

**ANALYSING MEDICATION ERRORS AND RELATED ADVERSE EVENTS IN AN
ONCOLOGY TERTIARY CARE 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

NILANJANA MANNA

Under the Supervision and Guidance of

Dr. PIYUSHA MAJUMDAR

Assistant Professor, IIHMR University

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DECLARATION BY STUDENT

I hereby declare that this dissertation “ANALYSING MEDICATION ERRORS AND RELATED ADVERSE EVENTS IN AN ONCOLOGY TERTIARY CARE HOSPITAL”

is the Bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

Nilanjana Manna.

01/07/2022

Certificate from Faculty Guide and School Dean

Abstract

Medications are a critical component of the care provided to patients and are used for diagnostic, symptomatic, preventive, curative, and palliative treatment and management of diseases and conditions. A medication system that supports optimal medication management must include processes that support safe and effective medication use. Safe, effective medication use involves a multidisciplinary, coordinated effort of health care practitioners applying the principles of process design, implementation, and improvement to all aspects of the medication management process, which includes the selecting, procuring, storing, ordering/prescribing, transcribing, distributing, preparing, dispensing, administering, documenting, and monitoring of medication therapies.

ACKNOWLEDGEMENT

First of all I would like to thank, our respected mentor Piyusha Majumdar Ma'am and our college placement cell to their support to fulfil all the needs to complete the project.

I thank to Assistant General Manager Ms. Soumita Ghose

of the Tata Medical Center,Kolkata & Medical Administrator Dr.Assem Mahajan for letting me do my training in my desired field that is Medication Management of Hospital and Project report on Assessing the Medication Error of the Oncology Care Hospital which includes in Quality Department.

I would like to thank all of them from the bottom of my heart for giving me the opportunity to perform my project work in Tata Medical Center,Kolkata. Apart from these, I want to thank each and every one of Medical Admin persons and Quality Department of TMC as they had guided and helped me so politely and solved each and every problem of mine.

Nilanjana Manna.

MBA.HM.

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Acronyms/ Abbreviations:-

- NABH – National Accreditation Board for Hospital & Healthcare
- NABL- National Accreditation Board of Laboratory
- CAP -College of American Pathologists
- DNB – Diploma in National Board of Education
- ITU – Intensive Therapy Unit
- CCU - Critical Care Unit
- CEO – Chief Executive Officer
- SOP – Standard Operating Procedure
- CAUTI – Catheter Associated Urinary Tract Infection
- CLABSI – Central Line Associated Blood Stream Infection
- VAP – Ventilator Associated Pneumonia
- HAPU – Hospital Acquired Pressure Ulcers
- SSI – Surgical Site Infection
- NSI – Neural Sensory Inducer
- ICU – Intensive Care Unit
- QRF – Quality Reference Number
- CPR – Cardio Pulmonary Resuscitation
- OT – Operation Theatre
- TAT – Turn Around Time
- OPD – Out Patient Department
- CKD – Chronic Kidney Disease
- UGI – Upper Gastro Intestine
- LGI – Lower Gastro Intestine
- EVL –Endoscopic Variceal Ligation
- APC – Argon Plasma Coagulation
- ERCP – Endoscopic Retrograde Cholangio Pancreatography
- MOR – Monthly Operational Review
- WOR – Weekly Operational Review
- BRM – Biological Response Modifier
- LAMA – Leave Against Medical Advice
- CSSD – Central Sterile Supply Department

- DAMA – Discharge Against Medical Advice
- DORB – Discharge on Patient Request
- TPA – Third Party Association
- MRD – Medical Record Department

Chapter: 1

INTRODUCTION

Hospital-According to WHO “A hospital is an integral part of a social and medical organization, the function of which is to provide for the population, complete health care, both curative and preventive and whose outpatient services reach out to the family in its homely environment, the hospital is also a centre for the training of health workers and for bio-social research and “an institution that provides in patients accommodation for medical and nursing care.”

Role of Hospital-

- a) To take care of sick and injured
- b) To take preventive care and health promotion of community
- c) Continuing care of patients
- d) Rehabilitation
- e) Education and training of staff Research

Classification of Hospitals-

- 1) Central Government- Hospitals administered by Government of India viz. hospital run by railways, military/defense, mining, post & telegraph.
- 2) State Government- Hospital administered by state/ UT government & public sector undertaking operated by state/ UTs. Like Police, canal departments etc.
- 3) Local Bodies- Hospitals owned by local bodies like municipality.
- 4) Private- Hospitals owned by an individual or by a private organization.
- 5) Autonomous Body- Hospital established under a special Act of parliament/state legislation and funded by central /state government/ UTs. State. Like- AIIMS.

