highlighted several barriers to reporting such as support

			pharmacist, two computer administrator and sample size of the incident was the amount needed until saturation. Staff was interviewed for data collection followed by analysis.	factors, facilities, and effective feedback system.
5	Knowledge and Barriers of Incident Report Among Nurses in Teaching Hospital, Bharatpur.	Sajina Lama, Dina Khanal	A study was conducted in a teaching hospital of Bharatpur to assess the knowledge and barriers of incident report among staff nurses. The study had a cross sectional design and the sample size was 208 nurses selected through simple random sampling, data collection was done from 8th June 2019 to 18th July 2019 by using a questionnaire. Collected data was entered and coded using SPSS (Statistical Package for Social Sciences) version 20 and was further analyzed by descriptive methods.	The study showed that three-fourth of the nurses had poor level of knowledge with respect to incident reporting and various barriers were faced by them in doing so, these barriers were identified as work complexity, lack of improvement post reporting by authorities, inert fear, blames and penalties, lack of appropriate protocols. The study suggested a need of improving the nurse's knowledge on IR which could be executed by planned training sessions and improvement in staff culture, encouragement of anonymity was also

				suggested to enhance IR by the staff nurses.
6	A Study to Assess the Knowledge, Attitude and Perceived Barriers on Incident Reporting among Staff Nurses Working in a Tertiary Care Hospital, Ludhiana, Punjab.	Sharma Kapil, Kaur Anoopji	A study was conducted in Dayanand Medical College and Hospital, Ludhiana in the Month of May 2017. Study design was descriptive, study sample included staff nurses and the sample size was 60 staff nurses selected through convenient sampling. A questionnaire was used to collect data, Likert scale was used to assess the attitude of the nurses towards IR and a check list was used to assess the barriers perceived by them.	The study showed that Majority of staff members who participated in the study had average knowledge yet positive attitude towards the incident reporting, the study also identified some common barriers perceived by the staff which would be fear of legal action, lack of time, fear of career prospects and personal reputation. The study also threw some light upon the fact that there was a weak positive correlation between knowledge and attitude of staff nurse.
7	Can Patient Safety Incident Reports Be Used to Compare Hospital Safety? Results from a Quantitative Analysis of the English National	Ann-Marie Howell, Elaine M Burns, George Bouras, Ara Darzi, Liam. Donaldson, Thanos Athanasiou	A study was conducted in England to analyze the data on incident reporting which is registered on the National Reporting and Learning System (NRLS) of the country. The study population	The study resulted in showing that 70.3% of incident reported produced no harm to patients, 0.9% resulted in causing severe harm to patients which included death at times. The study showed zero association

	Reporting and Learning System Data.		included all the incident report on patient safety from 31st May 2013 to 1st Jan 2023, sample size was 5,879,954 incidents collected from acute hospital over 10 years period. Investigation of the data was done using Pareto analysis and regression model.	between size of the organization, number of staff or patients with incident reporting. Study also revealed that an open environment and reduced fear of punitive actions increased incident reporting, it emphasizes that reporting of incident should not be considered as a standard to compare hospitals.
8	A study of medication errors in a tertiary care hospital	Nrupal Patel, Mira Desai, Samdih Shah, Prakruti Patel, Anuradha Gandhi	This study was conducted in General Medicine and Paediatric wards in Civil Hospital in Ahmadabad, Gujarat for the purpose of segregating various types of medication errors that occur in day-to-day practice in IPD. Duration of the study was from Oct 2012 to Jan 2014, study design was prospective observational design, the sample size was 1109 incidents reported, data collection was done from patient's case	The study highlighted Medication errors such as Prescription error, administration error, transcription error, and dispensing error. Out of 1109 incidents it was seen that 403 were medication errors and among them 236 were prescription error, 15 were dispensing error, 126 were administration error. 46% of the cases showed presence of dedicated drug-drug interaction(DDI). This study emphasises on requirement of an

			records and treatment charts, nurses were accompanied by an investigator for the same. Medscape software was used to record drug interaction. The validity and rationality of the prescriptions was recorded using Phalke's criteria.	established medication error reporting system to improve patient safety and care.
9	Application of failure mode and effects analysis (FMEA) to improve medication safety in the dispensing process – a study at a teaching hospital, Sri Lanka	J.A.L Anjalee, V. Rutter, N.R. Samaranayake	A study conducted in pharmacy department of a teaching hospital in Colombo, Sri Lanka. Study design was cross sectional descriptive design, duration of the study was 3 months starting from Aug 2018 to oct 2018. The study aimed at improving the dispensing process of the pharmacy for which FMEA was performed, wherein five meeting of two hour each were conducted. Dispensing process and sub process were discussed in these meetings, failure modes	This study identified 48 failure modes out of these 38 failure modes were prioritized for corrective and preventive action. Failure mode with high RPN score were potentially considered for CAPA. The study also identified that overcrowded dispensing counters was one of the main causes of various failure modes. The study suggests redesigning of dispensing table, dispensing labels, and establishing a patient counselling centre unit for further improving the

			and failure cause were identified. Severity score allotment was done, RPN was calculated and based on the RPN score, failure modes were prioritised followed by which corrective actions were designed for the same and put into action.	dispensing process in the hospital.
10	Patient Safety Management Re-Design by Using Hospital Failure Mode Effect Analysis1	Tina Oktarina, Muhardi Muhardi	A study was conducted in Assyifa Islamic Hospital, Sukabumi, Indonesia. Study design adopted was qualitative design, sample size for the same was 100 inpatients of the hospital. Data was collected through interview, observations, document research and focussed group discussions. The data was further analysed into an FMEA, and factors considered for the analysis were effective communication, medicine safety, location	The study shows that 30% of nurses often neglect patient identification process indicating that safety management is not optimally applied. FMEA conducted did result in improvement of some sort but there is further requirement of improvement which is concluded as there is existence of patient safety incidents after implication of precautious measures. redesigning of the process is done but the application is not optimum, and more

			accuracy, procedure and patient operation safety, minimization of infection risk and minimization of falls.	efforts need to be put to improve the processes.

Table 2.1: Review of Literature

Chapter 3: METHODOLOGY

3.1.Research Question

1. What type of Incident reporting system does the Amrita hospital have?
2. Which are the most common risks identified through Incident Reporting System (IRS) and What are the Measures adopted by the Hospital to mitigate these risks?

3.2.Research Objectives

1. To understand the process of incident reporting in Amrita super specialty hospital.
2. To profile and analyse the type of Incident and adverse event reported on Amrita Hospital incident management system.
3. To assess the gaps in the existing incident management system using Failure Mode and Effect Analysis (FMEA) and suggest remedial measures.

3.3. Methodology

1. Study Design: Secondary data Analysis
2. Study Setting: Study was conducted in Amrita Hospital and Research Centre, Faridabad, Haryana.
3. Study Population: Inclusive of all the staff members (clinical and non-clinical) who would actively involve themselves in incident reporting.
4. Duration of Study: Study was conducted over the period of 3 months w.e.f. 20th Feb 2023 to 20th May 2023.
5. Sample size: 102 Cases reported over the period of Oct 2022 to Mar 2023 on the Amrita Hospital Incident Reporting System.
6. Sampling Technique: Convenience Sampling.
7. Research approach: Qualitative and Qualitative assessment.
8. Study Instrument: study checklist created on MS-Excel.
9. Data Collection and Analysis: Data for the month of Jan, Feb and March 2023 was collected from the hospital Incident Management data base and data for the month of Oct, Nov, Dec 2022 is collected from paper-based incident management forms preserved in the hospital itself. A retrospective analysis is done on the acquired data. MS Excel is used to record,

study, and analyse the details of every incident that were recorded between Oct 2022 to Mar 2023 including CAPA.

10. Inclusion Criteria: All the incidents irrespective of the type and severity reported between Oct 2022 to Mar 2023.
11. Exclusion Criteria: The incidents that are not reported in the Incident database are excluded.
12. Ethical Consideration: At every stage of this Study, patients and the staff members privacy were strictly respected, verbal consent was taken before taking formal feedback or review of incidents. Confidentiality was guaranteed.

3.4. Operational Definitions:

1. Adverse event- Any unfavourable medical event that occurs in a patient or clinical trial participant after receiving a pharmaceutical product, but which does not necessarily have to be related to this treatment.
2. Adverse drug reaction- Adverse drug reactions are those that are noticeably detrimental or unpleasant that are brought on by a medical product intervention, product withdrawal, or change in medication regimen.
3. Corrective And Preventive Action (CAPA)- Corrective and Preventive Action (CAPA) are written protocols formulated and designed based on a specific issues and problems, with an aim to resolves the issues, pinpoint their causes, implements corrective futuristic actions, and guards against reoccurrence of the underlying issues.
4. Failure Mode and Effects Analysis (FMEA)- FMEA is a methodical, proactive strategy for reviewing a process to highlight potential failure of any process and evaluate the relative consequences of specific failures to anticipate the process elements that require the greatest improvement.
5. Incident Report- incident report is a written form, or an online Portal used to document the details of untoward events that occur on day-to-day bases in an organisation that has the potential of harm to either an individual or property of any sort. It records events such as accidents, near miss, property damage, safety issues, health issues and any sort of security breach etc.
6. Medication error- A medication error is any avoidable occurrence that could cause an inappropriate medication use resulting in patient harm while the medication is in the control

of the healthcare professional, pharmaceutical professional, patient, or care giver (nurse or caretaker).

