### **Medication safety**

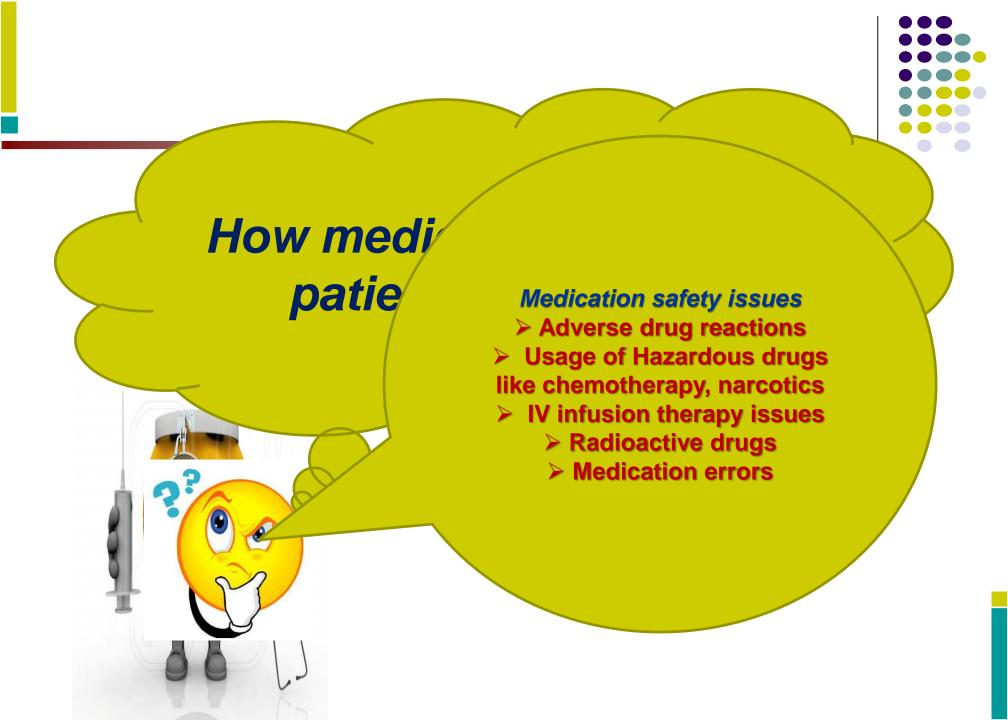
Dr. Subhrojyoti Bhowmick, MD (Pharmacology), FISQua (UK) ISQua certified Medication safety expert ISQua Lucian Leape Patient Safety Fellow 2019 Clinical Director, (Academics, Quality, Research Depts.) Peerless Hospital & BK Roy Research Centre, Kolkata NABH Assessor for Hospitals and EC accreditation Program





### "First do no harm."

Hippocratic Oath







### What is medication Safety?

Medication safety is defined as the freedom from accidental injury due to medical care or medical errors during the medication-use process, deserves the same prioritization, given the scope of medication use in patient care and the frequency and severity of potential harm.

#### WHO's Flagship Global Patient Safety Challenges









First Challenge -2005 Clean care is safer care

Second Challenge -2007 Safe Surgery Save Lives

Third Challenge -2017
Medication without Harm
(Medication safety)

### What is a Medication Error?



Any **PREVENTABLE** event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.

### **Medication Errors**



- Over 770,000 patients injured every year.
- USFDA At least 1 death occurs per day and 1.3 million people injured each year.
- > For India the extrapolated figures would be:
  - 400,000 deaths due to Adverse Drug Reaction and
  - 720,000 Adverse Events per annum
- More people die then Motor Vehicle Accidents or AIDS
- Serious mistakes involving prescription drugs occur in 3% to 7% of hospital inpatients.
- Considered worse than a crime
- > Serious economic consequences like extended hospital stays, additional treatment
- Malpractice Litigation.

# Advancing the responsible use of medicines

Applying levers for change







IMS INSTITUTE
HEALTHCARE INFORMATICS

OCTOBER 2012

## 4. RIGHT MEDICINE TO THE RIGHT PATIENT: PREVENT MEDICATION ERRORS

Medication errors contribute 9% of the world's total avoidable cost due to suboptimal medicine use.

A total of 0.7% of global total health expenditure (THE), or 42Bn USD worldwide, can be avoided if medication errors are prevented.



Global
Calculations which include

186 countries:

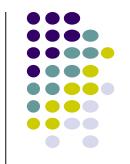
IMS MIDAS, 2009 and

**2011**; World Bank

2009; WHO 2009;

**USD** in 2011

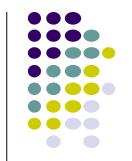
### **Medication Errors: Indian Experience**



M Parihar, G PR Passi. Medical Errors in pediatric practice. Ind Pediatrics 45 2008; 586-89.