- 6) Voluntary Organization- Hospital administered by a voluntary body/ a trust/ charitable society registered by appropriate authority under central /state government laws. Ex-missionary bodies and co-operative hospitals.

Chapter :2

About the Organization

- Tata Medical Center was conceptualised in Year 2004 by Mr. Ratan Tata
- Tata Medical Centre Trust established in Year 2005
- Tata Medical Center commenced operations with 167 beds on 16th May 2011
- Set up at a cost of INR 340 crores
- Bed strength augmented to 427 in Year 2022

Hospital vision and mission

The Tata Medical Centre is envisioned to be a state-of-the-art total Cancer Care Centre which will promote Prevention, Diagnosis and Treatment, Rehabilitation and Palliation and Research.

It is being established to serve all sections of the society, with 50% of the beds earmarked for the underprivileged sections. The institution's mission is to excel in patient service, as well as education and research in the field of oncology.

Diagnosis and treatment will be characterized by a multidisciplinary approach with disease management teams, where in experts from different streams surgery, radiation oncology, medical oncology, pathology, radiology, and medical social work would participate in decision making for treatment protocols, using evidence-based medicine strategies and documented clinical guidelines appropriate to our location. The facilities will be complemented by state-of-the-art equipment from the best of manufactures worldwide and supported by advanced technologies like digital and molecular imaging, molecular pathology, and the latest, radiation treatment delivery system. The comprehensive, state of art tertiary care oncology centre in the eastern part of the country will have a big impact on patients who presently have to travel to other parts of the country for cancer care. The centre shall function with the ethos and values cherished by the Tata Group TMC has brought together a team of dedicated, committed and well trained professionals from all parts of the country and beyond

to make this dream come to fruition.

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Hospital Accreditation

Joint Commission International (JCI):-

In pursuance of its mandate to provide quality comprehensive Cancer Care, TMC is committed to an Accreditation Program which will facilitate building of a world class infrastructure and adoption of a quality work culture which in turn results in enhanced patients satisfaction and public confidence. The salient features of Accreditation program are as follows:

Infrastructure-

TMC has engaged Joint Commission International (JCI) as a consultant to review the infrastructure in terms of the proposed lay out and facilities. The proposed infrastructure has since been cleared by JCI consultants as conducive for quality care and patient safety matching international standards.

Equipment-

The process of procuring equipment is under way. Some of this equipment will be most advanced in the region. To ensure continuous availability and quality, a program of preventive maintenance and calibration will be adopted.

Human resources-

In its pursuit of excellence, TMC proposes to recruit and retain Medical and Nursing Personnel of exemplary quality with competence, commitment and compassion by providing a good and safe work environment and opportunities for professional improvement.

Documentation and Information Technology-

TMC is committed to portability of health care information and confidentiality. In pursuance of this objective, Information technology will be adopted in a significant manner by having an enterprise wide hospital information system with filmless operation. Telemedicine will be used extensively to arrive at the most appropriate management plan in the best interest of patient care.

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NABL in Laboratory Services

CAHO in CSSD Services

NABH is Blood Center

And Ongoing process in NABH hospital Accreditation.

List of all the medical services under the scope of the hospital

Therapeutic

Services are provided under three broad categories:

1. Outpatient services
2. In patient services
3. Day care services

Primary services

Services through in-house full-time consultants

- i. Anaesthesia and Critical Care
- ii. Operation Theatre
- iii. Intensive Care and High Dependency Unit (HDU)
- iv. Pain Management
- v. Clinical Hematology and Cellular Therapies
- vi. Clinical Pharmacology
- vii. Dental Service for Cancer patients treated at this hospital in general
- viii. Support for Head and Neck Department
- ix. Emergency Services
- x. For acute oncology patients (in collaboration with DMG)
- xi. For general medical/surgical emergencies
- xii. If a patient attends the hospital with a General Medical or surgical emergency, the patient will
be assessed the medical officer or the on-duty oncology fellow in the emergency department,
stabilized of the emergency condition and referred to an appropriate institution abiding by the
transfer policy.
- xiii. Disaster Management
- xiv. Please refer to the Disaster Management policy.

