ADVERSE DRUG REACTIONS (ADR)

Group : 5

Dr. Pranabandhu Das

Dr. Jayaprada R.

Ms. Radhika K.

Ms. Bhargavi G.

Ms. Lakshmi Devi

Ms. Bhagyasree G.

Mr. Prakash B.

Mr. Bannerjee K.

Reviewed By :

Dr. Lallu Joseph

Dr. Saravana Kumar

Ms. Devasri Chatterjee

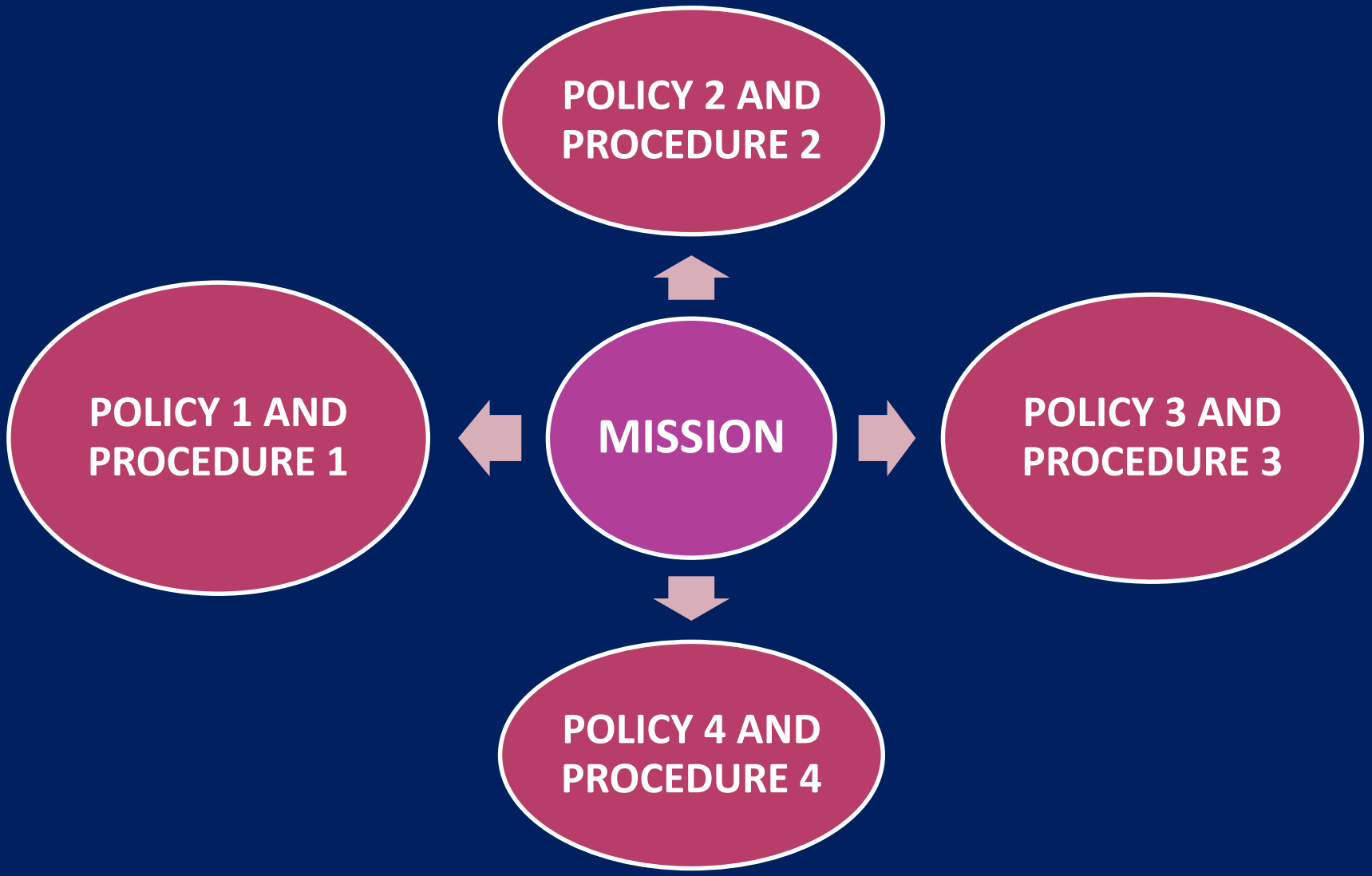
MISSION STATEMENTS

SVIMS HOSPITAL	స్విమ్స్ వైద్యశాల
OUR MISSION	మన లక్ష్యం
• Serve the underserved	ఏ ఆధారములేని పేదలకు సేవ చేయడం.
• Improve patient health out comes through focus in quality & patient safety	నాణ్యమైన మరియు భద్రతతో కూడిన వైద్యం అందించడం ద్వారా రోగి ఆరోగ్య పరిస్థితిని మెరుగుపరచడం.
• Increase patient satisfaction & enhance stakeholder experience	రోగి సంతృప్తిని పెంచడం ద్వారా భాగస్వాముల అనుభవాన్ని రెట్టింపు చేయడం.
• Decrease cost & waste in healthcare delivery	వైద్యం అందించడంలో ఖర్చుని వృధాని తగ్గించడం.

