Strengthening Adverse Drug Reaction Reporting: Knowledge, Attitudes, Barriers, Digital Innovations, And Strategies for Pharmacovigilance in India

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***Abstract*—Adverse drug reaction (ADR) reporting is a core component of pharmacovigilance and supports the detection, assessment, and prevention of medicine-related harm after products enter routine clinical use. Despite established reporting systems, underreporting and incomplete case information continue to limit the usefulness of spontaneous reports. This narrative review integrates themes from the three supplied manuscript drafts and selected literature on healthcare professionals' knowledge, attitudes and practices (KAP), barriers to reporting, the Pharmacovigilance Programme of India (PvPI), and digital approaches to safety surveillance. Across the supplied literature, a recurring gap appears between positive attitudes or general awareness and actual reporting behaviour. Common barriers include uncertainty about causality and reportability, limited knowledge of reporting routes, inadequate practical training, time pressure, cumbersome procedures, fear of blame, and lack of feedback. Digital tools may improve access and reduce duplicate data entry, but their value depends on usability, privacy, interoperability, data quality, and clinical oversight. Strategies proposed include practical and repeated education, simplified reporting pathways, clear institutional responsibilities, a non-punitive safety culture, feedback to reporters, patient participation, multidisciplinary collaboration, and routine assessment of report completeness and timeliness. This is a narrative synthesis rather than a systematic review; numerical findings reproduced from source extracts require verification against the original publications before submission. A coordinated, evaluated approach may improve the quantity and clinical usefulness of ADR reports and strengthen medicine-safety decision-making.**

***Index Terms*—Adverse drug reactions; pharmacovigilance; spontaneous reporting; knowledge, attitudes and practices; underreporting; digital health; medication safety; India; Pharmacovigilance Programme of India.**

I. INTRODUCTION

Medicines are central to disease prevention and treatment, but their use can produce unwanted and sometimes serious adverse drug reactions (ADRs). Pharmacovigilance encompasses the detection, assessment, understanding, and prevention of adverse effects and other medicine-related problems. Monitoring must continue after marketing authorization because premarketing trials cannot identify every risk that may emerge in larger, more diverse populations and under routine conditions of use [1]. [13–21,47–50]

Spontaneous reports from healthcare professionals and consumers are an important source of post-marketing safety information. They can reveal unexpected reactions, unusual clinical patterns, and concerns involving populations underrepresented in clinical trials. However, spontaneous reports are influenced by awareness, recognition, reporting workload, media attention, and perceptions of causality. They cannot, by themselves, establish ADR incidence or prove that a medicine caused an event.

Indian literature has repeatedly described gaps in awareness, reporting confidence, procedural knowledge, and actual reporting behaviour [2–4]. The existence of a national reporting programme is necessary but not sufficient: potential reporters must recognize suspected reactions, know where and how

to report, and be supported to provide useful information. This review combines the shared themes in the supplied drafts to discuss KAP patterns, barriers to reporting, report quality, India's reporting infrastructure, digital innovations, and practical strategies for improvement. [27–37]

II. REVIEW APPROACH

This manuscript was prepared as a narrative synthesis of the three supplied drafts and the literature and references cited within them. The source material included summaries of observational KAP surveys, reviews of underreporting, educational-intervention research, and discussion of digital reporting approaches and the Indian pharmacovigilance system. Recurring themes were compared narratively, with attention to differences in settings, professional groups, outcome definitions, and study methods.

The supplied materials did not provide a single reproducible database search strategy, complete full texts for all studies, or a uniform screening and quality-appraisal record. Therefore, this article is not presented as a systematic review or meta-analysis, and it does not claim exhaustive coverage. Numerical results are attributed to the studies or source extracts in which they were reported and should be checked against original publications before journal submission. In particular, institutional figures transcribed from an incomplete extract are not treated as independently verified evidence.

III. KNOWLEDGE, ATTITUDES, AND REPORTING PRACTICES

3.1 Knowledge does not always translate into reporting

The supplied KAP literature shows variation in pharmacovigilance knowledge across countries, professional groups, and healthcare settings. Some surveys report reasonable awareness of ADR concepts alongside lower levels of actual reporting. A systematic review and meta-analysis of Indian healthcare professionals reported that 55.6% of the included participants were unaware of the Pharmacovigilance Programme of India (PvPI), while 74.5% had never reported an ADR to a pharmacovigilance centre [2]. These figures describe the populations and studies included in that review and should not be interpreted as current national prevalence estimates.

The distinction between general awareness, procedural knowledge, and reporting behaviour is important. Knowing the definition of pharmacovigilance does not necessarily mean that a professional can recognize a suspected reaction, locate the current reporting form, identify the minimum information required, or submit a report promptly. Training and evaluation should therefore assess practical skills as well as factual knowledge.