- xv. Gastroenterology and Digestive Diseases
- xvi. Infectious Diseases
- xvii. Intensive Care (Adult)
- xviii. Interventional Radiology
- xix. Medical Oncology
- xx. Pediatric Oncology & Pediatric Intensive Care
- xxi. Palliative Care
- xxii. Hospital based service
- xxiii. Preventive Oncology
- xxiv. Psychiatry and Psycho-Oncology
- xxv. Radiation Oncology
- xxvi. Surgical Oncology
- xxvii. Breast Surgery
- xxviii. Gastro Intestinal and Hepato-Pancreatic-Biliary Surgery
- xxix. Gynecological Surgery
- xxx. Head and Neck Surgery
- xxxi. Plastic and Reconstruction Surgery
- xxxii. Thoracic Surgery
- xxxiii. Urology
- xxxiv. Therapeutic Nuclear Medicine
- xxxv. Transfusion Medicine and Blood Bank

Services through Visiting Consultants (see section Services that are out of scope at present)

- i. Cardiology
- ii. Dermatology
- iii. Endocrinology
- iv. Internal Medicine
- v. Nephrology
- vi. Neurology
- vii. Neuro Surgery
- viii. Ophthalmology

- ix. Orthopedic Surgery
- x. Pediatric Cardiology
- xi. Pediatric Pulmonology
- xii. Pediatric Surgery
- xiii. Pulmonary Management

Diagnostic Services

- i. Diagnostic Cardiology
- ii. ECG
- iii. Echocardiography
- iv. Diagnostic Nuclear Medicine
- v. PET-CT Scan
- vi. SPECT-CT Scan
- vii. Diagnostic Pulmonology
- viii. Diffusing Capacity for Carbon Monoxide (DLCO)
- ix. Pulmonary Function Tests
- x. Diagnostic Radiology
- xi. Bone Mineral Densitometry
- xii. CT Scan
- xiii. Mammography
- xiv. MRI Scan
- xv. Ultrasonography
- xvi. X-Ray
- xvii. Laboratories
- xviii. Biochemistry
- xix. Clinical Pathology
- xx. Cytogenetics
- xxi. Flow Cytometry
- xxii. Haemato-Pathology
- xxiii. Histopathology & Cytopathology

xxiv. Microbiology & Serology

xxv. Molecular Diagnostics

xxvi. Scopies

xxvii. Bronchoscopy

xxviii. Colonoscopy

xxix. Colposcopy

xxx. Endoscopy

Para-clinical

i. Clinical Nutrition

ii. Nursing

iii. Onco-rehabilitation and Physiotherapy

iv. Pharmacy

v. Speech & Swallow Therapy and Audiometry

vi. Stoma Care

1. The above services are provided on both inpatient and outpatient basis as per the timings fixed by the Hospital.

2. Emergency Services defined under the scope are available round the clock for all 365 days a year to all patients irrespective of their place of residence, paying capacity, caste, creed, gender, etc.

3. For services that are not available in this hospital and cases requiring care in different institutional setup are referred, after stabilization, to institution where such services are available. Services that are out of scope at present. All the services mentioned under the heading 'services through visiting consultants' are not available 24 hours a day. These services are provided by visiting consultants at varying times as per pre-determined schedule. Some consultants may be available to attend ward patients out of their scheduled time at the hospital, subject to their availability.

These services are:

i. Cardiology

ii. Dermatology

iii. Endocrinology

iv. Internal Medicine

- v. Nephrology
- vi. Neurology
- vii. Neuro Surgery
- viii. Ophthalmology
- ix. Orthopedic Surgery
- x. Pediatric Cardiology
- xi. Pediatric Pulmonology
- xii. Pediatric Surgery
- xiii. Pulmonary Management
- xiv. Other services that are not provided at this hospital are:
- xv. Obstetrics
- xvi. Neonatology

Objectives:

The objectives of this study are:

- To study the medication management process of the Tata Medical Centre
- To study the medication error rate for the study period
- To identify the causes of medication errors
- To suggest various measures to prevent medication errors
- Assess patient-specific data and interpret these findings to identify medication therapy problems
- Establish goals of therapy for each medical condition and medication therapy problem identified
- Formulate recommendations for resolving medication therapy problems, providing rationale, justification, and evidence
- Create a plan for patient follow-up

Chapter: 3

Review of Literature

A literature review was conducted using electronic databases, federal agencies', provincial health departments', health service delivery organizations' and health research organizations' websites, the Internet, and some hand searching. Interventions identified were categorized according to the Effective Practice and Organization of Care Group (EPOC) classification, with effectiveness based on the literature.