- Prospective study in a Teaching Hospital at Indore, MP -1286 children in PICU
- Out of the total 457 errors identified, medication errors 313 (68.5%)
- Majority were dosing errors (45.5%)
- Morbidity was nil in 375 (82%), mild in 49 (10.7%),
   moderate in 22 (4.8%) and severe in 11 (2.4%) errors.

### **Medication Errors: Indian Experience**



Patel, Nrupal et al. "A Study of Medication Errors in a Tertiary Care Hospital." Perspectives in Clinical Research 7.4 (2016): 168–173.

.

- Prospective study in a Teaching Hospital in Ahmedabad Gujarat
- A total of 1109 patients (511 in Medicine and 598 in Pediatric ward)
- Total number of MEs was 403 (36%) of which, 195 (38%) were in Medicine and 208 (35%) were in Pediatric wards.
- The most common ME was Prescribing errors: 262 (65%) followed by administration errors 126 (31%).
- Majority of prescriptions were semirational 555 (53%) followed by irrational 317 (30%), while 170 (17%) prescriptions were rational.



### Our medication errors Research work

International Journal of Basic & Clinical Pharmacology Bhowmick S et al. Int J Basic Clin Pharmacol. 2020 Jun;9(6):937-942 http://www.ijbcp.com

pISSN 2319-2003 | eISSN 2279-0780

DOI: http://dx.doi.org/10.18203/2319-2003.ijbcp20202186

Original Research Article

#### Medication errors reported in a tertiary care private hospital in Eastern India: a three years experience

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#### ABSTRACT

Background: Medication errors (MEs) can cause significant harm to patients. The MEs identified through reporting processes currently report only a fraction of the actual number of MEs. Data about MEs is limited in India, especially from eastern and north-eastern parts of India. The objective of this study was to analyse the various types of Medication errors reported in a tertiary care private hospital in Eastern India. The aim was to determine the various factors associated with these errors and steps to be taken to reduce the MEs in this healthcare setup.

Methods: We carried out a prospective passive surveillance study over the course of 3 years (2016-2018) on 50,822 admitted patients after obtaining approval from the Institutional Ethics Committee. A detailed root-cause analysis was performed for every reported error by a team of healthcare quality professionals and clinical pharmacists along with a clinical pharmacologist followed by appropriate preventive and corrective actions.

Results: In our study, a total number of 88 medication errors were reported from a sample size of 50,822 (0.0017%).

61 of the reported MEs were administration errors (69.3%). Higher preponderance of medication errors was seen in male patients (53.1%) in comparison to female patients (46.9%).

Conclusions: In this study gross under-reporting of MEs were observed which is in line with previously published studies in India. The reasons reported for gross under-reporting can function as an effective tool to ensure improved reporting of MEs and implementation of mitigation strategies.

### Who are affected?

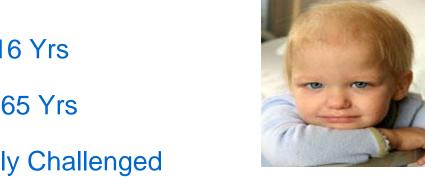


#### Medication errors are without doubt costly to

- Patients
- Patient Families
- Patient employers
- Hospitals
- Healthcare providers
  - Doctors
  - Nurses
  - Other Paramedic Staff
- Insurance companies etc

### Who are at greater risk?

- Child < 16 Yrs
- Aged > 65 Yrs
- Physically Challenged
- Patients receiving urgent, life-saving care
- Patients undergoing high-risk surgeries
- Patients on multiple medications
- Patients with multiple medication allergies
- Non-English speakers
- Anyone being discharged from the hospital







