GROUP 5 :ADVERSE DRUG REACTION

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Adverse Drug Reaction

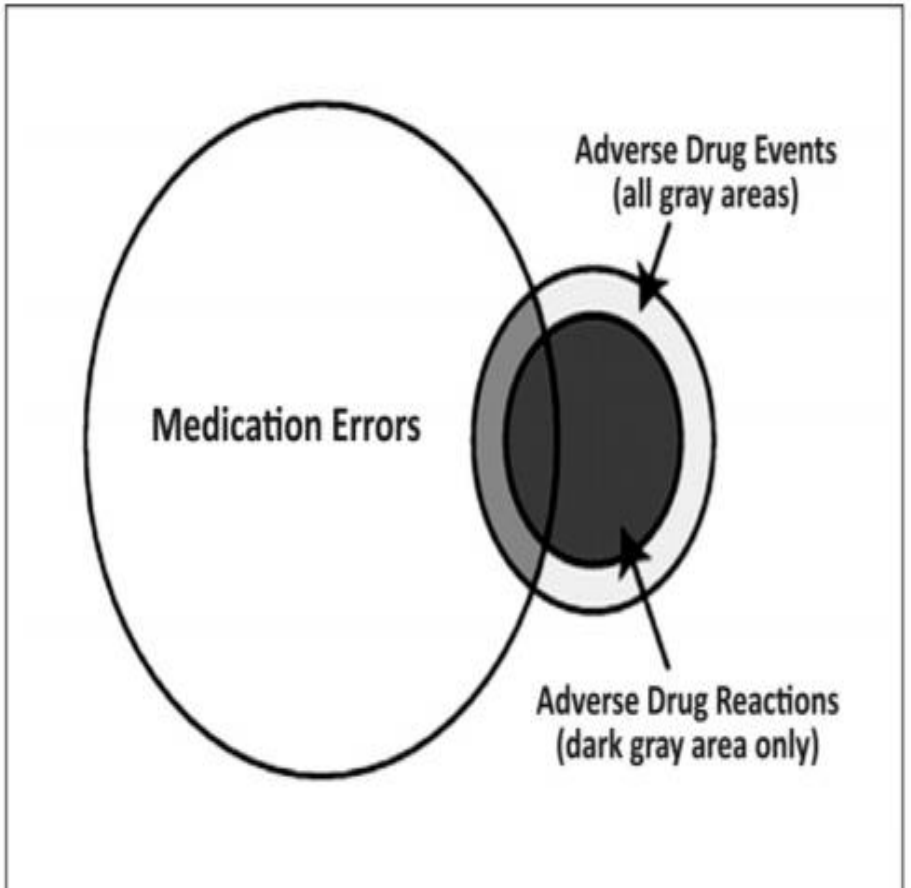
Learning Points:

- Definition
- Types Of ADR
- Population at risk
- Detection
- List of ADR Drug
- Management
- Incidence Reporting Form
- Pharmaco Vigilance

DEFINITION

- Medication error is administration of medicine or dose that differs from the doctors order

- Prescription error
- Transcription error
- Dispensing error
- Omission error
- Monitoring error
- Administration error



- ADE: Occurs with inappropriate use of the drug and allergic reactions – ADR, Overdose, allergic reactions
- ADR: Undesirable effect to the patient while taking a drug
- ADR occurs despite the correct drug, normal drug, during normal use

CLASSIFICATION OF ADR

There are 6 types of ADR (A-F)

- TYPE A- Dose dependent and predictable ADR

Eg: Hypotensive with antihypertensive medication

- TYPE B-Dose independent and unpredictable

Eg: Allergic/ Anaphylactic

LIST OF MEDICATION

- Antihistamines
- Anticoagulants
- Anti depressant
- Steroids
- Chemodrugs
- Antibiotics

Population at risk

- Paediatrics
- Geriatrics
- Patients with renal impairment
- Patients with liver impairment
- Pregnancy

DETECTION OF ADR

- The first sign of ADR is new or worsening symptom
- It may be severe/moderate/mild
- Reports of rash in the bed side chart, over sedation, lethargy are indications

MANAGEMENT OF ADR

- Reduce the dose
- Withhold the drug
- Obtaining detailed history of patients
- Identify the reaction
- Look up for the suspected drug and match with reaction

Sr. No

REPORT ON SUSPECTED SERIOUS ADVERSE DRUG REACTION

For Report to
Drugs Controller
Pak Secretariat, Block C,
Ministry of Health,

1. PARTICULARS OF PATIENT

Name of patient. _____

Age _____ Weight (kg) _____ Patient address _____

Sex ☐ Male Race _____

☐ Female

Pregnant ☐ Yes ☐ No ☐ Not applicable

Relevant Medical History _____

2. ADVERSE EVENT

Reason for reporting

☐ Requires or prolongs hospitalization ☐ Life threatening ☐ Death

☐ Permanently disabling or incapacitating ☐ Congenital anomaly ☐ Overdose

☐ Other (Please Specify) _____

3. SUSPECTED DRUG

Name of suspected Drug _____ Generic Name _____

Name of manufacturer _____

Date of occurrence _____ Duration of Event _____

Starting date of Medication _____

Route of administration _____

Discontinuation of Drug because of event ☐ No ☐ Yes Dated _____

4. REPORTING DOCTOR'S / PHARMACIST'S / NURSE'S SIGNATURE _____

Institution _____

Date _____

GUIDELINES TO FILL SERIOUS ADVERSE EVENT REPORT FORM

An adverse event is "Serious", if it

- Is life threatening
- Results in hospitalization
- Prolongation of hospitalization
- Causes malignancy
- Is an overdose resulting in clinically Relevant signs and / or symptoms
- Results in permanent disability
- Is associated with death
- Causes a birth defect
- Causes a relevant organ toxicity

An adverse drug event can be a manifestation of various etiologies such as

- Complication of an underlying disease
- Coincidental accident
- Concomitant medication
- Intercurrent disease
- Drug associated effect

REGULATORY BODIES

- CDSCO is the main regulatory body for regulation, clinical trials
- Pharmaco vigilance focuses on ADR, it involves the study of drug related injuries and insist on withdrawal of the drug, documentation and reporting

- ADR Cannot be prevented
- However it can be mitigated with better knowledge of the disease & better knowledge of the drug