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Review Article

Review on Adverse Drug Reaction Monitoring

Dhananjay Wasu*, Ram Ghotkar

P. R. Pote Patil College of Pharmacy, Amravati.

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ABSTRACT

Medicines are used to prevent, diagnose, control and treat disease, but they can also cause harmful and unintended effects known as adverse drug reactions (ADRs), ranging from nausea or rash to severe bleeding, liver injury, anaphylaxis, disability or death. ADR monitoring is a core component of pharmacovigilance. This narrative review summarises the definition and classification of ADRs, risk factors and burden, methods of detection, reporting and causality assessment, the Pharmacovigilance Programme of India (PvPI), the roles of healthcare professionals and patients, barriers to reporting and strategies to overcome them, and digital approaches. An anonymised case report of a suspected ADR is included for illustration. Published evidence shows that ADRs add to healthcare needs and that under-reporting limits the ability of monitoring systems to detect medicine-related risks [1–4]. Interactive education, simpler reporting pathways, pharmacist involvement, patient participation and feedback may improve reporting [5, 6]. Digital tools and data mining can help identify patterns, but their output needs careful clinical assessment [7, 8].

INTRODUCTION:

Medicines are central to modern healthcare, yet the same medicine that benefits one patient may harm another, even when prescribed and used correctly. Medicine safety therefore cannot be considered complete at marketing approval; it must be assessed throughout the product life cycle [9, 10].

An ADR is a harmful and unintended response to a medicinal product at doses normally used for prevention, diagnosis or treatment. An adverse event is broader: an unfavourable medical occurrence after exposure, without necessarily implying causation, because the event may arise from the underlying disease, another medicine or an unrelated condition [11, 12]. Pharmacovigilance is the science and set of activities concerned with detecting, assessing, understanding and preventing adverse effects and other medicine-related problems [9, 10].

Pre-approval trials establish efficacy, common adverse effects and dose ranges, but participants are selected by eligibility criteria and followed for limited periods, so very rare or late reactions may be missed and groups

***Corresponding Author:** Dhananjay Wasu
Address: P. R. Pote Patil College of Pharmacy, Amravati
Email ✉: dhananjaywasu7@gmail.com

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such as older adults, pregnant women, children and multimorbid patients may be under-represented [5, 10]. In routine use, patients take several prescription, non-prescription, traditional or supplement products together, revealing interactions and risks not seen in development [10, 13]. Post-marketing monitoring thus complements, rather than replaces, clinical trials. A suspected reaction becomes a safety signal when information suggests a new potentially causal association, or a new aspect of a known one; a signal is a reason to investigate, not proof [10, 14].

Internationally, the WHO Programme for International Drug Monitoring pools national reports, which can reveal patterns invisible in a single country, although reporting practices and healthcare access differ between countries [9, 14, 15]. In India, PvPI, with the Indian Pharmacopoeia Commission (IPC) as National Coordination Centre, collects, collates and analyses suspected adverse events through ADR Monitoring Centres (AMCs) [16, 17]. This review is a narrative synthesis organised by topic, with priority given to official guidance, systematic reviews and widely cited studies; it does not follow a systematic-review protocol or pool data quantitatively.

DEFINITIONS AND CLASSIFICATION OF ADRS:

Three distinctions matter in practice. First, an ADR (a reaction with a plausible causal link) differs from an adverse event (any occurrence after exposure) and from an adverse drug event, a wider medication-safety concept that also includes harm from errors in prescribing, dispensing, administration or monitoring [11, 12]. Second, seriousness (death, life-threatening event, hospitalisation or its prolongation, significant disability, congenital anomaly) is distinct from severity (mild, moderate, severe intensity); an intense symptom does not automatically meet a seriousness criterion [12]. Third, a safety signal requires verification and should not be communicated as a confirmed effect before the evidence supports that conclusion [10, 14].

Type A and Type B. Type A reactions are usually predictable from the pharmacology of the medicine and dose-related (for example hypoglycaemia with insulin, bleeding with anticoagulants). Type B reactions are less predictable and include immune-mediated responses such as anaphylaxis [11, 18]. **Expanded categories** add Type C (chronic or prolonged use), Type D (delayed), Type E (withdrawal) and Type F (failure of expected treatment, linked to interactions, resistance or adherence) [11, 19]. Reactions may also be described by mechanism (exaggerated pharmacological effect, hypersensitivity, altered metabolism, genetic susceptibility, interactions, organ dysfunction) and by seriousness, severity, preventability, expectedness and outcome, which answer different questions and are not interchangeable [19, 20].