7. 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 did not.
8. No Harm Event- It is an event experienced by the patient, such that no harm is done at the time of its occurrence, and there is no realistic chance that there will be any harm done in the future due to the same. However, the incident may have an occasional potential of causing harm on its recurrence in the future.
9. 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.
10. Root Cause Analysis (RCA) - A methodical procedure wherein the causes of an occurrence are determined by retrospectively retracing the course of the incident and requestioning until the true root causes are reached and understood.
11. Sentinel events- A systemic or procedural failure that results in a patient receiving services that lead to death or suffering, significant and long-lasting loss of function or severe temporary harm. A sensory, motor, physiological, or psychological impairment that wasn't existing when services were requested. The impairment is unrelated to any underlying conditions and lasts for at least two weeks.

3.5.Steps in process of FMEA at Amrita Hospital,Faridabad

Step 1: A team was assembled to conduct the FMEA

- Team comprised of 7 members, 3 from department of quality, 2 from department of Nursing, 1 from departemnt of IT, 2 from department of operations.

Step 2: Process of Incident reporting was understood and mapped

- The process of online incident reporting was mapped to undestand the sequence of steps that follow starting from identifying the incident to monitoring the Corrective and preventive actions implemented.

Step 3: Potential Failures were identified by brainstorming

- Potential failure modes were identified and various causes which result into these failure modes were listed down, the effectes of these failure causes are also enlisted.

Step 4: Severity rating was assigned

- A severity ranking starting from 10 to 1 was alloted depending upon the sevierity of the failure cause

Step 5: Occurrence rating was assigned

- Occurrence score was given to the failure cause based on the frequency of occurrence and chances of occurrence.

Step 6: Detection rating was assigned

- A detection score was given to the failure cause based on its ablility to be detected.

Step 7: RPN score was calculated

- Risk priority scoring was done by multiplication of severity, occurence and detection.

Step 8:Action plan was developed

- The incident was sent to the respective department responsible and a CAPA is generated.

Step 9: Action taken

- CAPA generated was implemeted and monitored

Step 10: Reassessment of FMEA after stipulated time period

- To further understand the challenges and loop holes in implemented CAPA and provide Further corrective actions.

3.6.Severity (SEV) Rating

SEV	Severity	Product/Process Criteria
10	Dangerous without warning	Very high severity rating when probable failure mode affects the system operations without warning
9	Dangerous with warning	Very high severity rating when a failure mode affects the system operation with warning
8	Very high	Makes product inoperable, disruption in operation are major(100%)
7	High	Product is operable but the performance is drastically reduced.
6	Moderate	Product is operable but existing disruptions cause patient disactifaction

5	Low	Product is operable but the resultant comfort and convenience are compromised/reduced level
4	Very Low	Minor disruptions in operation resulting in dissatisfaction by most customers.
3	Minor	Minor disruption in operation resulting in dissatisfaction by average number of customers
2	Very Minor	Minor disruptions in operations resulting in dissatifaction of few customers
1	None	No effect

Table 3.1: Severity Rating

3.7.Occurrence(OCC Rating)

OCC	Occurence	Criteria
10	Very high	More than 1 in 2 events
9	Very high	1 in 3 events , almost certain to occur
8	High	1 in 8 events
7	High	1 in 20 events, high probablity that the event will occur
6	Moderate	1 in 80 events
5	Moderate	1 in 200 events, moderate chances of occurence
4	Moderate	1 in 2000 events
3	Low	1 in 15,000 events, unlikely to occur
2	Low	1 in 150,000 events
1	Low	1 in 1,500,000 , very unlikely to occur

Table 3.2: Occurrence Rating

3.8.Detection (DET) Rating

DET	Detection	Criteria
10	Absolute uncertainty	No chances that the designed control will detect the failure mode/cause.

9	Very remote	Very remote chances that the designed control will detect failure mode/cause.
8	Remote	Remote chances that designed control will detect a failure mode/cause.
7	Very low	Very low chances that a designed control will detect a failure mode/cause.
6	low	Low chances that a designed control will detect a failure mode/cause.
5	Moderate	Moderate chances that a designed control will detect a failure mode/cause.
4	Moderately high	Moderately high chance that a designed control will detect failure mode/cause.
3	High	High chances that a designed control will detect failur mode/cause.
2	Very high	Very high chances that adesigned control will detect a failure mode/cause.
1	Almost certain	Designed control will almost certainly detect a failure mode/cause.

Table 3.3: Detection rating

Chapter 4: RESULTS

4.1.Process of Incident Reporting at Amrita Hospital, Faridabad

Incident reporting is a process of documenting and recording in detail the sequence of event that encompasses during the occurrence of an unprecedented event that takes place at the setting such as human or infrastructural harm. The purpose of incident reporting is to accurately describe what happened while it is still recent in the thoughts of people who were present at the site of the incident.

Incident reporting system at Amrita Hospital, Faridabad is relatively simple to understand, and most incident reports involve incidents which majorly involve patients but they also document incidents in which staff members and visitors are injured or affected. In case of patient harm, it becomes the duty of the organisation to provide additional care and vigil over the involved patient and often monitor the patient to prevent the recurrence of the event.

Process of Incident reporting at Amrita Hospital Begins with occurrence of an adverse event with potential harm in one way or the other which are reported by the staff on the online portal of Amrita Hospital, these events are recorded within a day of occurrence of the event (24 hours). The record of the same is maintained by the Quality Department. The event entered are read and understood by the quality department following which the department takes adequate measures to investigate the event for better understanding and to know the intricacies of the event, Quality personnel gets into conversation with all the stakeholders of the event and individually interviews each involved member, which at times could include the patient as well to understand and draw a clear picture of the event. Responsibility of the event is handed over by the quality department to the specific department concerned with the event such as nursing in case of medication administration error and any clinical department in case of diagnostic or treatment errors, the floor coordinator / In charge / Supervisor is kept in loop and is aware on the know-how of the event in their area of function.

RCA is required in case of certain crucial events that has process flaws; RCA is done immediately following the incident. The analysis and action plan is completed within 45 days of occurrence of the event and redesigning of the processes is done to prevent or reduce the risk of sentinel events recurring. CAPA is formulated by the responsible department which is then validated by the quality department before it is put to action. Escalation Matrix is initiated in cases where CAPA is not done. the following figure shows a detailed process of Incident management at Amrita Hospital.

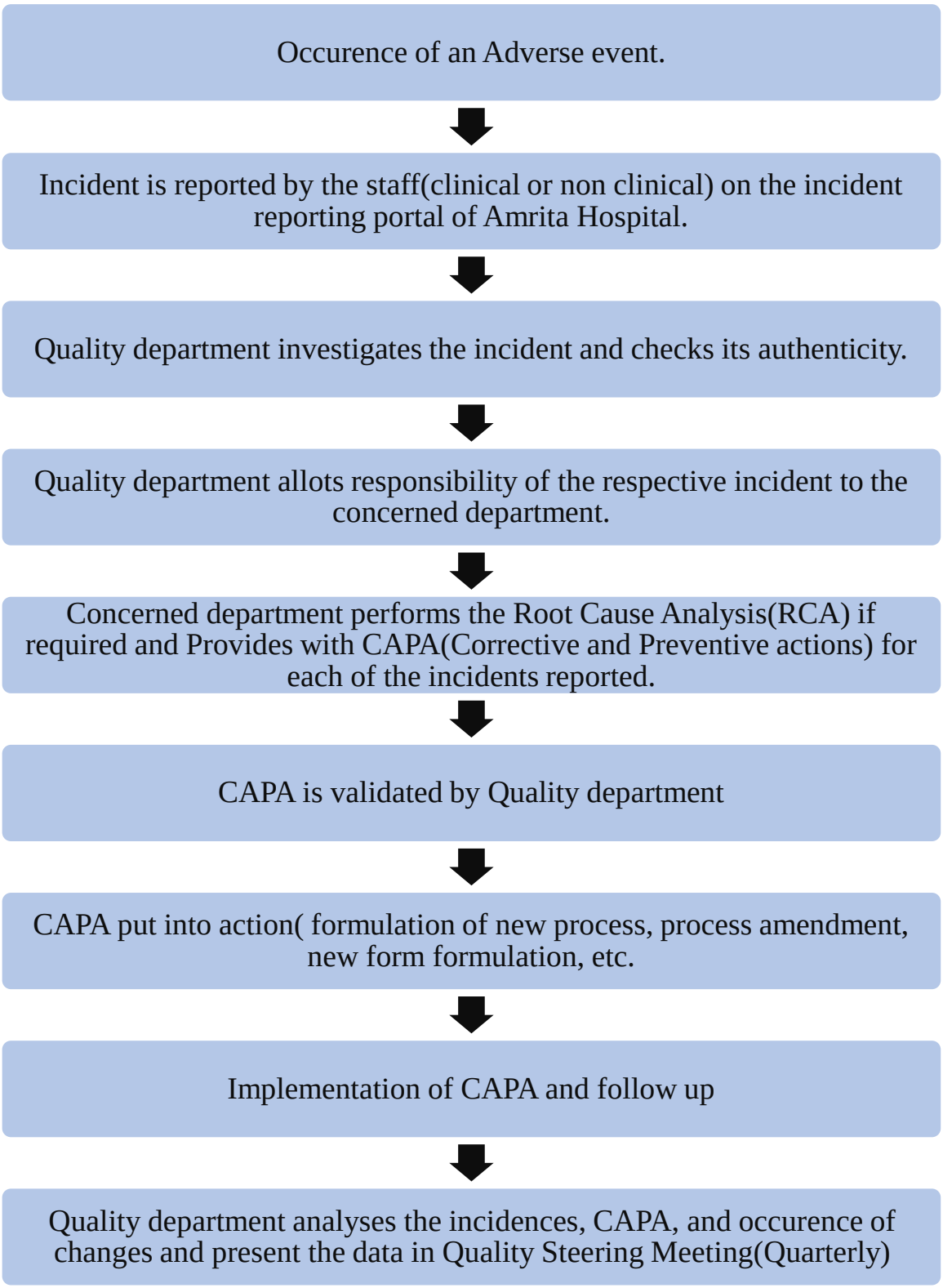

Figure 4.1: Process of Incident Reporting

4.2.Classification of Incident Reporting

According to severity, incidents are broadly categorised into:

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

4.3.Analysis of Incidents

On Analysing the data obtained from the incident reporting system of Amrita Hospital we can observe that 63.7% of the total reported incidents were closed, , an incident is said to be closed when the responsible department for the respective incident formulates and implements the CAPA and sends the CAPA report to the Quality department, nearly one fourth of the reported incidents i.e., 36.2% were not closed and were pending, were as nearly half i.e. 43.1% of the reported incidents were analysed with satisfactory CAPA.