SVIMS :OUR MISSION

Serve the Unserved
To Improve Patients health outcome through focus on Quality and Patient Safety.
To Increase Patients Satisfaction and Enhance Stake holder's Experience
To Decrease Cost and Waste in healthcare delivery

MISSION CENTERED APPROACH




MISSION
POLICY
(NABH Chapters &Standards)
PROCEDURE
(Objective Elements)

ADVERSE DRUG REACTION (ADR)

- CHAPTER -3/10, **(MOM**)
  - STANDARD-8 /13 (**Near misses, medication errors and Adverse Drug Events are reported and analysed)**

POLICY

- **ADRs are reported and analyzed and appropriate corrective and preventive actions to be taken**

PROCEDURES

- **Objective Elements**
- A. ADRs are defined. *
- Which are in consonance with best practices.

- **SIDE EFFECT:** Any unintended effect of a pharmaceutical product at normal dose which is related to the pharmacological properties of the drug.

  (ACCEPTABLE and NON DELETERIOUS)

- **ADVERSE EVENT:** Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment. **(UNACCEPTABLE and DELETERIOUS)**

- **ADVERSE DRUG REACTION (ADR):** A response to a drug which is Noxious and Unintended *occurs at doses normally used in man* for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function. (WHO, 1972)

SERIOUS ADVERSE DRUG REACTION

Serious adverse reaction is defined as one in which the patient outcome is

- Death- if the patient died due to adverse event
- Life-threatening- if patient was at substantial risk of dying at the time of the adverse event.
- Hospitalisation/prolonged- if the adverse event caused hospitalisation or increased the hospital stay of the patient.
- Disability- if adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions.

Contd…

- Congenital anomaly- if exposure of drug prior to conception or during pregnancy may have resulted in an adverse outcome in the child.
- Required intervention or prevent permanent impairment/damage- if medical or surgical intervention was necessary to preclude permanent impairment of a body function, or prevent permanent damage to a body structure.

Drug group	No (%) ADRs	Top ten causative drug groups	Rank by frequency of use of drugs	Drugs (number of ADRs for each causative drug)	Adverse drug reactions
Loop diuretics	151 (20.6)	1	14	Furosemide (123), bumetanide (40)	Electrolyte disturbances, gout, hypotension, ileus, nausea, renal failure
Opioids	118 (16.1)	2	1	Morphine (88), tramadol (53), dihydrocodeine(10), fentanyl (8), codeine(8), oxycodone (7), pethidine (2)	Confusion, constipation, sedation, dizziness, respiratory depression, hallucinations, ileus, hypotension, itching, nausea, rash, dependence
Systemic corticosteroids	87 (11.9)	3	18	Prednisolone (67), dexamethasone (14), hydrocortisone (11), methylprednisolone (1), fludrocortisone	Electrolyte disturbances, increased INR, bleeding, hallucination, hyperglycemia, fracture, hypertension,

Beta-agonists (inhaled)	85 (11.4)	4	12	Salbutamol (85), terbutaline (4), salmeterol (3)	Electrolyte disturbances, nausea, tachycardia
Penicillins	66 (9.0)	5	6	Co-amoxiclav (34), amoxicillin (24), flucloxacillin (15), benzylpenicillin (7), penicillin v (1), ampicillin (1)	CDT, bleeding, rash, nausea, diarrhoea, increased INR, candidal infection

Adverse drug reaction	No associated patient deaths	Drugs (number of deaths)	Avoidability (definite, possible, unavoidable)
Renal failure	7*	Gentamicin (1), bumetanide, valsartan (1), bumetanide, furosemide, spironolactone, ramipril (1), allopurinol, ceftriaxone, furosemide (1), diclofenac (1), furosemide, spironolactone (1), bumetanide,	1 definite, 2 possible, 4 unavoidable
***Clostridium difficile* infection**	5*	Ceftriaxone and ciprofloxacin and gentamicin (1), ceftriaxone, ciprofloxacin, lansoprazole (1),	3 possible, 2 unavoidable

GI Bleed	2	Dalteparin, diclofenac (1), aspirin, dalteparin, dipyridamole, enoxaparin (1)	1 definite, 1 possible
Ischaemic bowel	1	Glypressin (1)	

- **B**. Documented procedure outlines the process for identifying, documenting, reporting, analyzing and taking action

- These are reported within a specified time frame.
- **Interpretation: The organization shall define the timeframe for reporting once.**

C. They are collected and analyzed.

(All these incidents are analyzed regularly by the multi-disciplinary committee. The analysis shall be completed in a defined time frame.)

- **D**. Corrective and/or preventive action(s) are taken based on the analysis where

Pharmacovigilance

Pharmacovigilance is the science and activities dealing with

- Detection
- Assessment
- Understanding
- Prevention

of adverse drug reactions or any other possible drug related problems (WHO 2002)

PHARMACOVIGILANCE PROGRAMME OF INDIA

- In July, 2010, under the ministry of Health and family welfare, a nation-wide revised ADR monitoring programme was launched and named as **Pharmacovigilance Programme of India (PvPI)** to improve ADR monitoring in the country,

- Initially, under this National programme, All India Institute of Medical Sciences, New Delhi was the **National Coordination Centre (NCC)** and in April, 2011, it was shifted to Indian **Pharmacopoeia Commission (IPC)**, Ghaziabad.