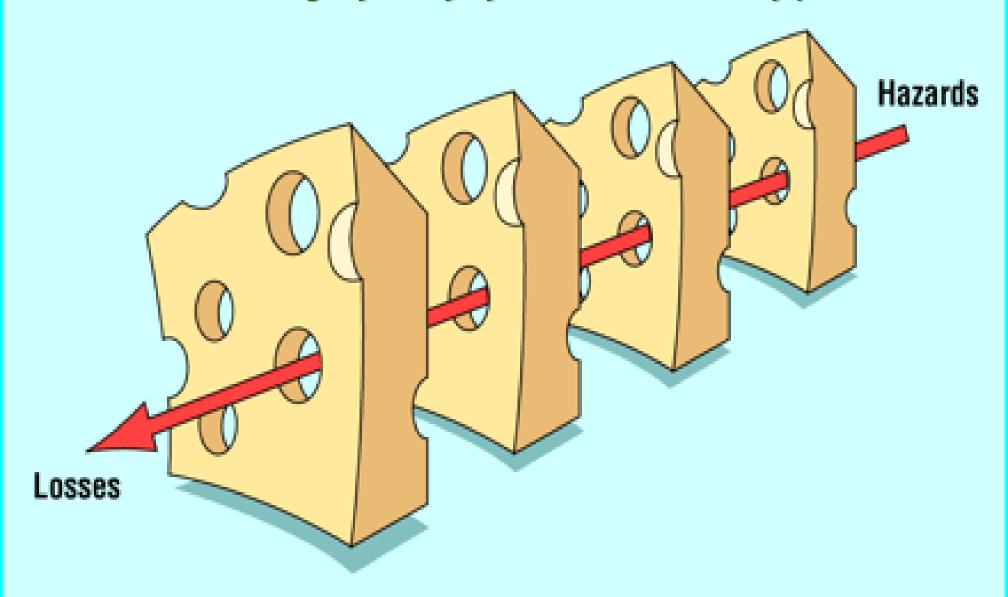
### Common causes of medication errors



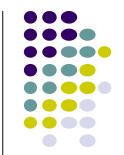
- A. Human factors
- B. Systems
- C. Abbreviations
- D. Oral orders
- E. Look-alike and sound-alike drugs
- F. Dosage calculation
- G. At-risk population
- H. At-risk drugs

Patel, Nrupal et al. "A Study of Medication Errors in a Tertiary Care Hospital." Perspectives in Clinical Research 7.4 (2016): 168–173.

### Medication Errors signify faulty systems and not faulty professionals



# Human factors that lead to medication errors



- Mental Slip
- Having the knowledge, but not using it
- Lack of knowledge
- Poor handwriting
- Lack of understanding
- Stress
- Improper label reading, etc.

- Fatigue/Lack of sleep
- Illness
- Drugs or alcohol
- Boredom
- Frustration
- Fear
- Conflicts

Patel, Nrupal et al. "A Study of Medication Errors in a Tertiary Care Hospital." Perspectives in Clinical Research 7.4 (2016): 168–173.

# Systems factors that lead to medication errors



- Distractions
- Noise
- Heat
- Clutter
- Motion
- Lighting
- Unnatural workflow
- Poorly designed procedures or devices

- Lack of time
- Too many customers
- Shift Changing
- Emergencies etc



### Look-alike or sound-alike (LA/SA) drugs



- Tens of thousands of drugs currently in the market, the potential for error due to confusing drug names is significant
- Look-alike or sound-alike (LA/SA) health products refer to names of different drugs that have orthographic similarities and/or similar phonetics (i.e. similar when written or spoken).
- These similarities may pose a risk to health by contributing to medical errors in prescribing, documenting, dispensing or administering a product
- The increasing potential for LASA medication is recognized by NABH and requires each accredited organization to identify a list of look-alike or sound alike drugs.

### Sound-alike drugs

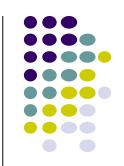


Avanza	Avandia
(Mirtazapine)	(Rosiglitazone)
Diamox	Zimox
(Acetazolamide)	(Amoxycillin)
Glynase	Zinase
(Glyburide)	(Serratiopeptidase)
Incidal	Inderal
(Cetrizine)	(Propanolol)

Brand name in black
Non proprietary name in blue

Thousands more, some reported, Most not!!

### Look-alike drugs



Domstal	Alprax
(Domperidone)	(Alprazolam)
Zyloric	Buscopan
(Allopurinol)	(Hyoscine)
Lasix	Avil
(Fursemide)	(Pheniramine)
Veltam	Pantium
(Tamsulosin)	(Pantoprazole)

Brand name in black
Non proprietary name in blue

Thousands more, some reported, Most not!!



Ampoules of Bupivacaine (Sensovac Heavy) and Tranexamic acid (Nexamin) look alike

### High risk Medications



## High Risk/High Alert Medication/ At Risk Drugs

Medications that bear heightened risk of causing patient harm when they are used in error.

- Neuromuscular Blockers
- Insulins
- Opiates
- Anticoagulants
- Chemotherapeutic agents
- Concentrated electrolytes Opiates
- IV Adrenergic Antagonist
- IV Digoxin
- Theophyliine
- Concentrated Electrolytes

#### **Spurious drugs**

Is a major concern with most of the small and medium-sized hospital.