Factors affecting prescribing relate to the patient and society, medication, prescriber, practice environment and organization, available information and other external factors. Interventions reported as generally effective are multi-faceted interventions, academic detailing, and reminders. Interventions reported as sometimes effective are audit and feedback or physician profiling, local opinion leaders, drug utilization review, and local consensus guidelines. Passive dissemination of educational materials is deemed generally ineffective.

No single approach is appropriate for every prescribing problem, health professional prescriber practice or health care setting. Interventions to improve prescribing in community and institutional settings have variable effect sizes. Effectiveness is related to content, delivery mechanisms, intensity, intervention's context, and implementation environment. Even an intervention with a small effect size (< 10%) may yield important changes in drug use when applied on a population basis. Further research and evaluation is needed to determine how or why the interventions work and identify barriers to effective implementation.

- Improving drug safety in hospitals: a retrospective study on the potential of adverse drug events coded in routine data; Research article 19: Published: 08 August 2019: BMC Health Services Research.
- Targeted medication safety best practices for hospitals based on ISMP National Medication errors reporting forms.
- Creating a Pediatric Joint Council to Promote Patient Safety and Quality, Governance, and Accountability Across Johns Hopkins Medicine: Published: March 28, 2017 0.1186/1472-6963-12-60

- Medication Error Prevention by Clinical Pharmacists in Two Children's Hospitals
Hugo L. Folli;Robert L. Poole;William E. Benitz;Janita C. Russo
- A literature review of the individual and systems factors that contribute to medication errors in nursing practice ANNE-MARIE BRADY BSN, MSc, PGDip, CHSE, RGN, RNT,ANNE-MARIE MALONE MBA, BNS, RNT, RCN, RGN, RM,SANDRA FLEMING MSc, Cert Ed (FE), RNID, RPN, RGN, RCT, RNT.First published: 11 August 2009
- NCBI Bookshelf. A service of the National Library of Medicine, National Institutes of Health.Hughes RG, editor. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville (MD): Agency for Healthcare Research and Quality (US); 2008 Apr.Chapter 37 Medication Administration Safety:Authors Ronda G. Hughes;¹ Mary A. Blegen.²
- Institute of Medicine. To err is human: building a safer health system. Washington, DC: National Academy Press; 1999. [PubMed: 25077248]
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- National Coordinating Council for Medication Error Reporting and Prevention. What is a medication error? [Accessed October 1, 2007]. www.nccmerp.org/aboutMedErrors.html.

Chapter: 3

Methodology:-

The practical project at Tata Medical Centre, Kolkata was aimed at learning the essence of the practical field of work in the Hospital industry and gaining practical experience.

Objective of the study is to

- To learn the functioning of the institution.
- To study the workflow pattern and other major departments and record the observations of medication management.
- To understand the role played by the various departments in the delivery of ultimate quality health care services.
- To learn the techniques of Problem Handling.
- To canvas the patient satisfaction, by conducting a survey and then provide proffers as required.
- To study the Patient turnover in the departments and draw suitable cause & effect relation with suitable suggestions.
- To study the level of Quality Control Department and areas which need improvement?
- To study the Hospital NABH audit programme.
- Suggest remedial measures for the problems, if any.

Study Setting: Tata Memorial Hospital

Research Design: Descriptive Observational

Training Period- 22nd March to 17th June ,2022

Study Tools-

- Primary data - Through questionnaire and observation.
- Secondary data – Hospital Websites.

Data Analysis

Chapter: 5

Result and Discussion

Key Learnings -Medication Error in Medication Management

A medication error is defined as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer," (FDA, National Coordinating Council for Medication Error Reporting and Prevention). Medication errors can occur throughout the medication-use system. Such as, when prescribing a drug, upon entering information into a computer system, when the drug is being prepared or dispensed, or when the drug is given to or taken by a patient.

Serious harmful results of a medication error may include:

- Death
- Life threatening situation
- Hospitalization
- Disability
- Birth defect

Medication Management is the standard of care that ensures each patient's medications are individually assessed to determine that each medication is appropriate for the patient, effective for the medical condition, safe given the comorbidities and other medications being taken, and able to be taken by the patient as intended.