3.2 Positive attitudes but limited practice

Several supplied abstracts describe professionals who consider ADR reporting important or regard it as a professional responsibility, while reporting practice remains limited. This attitude–practice gap suggests that motivation alone is insufficient. Reporting may be omitted because the procedure is unfamiliar, the form is difficult to locate, workload is high, or the professional believes that causality must be established before reporting. Self-reported KAP measures may also be affected by recall and social-desirability bias.

Future evaluations should combine questionnaires with objective indicators, such as report counts using an appropriate denominator, report completeness, and time from recognition to submission. These measures can provide a more realistic picture of whether education and policy changes alter behaviour.

IV. BARRIERS TO ADR REPORTING

4.1 Uncertainty about causality and reportability

A recurring barrier is the belief that a suspected ADR should be reported only after a causal relationship has been conclusively established. Spontaneous reporting systems are intended to collect suspicions for further evaluation; reporters are not generally expected to prove causality before submitting a report [3,4]. Practical guidance should explain what constitutes a suspected reaction, which details to record, and how to handle uncertainty. Useful details include the suspected medicine and dose, timing of exposure, event description, relevant medical history, concomitant medicines, action taken, and outcome.

4.2 Limited awareness and inadequate training

The supplied literature describes healthcare professionals who did not know the national reporting

centre, had never seen a reporting form, or had not received practical training. Training should go beyond general awareness campaigns. Short, role-specific sessions can demonstrate how to locate the reporting route, complete a report, submit follow-up information, and obtain assistance. Orientation for new staff and students should be supplemented by periodic refreshers.

4.3 Time pressure and workflow complexity

Reporting may compete with clinical duties, particularly when forms are lengthy, responsibilities are unclear, or information must be entered more than once. These obstacles cannot be solved through education alone. Institutions can reduce friction by making reporting links and forms accessible at the point of care, defining who is responsible for submission, providing a named pharmacovigilance contact, and allowing follow-up information to be added when it becomes available.

4.4 Fear of blame and perceived consequences

Some professionals may fear criticism, reputational harm, or legal consequences if they report a suspected reaction. A non-punitive learning culture should distinguish good-faith safety reporting from separate processes used to investigate misconduct or unsafe practice. Clear confidentiality arrangements, transparent procedures, and visible examples of how reports support safety learning can help build trust. [22–24,28–33]

4.5 Limited feedback

When reporters receive no acknowledgement or cannot see how their information is used, they may become disengaged. Feedback can include confirmation of receipt, requests for missing information, and anonymized summaries of lessons learned. Such feedback should protect confidentiality and should not imply that an individual report alone proves causation.

4.6 Patient and public participation

Patients and caregivers may provide information about symptoms, timing, adherence, non-prescription products, and effects on daily life that is not fully captured in clinical records. Patient-facing routes should use plain language, accessible formats, and appropriate multilingual support. Guidance should also explain when urgent medical assessment is needed. Patient reports can complement professional reports, while coordinated processes can reduce avoidable duplication and protect confidentiality [7].

V. REPORT COMPLETENESS AND CLINICAL USEFULNESS

The value of a spontaneous report depends on more than its existence. Incomplete or unclear information may limit clinical assessment, follow-up, and signal evaluation. Depending on the current reporting instrument, useful information commonly includes identifiable patient and reporter details, the suspected medicine, a description of the reaction, relevant timing, and outcome information. The applicable PvPI/National Coordination Centre form and instructions should be used to determine required fields. [15,19,41–46]

The supplied India-focused draft transcribed a retrospective institutional analysis of 104 ADR reports from 2017–2021, including 61 reports (58.6%) involving female patients and 43 (41.4%) involving male patients; adults aged 18–65 years accounted for 82 reports (79%). Antibiotics, antitubercular medicines, and vaccines were described among frequently implicated medicine groups. The source extract did not provide sufficient complete bibliographic details, the original dataset, or methods for independent verification. These figures must therefore be checked against the original publication or dataset before publication and must not be used to infer comparative risk or population incidence.

Completeness measures should be defined transparently. Authors and institutions should specify the fields assessed, numerator and denominator, treatment of fields that are not applicable, and the method used to calculate scores. Reporting performance should consider completeness, timeliness, relevance, duplicate frequency, and follow-up needs rather than report volume alone.

VI. THE ROLE OF PvPI AND INSTITUTIONAL SYSTEMS

The Pharmacovigilance Programme of India provides a national structure for collecting suspected ADR reports through ADR Monitoring Centres and other reporting routes. Official programme information

provides reporting options for healthcare professionals and consumers, including consumer-facing forms and digital routes [8,9]. Availability of a reporting route is only one part of an effective system: users must know that the route exists and understand how to use it. [13–17,41,61]

Healthcare facilities and educational institutions can display current instructions in clinical areas, include reporting guidance in staff induction, identify pharmacovigilance coordinators, and incorporate reporting into clinical pharmacy services, ward rounds, medication-safety meetings, and continuing professional development. Forms, links, contact details, and instructions should be checked periodically against current official PvPI information so that outdated materials are not circulated.