To address this problem, the hospital pharmacy must have a system of regular periodic physical audit of the products that are most preferred brand and in the lowest priced brand

### **Medication Errors**



### **Abbreviations**

- Although widely used in prescription writing, abbreviations can kill!!
- Most of the time, prescribers invent their own.
- Secondly, different individuals/pharmacists may assume or interpret abbreviations differently.
- Please stick to standard abbreviations

### **Medication Errors**



Some examples that illustrate the pit falls are-

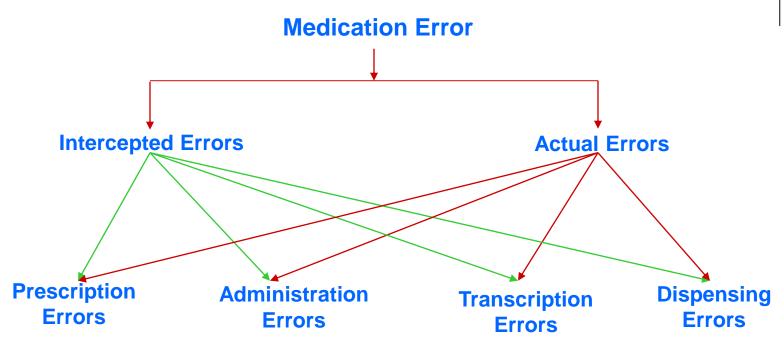
HCT 250mg intended drug hydrocortisone but dispensed hydrochlorthiazide.

CPZ – intended drug was chlorpromazine but mistaken for carbamazepine

AZT – intended drug was zidovidine but mistaken for azathioprine.

### **Types of Medication Error**



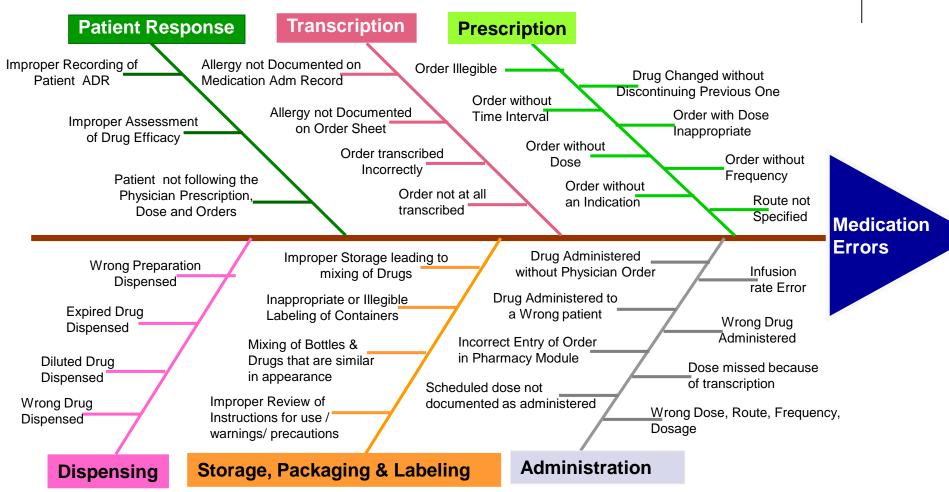


#### Note:

- 1. The "intercepted errors" are the error which has 'not reached the patient' are documented by preserving a copy of the indent
- 2. The "actual errors" or an "error of omission", are the errors which 'has reached the patient' inspite of auditing, are reported on a proper format called as quality variance report