RISK FACTORS AND BURDEN:

Patient-related factors include age, body weight, pregnancy, coexisting disease, prior allergy, organ function and genetic variation; older adults may have reduced renal clearance and take many medicines, while children need carefully calculated doses [13, 21]. **Polypharmacy** increases the chance of interactions, duplicate therapy and confusion, so regular medication reconciliation is valuable [13]. **Dose, route and duration** also matter: high doses, rapid administration, inappropriate routes and prolonged exposure raise risk, and some ADRs are preventable because they involve prescribing or administration errors [11, 22, 23]. **Interactions** can involve prescription and non-prescription medicines, herbal products, supplements and food, so a complete medication history should include products patients may not regard as medicines [13]. **System-related factors**, such as unclear prescriptions, incomplete records, limited laboratory access and insufficient training, make reactions harder to prevent or recognise [13, 22, 23].

ADRs can cause discomfort, extra treatment, emergency visits, admission, prolonged stay, disability or death, and can interrupt effective therapy and erode trust in treatment. Their burden has been documented in primary care [1] and in a seven-year surveillance study from an Indian AMC [2]. Reported rates vary substantially between studies because definitions, patient populations, observation periods and surveillance methods differ; such figures should not be compared directly or treated as universal [1, 2]. Economic costs (investigations, treatment of the reaction, longer stays, follow-up, lost work time and caregiver burden) should

be reported with the perspective, data sources and time period stated [1, 13].

METHODS OF ADR MONITORING:

Spontaneous reporting allows professionals and patients to report suspected reactions from routine care. It is valuable for detecting rare or unexpected events but is limited by under-reporting, incomplete or duplicate reports, stimulated reporting after publicity and the lack of a denominator for incidence [3, 4, 9, 10]. **Active surveillance** seeks information deliberately, through chart review, patient follow-up or laboratory monitoring; it captures otherwise unreported cases and richer data but needs trained staff and resources [5, 10]. **Cohort event monitoring** follows patients who start a medicine and records events over a defined period, but events due to treatment must be distinguished from those due to underlying illness [10]. **Electronic health records, claims data and registries** support large-scale screening and automated alerts, with quality depending on coding, data completeness, algorithm validity and clinical review [7, 24, 25]. **Case reports and series** describe unusual reactions and generate hypotheses, but lack comparison groups and may be affected by publication bias [10]. No single method identifies every reaction; spontaneous reports generate signals, while analytical studies estimate risk or test hypotheses, so a strong system combines approaches according to the question, resources and seriousness of the potential harm [5, 7, 10].

Table 1: Comparison of ADR Monitoring Methods

Method	Strength	Main limitation	Ref.
Spontaneous reporting	Detects rare and unexpected signals	Under-reporting; incomplete data; no denominator	[3, 4, 9, 10]
Active surveillance	Systematic case finding and follow-up	Resource-intensive	[5, 10]
Cohort event monitoring	Follows exposed patients over time	Needs a defined cohort and follow-up	[10]
Case-control / cohort studies	Test associations using comparison groups	Confounding and bias must be controlled	[7, 10]
Electronic records / registries	Large-scale screening, timely alerts	Data quality, privacy, false alerts	[7, 24, 25]
Case reports / literature	Detail on unusual cases	Cannot estimate incidence	[10]

ADR REPORTING AND THE PHARMACOVIGILANCE PROGRAMME OF INDIA:

Reporting begins when a new symptom, sign, laboratory abnormality or deterioration is noticed after exposure. The reviewer considers timing, dose, recent changes, known effects, alternative causes and other medicines; proof of causation is not required before reporting [12, 16, 17]. A useful individual case safety report needs an identifiable patient, an identifiable reporter, a suspected product and a suspected reaction; missing details should be recorded as unknown, not invented [12]. Monitoring centres may request clarification, check duplicates, assess causality and enter data into the database, and good documentation reduces the risk of incorrect conclusions from incomplete data [7, 10, 12].

