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ADVERSE DRUG REACTIONS (ADRS) DETECTION AND REPORTING IN INDIA: CURRENT STATUS, CHALLENGES, AND FUTURE PERSPECTIVES

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1.ABSTRACT

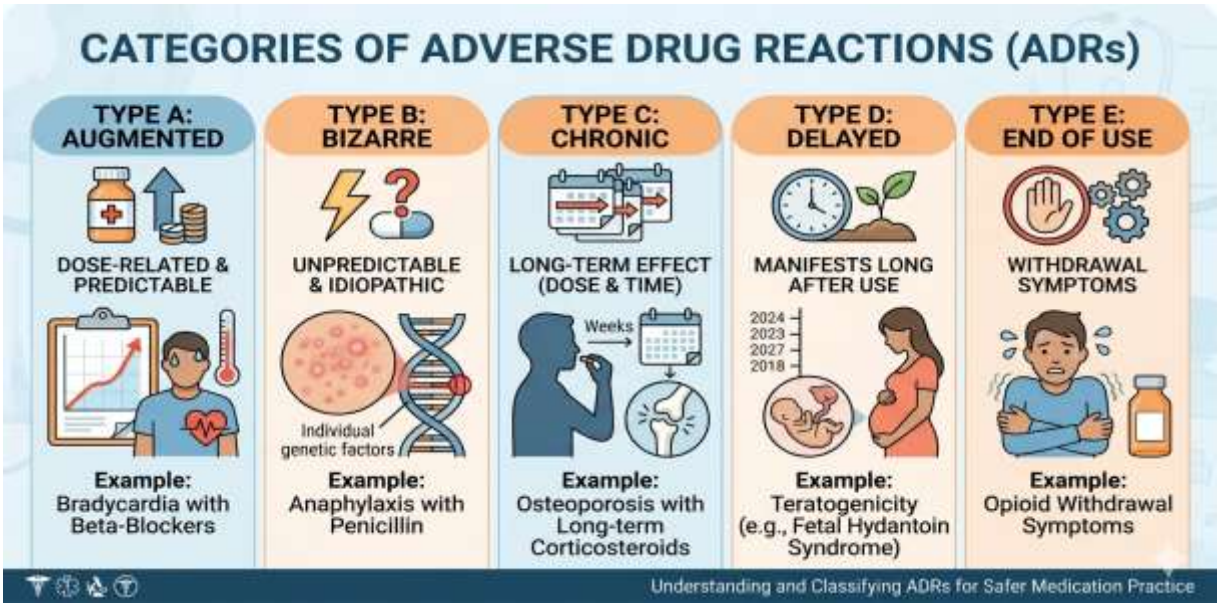
Adverse Drug Reactions (ADRs) are a major concern in clinical practice and significantly contribute to morbidity and mortality worldwide [1]. Pharmacovigilance plays a crucial role in detecting, assessing, and preventing ADRs [2]. In India, the Pharmacovigilance Programme of India (PvPI) has been established to monitor drug safety [3]. However, underreporting remains a major challenge due to lack of awareness and inadequate training [4].

2.INTRODUCTION

According to the World Health Organization, an ADR is defined as any harmful and unintended response to a drug at normal doses [1]. ADRs account for approximately 5–10% of hospital admissions globally [5].
Pharmacovigilance ensures drug safety by identifying risks associated with medicines [2]. In India, increasing drug use makes ADR monitoring essential [3].

3. CLASSIFICATION OF ADR

ADRs are classified into different types [6]:
Type A (Augmented): Dose-dependent and predictable.
Type B (Bizarre): Unpredictable and idiosyncratic.
Type C (Chronic): Relates to long-term use.
Type D (Delayed): Delayed effects, such as teratogenesis.
Type E (End of use): Withdrawal effects upon stopping the drug.



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4. METHODS OF ADR DETECTION

Various methods are used for ADR detection [7]:
Spontaneous reporting system [7]
Cohort studies [8]
Case-control studies [8]
Clinical trials [9]
Data mining techniques [10]

5.PHARMACOVIGILANCE PROGRAMME IN INDIA (PvPI)

The Pharmacovigilance Programme of India was launched in 2010 and is coordinated by the Indian Pharmacopoeia Commission [3]. India contributes ADR data to the global database managed by the Uppsala Monitoring Centre [11].

6.ADR REPORTING PROCESS IN INDIA

The structural flow of ADR reporting in India, coordinated by PvPI, involves several critical steps to ensure patient safety from detection to global analysis.

Process Overview:
Step 1: ADR Detection: Noticing a potential adverse reaction by patients or healthcare professionals (doctors, pharmacists, nurses).
Step 2: ADR Reporting: Submission of reports via formal channels like spontaneous reporting forms (Vigiflow), mobile apps, or emails. These flow to ADR Monitoring Centres (AMCs).
Step 3: National Analysis: Data from AMCs is collected at the National Coordinating Centre (NCC-PvPI, Ghaziabad). Here, validation, causality assessment, quality assurance, and signal detection are performed.
Step 4: Global Collaboration: Validated national data is securely submitted to the Uppsala Monitoring Centre (UMC) in Sweden for analysis by global scientists and inclusion in the WHO Global Individual Case Safety Reports (ICSR) Database.

7. CHALLENGES IN ADR REPORTING

Major challenges include:
Underreporting of ADRs [4]
Lack of awareness [12]

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Time constraints [12]
Fear of legal issues [13]
Lack of training [12]

8.ROLE OF HEALTHCARE PROFESSIONALS

Healthcare professionals are key to pharmacovigilance [14]:
Pharmacists: Play a major role in ADR reporting [14]
Doctors: Diagnose and manage ADRs [14]
Nurses: Monitor patient responses [14]

9.STRATEGIES TO IMPROVE ADR REPORTING

Improvement strategies include:
Awareness programs [12]
Training workshops [12]
Digital reporting systems [3]
Use of AI and big data [10]

10. FUTURE PERSPECTIVES

Future advancements may include:
Integration of artificial intelligence [10]
Strengthening national systems [3]
Global collaboration [11]

11. CONCLUSION

ADR detection and reporting are essential for drug safety [2]. Although India has developed a structured system through the Pharmacovigilance Programme of India, challenges like underreporting persist [4]. Strengthening awareness and adopting new technologies can significantly improve pharmacovigilance in India.

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