On monthly analysis of these incidents, it was observed that number of incidents not closed were highest in the month of march i.e., 70% of the cases were not closed and the reason being lack of importance to the incident reported and pilling up of older cases. It is also observed that the number of cases reported in the month of January were very few, reason being a drastic shift from a paper-based incident reporting system to an online mode of incident reporting. Table 4.1 gives a detailed analysis of the reported incidents.

On analysing the incidents according to classification of incidents based on severity it was observed that only 1.9% of the total incidents contributed to sentinel events which occurred in the month of October and December 2022 and 11% of cases were near misses whereas all others belong to the category of no harm events. Table 4.2 gives a detailed monthly analysis of these events according to classification.

S.NO	DATA	MONTH (OCT 2022 TO MAR 2023)						TOTAL
		Oct'22	Nov'22	Dec'22	Jan'23	Feb'23	Mar'23	
1	Total number of Incidents raised	7	16	12	3	34	30	102
2	Total number of incidents closed	5(71.4%)	15(93.7%)	9(75%)	2(66.6%)	25(73.5%)	9(30%)	65(63.7%)

3	Total number of incidents Not closed	2(28.6%)	1(6.3%)	3(25%)	1(33.4%)	9(26.5%)	21(70%)	37(36.2%)
4	Total number of Satisfactory CAPA (Among incident closed)	5(71.4%)	11(68.7%)	5(41.6%)	2(66.6%)	15((44.1%)	6(20%)	44(43.1%)

Table 4.1: Number of incidents Based on Satisfactory CAPA

S.NO	DATA	MONTH (OCT 2022 TO MAR 2023)						TOTAL
		Oct'22	Nov'22	Dec'22	Jan'23	Feb'23	Mar'23	
1	Total number of Incidents raised	7	16	12	3	34	30	102
2	Total number of sentinel events (Among all incident)	1(14.2%)	0(0%)	1(8.3%)	0(0%)	0(0%)	0(0%)	2(1.9%)
3	Near miss incidence (Among all incident)	0(0%)	4(25%)	2(16.2%)	0(0%)	2(5.8%)	3(10%)	11(10.7%)
4	No Harm event (Among all incident)	6(85.7%)	12(75%)	9((75%)	3(100%)	32(94.2%)	27(90%)	89(87.2%)

Table 4.2: Number of Incidents Based on Classification of Severity

4.4.Factors contributing to Near Miss Events in Amrita Hospital: -

- Unclear lines of authority and lack of coordination and communication either verbal or written with consultants, nurses and administrative staff can result in near misses such as Medication Error.
- Chances of administration of look-alike and sound-alike(LASA) medicines if not kept at designated places.
- Environment and design factors like rush hour traffic in corridor, waiting area and diagnostic area.

- Medical Equipment Failure.

4.5.Factors Contributing to No Harm Events at Amrita Hospital: -

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

4.6.Factors contributing of Sentinel Events at Amrita Hospital: -

Surgical Sentinel 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 Sentinel 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 Sentinel Event

- A slide, accident, or fall resulting in injury.
- An electrocution resulting in death.

Medication Sentinel Event

- Drug error resulting in patient mortality or severe impairment because of improper drug delivery, for instance:
  - Omission Mistake
  - Improper Dosage
  - Error in dose formulation
  - Incorrect timing error o 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 Sentinel 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.

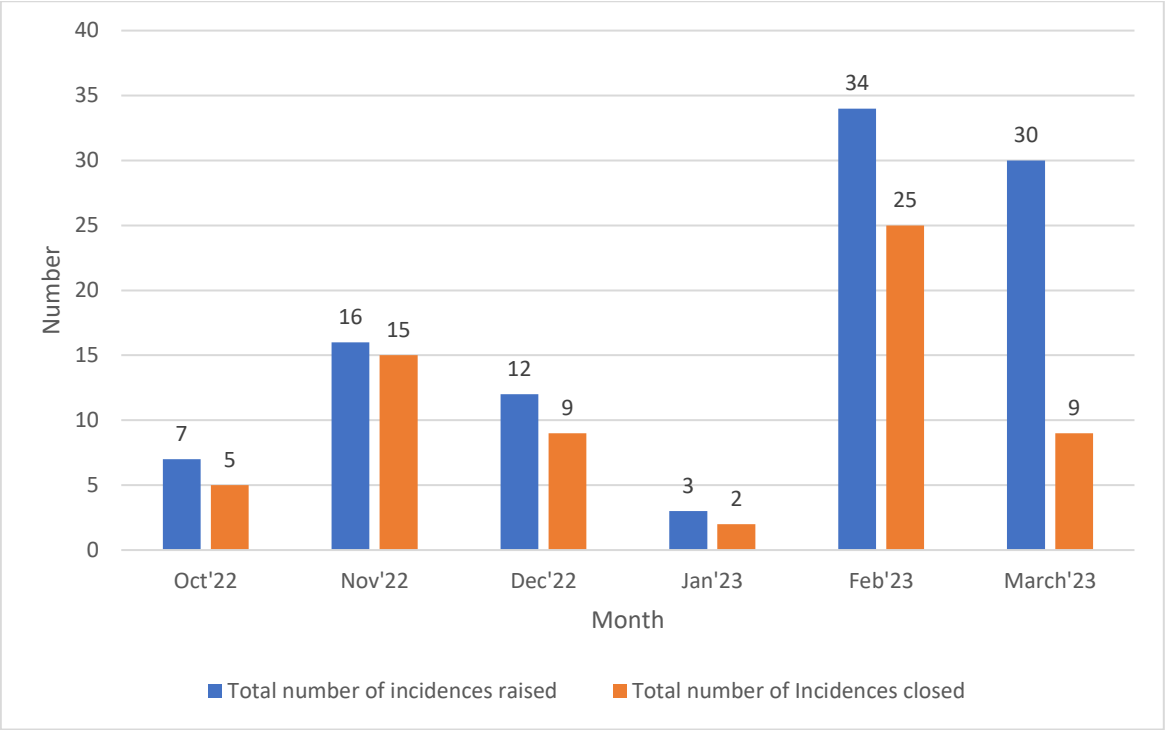

Figure 4.2: Number of Incident Reported and Closed on Monthly Bases

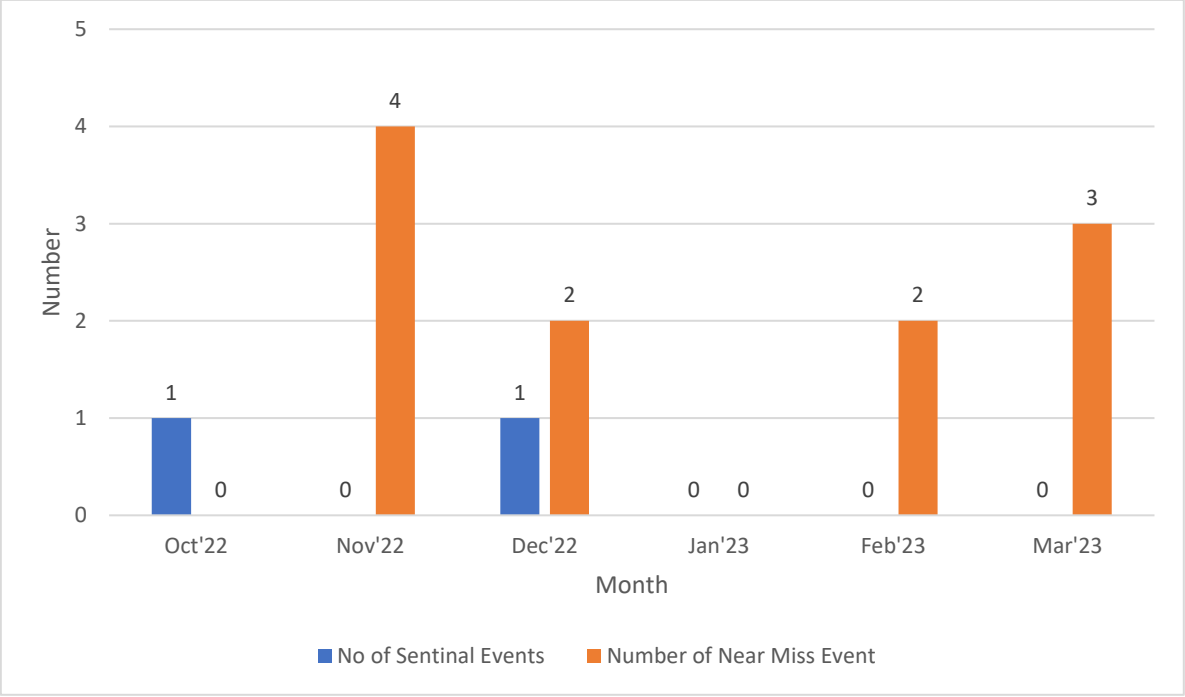

Figure 4.3:Number of Sentinel Events and Near Miss Events on Monthly Bases

On analysing the type of incidents reported it was evident that 30.4% of the total cases reported were medication errors followed by patient care related errors which made a good 12.7% of the cases and 21.6% were bedsore and safety associated errors. Table 4.4 give a detailed analysis of type of errors that occurred in Amrita hospital through a period of six months.