In India, the IPC/PvPI provides suspected-ADR forms for healthcare professionals, patient forms in several Indian languages, a mobile application and a helpline; reports go to an appropriate AMC [16, 17, 26]. Because forms, contacts and procedures are updated, the official website should be checked before submission [16, 17]. The functions of PvPI and its AMCs are to:

- receive and collate suspected ADR reports [16, 17];
- promote awareness and training among professionals and the public [16, 17];
- support review of potential safety signals and communicate relevant safety information [14, 16];
- contribute to national and international collaboration, including WHO programmes [9, 14, 15].

AMCs provide a local reporting route and completeness checks; institutions can strengthen this role by

assigning trained staff, displaying current instructions and reviewing local reporting performance [16, 17].

ASSESSMENT OF SUSPECTED ADRS:

Causality assessment estimates how likely it is that a medicine contributed to an event, considering timing, known pharmacology, response to withdrawal, alternative explanations, prior evidence and information quality. Certainty is often impossible in an individual patient with several medicines and diseases [11, 20, 27]. The **WHO–UMC system** classifies reports as certain, probable/likely, possible, unlikely, conditional/unclassified or unassessable/unclassifiable, relying on clinical judgement [20, 27]. The **Naranjo algorithm** scores answers to questions on timing, previous reports, dechallenge, rechallenge, alternative causes, dose–response and objective evidence; it supports structured assessment but is limited when information is missing or rechallenge is inappropriate [20, 27]. Both are aids to, not replacements for, clinical judgement, and their agreement has been examined formally [27].

Seriousness and severity should be recorded separately. Preventability review asks whether the medicine was indicated, dose and route suitable, interactions and contraindications considered and necessary monitoring performed [19, 20, 28]. Outcome is documented as recovered, recovering, not recovered, recovered with sequelae, fatal or unknown [16].

ROLES OF HEALTHCARE PROFESSIONALS AND PATIENTS:

Each group sees a different part of a reaction, and sharing these perspectives improves report completeness [12, 29]. **Doctors** evaluate the patient, consider alternative diagnoses, manage the reaction and report suspected cases, especially when serious [12]. **Pharmacists** review prescriptions and medication charts, identify dose problems and interactions, check allergy history, counsel patients and help complete reports across hospital and community settings; their contribution is most effective when reporting is part of routine work with institutional support [30, 31]. **Nurses** are often first to observe symptoms after administration and can record administration times, vital signs and clinical response [29]. **Patients and caregivers** can describe symptoms, treatment timing, non-prescription and herbal products and previous reactions; patient-friendly, local-language forms support participation, and reporting must never delay urgent care [16, 17].

BARRIERS TO REPORTING AND STRATEGIES FOR IMPROVEMENT:

Under-reporting is the main weakness of spontaneous systems. Systematic reviews repeatedly associate it with lack of knowledge, uncertainty about causality, time pressure, low motivation and fear of reporting an event that may not be drug-related [3, 4]. Consequences include delayed recognition of new risks and less information for regulators and clinicians [3, 4]. Table 2 links each barrier to the strategy best supported by the reviewed literature.

Table 2: Barriers to ADR Reporting and Corresponding Strategies

Barrier	Evidence	Strategy
Knowledge gaps (belief that only serious or confirmed reactions need reporting)	Recurring factor in reviews [3, 4, 32]	Case-based, interactive training clarifying what, when and how to report [5, 6, 32]
Time and workload	Complicated forms discourage reporting [4, 5]	Short, accessible forms in local languages; electronic and mobile reporting; reporting built into routine work [5, 16, 17]
Uncertainty about causality	Multiple illnesses and medicines obscure cause [27]	Encourage reporting of suspicion; use structured causality tools [20, 27]
Fear of blame; no feedback	Reported as a recurring barrier [3, 4]	Acknowledge reports, share de-identified lessons, fair learning-focused safety culture [3–5]
Unequal access (rural, small facilities)	Limited staff, internet and AMC contact [5, 16]	Regional training, mobile access, local-language resources, with effectiveness measured [5, 16, 17]

A systematic review and meta-analysis found that educational interventions increased reporting in the included studies, but certainty varied and most studies were from high-income settings [5]. Pharmacist-led monitoring (screening high-risk medicines, reconciling medication lists, counselling and reviewing possible ADRs during rounds) with a defined referral and reporting process can make this work more consistent [30, 31]. Institutions should track report numbers together with completeness, timeliness, follow-up, the proportion assessed for causality, staff training coverage and actions arising from reports, using clear definitions reviewed over time [5, 7].