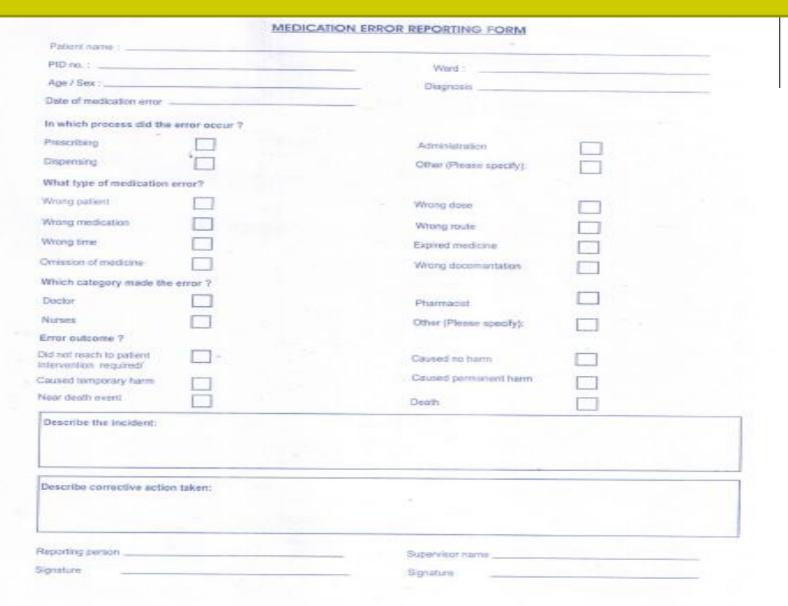
### RCA of Medication Error





Note: Errors are more frequent during "Prescription" and "Administration" stage

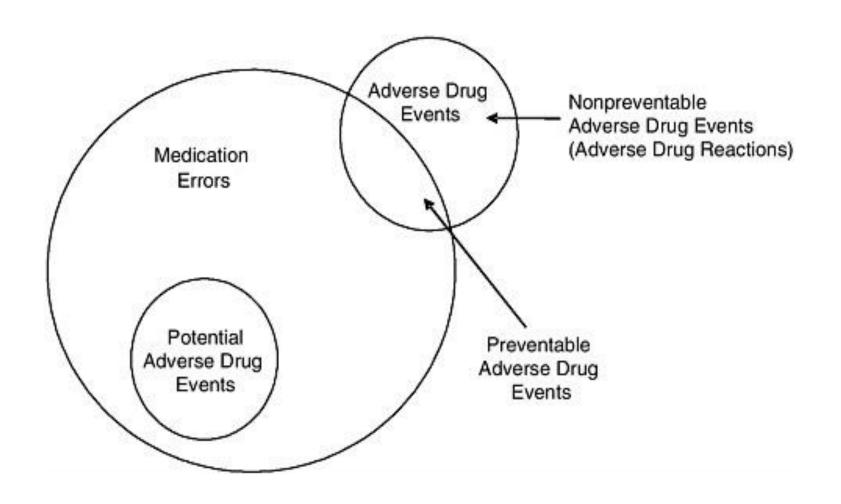
#### Medication error reporting format





# Relationship among medication errors, adverse drug events, and potential adverse drug events





# Need for Pharmacovigilance



- Safety data from pre clinical studies not reliable
- Insufficient safety data from clinical trials
  - narrow population studied
  - Specific indications only
  - Shorter duration
- To promote rational use of medicines

# Need for Pharmacovigilance



Clinical and economic burden of ADRs

#### **Economic burden**

- \$US 2262 per ADR /patient, 30.1 billion dollars annually
- Cost due to ADRs in EU is 79 billion euros/year
- In India, Rs 6197/patient

Sultana J, Cutroneo P, Trifirò G. Clinical and economic burden of adverse drug reactions. Journal of Pharmacology and Pharmacotherapeutics. 2013;4(5):73.

## Causality assessment



- Most case reports concern suspected adverse drug reactions
- In practice few adverse reactions are 'certain' or 'unlikely'

- WHO UMC Causality Assessment
- Naranjo scale

### WHO – UMC Causality Assessment Scale



- Developed in consultation with the National Centres
- Causality categories
  - Certain
  - Probable/likely
  - Possible
  - Unlikely
  - Conditional/ Unclassified
  - Unassessable/ Unclassifiable

Naranjo ADR
Causality Scale

Naranjo CA. Clin Pharmacol Ther 1981;30:239-45

10 000	ress the dure se at agreaterin, prease answer the join wing qui				~
		Yes	No	Do Not Know	Score
1.	Are there previous <i>conclusive</i> reports on	+1	0	0	
	this reaction?				
2.	Did the adverse event appear after the	+2	-1	0	
	suspected drug was administered?				
3.	Did the adverse reaction improve when the	+1	0	0	
<u> </u>	drug was discontinued or a specific		Ü		
	antagonist was administered?				
4.	Did the adverse reactions appear when the	+2	-1	0	
т.	drug was readministered?	1 2	-1	U	
5.	Are there alternative causes (other than the	-1	+2	0	
٥.	· · · · · · · · · · · · · · · · · · ·	-1	12	U	
	drug) that could on their own have caused				
	the reaction?	1	. 1	0	
6.	Did the reaction reappear when a placebo	-1	+1	0	
_	was given?		•	•	
7.	Was the drug detected in the blood (or	+1	0	0	
	other fluids) in concentrations known to be				
	toxic?				
8.	Was the reaction more severe when the	+1	0	0	
	dose was increased, or less severe when the				
	dose was decreased?				
9.	Did the patient have a similar reaction to	+1	0	0	
	the same or similar drugs in <i>any</i> previous				
	exposure?				
10.	Was the adverse event confirmed by any	+1	0	0	
	objective evidence?				
				Total Score	