At Tata Medical Centre, oversight on the Medication Management Process had been implemented since 2011. The primary focus of the medication management system at the centre is reduction of medication errors in each step of the process, starting from prescription writing till administration and post administration monitoring. For this purpose, a centralized adverse event reporting system, a dedicated adverse drug reaction reporting system and various prescription, indenting, storage, reconstitution and administration audits are implemented in the hospital. The hospital has experienced and analysed medication errors

and associated serious adverse events on a yearly basis. From the year 2019, the medication management processes were further streamlined with augmentation of prescription audit pharmacists, clinical pharmacologists, medication safety focused nurse as well as quality assurance professionals.

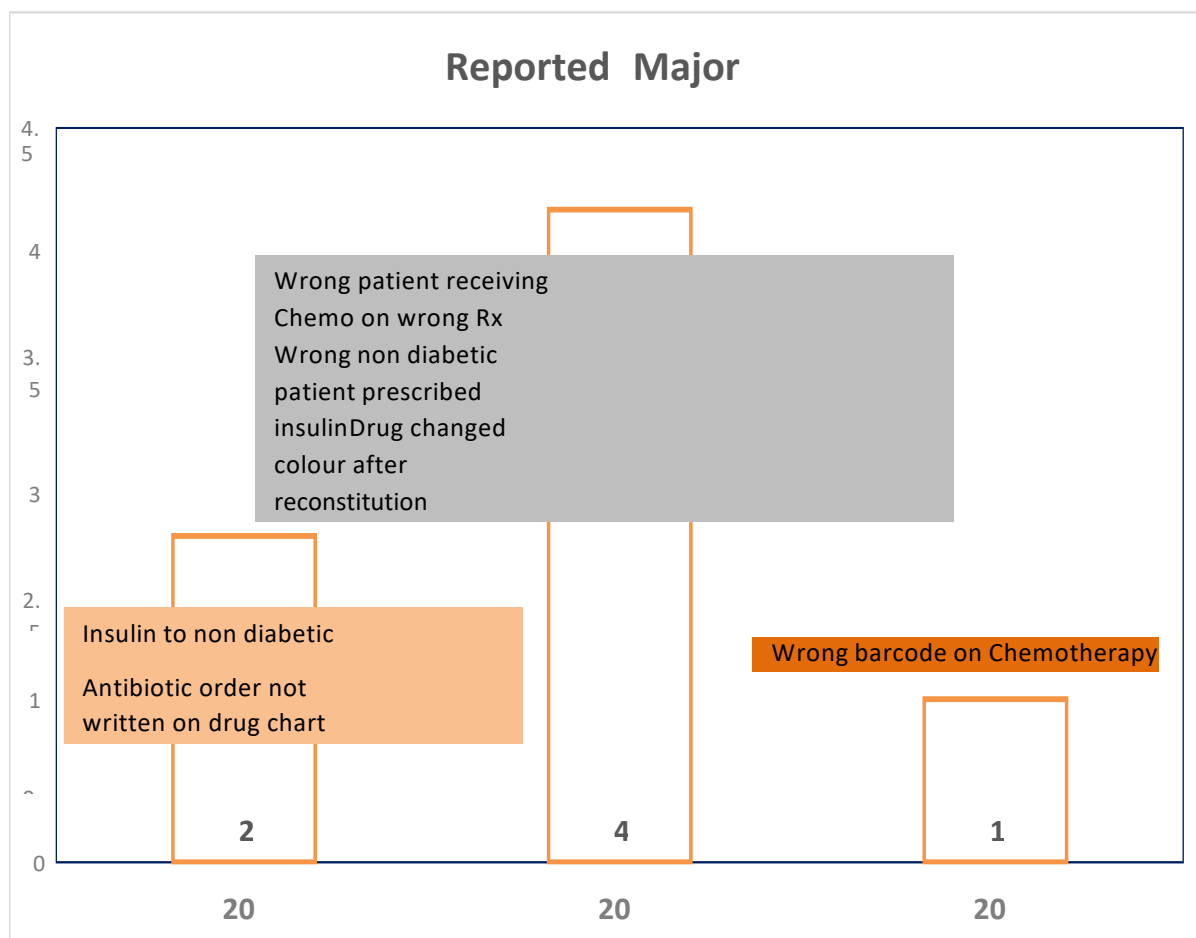
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A summary of various errors reported is depicted below:

In addition to the reported adverse incidents, including on Sentinel Event in 2020, the medication management system also collected data on Medication Errors through prescription audit, reported administration errors, adverse drug reaction reporting systems and internal audit system.