DIGITAL PHARMACOVIGILANCE AND FUTURE DIRECTIONS:

Electronic and mobile reporting improve legibility, tracking and data transfer, and structured fields support consistent coding, but systems need access controls, data-quality checks and training [7, 16, 17]. Statistical data-mining tools highlight medicine–event combinations reported more often than expected; they help prioritise review but are affected by publicity, changes in medicine use, duplicates and incomplete data, and an association is a signal, not proof of causality [7]. Machine learning and natural language processing can identify possible ADR terms in clinical notes, detect duplicates and assist coding, but risk false positives, missed context, bias and privacy concerns, and need validation in the intended setting with human oversight [8, 24, 33]. Routinely collected health data can also support signal validation and prioritisation [10, 25]. Patient portals and mobile apps may capture symptoms occurring outside facilities, but require verification and evaluation across age groups, languages and digital literacy [16, 17].

ILLUSTRATIVE CASE REPORT:

Source and objective. The case was taken from a Suspected Adverse Drug Reaction Reporting Form (version 1.4) [26], with patient-identifying information omitted. The objective was to document a suspected ADR, review the medicines involved and describe the role of withdrawal and monitoring.

Case. A patient of approximately 56 years (gender not clearly recorded; weight unavailable) with known hypertension and a severe bacterial infection received amlodipine 5 mg orally once daily, doxycycline 100 mg orally three times daily and pantoprazole 40 mg orally three times daily (as recorded on the form; the infection indication written for pantoprazole and the recorded doses and frequencies should be verified against the original prescription). Reaction onset was 16/09/2026. The patient developed restlessness, anxiety, severe irritability, dizziness and mild hair loss. The reaction was marked non-serious, the suspected medicines were discontinued, and the patient recovered. Causality assessment was not completed on the form.

Table 3: Summary of the Reported Case (Anonymised)

Parameter	Recorded information
Age / gender / weight	Approximately 56 years / not clearly recorded / not available
Medical history	Hypertension; severe bacterial infection
Suspected medicines	Amlodipine 5 mg OD; doxycycline 100 mg TDS; pantoprazole 40 mg TDS (oral)
Reaction onset	16/09/2026
Reactions	Restlessness, anxiety, severe irritability, dizziness, mild hair loss
Action taken / outcome	Suspected medicines discontinued / recovered
Seriousness / causality	Non-serious, as marked on the form / not assessed on the form

DISCUSSION.

Amlodipine is a calcium channel blocker that relaxes blood vessels and lowers blood pressure; doxycycline is a tetracycline antibiotic that inhibits bacterial protein synthesis; pantoprazole is a proton pump inhibitor that reduces gastric acid [34]. A CDSCO notification dated 17 February 2026 lists restlessness, anxiety, irritability, nervousness and dizziness in association with doxycycline [35]. These overlap with the symptoms in this case and provide relevant safety context, but they do not

establish that doxycycline caused them, and the available information does not show whether all symptoms arose from one medicine. A formal WHO–UMC or Naranjo assessment, together with review of all concomitant medicines, would be the appropriate next step [20, 27]. The case illustrates why a report indicates suspicion, not proof, and why complete documentation, withdrawal review and monitoring are essential.

SYNTHESIS OF THE LITERATURE:

Taken together, the literature supports four conclusions. First, ADRs are a clinically important source of harm, although reported rates vary with study design, patient population and case definition [1, 2]. Second, spontaneous reporting remains useful for identifying possible safety signals but is weakened by under-reporting and incomplete reports [3, 4, 10]. Third, structured causality assessment supports consistency but cannot establish certainty in every case [20, 27]. Fourth, education and practical reporting support can increase reporting, but the durability and transferability of these interventions remain uncertain [5, 6].