To assess the adverse drug reaction, please answer the following questionnaire and give the pertinent seems

Total Score	ADR Probability Classification
9	Highly Probable
5-8	Probable
1-4	Possible
0	Doubtful

#### IJBCP International Journal of Basic & Clinical Pharmacology

doi: 10.5455/2319-2003.ijbep20141226

Research Article

#### A study on adverse drug reactions to non-ionic contrast medium in an Indian population: a 1-year experience

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Pharmacologist and Medical Superintendent (Academics, Quality & Research), Peerless Hospitex Hospital and Research Center Limited, Kolkata, West Bengal, India, 2Student of Certificate Course on Pharmacovigilance in Clinical Research, Jadavpur University, Kolkata, West Bengal, India, <sup>3</sup>Department of Pharmacology, MGM Medical College & LSK Hospital, Kishangani, Bihar, India, Department of Pediatrics, BR Singh Hospital, Kolkata, West Bengal, India, 5Executive, Clinical Research, Peerless Hospitex Hospital And Research Center Limited. Kolkata, West Bengal, India, Department of Clinical Imaging and Radio Diagnosis, Medica Superspecialty Hospital, Kolkata, West Bengal, India, Director, Clinical Research Centre, Jadavpur University, Kolkata, West

Consultant Clinical

#### ABSTRACT

Background: To the best of our understanding, very few studies focusing on the adverse drug reaction (ADR) profile of non-ionic contrast medium (NICM) has been carried out until date among the Indian population. Hence, this study was planned. We sincerely believe that the knowledge gathered from this study can improve safer usage of these agents among the patients of Indian origin. The objective was to evaluate the incidence and severity of ADRs of non-ionic radio contrast media (CM) used in tertiary care hospital in Eastern India.

Methods: For the duration of 1-year from July 2011 to July 2012, we prospectively recorded all the ADRs associated with the administration of NICM (iohexol and ioversol) in 3708 patients of Indian origin undergoing computed tomography scan at the hospital. The average median age, weight, dose used; types of ADRs, concomitant medication, final diagnosis, reasons for use were recorded and analyzed with appropriate statistical tools. Causality assessment was performed using Naranjo scale. Results: Eleven of 3708 patients who received either ioversol or iohexol developed ADRs (i.e. 0.3% of patients). The most common ADR was rigor. The incidences of mild, moderate and severe reactions were 55%, 36% and 9%, respectively. Average median age, weight, and dose used were 35 years, 66 kg and 70 ml, respectively. All the ADRs were early (occurred within 1 hr of CM administration). Due to logical constraints, the follow-up of these patients was not possible and hence late ADRs



# Adverse drug reaction monitoring in psychiatry out-patient department of an Indian teaching hospital

Oairik Sengupta, Subhrojyoti Bhowmick, Avijit Hazra, Ananya Datta, Musfikur Rahaman

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> Received: 07-04-2010 Revised: 07-07-2010 Accepted: 21-10-2010

#### Correspondence to:

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#### ABSTRACT

**Objectives:** Adverse drug reactions (ADRs) to psychotropic agents are common and can lead to noncompliance or even discontinuation of therapy. There is paucity of such data in the Indian context. We deemed it worthwhile to assess the suspected ADR profile of psychotropic drugs in an ambulatory setting in a public teaching hospital in Kolkata.

Materials and Methods: A longitudinal observational study was conducted in the outpatient department (OPD) of the concerned psychiatry unit. Twenty consecutive patients per day, irrespective of their psychiatric diagnosis, were screened for suspected ADRs, 2 days in a week, over 15 months. Adverse event history, medication history and other relevant details were captured in a format as adopted in the Indian National Pharmacovigilance Programme. Causality was assessed by criteria of World Health Organization-Uppsala Monitoring Center (WHO-UPC).

Results: We screened 2000 patients (68.69% males, median age 34.4 years), of whom 429 were suspected of having at least one ADR; 84 cases had insufficient evidence about causality (WHO-UMC causality status "unlikely") and were excluded from further analysis. Thus, 17.25% (95% confidence interval: 15.59–18.91%) of our study population reported ADRs with at least "possible" causality. Of 352 events recorded, 327 (92.90%) were "probable" and the rest "possible". None was labeled "certain" as rechallenge was not performed. Patients received a median of 3.2 psychotropic drugs each. Thirty-three different kinds of ADRs were noted, including tremor (19.60%), weight gain (15.34%) and constipation (14.49%). Among the incriminated drugs, antipsychotics represented the majority (57.10%), with olanzapine topping the list.

