Chapter 13

Adverse Drug Reactions and the Silence of Reporting

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Introduction: When Medicines Harm Instead of Heal

While medicines are central to modern healthcare, they are not without risk. **Adverse Drug Reactions (ADRs)**—unintended, harmful effects from medications—are a growing but under-reported public health threat in India.

Globally, ADRs are a **leading cause of hospitalisation and death**, often preventable through early detection and surveillance. However, India's **pharmacovigilance ecosystem remains severely underdeveloped**, leaving millions vulnerable to drug-induced harm without recourse or accountability.

This chapter investigates the **silence around ADRs**, examining the weaknesses of India's pharmacovigilance systems and the urgent need for a patient-centred drug safety culture.

1. What Are Adverse Drug Reactions (ADRs)?

According to the WHO, an ADR is a **harmful or unintended response to a medicine at normal doses** used for prophylaxis, diagnosis, or treatment [1].

Examples include:

- **Rashes, allergies, or anaphylaxis**
- **Organ damage (e.g., liver, kidneys)**
- **Neuropsychiatric effects**
- **Fatal arrhythmias or bleeding episodes**

While some ADRs are unavoidable, **most are predictable and preventable** with robust monitoring.

2. The Indian Burden: Undercounted and Understood Poorly

India's true ADR burden is unknown due to **severe under-reporting**, but research suggests:

- **3–5% of hospital admissions** are due to ADRs [2]
- **10–15% of hospitalised patients** experience at least one ADR
- **Fatal ADRs may affect up to 0.2% of inpatients**

| **Table 1: Estimated ADR Burden in India (2022)** |

Metric	Estimate
Annual hospitalisations from ADRs	~2 million
Annual deaths (likely ADR-linked)	80,000–100,000
ADR reports submitted (PvPI, 2022)	~220,000

Source: PvPI, AIIMS pharmacovigilance reports, 2022 [3]

This means **<10% of ADRs are formally reported**, a rate far below global norms.

3. The Pharmacovigilance Programme of India (PvPI)

Started in 2010 by the Central Drugs Standard Control Organization (CDSCO), PvPI:

- Collects ADR data from **600+ centres**
- Coordinates with WHO-Uppsala Monitoring Centre
- Operates via AIIMS, IPC (Ghaziabad)

Yet the system is **passive and fragmented**:

- Most centres are located in urban tertiary hospitals
- **Private hospitals rarely report**
- **Doctors and pharmacists lack training in ADR recognition**

"Unless a patient dies or files a lawsuit, ADRs go unreported." — Clinical pharmacologist, Mumbai

4. Cultural and Institutional Silence

Several reasons contribute to underreporting:

- **Fear of legal liability** among doctors
- **Lack of incentive or mandatory protocols**
- Patients are **rarely informed about side effects**
- Misattribution of symptoms to disease rather than drugs

In a 2022 study at a Delhi hospital, only **11% of doctors** had ever reported an ADR [4].

5. Common Drugs Behind ADRs in India

| Table 2: Top Drug Classes Implicated in ADRs (PvPI Data, 2022) |

Drug Class	Common Reactions	% of Total Reports
NSAIDs (e.g., diclofenac)	GI bleeding, kidney injury	22%
Antibiotics (e.g., ciprofloxacin)	Rash, diarrhoea, liver issues	18%
Antiepileptics	Sedation, rash, liver dysfunction	11%
Antitubercular drugs	Hepatitis, neuropathy	9%
Chemotherapy agents	Bone marrow suppression	8%

Source: Indian Pharmacopoeia Commission, 2023 [5]

Some ADRs are **life-threatening**, yet **patients are rarely counselled before use**, especially in public hospitals.

6. Lack of Patient-Centric Risk Communication

Patients are almost **never warned about side effects**, due to:

This leads to:

- Patients not recognising ADRs
- Stopping essential medications unnecessarily
- Continuing toxic drugs unaware of harm

"My father developed yellow eyes while on TB treatment, but we thought it was a liver problem—not the medicine." – Caregiver, Varanasi

7. Special Populations: Higher Risk, Lower Reporting

a) Children

- Often **receive off-label dosages**
- Cannot describe symptoms clearly
- **ADR rates can be 3x higher** in neonatal units

b) Elderly

- More vulnerable to drug interactions
- Polypharmacy is common
- **Kidney/liver impairments** make drug elimination harder

c) Women

- Underrepresented in trials
- May report ADRs differently
- Face **dismissal of symptoms** as psychosomatic

8. The Hidden Cost of ADRs

Apart from patient harm, ADRs create:

- **Longer hospital stays (avg. 3–5 extra days)**
- **Increased healthcare cost (~5,000–50,000/event)**
- **Medicolegal risks for institutions**

A 2023 AIIMS study found that **ADR-related costs contributed 18% of total inpatient bill** for affected patients in surgical ICUs [6].

9. Missed Opportunities in Pharmacovigilance

Other countries have adopted stronger systems:

| Table 3: Global ADR Reporting Models |

Country	Key Feature	Reporting Rate*
UK	Yellow Card Scheme – open to patients	High (70 reports/million)
Sweden	Electronic mandatory ADR reporting	Very High

India	Paper/PDF forms; no mandate	Low (~15 reports/ million)

*Reporting rate: Reports per million population/year

In India:

- Patients **can** report via the PvPI website or app, but awareness is near zero
- There are **no financial or professional incentives** for healthcare professionals to report
- Private hospitals often **withhold ADR reports** to avoid scrutiny.

10. Solutions for Safer Medicine Use

| Table 4: Strengthening Pharmacovigilance – Policy Needs |

Recommendation	Status
Mandatory ADR reporting for hospitals	Proposed (2020)
Patient-friendly digital reporting portal	Exists, underused
Training for clinicians on ADR detection	Sparse
Public awareness campaigns	Absent
Real-time ADR data dashboards	Not implemented

India must treat pharmacovigilance as **a critical safety net**, not an academic exercise. This includes:

- Creating **legal frameworks for mandatory reporting**
- Incentivising healthcare providers
- Building **patient-facing communication tools** in local languages
- Including pharmacovigilance modules in **MBBS and pharmacy education**

Conclusion: Safety is Not Optional

When a drug harms instead of heals, silence can be fatal. India's ADR crisis isn't just about biology—it's about a system that doesn't listen, doesn't track, and doesn't learn.

No drug is 100% safe—but the public has a right to be informed, protected, and heard. Until pharmacovigilance becomes embedded in practice and policy, **India's pharmaceutical power will remain incomplete and unsafe.**

References

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