The Indian evidence is especially relevant: a seven-year AMC surveillance study documents ADR patterns in a real Indian setting [2], and PvPI offers a national reporting route, including patient forms [16, 17]. The key implementation question is how effectively these routes are used in different institutions and how reports are translated into safer care. A recurring theme is the difference between report quantity and report usefulness: more reports improve the chance of detecting a signal, but reports with missing dates, unclear drug histories or unknown outcomes are difficult to assess, so programmes should measure completeness, timeliness, follow-up and actions taken in addition to counting forms [5–7].

Table 4: Key Studies, Contribution and Remaining Gap

Study	Main contribution	Remaining gap
Alomar et al. 2020 [9]	Reviewed status, challenges and future of spontaneous reporting	Under-reporting and incomplete data still limit interpretation
Harpaz et al. 2012 [7]	Reviewed data-mining methods for adverse drug event discovery	Statistical signals need clinical review; affected by reporting patterns and data quality
Insani et al. 2021 [1]	Pooled prevalence of ADRs in primary care	Rates depend on definitions and methods
Sharma et al. 2021 [2]	Seven-year ADR surveillance at an Indian AMC	Single-centre; multicentre standardised studies needed
Tandon et al. 2015 [3]	Described under-reporting as a challenge for PvPI	Barriers need local, group-specific study
García-Abeijon et al. 2023 [4]	Updated review of factors associated with under-reporting	Relative weight of factors varies by setting
Alshammari et al. 2021 [27]	Compared WHO–UMC and Naranjo agreement	Assessor judgement still matters with incomplete data
Cervantes-Arellano et al. 2024 [5]	Meta-analysis of educational interventions on reporting	Long-term effect and low-resource settings under-studied
Prakash et al. 2021 [16]	Described PvPI reporting tools and regulatory measures	Use and impact across institutions need evaluation
Pilipiec et al. 2022 [8]	Systematic review of machine learning in pharmacovigilance	Local validation, privacy and clinical usefulness need testing

RESEARCH GAPS:

- **Comparability of incidence estimates:** differing definitions, observation periods and case-finding methods prevent direct comparison; multicentre Indian studies with standardised definitions and transparent denominators are needed [1, 2].
- **Persistent under-reporting:** the relative importance of barriers may differ among doctors, pharmacists, nurses and students, so local studies should guide interventions [3, 4].

- **Long-term effect of interventions:** a short-term rise in reports after a workshop may not be sustained; sustainability, completeness, time per report and cost-effectiveness should be assessed [5, 6].
- **Report quality:** programmes should test whether electronic prompts, pharmacist review, structured forms and feedback increase the proportion of reports assessable without extensive follow-up [5–7].
- **Patient and caregiver participation:** access, awareness, health literacy and language may influence use of patient forms and need study [16, 17].
- **Digital tools and AI:** locally validated tools for Indian documentation and languages are needed, reporting false positives, missed cases and workload effects [7, 8, 24].
- **Linking reports to action:** evidence is needed on how local reports lead to medication review, practice change and prevention of recurrence [5, 9, 16].

Scope and limitations of this review. Sources were selected to cover foundational definitions, international and Indian pharmacovigilance guidance, burden studies, causality assessment, under-reporting and interventions to improve reporting. The review does not claim to include every study on ADR monitoring. A formal systematic review would require a reproducible search strategy, predefined eligibility criteria, duplicate screening, risk-of-bias assessment and documented reasons for inclusion or exclusion of each study [5, 9, 10].

CONCLUSION:

ADR monitoring is a central part of pharmacovigilance because clinical trials cannot identify every risk. Spontaneous reporting is useful for signal detection, while active surveillance, observational studies, electronic records and clinical review provide complementary evidence; a report indicates suspicion, not proof, and causality, seriousness, severity, preventability and outcome should be assessed and documented separately. Under-reporting remains the major challenge, and interactive education, simple reporting systems, pharmacist involvement, patient participation, feedback and measurable quality indicators can help, although their long-term effectiveness in Indian settings needs further study. PvPI and its AMCs provide an essential national framework, and digital tools may strengthen detection if supported by quality data, privacy safeguards, validation and human review. A continuous, collaborative and learning-focused pharmacovigilance culture can contribute to safer treatment and better patient outcomes [3–5, 9, 16].

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