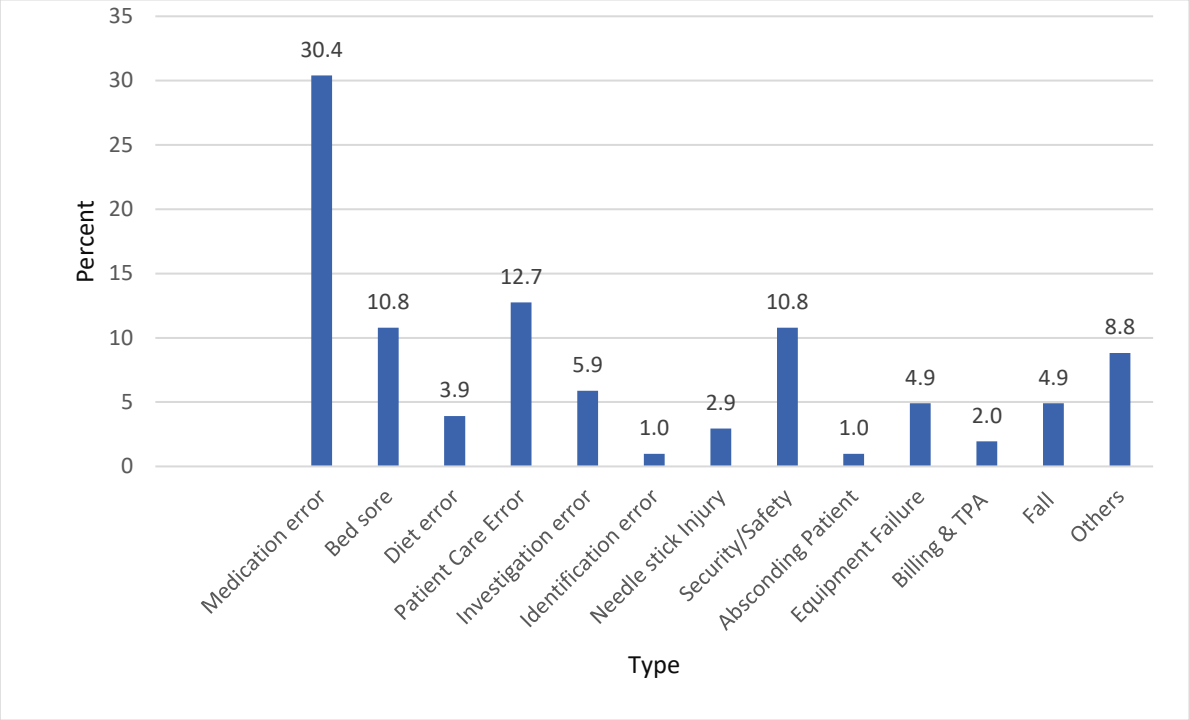

Figure 4.4:Type of Incident Reported From OCT'22 TO MAR'23

4.7.Medication Error

After analysing the type of incidents, it was evident that medication error were maximum in number among the total cases reported and it was seen in this study that administration error were more than half in number followed by transcription error which were nearly one-fourth in number. Table 4.3 gives a detailed analysis of medication errors which occurred at Amrita Hospital in six-month period. Considering that these errors were so high in number it was crucial to perform a root cause analysis to understand the exact cause of these errors. Figure 4.5 shows the root cause analysis of medication errors that occurred in Amrita Hospital over the period of six months.

Medication Error							
Month	October	November	December	January	February	March	Number (OCT2022 TO MAR2023)
Administration Error	3	0	2	0	9	3	17
Transcription Error	0	4	1	1	2	0	8
Dispensing Error	0	5	0	0	0	0	5
Prescription Error	0	1	0	0	0	0	1

Table 4.3: Segregation of Medication errors According to Type on Monthly Bases

4.7.1. Root Cause Analysis of Medication Error

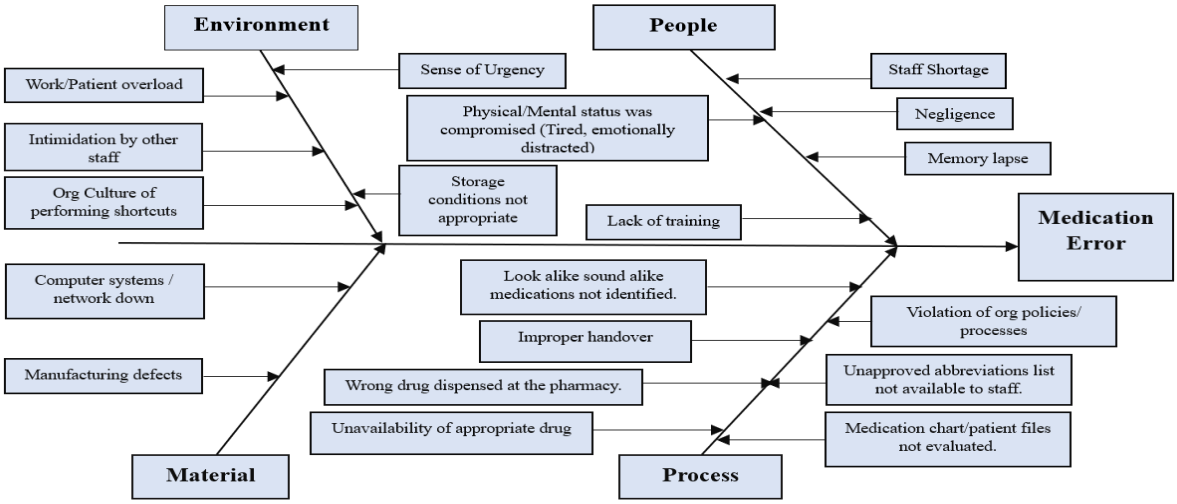

Figure 4.5: showing root cause analysis (RCA) diagram of medication error.

Root causes of medication errors is segregated into sub causes under People, Process, Material and Environment. Most of the causes were found to be in people and process category. Staff with lack of training, shortage of staff, negligence of staff and physical and mental status of staff were some of the reasons under people category. In Process category, incorrect documentation, improper handover, evaluation of medication chart and file and lack of provision on usage of LASA drug contributed to medication error. In material category, unavailability of the respective prescribed medication was considered the root cause of mediation error.

4.7.1. Medication Management Process Flow

It is important to understand the process flow of medication management to determine the type of errors that can occur in medication management.

Six stages of medication management are:

- Prescribing
- Transcribing
- Indenting
- Dispensing
- Administration and
- Monitoring.

Doctor prescribes the drug which is rechecked by a junior resident doctor followed by which the medication order is transcribed by a duty nurse into the HIS. After receiving the order, the pharmacist will indent the prescribed medication. Medication is then dispensed by the pharmacist of the hospital IPD pharmacy and GDA is responsible for distributing them to the respective wards. The nurse, then, checks the medication and administers the medicine to the patient as ordered by the doctor and post administration monitoring for any adverse drug reaction is done. This is how a normal medication management is followed in IPD. Breach in any of the steps may lead to a medication error.