Data on the same is summarized below.



Chapter:7 Results & Discussions

Medication Error Rate

Prospective audit by Clinical Pharmacology and D Pharm teams

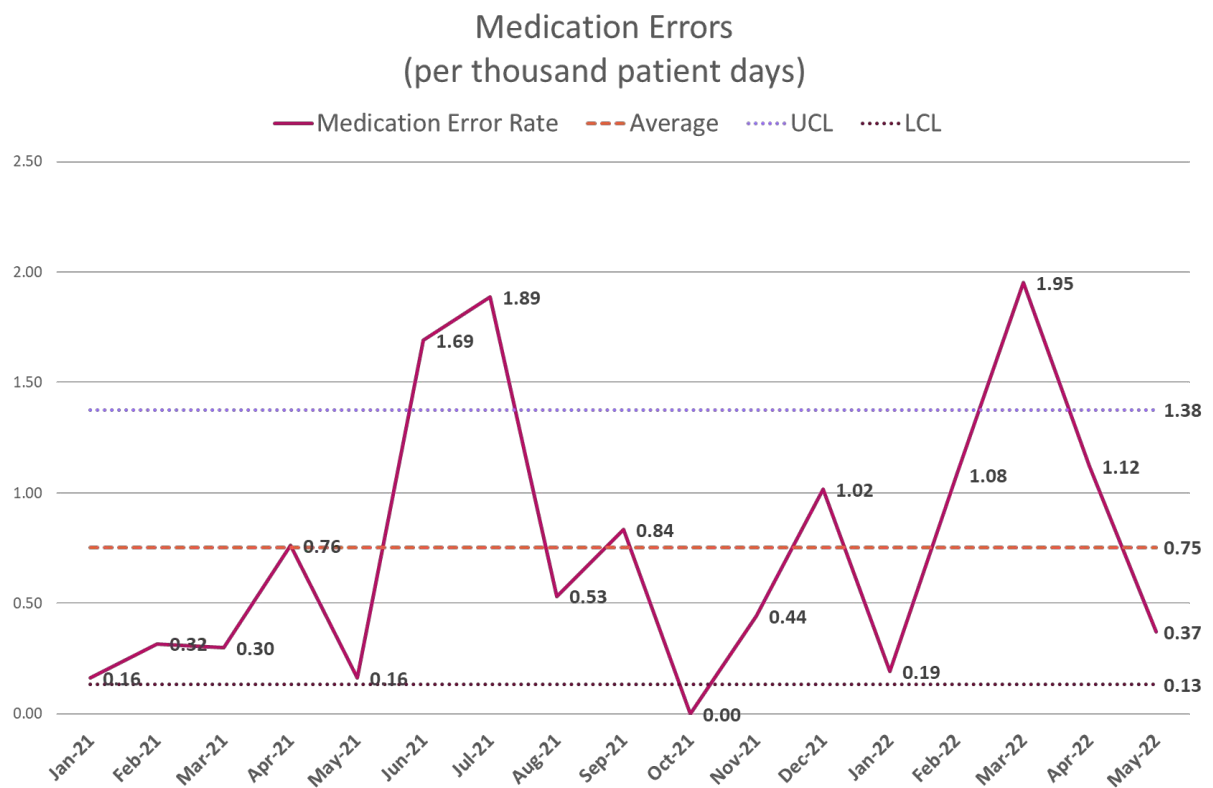
Reported administration and other errors through the adverse event registry

Auditors: Clinical Pharmacology

Standardized checklist , online

Data Verification: QA auditors' audit on smaller retrospective sample size, data correlated monthly, deviations discussed for root cause

Denominator: TMC uses patient days as the denominator



Most frequent Root Causes of Medication Errors

- i. Cut strip medications stored separated from the same lot with the same batch number.
 - a. (IPSG Audit report, May-July, 2021)
- ii. Look Alike drugs stored in same place with different strengths (IPSG Audit report, May-July, 2021)
- iii. Absence of labelling of the High Alert Drugs with High Alert stickers (IPSG Audit report, May-July, 2021)
- iv. Patient is not prescribed right drug (Adverse Incident dated 07-02-2020 & 14-07-2021)
- v. Patient is not prescribed the correct dose (Adverse Incident dated 20-03-2020)

Corrective Actions and Interventions

Corrective Actions:

- i. Prescription errors are corrected on the spot by the team of auditors from Medical Records and Pharmacology departments by discussing with the ordering clinicians.
- ii. Administration errors are immediately addressed with necessary clinical interventions and an adverse event report is completed for further analysis of root causes.

