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Review Article
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Pharmacovigilance Trends in Adverse Drug Reaction (ADR) Reporting in India

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Abstract
Pharmacovigilance in India has grown rapidly over the past decade, driven by the establishment of the Pharmacovigilance Programme of India (PvPI), increasing public health initiatives, and evolving regulatory requirements. This review explores trends in adverse drug reaction (ADR) reporting in India, the impact of the COVID-19 pandemic, digital reporting innovations, and remaining challenges. While ADR reporting volumes have increased significantly, persistent under-reporting, uneven data quality, and regional disparities remain key concerns. Enhanced active surveillance, regulatory harmonization, and patient-centric digital tools are essential to sustain and strengthen pharmacovigilance in India.

Keywords: *Pharmacovigilance Programme of India (PvPI), Adverse Drug Reaction, (ADR) reporting, Drug safety surveillance, COVID-19 pandemic, Digital health reporting tools, Regulatory challenges in India.*

INTRODUCTION

Pharmacovigilance (PV) is defined by the World Health Organization (WHO) as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.

In India, pharmacovigilance gained momentum with the launch of the Pharmacovigilance Programme of India (PvPI) in 2010, coordinated by the Indian Pharmacopoeia Commission (IPC) under the Central Drugs Standard Control Organization (CDSCO). The program aims to ensure the safety of medicines and to protect the health of patients by detecting and analyzing adverse drug reactions (ADRs) across the country.

Despite steady improvements, ADR under-reporting remains a major issue. It is estimated that only a small fraction of ADRs are reported in India compared to global benchmarks.

This review aims to assess recent trends in ADR reporting, discuss key developments, analyze challenges, and highlight future opportunities for strengthening PV in India [1-2].

METHODOLOGY

A narrative review approach was adopted. Literature from PubMed, Scopus, Google Scholar, and official PvPI and CDSCO documents published between 2010 and 2025 were reviewed. Relevant studies focusing on reporting patterns, regulatory updates, and the impact of digital tools were analyzed to synthesize current trends and challenges in ADR reporting in India [3].

TRENDS IN ADR REPORTING IN INDIA

The establishment of PvPI led to a marked increase in ADR reporting nationwide. From fewer than 20,000 Individual Case Safety Reports (ICSRs) in 2011, India now contributes over 3% of the global database (Vigibase) managed by the WHO-Uppsala Monitoring Centre.

The number of ADR Monitoring Centres (AMCs) expanded from 22 in 2011 to more than 600 by 2025. This expansion reflects improved coverage and awareness among healthcare professionals.

During the COVID-19 pandemic, ADR reporting saw a major shift with vaccine-related reports dominating national data. The large-scale vaccination campaigns led to an unprecedented volume of reports, highlighting both the capacity and responsiveness of India's PV system [4].

QUALITY AND SOURCES OF ADR REPORTS

Most ADRs in India are still reported by healthcare professionals, particularly physicians and pharmacists.

However, recent years have seen increasing participation from nurses, patients, and pharmaceutical companies.

To improve accessibility, PvPI launched several digital tools such as the "ADR PvPI" mobile app, a toll-free helpline, and an online reporting portal.

These initiatives contributed to better quality and completeness of reports, although regional variability persists [5].

IMPACT OF COVID-19 PANDEMIC

The COVID-19 pandemic significantly influenced pharmacovigilance in India. The introduction of COVID-19 vaccines required rapid monitoring of vaccine safety, leading to a spike in ADR reports.

Vaccine-related ADRs, including mild to moderate events like fever, headache, and injection-site pain, were the most commonly reported.

The pandemic also accelerated the adoption of electronic reporting tools, making ADR submission faster and more transparent [6].

REGULATORY DEVELOPMENTS AND STRENGTHENING OF PvPI

India's regulatory framework for pharmacovigilance has evolved considerably. The New Drugs and Clinical Trials (NDCT) Rules, 2019, mandated that all Marketing Authorization Holders (MAHs) establish functional PV systems and maintain a Pharmacovigilance System Master File (PSMF).

CDSCO also introduced guidance documents outlining timelines for ADR reporting, risk management plans, and signal detection.

These measures align Indian PV practices with international standards such as those of the European Medicines Agency (EMA) and the U.S. FDA [7].

CHALLENGES IN ADR REPORTING

Despite notable progress, several challenges hinder the efficiency of India's pharmacovigilance system:

1. Persistent under-reporting due to lack of awareness and motivation among healthcare providers.
2. Variability in report completeness and causality assessment.
3. Geographic disparities, with most reports coming from urban tertiary-care centers.
4. Limited integration of hospital information systems with PV databases.
5. Insufficient feedback to reporters, which reduces motivation to continue reporting [8].

FUTURE DIRECTIONS AND OPPORTUNITIES

To strengthen ADR reporting, India must emphasize capacity building, technological integration, and community participation. Key strategies include expanding active surveillance programs, incorporating pharmacovigilance training into medical and pharmacy curricula, and incentivizing reporting. Artificial intelligence and big-data analytics can further improve signal detection, while patient-centered reporting platforms can empower individuals to contribute directly to medicine safety [9, 10].

CONCLUSION

India's pharmacovigilance system has made substantial strides, particularly through the expansion of PvPI and the integration of digital tools. However, challenges like under-reporting, inconsistent data quality, and uneven geographical coverage persist. Addressing these issues through regulatory reinforcement, active surveillance, and continuous education will be vital to ensure medicine safety and protect public health.

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