ADVERSE DRUG REACTIONS

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INTRODUCTION

Adverse Drug Event (ADE): An injury resulting from medical intervention related to drug.

→ Adverse Drug Reactions [ADR]

→ Medication errors

→ Overdoses

→ Allergic Reactions

Adverse Drug Reaction (ADR):

- WHO defines ADR as "A response to a drug which is noxious, unintended and occurs at doses used in man for prophylaxis, diagnosis or therapy."
- "ADR is any undesirable experience that has happened to the patient while taking a drug that is suspected to be caused by the drug or drugs."
- In conclusion, ADR is **harm** directly caused by the drug at **normal doses**, during **normal use**.
- Example : Patient experiencing anaphylaxis shortly after taking the drug.

Types of ADR's in Brief:

Type	Mnemonic	Example
A	Augmented	Diarrohea due to antibiotics
B	Bizzare	Hypersensitivity due to penicillin
C	Chronic	Steroid decrease HPA axis
D	Delayed	Teratogenicity, carcinogenesis
E	End of use	Precipitation of MI by β blocker withdrawl
F	Failure	OCP failure

- **MILD:** No need of Rx, antidote or hospitalization
- **MODERATE:** Requires drug change specific Rx & hospitalization
- **SEVERE:** Potentially life threatening; permanent damage & prolonged hospitalization
- **LETHAL:** Directly or indirectly leads to death

ADR GRADING

ADR

It is necessary to detect as well as evaluate ADR, and further develop mechanisms to prevent ADRs and their associated morbidity and mortality, hence it needs to be reported.

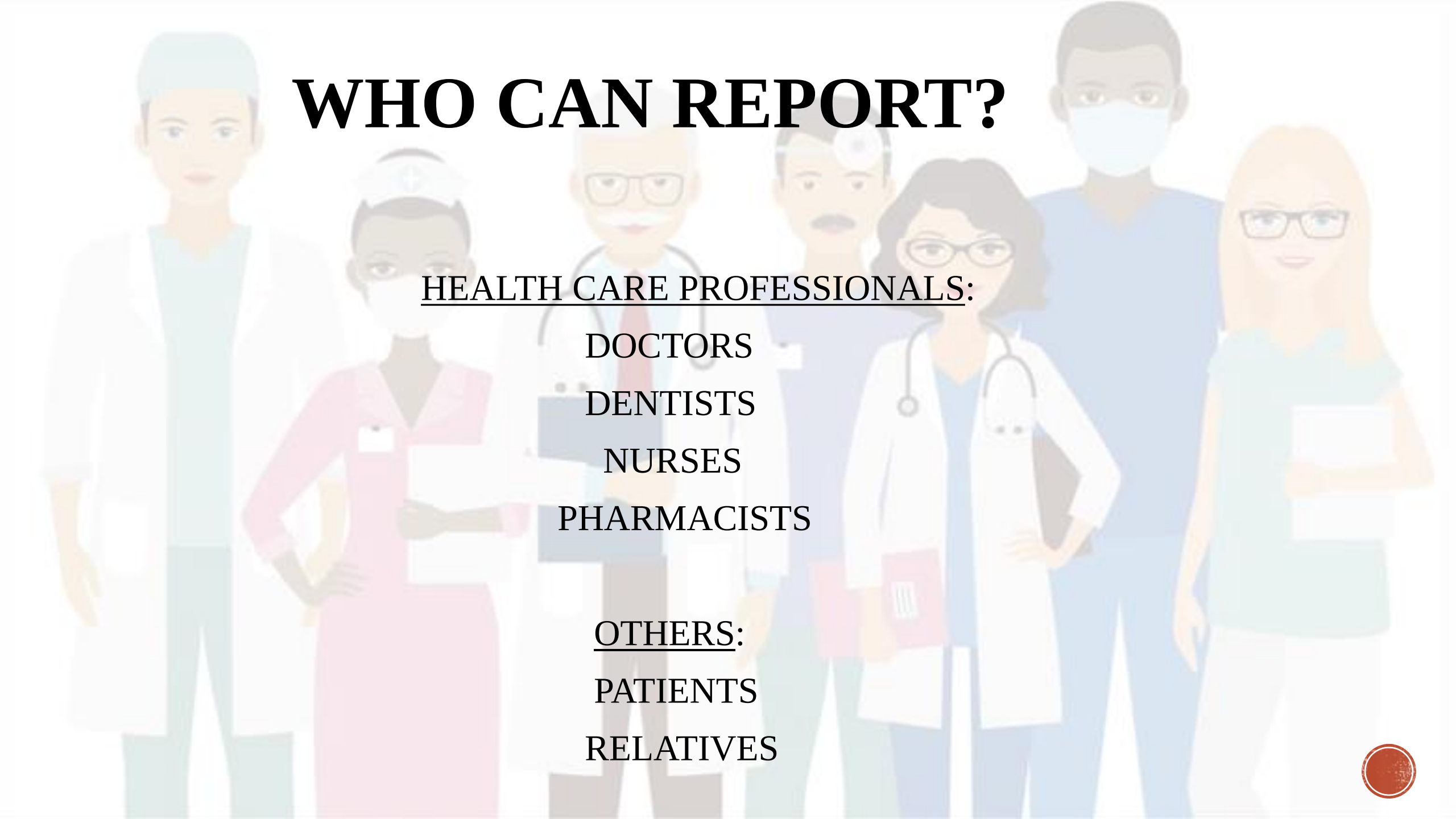
There should be a reporting structure.

