GROUP- 5
ADVERSE DRUG REACTIONS

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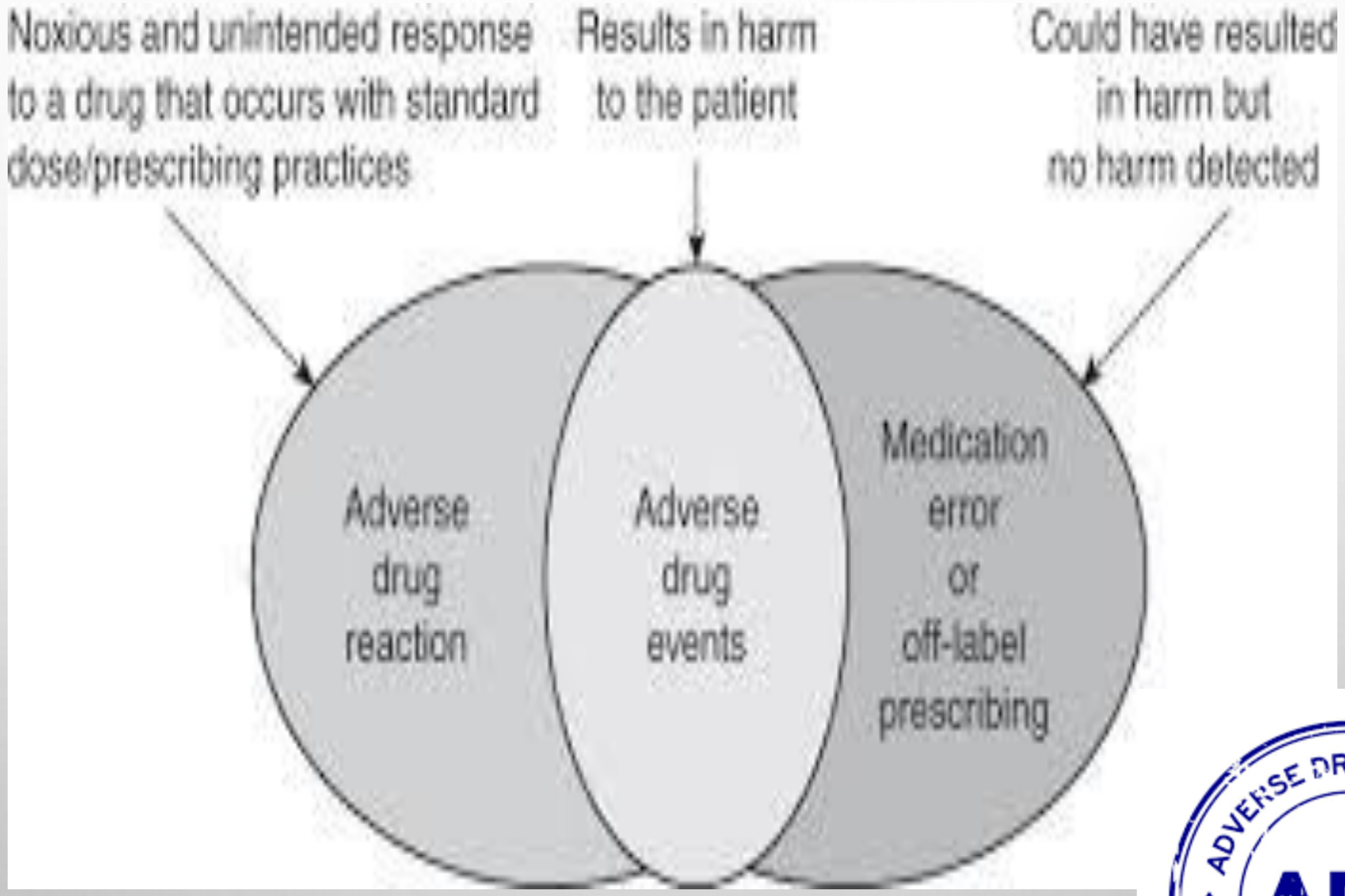
1st Step
CREATED USING
POWTOO


ADVERSE DRUG REACTION
ADR
ADVERSE DRUG REACTION

DEFINITIONS



WHAT ARE ADVERSE DRUG REACTIONS?

'Cured yesterday of my disease

I died last night of my physician'

So ALWAYS the important question is:

Do the potential benefits of the medication outweigh the potential risks for the individual?