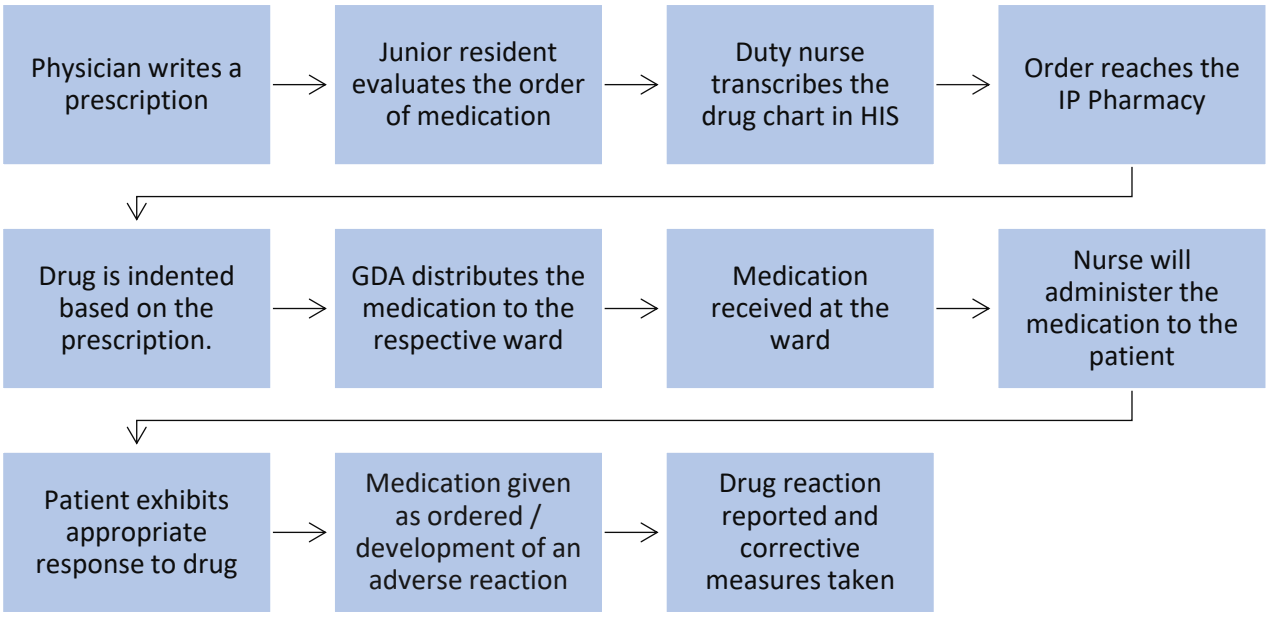

Figure 4.6: Medication Management Process

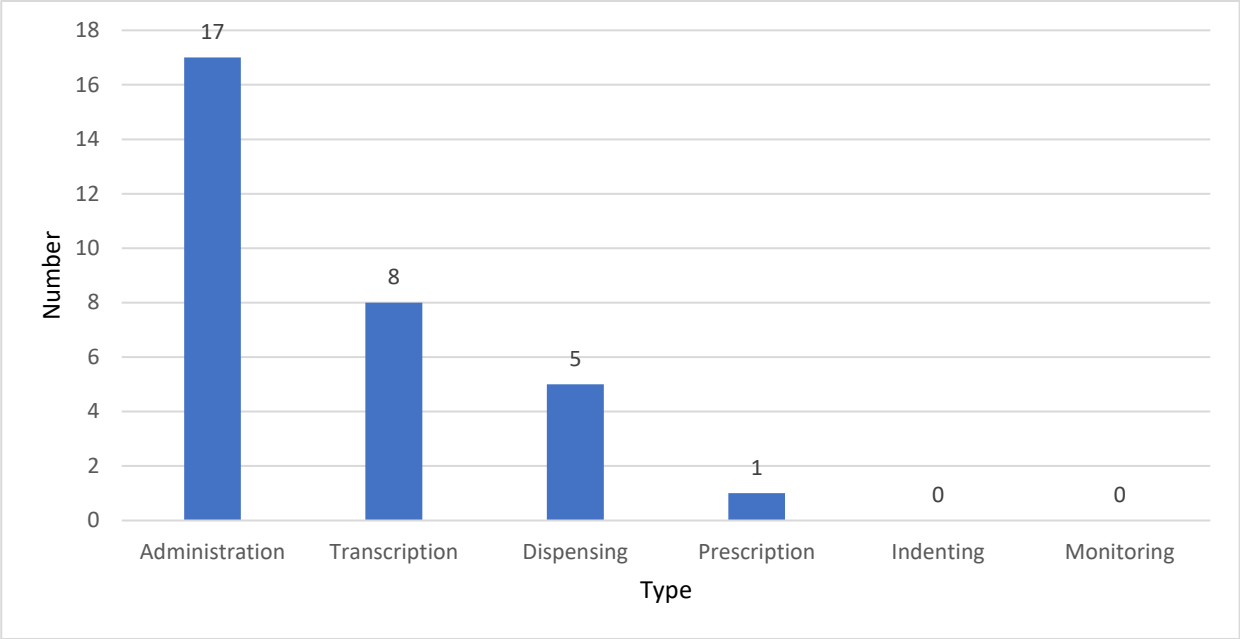

Figure 4.7: Number and Type of Medication Error From OCT'22 TO MAR '23

4.8. Gap Analysis of Incident Management system of Amrita Hospital using Failure Mode and Effect Analysis

FMEAs, commonly known as Failure Mode and Effects Analysis, is an organized approach for evaluating unfavourable events to identify probable flaws in procedures, goods, or services. FMEAs often concentrate on the modification of processes rather than analysing the existing incidents/ problems.

4.8.1. Salient features in each step of FMEA -Incident Management System(consolidated table of FMEA attached as ANNEXURE V)

Step 1:Staff recognises an incident

Failure Cause:

- Lack of understanding on the types of events to be identified.

Effect:

- Risk of recurrence of same incident persists due to non-reporting
- High risk incidents pose higher adverse outcomes as they were missed reporting earlier.
- Loss of opportunity for improvement

Action taken

- frequent training on understanding of events and importance of incident reporting

Step 2: Incident Identified & directly reported to Quality department

Failure Cause:

- Lack of sensitisation & awareness on importance of immediate reporting of incidents and their relationship with the safe environment.
- A relaxed outlook towards Safety & Quality in the facility
- Staff occupied with regular job-related tasks.

Effect:

- Timely reporting of incident does not take place.
- An incident left unreported to the management.

Action Taken

- Focus on more frequent training regarding understanding on the types of events/ incidents to be reported & its link with Quality & Patient Safety.
- To modify the process of incident reporting such that incident notification are received by Authorized personnel only.

Step:3: Incident reported through the online incidence reporting form

Failure cause:

- Incident entered but not registered or saved on the online portal.
- Person not aware on how to use the online portal for incident reporting.

Effect:

- Delay in Incident recognition to Quality department

Action Taken:

- Enforcement of the defined timeline for reporting/ Submission of the Incident
- Incorporation of new technological features in the Incident Reporting Process to make it hassle free.

Step 4: Categorization of incident based on Severity (Risk)

Failure Cause:

- Improper Language / grammar used to narrate the incidence in the online form difficult to comprehend.

Effect:

- Delay in initiating the investigation
- Risk of recurrence of same incident persist

Action Taken:

- Training on how to write the incidences in a legible and understandable format.

Step 5: Quality Assurance conducts initial investigation & suggests recommendation for improvement.

Failure Cause:

- Unavailability of Quality Personnel & no handover to the colleague
- Quality personnel assigned to another task.

Effect:

- Delay in report finalization
- Investigated findings and recommendations not documented on time.

Action Taken:

- Modifications in the Incident reporting Mechanism by including the provision of "Prompts" on the visibility of Pending status of the Incident to the authorized personnels

Step 6: CAPA(Corrective and Preventive action) designed and put into action by respective department

Failure cause:

- Improper design of CAPA

- CAPA not taken seriously by the staff and considered non-Imperative for implementation.

Effect:

- Further delay for Actions to be implemented
- Risk of recurrence of same incident persist

Action Taken:

- Training of staff on Importance of CAPA and its implementation

Step 7: Monitoring

Failure cause:

- Knowledge deficit on how to implement recommended actions

Effects:

- Delay in implementation of recommended actions.

Action Taken:

- Training of staff on new Corrective and preventive actions.

4.8.2. Interpretation of FMEA-Incident Management System

Steps involved in the process of incident reporting are listed in the above table. From the FMEA conducted it is observed that 11 failure modes were identified, and 32 failure causes were resulting into these failure modes. Failure causes for each of the failue mode are listed in the above table. A few failure causes with a high RPN number were identified and prioritised, total number of failure causes identified for corective and preventive action were 18 in number and their RPN score were more than 100.

The most common type of failure causes that were identified were lack of sensitization and awareness on importance of immediate reporting of incident, a relaxed outlook of staff, over occupied and overburdened staff, complexity in operation of the online portal, apprehension and punitive actions etc.

The corrective and preventive action taken to prevent these failure modes include training of staff on understanding the types of incidents to be reported and the importance of there promt reporting, Modification of the online portal such that it is made user friendly and comprehensive, regulations on time line for all the incident reporting, emphasis on seriousness of CAPA implementation and its regular monitoring.

Chapter 5: DISCUSSION

A study was carried out to understand process of incident reporting in a super speciality hospital to analyse the incident management database of the hospital. The study made it possible to understand the importance of incident management system in a hospital and its relevance in the healthcare system. This study carrying a cross-sectional study design with retrospective data analysis had certain limitations such as, it did not show cause and effect relations but rather it identifies patient safety incidents and makes it possible to understand and learn from the consequences of the incidences. These limitations exist solely because of time constrains. The root cause analysis approach enables a detailed assessment of the incidents that occur, it helps in the identification of the numerous elements and factors that contributed to the occurrence of incident and enables formulation 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.

Incident Reporting

The analysis of incidents that were raised over the period of six months reveals that out of the total incidents reported, nearly 63% of the incidents were closed. Non closure of certain incident at times cannot be represented as a risk to patient safety as, a few incidents occur as a chance factor and there may not be a specific corrective action for the same however a root cause analysis is necessary to understand the cause of the incident to prevent future incidents. Further, nearly half of the incident reports i.e., somewhere around 45% of them were reverted with satisfactory RCA and with satisfactory CAPA. Also, almost all the incidents were raised within time and were given to Quality department. There were a few incidents which were reported very late due to memory lapse and various other reasons, this was one of the gaps in incident reporting where incidents were not reported within time. If we talk about incidents according to their type, most of the incidents reported were medication errors followed by bed sores and other care related errors. If we talk about near miss error, it is observed that there were very few near misses which indicates that errors reached the individual whether it resulted in no harm or required monitoring/intervention. The study also saw the occurrence of a few sentinel events which were just 2 in number but did permanent damage to the patient and required to be compensated in some way or the other by the hospital. A study conducted over a period of 10 years on a sample of 5,879,954 incident reports registered on National Reporting and Learning System (NRLS) in United Kingdom found that 70% of incidents were no harm events, 0.95 were for sentinel events, and 29.1% were near miss events.

FMEA of Incident Reporting System

FMEA is an important tool to determine gaps in any kind of process, the use of FMEA in this study showed various failure modes and their effects that need to be corrected over the period to improve the process of incident reporting in the hospital. Various failure modes were identified through the FMEA of the incident management system of the hospital and their effects were studied. Based on the effects corrective actions and preventive actions were formulated and implemented across the organisation. The only drawback the study was while doing this FMEA was lack shortage of time to further evaluate the challenges posed in implementation of the CAPA actions. The study also threw some light on the opinions of staff about the incident reporting system and that helped in building grounds for preventive actions.