Preventive Actions:

- i. A Failure Mode Effects Analysis was conducted to assign risks to each step of the medication management process and determine its impact.
- ii. All reported medication errors are analysed by the Medication Management team consisting of Nurses, D Pharms, Clinical Pharmacologists and Quality Assurance.
- iii. Errors types are coded with a harm score and analysed for their impact as well as root causes.
- iv. This analysis is shared with stakeholders and discussed in Hospital Drug and Therapeutic Committee meetings.
- v. Periodic training, mandatory induction training, preceptorship training is organized on this topic.

The following processes in the Medication Management System were identified as High and Very High Risk based on the FMEA

- i. **Patient consent for high risk drugs:** The Apollo Pharmacy is implementing a consent form to be signed by all patients after being counseled on all high-risk drugs (side effects, dose and frequency and adverse effects if misused) before being dispensed for home use.
- ii. **Prescription Policy training for all doctors:** The focus of training imparted to doctors in 2021 has been on Medication Safety, prescription writing and patient counseling on medication safety.
- iii. **International Patient Safety Goal training emphasizing on Drug Safety:** Mandatory training for all staff were taken in 2020, 2021 on International Patient Safety Goals, with focus on Medication Safety. Data on TMC's adverse incidents

were presented with root causes during these training for developing staff awareness and understanding.

- iv. **Two nurses signing upon administration:** There is a control devised in the process of medicine administration where two nurses sign during administration of medicines. The role of the second nurse primarily is to check the drug, dose, route, reconstitution and frequency.
- v. **Storage of LASA and High-Risk drugs:** Regular drug storage rounds were implemented from early 2021 with emphasis on storage safety.
- vi. The hospital is in the process of implementing a policy where cut strips of high-risk drugs and antibiotics will not be dispensed by pharmacy
- vii. **Prescription audit sample size optimized with dedicated auditors and online audit methodology:** There are dedicated Pharmacology staff who conducts daily prescription and medication safety and usage audit in wards. This is done by using an online checklist and data is analyzed on a monthly basis.

Adverse Drug Reactions

- i. Centralized reporting system for ADR. All forms are routed to Clinical Pharmacologist and thereafter microbiology, pharmacy as applicable.
- ii. Auditors: Prospective reporting of data
- iii. Standardized format, paper form
- iv. Data Verification: QA auditors' tally total number of ADRs reported through the form and total reported as QI monthly, discrepancies discussed

Chapter: 8

Conclusion and Recommendations: -

1. Provision of sufficient undergraduate learning opportunities to make medical students safe prescribers.
2. Provision of opportunities for students to practise skills that help to reduce errors.
3. Education of students about common types of medication errors and how to avoid them.
4. Education of prescribers in taking accurate drug histories.
5. Assessment in medical schools of prescribing knowledge and skills and demonstration that newly qualified doctors are safe prescribers.
6. European harmonization of prescribing and safety recommendations and regulatory measures, with regular feedback about rational drug use.
7. Comprehensive assessment of elderly patients for declining function.

8. Exploration of low-dose regimens for elderly patients and preparation of special formulations as required.
9. Training for all health-care professionals in drug use, adverse effects, and medication errors in elderly people.
10. More involvement of pharmacists in clinical practice.
11. Introduction of integrated prescription forms and national implementation in individual countries.
12. Development of better monitoring systems for detecting medication errors, based on classification and analysis of spontaneous reports of previous reactions, and for investigating the possible role of medication errors when patients die.
13. Use of IT systems, when available, to provide methods of avoiding medication errors; standardization, proper evaluation, and certification of clinical information systems.
14. Non-judgmental communication with patients about their concerns and elicitation of symptoms that they perceive to be adverse drug reactions.
15. Avoidance of defensive reactions if patients mention symptoms resulting from medication errors.

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References:

Research study from google scholar, NABH Medication Management chapter and references, hospital policy etc.

- **Improving drug safety in hospitals: a retrospective study on the potential of adverse drug events coded in routine data;** Research article 19: [Published: 08 August 2019](#): BMC Health Services Research.
- Targeted medication safety best practices for hospitals based on ISMP National Medication errors reporting forms.

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