Conclusions: This study offers a representative profile of ADRs to be expected in psychiatry out-patients in an Indian public hospital. Establishment of a psychotropic drug ADR database can be a worthy long-term goal in the Indian context.

KEY WORDS: Adverse drug reactions, pharmacovigilance, psychiatry, psychotropic drugs

#### Introduction

Psychotropic drugs are plentiful in number and their use

psychotropic agents in particular. This prompted us to evaluate the ADR profile of psychotropic drugs used by ambulatory patients in a teaching hospital.



# Strategies for preventing Medication Errors



#### At Doctor level

- Ensuring prescription legibility through "Write in Capital Letters" policy
- Medication orders and prescription to include both generic and brand name along with dose, strength, directions for use
- Implementation of "Verbal order policy" for oral orders
- Protocols for High risk Medication (e.g Anticoagulant) usage
- Usage of standardized abbreviations & acronyms through out the organization
- Introduction of Hospital Formulary
- "Tall man" (mixed case) lettering to emphasize drug name differences (example RABEprazole and ARIPiprazole)
- Regular Prescription audit followed by appropriate corrective and preventive actions



#### Prescription audit improves prescribing habits

#### **Original Article**

# Prescription Audit Study from a Tertiary Care Private Hospital in Kolkata, India

Subhrojyoti Bhowmick, Shubham Jana<sup>1</sup>, Saksham Parolia<sup>2</sup>, Anupam Das<sup>3</sup>, Protim Saren<sup>4</sup>

Departments of Academics, Quality and Research, <sup>1</sup>Clinical Research and Academics, <sup>2</sup>Medical Administration and Quality Assurance and <sup>4</sup>Quality Assurance, Peerless Hospitex Hospital and Research Center Ltd., Kolkata, West Bengal, <sup>2</sup>Department of Pharmacy Practice, Manipal College of Pharmacy, Manipal, Karnataka, India

#### **Abstract**

Introduction: Prescription writing is an important aspect of safe medication practices. Prescriptions should adhere to best practices mentioned in the World Health Organization guidelines and the National Accreditation Board for Hospitals and Healthcare Providers guidelines. Aim: Evidence about prescription audit study conducted in developing countries like India is scarce, especially from the Eastern part of the country. Hence, the current prescription audit study was conducted in a tertiary care private hospital in Eastern India in the city of Kolkata. Materials and Methods: This study presents an assessment of the quality of prescribing practice in a tertiary care private hospital in Kolkata. Six thousand four hundred and six medicine cards (6406) of inpatients were prospectively analyzed for the duration of 6 months. Results: The audit revealed that only 69.24% of medicine cards had captured drug allergy, 99.53% had mentioned the route of administration, 99.85% had dose strength, 99.89% had mentioned the frequency of dose, and only 75.35% had mentioned the indication/diagnosis of patients. Surprisingly, 90.75% of medicine cards had an error-prone abbreviation which was an issue of major concent. Conclusions: The audit report was shared with the clinicians every month along with regular training of good prescribing practices, which improved the quality of prescribing practice. Regular prescriptions and followed by dedicated clinical pharmacology team along with constant communication with clinicians can improve the quality of prescriptions in long run.

Keywords: Medicine cards, National Accreditation Board for Hospitals and Healthcare Providers guidelines, prescribing indicators, prescription audit, World Health Organization guidelines

#### **OXYTOCIN INFUSION REGIME**

		INFUSION PUMP OR DIAL FLOW	MICRODRIP SET	ORDINARY SET			
TIME	mu / mt	ml per hour	microdrops per minute	drops per minute			
0 hrs	1	5	6	1			
0.5 hrs	2	10	12	3			
1 hrs	4	25	24	6			
1.5 hrs	6	35	36	9			
2 hrs	8	50	48	12			
2.5 hrs	10	60	60	15			
3 hrs	12	70	72	18			
		WAIT FOR ONE HOUR BEFORE INCREASING					
4 hrs	14	85	84	21			
4.5 hrs	16	95	96	24			
5 hrs	18	110	96	24			
5.5 hrs	20	120	120	30			



#### At Nursing Level

- Labeling all medications before preparing
- All medicines and labels to be verified by two qualified nursing professionals before administration
- Not more than one medication is labeled at one time
- All medications found unlabeled should be discarded immediately
- Continuous training and updation on LASA and High risk medication and Medication Error reporting
- Separate storing of LASA and High risk medication