Chapter 6: CONCLUSION AND RECOMMENDATIONS

Any system that supports an organisation in keeping track of, investigating, and recording risky occurrences 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.

These incidences should be taken positively and must motivate the staff to build and enhance the mechanism connected with identifying the systematic reasons of the error. Healthcare organisations should develop a culture that encourages reporting so that preventive 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 should take place. Future research should focus on techniques for changing behaviour and reflecting on past errors. This adjustment ought to be made considering 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.

6.1.Recommendations to encourage incident reporting-

- Training of staff on the type of incidents to be reported and significance of incident reporting.
- Training of staff on how to use the online incident reporting system.
- The reported incidents should be analysed on regular bases and corrective and preventive actions should be taken followed by monitoring to ensure change has been accomplished.
- Challenges in implementation of CAPA should be address as soon as possible.
- Training of staff on responsibilities w.r.t formulation of CAPA and its proper implementation.
- Adoption of new features in the online portal to make the incident reporting easy and comprehensive.
- Instead of punishing people responsible for the errors, the organisation should inculcate a culture to learn and improve from the adverse events that have occurred.

6.2.Recommendations to reduce errors.

6.2.1. Medication errors-

- Nursing staff should be trained 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)
- Process of documentation of medication should be improved with training of junior residents and nursing staff on proper transcription of medication.
- Frequent audit by clinical pharmacologist should be conducted.
- work done by junior staff or new joiners should be supervised by senior staff.
- patient safety audits should be conducted by the Quality department.
- Enforcement of double- and triple-checking
- Work to manpower balance should be maintained by the organisation to prevent overload on staff which may result in fatigue induced errors.
- Training of staff on their responsibilities to prevent ignorance induced errors.
- Communication between pharmacy, nursing and doctor should be clear in case of nonavailability 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.

6.2.2. Falls-

- Make use of side railing of the beds.
- Set bed alerts for close monitoring of patients at high-risk.
- Identify high-risk patients such as patient with neurologic symptoms and provide them with additional vigilance.
- Educate patient and family on fall prevention.
- Counselling of patients on neurological medication
- Making patient familiar with the surroundings of his hospital room/bed.
- Illumination of dark areas across the organisation.
- Prevent spills and dampness across the hospital.

6.2.3. Pressure ulcer-

- Providing soft cushioning beds to decrease pressure.
- Training of staff on management of recumbent patients such as turning and reposition patients every two hours.
- Provision of good nutrition supply to patients with pressure ulcers.
- Provision of proper skin care and training on management of pressure ulcers.

6.2.4. Device associated injuries-

- The patient's age and the type of intervention needed should be considered while selecting device to be used such as 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)
- Educating on proper device use and skin breakdown management

6.2.5. Equipment failure-

- Ensure timely maintenance of reusable devices and equipment's.
- Ensuring that the technology utilised adheres to the highest quality and safety standards.

6.2.6. Patient identification errors-

- Training on patient identification
- Proper usage of ID bands in all IPD areas until the patient is hospitalized.
- The patient must be confirmed using the patient's ID with at least two identifiers, such as the patient's complete name and ID number before administration or before any kind of investigative procedure.
- The staff on duty should see to it that the patient's ID band is replaced right away if it has been damaged, rubbed off, or removed for any other reason.

6.3.Recommendation to improve the incident reporting system.

- Focus on more frequent training regarding understanding of the types of events/ incidents to be reported & its link with Quality & Patient Safety.
- To modify the process of incident reporting such that incident notification are received by Authorized personnel only.
- Add a feature of anonymity wherever possible in the online reporting system.
- Allotment of responsibility to report incidences to a specific person in the department.
- Communicating & training the hospital staff on One Timeline for All for Incident Reporting.
- Enforcement of the defined timeline for reporting/ Submission of the Incident
- Incorporation of new technological features in the Incident Reporting Process to make it hassle free.
- Training on how to use online incident reporting portal.
- Ensure proper design of the online incident reporting portal for provisions for saving and retrieval of old data.
- To modify Incident Reporting Format, in such a way so as to incorporate a standardized comprehensive Incident documentation structure.
- Training on how to write the incidences in a legible and understandable format.
- Automation of Incident Reporting Process & including the provision of Auto Capture of Incidents & updates in the same
- Modifications in the Incident reporting Mechanism by including the provision of Prompts on the visibility of Pending status of the Incident to the authorized personnels.
- Training of Quality department staff on appropriate investigative measures to be taken and the importance of investigation of an incident.
- Training of staff on the importance of CAPA and provision of guidance on formulation of CAPA if needed, by the QA department.
- Formulation of standards for CAPA acceptance, verification of CAPA by Quality department.
- Training of staff on Importance of CAPA and its implementation
- Monitoring of new Corrective and preventive actions implemented.

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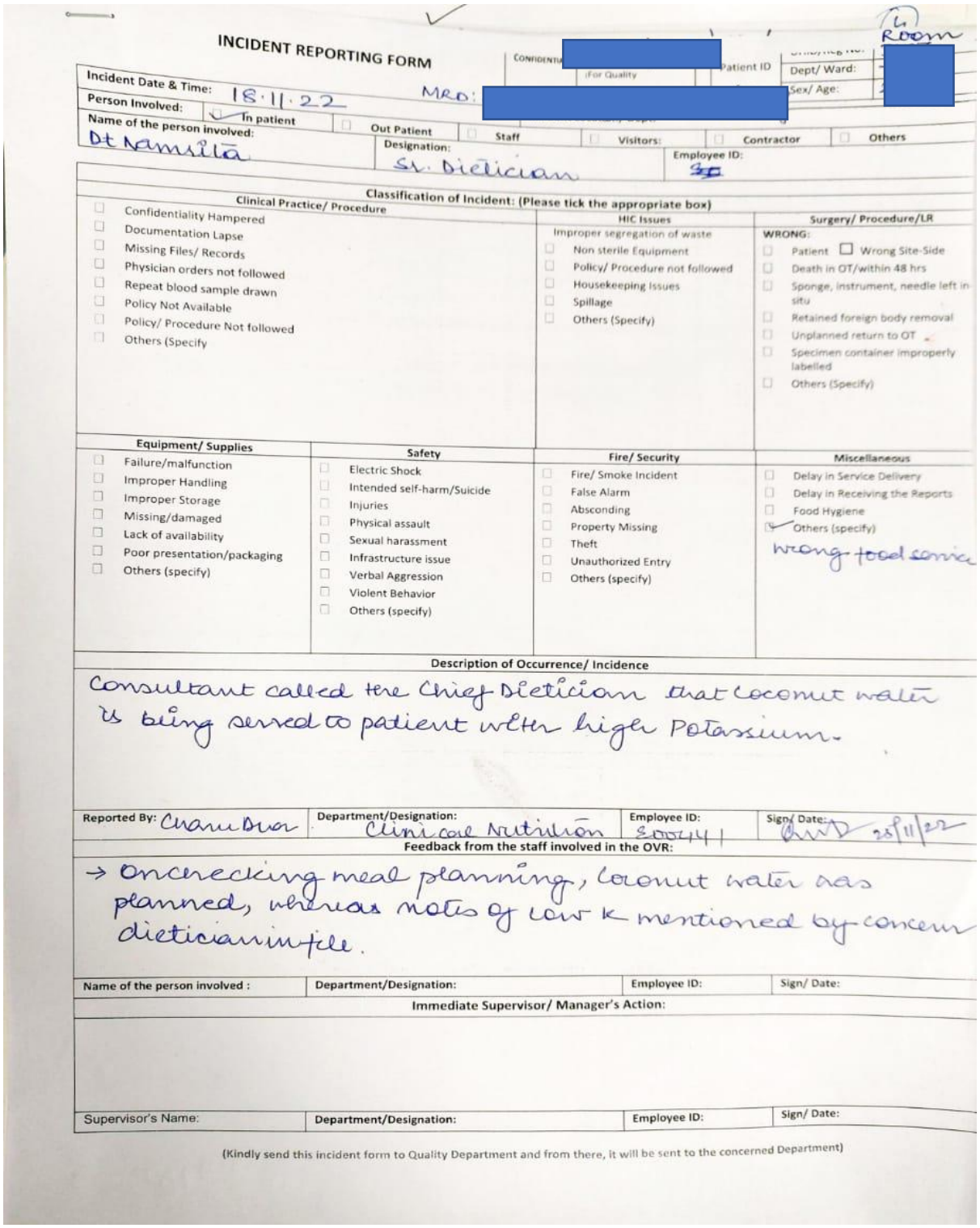
ANNEXURE I



INCIDENT REPORTING FORM

Incident Date & Time: 18.11.22 MRD: [redacted] Patient ID Dept/ Ward: [redacted] Sex/ Age:

Person Involved: ☑ In patient ☐ Out Patient ☐ Staff ☐ Visitors: ☐ Contractor ☐ Others

Name of the person involved: Dt Namsila Designation: Sr. Dietician Employee ID: 350

Classification of Incident: (Please tick the appropriate box)

Clinical Practice/ Procedure
- ☐ Confidentiality Hampered
- ☐ Documentation Lapse
- ☐ Missing Files/ Records
- ☐ Physician orders not followed
- ☐ Repeat blood sample drawn
- ☐ Policy Not Available
- ☐ Policy/ Procedure Not followed
- ☐ Others (Specify

HIC Issues
Improper segregation of waste
- ☐ Non sterile Equipment
- ☐ Policy/ Procedure not followed
- ☐ Housekeeping Issues
- ☐ Spillage
- ☐ Others (Specify)

Surgery/ Procedure/LR
WRONG:
- ☐ Patient ☐ Wrong Site-Side
- ☐ Death in OT/within 48 hrs
- ☐ Sponge, instrument, needle left in situ
- ☐ Retained foreign body removal
- ☐ Unplanned return to OT
- ☐ Specimen container improperly labelled
- ☐ Others (Specify)

Equipment/ Supplies
- ☐ Failure/malfunction
- ☐ Improper Handling
- ☐ Improper Storage
- ☐ Missing/damaged
- ☐ Lack of availability
- ☐ Poor presentation/packaging
- ☐ Others (specify)

Safety
- ☐ Electric Shock
- ☐ Intended self-harm/Suicide
- ☐ Injuries
- ☐ Physical assault
- ☐ Sexual harassment
- ☐ Infrastructure issue
- ☐ Verbal Aggression
- ☐ Violent Behavior
- ☐ Others (specify)

Fire/ Security
- ☐ Fire/ Smoke Incident
- ☐ False Alarm
- ☐ Absconding
- ☐ Property Missing
- ☐ Theft
- ☐ Unauthorized Entry
- ☐ Others (specify)

Miscellaneous
- ☐ Delay in Service Delivery
- ☐ Delay in Receiving the Reports
- ☐ Food Hygiene
- ☑ Others (specify)

wrong food servic

Description of Occurrence/ Incidence

Consultant called the Chief Dietician that Coconut water is being served to patient with high Potassium.