It should be reported within the defined time frame. Preferably within 24 hours.

The relevant staff should be aware of the ADRs, how to detect them and further how to report them to the concerned authorities.

Proper corrective and preventive actions should be taken based on analysis after ADR is been reported.

WHO CAN REPORT?



HEALTH CARE PROFESSIONALS:

DOCTORS

DENTISTS

NURSES

PHARMACISTS

OTHERS:

PATIENTS

RELATIVES

ADR REPORTING PROCESS

SUSPECTED ADR

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ADR FORM

↓

CLINICAL PHARMACIST / QUALITY DEPARTMENT

↓

RCA BY PHARMACOLOGY DEPARTMENT

↓

PHARMACY AND THERAPEUTIC COMMITTEE → DRUG CONTROLLER

↓

INFORMATION DISSEMINATION + ACTIONABLES DEFINED FOR HEALTHCARE PERSONNEL (PREVENTIVE MEASURES)

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
☐ 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: Date started	Therapy dates: Date stopped	Indication	Causality Assessment
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: 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.

National Coordination Centre
Pharmacovigilance Programme of India
Ministry of Health & Family Welfare,
Government of India
Sector-23, Raj Nagar, Ghaziabad-201002
Tel.: 0120-2783400, 2783401, 2783392
Fax: 0120-2783311
www.ipc.nic.in

Pharmacovigilance Programme of India for Assuring Drug Safety

ADVICE ABOUT REPORTING

A. What to report

- Report serious adverse drug reactions. A reaction is serious when the patient outcome is:
  - Death
  - Life-threatening
  - Hospitalization (initial or prolonged)
  - Disability (significant, persistent or permanent)
  - Congenital anomaly
  - Required intervention to prevent permanent impairment or damage
- Report non-serious, known or unknown, frequent or rare adverse drug reactions due to Medicines, Vaccines and Herbal products.

B. Who can report

- All healthcare professionals (Clinicians, Dentists, Pharmacists and Nurses) can report adverse drug reactions

C. Where to report

- Duly filled Suspected Adverse Drug Reaction Reporting Form can be send to the nearest Adverse Drug Reaction Monitoring Centre (AMC) or directly to the National Coordination Centre (NCC).
- Call on Helpline (Toll Free) 1800 180 3024 to report ADRs.
- Or can directly mail this filled form to pvpi@ipcindia.net or pvpi.ipcindia@gmail.com
- A list of nationwide AMCs is available at:
  http://www.ipc.gov.in, http://www.ipc.gov.in/PvPI/pv_home.html

D. What happens to the submitted information

- Information provided in this form is handled in strict confidence. The causality assessment is carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC through ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Centre in Sweden.
- The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.
- The information is submitted to the Steering committee of PvPI constituted by the Ministry of Health & Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required.

E. Mandatory field for suspected ADR reporting form

- Patient initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) and reporter information.

For ADRs Reporting Call on PvPI Helpline (Toll Free)

1800 180 3024

(9:00 AM to 5:30 PM, Working Days)

PREVENTION OF ADR

Some ADRs are unavoidable and cannot be prevented. However, most ADRs can be prevented by :

1) Rational use of drugs. Avoid any inappropriate use.
2) Pay attention to patient's past medical history & medication history. Elicit and take into consideration previous history of drug reactions.
3) Take extra care while prescribing drugs known to exhibit interactions and adverse reactions with careful monitoring of patients with such reactions.
4) Beware of interaction of drugs with certain food, alcohol etc.
5) Be particularly careful while prescribing to children, elderly, pregnant and nursing women, seriously ill and patients with hepatic and renal diseases.
6) Use of appropriate dose, route and frequency of drug administration.
7) Think of ADR, when patient shows signs or symptoms not clearly explained by course of their illness and immediately consider stopping the drug or reducing the dosage.


thank you