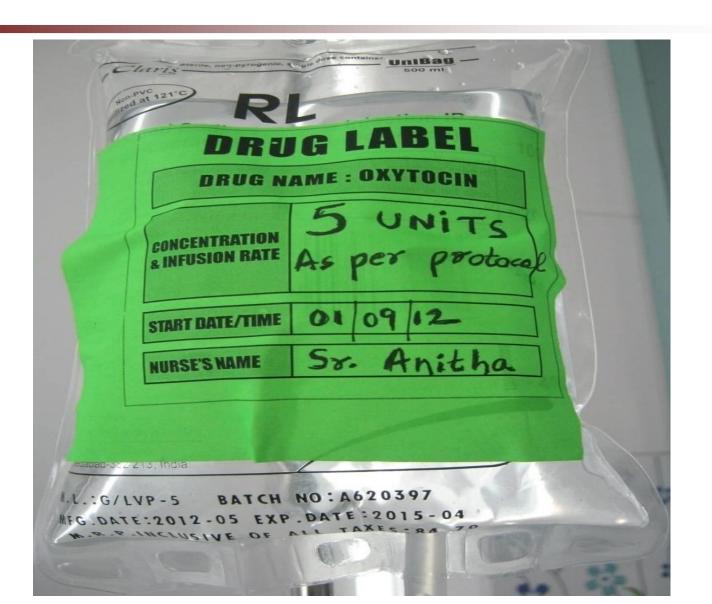




REGULA	R MEDICATION		Name	):	Allow Here and	Belle Comment of the	M. R. No	:1043	√ Weig	ht: 621
Drug Form:  Tab. Cap.	Drug Name: CFFA ZOLIN	Dose: mg Units	Day→	TUES	WED 2	THURS	FRI	SAT	SUN	MON.
☐ Drops ☑ Inj.	(DNE GRAM)	☐ Micrograms ☐ ml	Date→	20/5//2	21/5/12					
Syrup		☐ Grams ☐ Drops	Time 8 Am	Blandon.	Nancy					
Frequency: T	TO BEEKE !	fany:	Time 8 PM	Navy deen	2 osiva hal					
Start: THES Sign:	Date : 20/5 Stop : 21/5 Time : 0800 kg Sign : April	Date: 21/5	Time 1V1 \ OM							
Name of the D	octor: Name of the I	Doctor:	Time							

## Proper labeling of all infusions





### **Drugs Labeled in Medication Racks**







#### At Pharmacist level

- Ensuring dispensing in carried out by competent individuals
- Separate storing of LASA and High risk medication
- Implementation of Medication error reporting culture
- Continuous training and updation on LASA and High risk medication
- Training on Hospital Formulary and Good Pharmacy Practices



#### At Management level

- Development of a blame free & punishment free culture of medication error reporting
- Punitive action is not an effective way to prevent recurrence
- Medication error does not signify faulty personnel
- It signifies faulty systems that need to be made safer
- Establishment of a voluntary reporting system which does not lead to blaming and shaming of the individual care provider
- Dedicated personnel (Clinical Pharmacologist)/ Team to collect and analyze Medication errors & device strategy for process improvement

#### MEDICATION ERROR REPORTING FORM

	Date :
Patient Name:	
PRN:	Consultant:
Bed / Ward :	→ Prescription Error
Nursing: Report on Medication error	→ Indenting Error  → Dispatching Error  → Administering Error  Near Miss
Description of the Error Event:	
Signature: Nursing Team Leader	Ward Date & time
Action Taken:	
Signature : GM Nursing	Date / time
PHARMACY: Issue of wrong drug /wrong dosa	Dispensing Error  Indenting Error
	Near Miss
	Date / time
	ologist
Date / time:	Signature
Date / time:	Signature
Sent to Quality Assurance Depa	artment.

## Role of IT in Reducing Errors





#### **Computerized Physician Order Entry**

- Reduce errors / adverse drug events 55-80%;
- Produce legible and complete orders;
- Flag laboratory results that affect prescribing;
- Inform ordering Doctors of drug interactions, allergies, and duplication;
- Transmit orders to pharmacy when written;
- Minimize dosing errors; and
- Automatically calculate total doses.



CPOE cant eliminate "All Medication Errors especially prescribing errors"

# **Summary**



- Medication safety in healthcare is a very important patient safety challenge
- Medication errors are common entity in health care
- It results from poorly designed health care systems rather than negligence of healthcare providers
- Safety improvement activities include identification, reporting and analysis of the errors by dedicated team
- Goal is to develop a culture of patient safety and "fault tolerant" health care system
- Health care professionals should be encouraged to participate in blame free environment and initiate voluntary reporting systems as a commitment to patient safety

#### To conclude...



We must always remember that "there are no biologically safe drugs; there are only safe physicians, nurses and pharmacists".

### Join us in achieving...

#### **Medication Without Harm**