Reported By: Chanu Devi	Department/Designation: Clinical Nutrition	Employee ID: 5005414	Sign/ Date: 25/11/22

Feedback from the staff involved in the OVR:

→ On checking meal planning, coconut water was planned, whereas notes of Low K mentioned by concern dietician in file.

Name of the person involved :	Department/Designation:	Employee ID:	Sign/ Date:

Immediate Supervisor/ Manager's Action:

Supervisor's Name:	Department/Designation:	Employee ID:	Sign/ Date:

(Kindly send this incident form to Quality Department and from there, it will be sent to the concerned Department)

ANNEXURE II

Amrita Hospital and Research Center

Patient Name: [redacted]
UHID No:
Age:
Gender:
Consultant Name: Dr PANCHOLY KARTIK NITIN

MEDICATION ERROR REPORTING FORM

Date when event occurred: 14/11/22 | Time of event: 11:40pm | Location: ER
Diagnosis: B- CELL ALL
Report Date and Time: 15/11/22, 11:30am
Details of Medication involved in the event: INJ AMIKACIN

S. No	Name of the medication (Brand & Generic)	Strength	Dosage Form	Route of Administration	Frequency
1.	AMIKACIN	1gm	(IV) 1gm	IV	STAT

Where did the initial error occur: INSTEAD of 1000mg → it was documented 100mg INJ AMIKACIN

Type of error (may select more than one):

☐ Prescribing	☐ Wrong patient ☐ Wrong drug ☐ Wrong route ☐ Wrong dose ☐ Wrong strength/concentration ☐ Dose not adjusted ☐ Wrong formulation ☐ Allergic Drug prescribed ☐ Wrong dosing schedule ☐ Others.....
☐ Transcription	☐ Wrong patient ☐ Wrong drug ☐ Wrong route ☐ Wrong dose ☐ Wrong strength/concentration ☐ Wrong Schedule ☐ Wrong formulation ☐ Verbal Order ☐ Others.....
☐ Dispensing	☐ Wrong patient ☐ Wrong drug ☐ Wrong preparation ☐ Wrong dose ☐ Wrong strength/concentration ☐ Wrong formulation ☐ Expired drugs ☐ Damaged/Deteriorated drugs ☐ Delay in dispensing ☐ Counselling ☐ Others.....
☐ Administration	☐ Wrong patient ☐ Wrong drug ☐ Wrong route ☐ Wrong dose ☐ Wrong strength/concentration ☐ Dose not adjusted ☐ Wrong formulation ☐ Wrong frequency ☐ Wrong calculation ☐ Mislabelling ☐ Administered when ceased/withheld ☐ Wrong Technique ☐ Omitted drug/dose ☐ Others.....
☐ Monitoring	☐ Monitoring not done ☐ Monitoring not documented ☐ Others.....
☐ Documentation	☐ No documentation ☐ Wrong documentation ☐ Others.....

Stage(s) involved (may select more than one):

☐ Physician ordering ☐ Dispensing & delivery ☐ Monitoring (drug level/allergy/interaction/clinical)
☐ Transcription and entering process ☐ Administration error ☐ Documentation error
☐ Others

Description of the Event (how the event occured and how it was detected):
[Include ID of Personnel involved in error]
Instead of INJ AMIKACIN 1gm → it was documented INJ AMIKACIN 100mg to be given. by Doctor Tony (me00131)

ANNEXURE III

3rd Floor

Patient Fall Reporting Form

Patient Name	[redacted]	UHID/Reg No	16581	Age	[redacted]	Sex	Unit: Gastro
Diagnosis	[redacted] with Ascitis	DOA	[redacted]	Department	[redacted]		
Date & Time of Fall: 22/10/22 at 3-00 am							

Fall from	☐ Patient cot ☐ Bystander cot ☐ Wheel chair ☐ Trolley ☐ Others: Room/attato walking
Location	☐ Bathroom/Toilet ☐ Corridor ☑ Patient room ☐ Others:
Neurological Status before fall	☑ Conscious ☐ Unconscious ☐ Oriented ☐ Disoriented ☑ Confused ☐ Coma
Latest Fall Assessment Score (in case available): Moderate Risk.	Patient/Attendant counselled on Fall prevention protocols ☑ Yes ☐ No
Vitals prior to fall (Time):	BP: 126/76 Temp: 98.6°F Pulse: 118/mt RR: 26/mt O2 Saturation: 98%

Factors Associated with Patient Fall

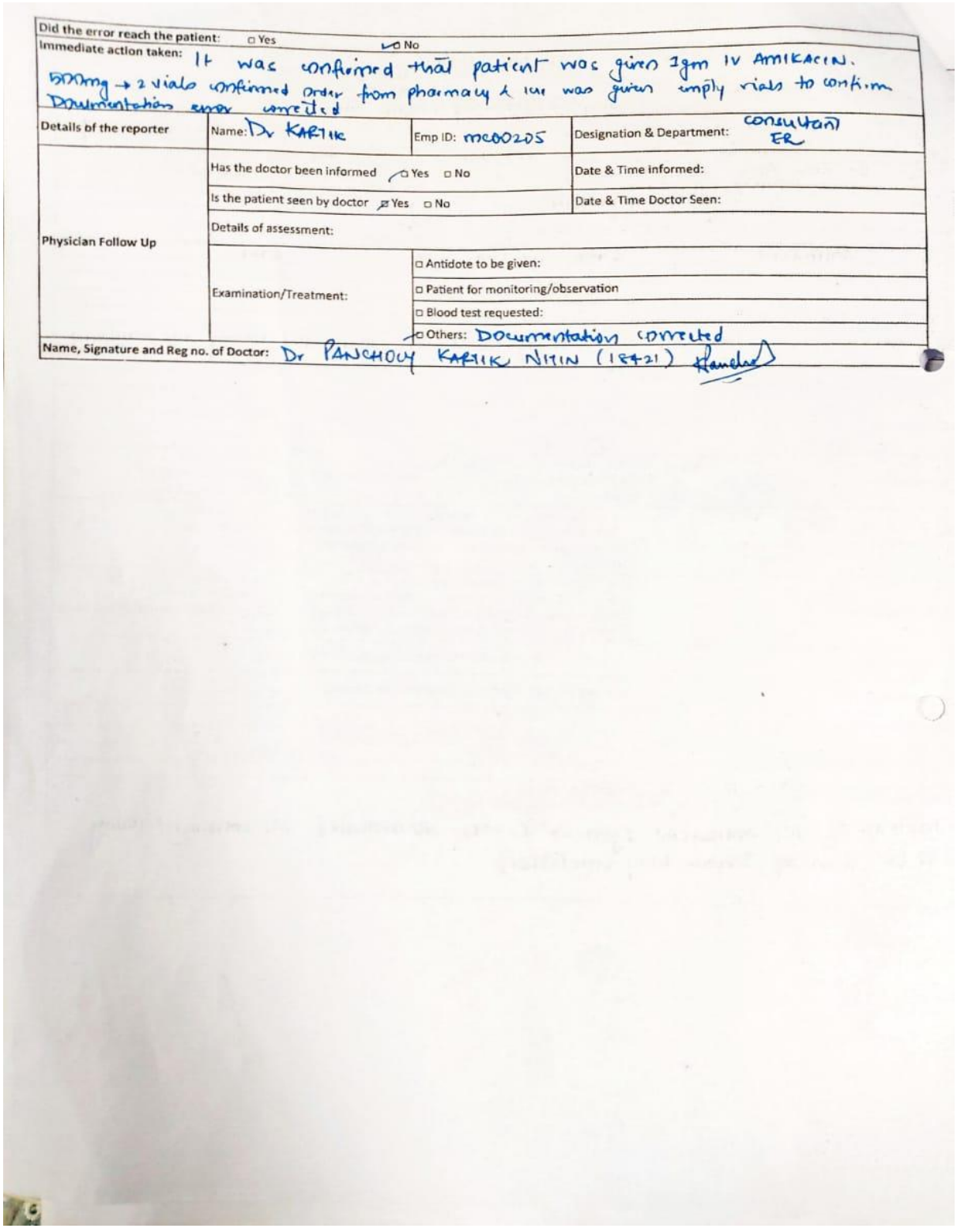
Patient - Specific	Environmental	Situational	Organizational
Age ☐ Geriatric (>60yrs) ☐ Paediatric (<12yrs)	☐ Poor lighting ☐ Call bell not working/not available/not within reach	☐ Safety belt was not used	
Patient condition ☐ Impaired vision ☐ Hypotension ☐ Hypertension ☐ Hyperglycaemia ☐ Hypoglycaemia ☐ Psychiatric disorder ☐ Epilepsy ☐ Vertigo ☐ Pregnancy ☐ Known history of fall ☐ Non ambulatory ☐ Gait disturbances	☐ Slippery floor ☐ Wet floor ☐ No footwear ☐ Side rails up ☐ Side rails down ☐ No assistive devices ☐ Cluttered pathway	☐ Leaning forward ☐ Reaching up ☐ Tripped ☐ Transferring on ☐ Transferring off ☐ Fell over side rails ☐ Lowering to floor	☐ Defective Furniture ☐ Defective Equipments ☐ Height of bed ☐ No Grab bars in toilet ☐ Others (specify)
Medication ☐ Sedatives ☐ Psychotropic ☐ Anticonvulsants ☐ Anticoagulant ☐ Antidepressants ☐ Anti-hypertensive ☐ Diuretics ☐ Laxatives ☐ Opioids ☐ Vasodilators ☐ Benzodiazepines ☐ Anti-diabetics ☑ Others (specify) Alcohol withdrawal	Medical devices ☐ IV Poles ☐ Urinary catheter ☐ ICD tubes ☐ Others (specify)	☐ No assistance ☐ Bed/wheelchair/ trolley not locked ☐ Restraints on at the time of fall ☐ Bed in high Position ☐ Ambulato-ry/standing still ☐ Bathing/Toileting ☐ Others (specify)	