INTERNATIONAL COLLABORATION CENTRE	
WHO-UMC	SWEDEN

NATIONAL COORDINATION CENTRE	
IPC	GHAZIABAD

ADVERSE DRUG REACTION MONITORING CENTRE	
SVIMS,SPMC(W)	TIRUPATI

TIMELINE

- Expedited reporting of serious ADR’s is required as soon as possible, but in no case later than 24 hours of initial receipt of information by the health care provider.

PROCEDURE

NURSE

Observe, Report, Document and Begin ADR report

- Staff nurse who identifies an ADR should immediately inform the on duty doctor.
- Staff nurse should also assess the patient and if the event is significant or with the potential to cause patient harm, should provide immediate care to the patient.
- Staff nurse should be aware of side effects/ADR of various drugs to anticipate and monitor accordingly.

Contd..

- The staff nurse should provide the treatment as per directive from the doctor.
- The staff nurse should inform the senior nurse immediately.
- The patient should be monitored cautiously by a staff nurse till the patient is clinically stabilized.
- Staff nurse should document the events in the nursing notes.

RESPONSIBILITIES

DOCTOR

Observe, assess, prescribe, document and complete ADR report

- In case of ADR, the drug should be stopped immediately and the doctor after evaluating the patient should advise the treatment as appropriate.
- The doctor reports the ADR to the consultant immediately and obtains his advice.
- The doctor should document the events in progress notes and discharge summary.
- The on duty doctor should fill the suspected adverse drug reaction reporting form and submit to the Pharmacovigilance committee or Pharmacovigilance associate for further evaluation of the report.

PREVENTION

- Avoid all inappropriate use of drugs in the context of patient's clinical condition.
- Use appropriate dose, route and frequency of drug administration based on patient specific variables.
- Elicit and take into consideration previous history of drug reactions`/Allergies.
- Rule out possibility of drug interactions when more than one drug prescribed.
- Adopt correct drug administration technique.

Benefits of ADR Reporting

1. Assesses the safety of drug therapies, especially recently approved drugs.
2. Provides updated drug safety information to healthcare professionals and other stakeholders.
3. Measures the economic impact of ADR prevention.
4. Regulatory action on the basis of ADR reports to ensure patient’s safety

Suspected Adverse Drug Reaction Reporting Form

This form is divided into four sections:

A. Patient Information

B. Suspected Adverse Reaction

C. Suspected Medication(s)

D. Reporter Details

Version-1.2

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION

(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India
Sector-23, Raj Nagar, Ghaziabad-201002

Report Type ☐ Initial ☐ Follow up

FOR AMC/NCC USE ONLY

AMC Report No. :

Worldwide Unique No. :

A. PATIENT INFORMATION

1. Patient Initials _____

2. Age at time of Event or Date of Birth _____

3. M ☐ F ☐ Other ☐

4. Weight_____Kgs

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy)

6. Date of recovery (dd/mm/yyyy)

7. Describe reaction or problem

12. Relevant tests/ laboratory data with dates

13. Relevant medical/ medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)

14. Seriousness of the reaction: No ☐ if Yes ☐ (please tick anyone)

☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Required intervention to Prevent permanent
☐ Hospitalization/Prolonged impairment/damage
☐ Disability ☐ Other (specify)

15. Outcomes

☐ Recovered ☐ Recovering ☐ Not recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S)

S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates		Indication	Causality Assessment
								Date started	Date stopped		
i											
ii											
iii											
Iv											

S.No as per C	9. Action Taken (please tick)						10. Reaction reappeared after reintroduction (please tick)			
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if reintroduced)
i										
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates		Indication
					Date started	Date stopped	
i							
ii							
iii							

Additional Information:

D. REPORTER DETAILS

16. Name and Professional Address:_____
_____
Pin:_____E-mail_____
Tel. No. (with STD code)_____
Occupation:_____ Signature:_____

17. Date of this report (dd/mm/yyyy):

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

Casulity Assessment

Causality assessment is defined as “the evaluation of the likelihood that a medicine OR drug was the causative agent of an observed adverse reaction”

Causality Assessment committee:

Assess the causal relationship between drug and adverse reaction.

PHARMACOVIGILANCE COMMITTEE

- Evaluate ADR reports.
- Take necessary steps for reporting of ADRs.
- Ensures timely submission of reported ADRs to National Coordinating Centre.
- Close monitoring of drugs causing Serious ADR’s.
- Withdrawal of the suspected medication throughout the hospital (in extreme cases).
- Taking preventive measures (in case of definitively preventable ADR’s).
- Informing to the regulatory authority.

EVIDENCES

- Documented definition of ADR, IN APEX MANUAL, ADR Reporting forms
- Evidence for analysis, Corrective action, Preventive action
- Training records,
- Staff Interview

THANK YOU