Tired
Feel funny
Insomnia
Light-headed
Swelling
Hair loss
Pressure
Panic attacks
Sore
Blurry
Back pain
Pain
Crying
Dull Neck
Ache
Nausea
Worried
Weird spots
Knee
Dizzy
Sad
Can't sleep
Stiff
Rash
Help
Migraine
Joints
Bright spots
Angry
Depressed
Weak
Pounding heart
Terrified
Spasm
Uncomfortable
Double vision

ADR'S DOES NOT INCLUDE

- Non therapeutic overdosage
- Lack of efficacy of drug
- Drug abuse
- Medication errors

CONSEQUENCES OF ADR

- Adversely affect patient's quality of life
- Complicate drug therapy
- Decrease compliance and delay cure
- Increase in cost of treatment
- Lack of confidence on their doctors
- Mimics disease and lead to unnecessary investigations

WHO MIGHT GET AFFECTED BY ADVERSE DRUG REACTION?

- Anyone who takes the medicine

WHAT SHOULD RAISE SUSPICION OF ADR?

Symptoms that may:

- Appear soon after a new drug is started
- Occur after increase in dosage


REPORT ALL
adverse events


Report
Drug
Adverse
Reactions

ADR REPORTING FORM

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

FOR AMC/NCC USE ONLY

AMC Report No. :

Report Type ☐ Initial ☐ Follow up

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

12. Relevant tests/ laboratory data with dates

B. SUSPECTED ADVERSE REACTION

5. Date of reaction started (dd/mm/yyyy)
6. Date of recovery (dd/mm/yyyy)
7. Describe reaction or problem

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 impairment/damage
☐ Hospitalization/Prolonged ☐ Other (specify)
☐ Disability

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: Date started	Therapy dates: Date stopped	Indication	Causality Assessment
i											
ii											
iii											
iv											

S.No as per C	9. Action Taken (please tick) Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	10. Reaction reappeared after reintroduction (please tick) 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: Date started	Therapy dates: Date stopped	Indication
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.

The relationship between Medication Error, ADE & ADR

MEDICATION ERROR

- A **MEDICATION ERROR** IS 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.

EXAMPLE OF MEDICATION ERROR

- A 25 KG CHILD WITH NO PRIOR HISTORY OF PENICILLIN ALLERGY WAS PRESCRIBED 250 MG ORALLY OF AMOXICILLIN SUSPENSION TWICE DAILY (MORNING AND EVENING) FOR 7 DAYS. ON THE SEVENTH DAY, THE CHILD INADVERTENTLY RECEIVED A MORNING DOSE OF 500 MG INSTEAD OF 250 MG. THE CHILD DID NOT SUFFER ANY NEGATIVE CONSEQUENCES FROM THE ERROR.

ADVERSE DRUG EVENT

- AN **ADVERSE DRUG EVENT** (ADE) IS AN INJURY RESULTING FROM MEDICAL INTERVENTION RELATED TO A **DRUG.**

EXAMPLE OF ADVERSE DRUG EVENT

- A 37 YEAR OLD PATIENT DIAGNOSED WITH AN INFECTION FOR WHICH AMOXICILLIN AND CLAVULANATE POTASSIUM IS A CLINICALLY REASONABLE CHOICE. PATIENT HAS USED AMOXICILLIN AND OTHER ANTIBIOTICS IN PAST WITHOUT ADVERSE EFF ECTS. PRESCRIBER ORDERED AMOXICILLIN AND CLAVULANATE POTASSIUM 500 MG EVERY 12 HOURS. AFTER TAKING 3 DOSES, PATIENT EXPERIENCED RASH AND FACIAL SWELLING. HE WAS TRANSPORTED TO THE EMERGENCY DEPARTMENT AND TREATED.


PHARMACOVIGILANCE

THE ROLE OF PHARMACOVIGILANCE

- THE ROLE OF **PHARMACOVIGILANCE** IS TO DETERMINE WHICH ADVERSE EVENTS CROSS THE LINE OF A DRUG'S EFFICACY. IN OTHER WORDS, ANALYSING WHICH SIDE EFFECTS ARE WORTH THE RISK TO PATIENTS COMPARED WITH HOW EFFECTIVE THEY ARE AT TREATING A DISEASE.


HMM... DO YOU THINK THIS COUNTS AS AN 'ADVERSE DRUG REACTION'?
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THANK YOU