Witnessed ☐ Yes ☑ No	Witnessed By: ☐ Nurse ☐ Attendant ☐ Others Name & Signature: Name & Relationship: Name:

Assessment Details Of Patient After Fall

Neurological status after fall	☑ Conscious ☐ Unconscious ☐ Oriented ☐ Disoriented ☑ Confused ☐ Coma
Post Fall Vital Signs	Temp: 98.6°F Pulse: 120/mt RR: 26/mt BP: 120/70 mm Hg SPO2: 98% Blood Sugar:

ANNEXURE IV



Did the error reach the patient: ☐ Yes ☑ No			
Immediate action taken: It was confirmed that patient was given 1gm IV AMIKACIN. Dosing → 2 vials confirmed Order from pharmacy & vial was given empty vials to confirm Documentation error corrected			
Details of the reporter	Name: Dr KARTIK	Emp ID: MC00205	Designation & Department: Consultant ER
Physician Follow Up	Has the doctor been informed ☑ Yes ☐ No		Date & Time informed:
	Is the patient seen by doctor ☑ Yes ☐ No		Date & Time Doctor Seen:
	Details of assessment:		
	Examination/Treatment:	☐ Antidote to be given:	
		☐ Patient for monitoring/observation	
		☐ Blood test requested:	
		☑ Others: Documentation corrected	
Name, Signature and Reg no. of Doctor: Dr PANCHOLY KARTIK NITIN (18421) Handed			

ANNEXURE V

FMEA - Incident Reporting System Amrita Hospital Faridabad

Steps in Process	Failure Mode	Failure Cause	Effect	Occurrence	Detection	Severity	RPN	Actions to Reduce Occurrence of Failure
Staff recognises an incident	Event not recognised as Incident	Lack of understanding on the types of events to be identified	Risk of recurrence of same incident persists due to non-reporting; High risk incidents pose higher adverse outcomes as they were missed reporting earlier; Loss of opportunity for improvement.	3	5	5	75	frequent training on understanding of events and importance of incident reporting
Incident Identified & directly reported to Quality department &/or Incident identified by the staff & informed to the respective HOD/Supervisor	Event recognised as incident but not deemed important for reporting.	Lack of sensitisation & awareness on importance of immediate reporting of incidents and their relation with the safe environment.	Timely reporting of incident does not take place. An incident left unreported to the management. Risk of recurrence of same incident persists due to non-reporting; High risk incidents pose higher adverse outcomes as they were missed reporting earlier; Loss of opportunity for improvement	5	5	5	125	Focus on more frequent training regarding understanding on the types of events/ incidents to be reported & its link with Quality & Patient Safety. To modify the process of incident reporting such that incident notification are received by Authorized personnel only. Add a feature of anonimity whereever possible in the online reporting system.
		A relaxed outlook towards Safety & Quality in the facility.		6	4	5	120	
		Staff occupied with regular job related tasks.		6	5	6	180	
		Fear of reporting due to fear of punitive actions.		4	6	6	144	
		Apprehensions of the staff (step 1) in reporting the event, due to lack of the provision of Anonimity of the requestor in the current Incident Reporting system.		5	8	7	280	
		Memory Lapse of the person who identified the incident leading to non reporting.		4	8	4	128	
		Confirmation Bias: staff may ignore the incident beleiving that his/ her other colleague may report it.		6	7	5	210	
	Event recognised as an incident but not reported yet informed to respective supervisor	Apprehensions of the staff (step 1) in reporting the event, due to lack of the provision of Anonimity of the requestor in the current Incident Reporting system.	Delay in Incident recognition by Quality Department Risk of recurrence of same incident persists.	3	6	7	126	Allotment of responsibility to report incidences to a specific person in the department
Incident reported through the online incidence reporting form.	Incident not entered on the online portal.	Person too busy to make extra time to report the incidence.	Risk of recurrence of same incident persists	4	8	6	192	hospital staff on "One Timeline for All" for Incident Reporting. Enforcement of the defined timeline for reporting/ Submission of the Incident Incorporation of new technological features in the Incident Reporting Process to make it hassle free. Training on how to use online incident reporting portal
		Person not aware on how to use the online portal for incident reporting.	Delay in Incident recognition to Quality department	5	5	6	150	
		Memory Lapse		2	6	4	48	
		Staff perceives that filling & submission of online incident from is difficult and a tedious task.	Delay in Incident recognition to QA	6	7	5	210	
	Incident entered but not registered or saved on the online portal.	Due to lack of awareness/ sensitization to use the online portal.	Delay in Incident recognition to Quality department Risk of recurrence of same incident persists Delay in Corrective & Preventive Action	5	7	5	175	Ensure proper design of the online incident reporting portal for provisions for saving and retrival of old data.
		Technical glitch in the online portal for incident reporting.						
Categorization of incident based on Severity (Risk).	Incorrect Risk Categorization of Incident	Lack of understanding of Risk Identification criteria by the formulator of the online portal.	Delay in initiating the investigation Risk of recurrence of same incident persist	1	9	8	72	To modify Incident Reporting Format, in such a way so as to incorporate a standardised comprehensive Incident documentation structure. Training on how to write the incidences in a legible and understandable format. Automation of Incident Reporting Process & including the provision of Auto Capture of Incidents & updates in the same
		online form not comprehensively designed enough to incorporate incident specific details.		3	4	7	84	
	Incident categorization cannot be ascertained by the Quality department personnel.	Improper Language / grammar used to narrate the incidence in the online form difficult to comprehend.		9	1	9	81	
Quality Assurance conducts initial investigation & suggests recommendation for improvement.	Delay in initiating the Investigation	Memory Lapse	Delay in identifying the corrective & preventive action for the incident based on the investigations.	3	5	4	60	Modifications in the Incident reporting Mechanism by including the provision of "Prompts" on the visibility of Pending status of the Incident to the authorized personnels. Training of Quality department staff on appropriate investigative measures to be taken and the importance of investigationg an incident.
		No system based reminders in place to identify the pending actions.		6	7	7	294	
		Quality personnel assigned to another task.	Delay in report finalization	3	5	3	45	
		Unavailability of Quality Personnel & no handover to the colleague	Delay in report finalization	5	2	3	30	
		Unavailability of the Involved staff at the time of investigation	Investigated findings and recommendations not documented on time. Delay in identifying the corrective & preventive action for the incident based on the investigations.	5	3	4	60	

CAPA(Corrective and Preventive action) designed and put into action by respective department	CAPA(Corrective and Preventive action) not designed	Staff occupied with regular task and responsibilities.	Further delay for Actions to be implemented Risk of recurrence of same incident persist	7	4	6	168	To modify the incident reporting system to include a standardised comprehensive Incident documentation structure. Training of staff on the importance of CAPA and provission of guidence on formulation of CAPA if needed by the QA department.
		Memory Lapse		5	4	4	80	
		Staff not aware about the corrective actions to be taken.		6	4	6	144	
	CAPA(Corrective and Preventive actions) designed but not implemented	Improper design of CAPA	Further delay for Actions to be implemented Risk of recurrence of same incident persist	7	3	7	147	Formulation of standards for CAPA acceptance, varification of CAPA by Quality department. Training of staff on Importance of CAPA and its implementation
		CAPA not taken seriously by the staff and considered non Imperative for implementation.		7	4	6	168	
Monitoring	Preventive action not implemented as per the decided time line	Knowledge deficit on how to implement recommended actions	Ineffective Implementation of Action Plan Risk of recurrence of same incident persists	2	4	4	32	Training of staff on new Corrective and preventive actions.
		Memory Lapse.	Delay in implementation of recommended actions. Delay in mitigation of risk leading to chances of error occuring again.	3	5	4	60	
		A relaxed outlook towards implementation of action Plan	Delay in implementation of recommended actions.	3	5	5	75	
		delay in dissemination of information on preventive measures taken	Delay in implementation of recommended actions. Delay in mitigation Risk of recurrence of same incident persists	4	6	5	120	