Pharmacists can contribute through medication-history review, recognition of suspected reactions, documentation, and follow-up. Nurses may observe changes in patients' condition and medicine administration, physicians contribute diagnostic and clinical context, and patients can describe experiences outside clinical settings. Clear communication and referral pathways can combine these perspectives while protecting confidentiality.

VII. DIGITAL INNOVATIONS AND RESPONSIBLE IMPLEMENTATION

Electronic reporting portals, mobile applications, structured electronic forms, and integration with electronic health records may make reporting more convenient and support consistent data capture. Pre-population of appropriate demographic and medicine details can reduce duplicate entry when reporters can verify and correct the information. Digital systems should distinguish essential from optional fields, provide confirmation of receipt, support follow-up, and remain usable for people with limited connectivity or digital literacy. [42–45,51–60]

Digital implementation also introduces risks. Systems require attention to privacy, cybersecurity, interoperability, accessibility, duplicate submissions, and data quality. Automated text processing or artificial intelligence may assist in identifying possible events or organizing clinical narratives, but such tools should be treated as decision support, not as substitutes for clinical review or formal causality assessment. Performance, bias, false positives, missing information, and preservation of clinical context should be evaluated before routine implementation. Digital solutions should complement not exclude paper-based or assisted reporting routes where these remain necessary.

VIII. STRATEGIES TO STRENGTHEN ADR REPORTING

A coordinated improvement programme should address individual knowledge, institutional workflow, reporting technology, and feedback.

8.1 Practical and repeated education. Integrate ADR reporting into undergraduate and postgraduate curricula, staff induction, and continuing professional development. Use case-based workshops, demonstrations, and report-completion exercises. A systematic review and meta-analysis of educational interventions reported higher ADR reporting in intervention groups than in control groups, although substantial heterogeneity limits assumptions that every intervention will have the same effect [6]. Education should be assessed through retention, confidence, report completeness, and actual reporting behaviour, not attendance alone. [25–27,31–37]

8.2 Simplified reporting pathways. Make official reporting routes easy to find from the point of care. Clarify responsibilities, minimize avoidable duplicate data entry, distinguish required from optional fields, and provide support for follow-up. A report should not be delayed solely because causality is uncertain.

8.3 Leadership and a non-punitive safety culture. Assign clear responsibilities and provide staff with access to practical support. Discuss reports as opportunities for learning and risk reduction, while maintaining appropriate processes for any separate investigation of misconduct.

8.4 Feedback and visible learning. Acknowledge submissions, request missing information where needed, and share anonymized safety lessons. Feedback can help reporters understand the purpose and value of their contribution.

8.5 Patient participation and accessible communication. Provide plain-language instructions and appropriate multilingual options. Explain how

patients can report suspected reactions and when symptoms require urgent clinical attention.

8.6 Multidisciplinary collaboration. Establish workable communication among physicians, pharmacists, nurses, other healthcare professionals, patients, institutional pharmacovigilance teams, and regulatory bodies. Different contributors may hold complementary information about medicine exposure, timing, symptoms, laboratory findings, adherence, and outcomes.

8.7 Routine monitoring and evaluation. Establish a baseline and define outcomes before introducing an intervention. Useful indicators include reports per appropriate denominator, time from recognition to submission, completeness of core clinical fields, proportion requiring follow-up, duplicate-report frequency, training coverage, and user-reported ease of reporting. Interpret increases in report volume cautiously because they may reflect improved awareness rather than a rise in ADR incidence. Where feasible, comparison groups or time-series approaches can help distinguish intervention effects from changes in staffing, patient volume, medicine use, or reporting policy.

IX. RESEARCH GAPS AND LIMITATIONS

The evidence summarized in this manuscript is heterogeneous in setting, professional group, questionnaire, outcome definition, and follow-up duration. Much of the supplied material consists of abstracts or extracts rather than full texts, and not every study had complete bibliographic or methodological details available. Cross-sectional KAP surveys can describe patterns and associations but cannot establish causality. Self-reported practice may be affected by recall and social-desirability bias. The narrative approach is not exhaustive or reproducible, and no new pooled estimate or empirical dataset was generated. [22,23,27–37]

The institutional 2017–2021 figures transcribed from the supplied source require verification against the original publication or dataset before they can be retained as evidence. Future studies should use clearly described and validated measures, objective reporting outcomes, appropriate comparison groups, and follow-up long enough to assess sustainability. Research should also examine implementation costs, workload, equity, privacy, digital access, and whether improved reporting leads to more useful safety signals or changes in clinical and regulatory decisions.

X. IMPLICATIONS FOR PRACTICE AND POLICY

Improving ADR reporting requires more than increasing the number of forms submitted. The objective is to generate timely, sufficiently detailed, clinically interpretable reports that can contribute to signal detection and risk assessment. National programme guidance, institutional processes, professional education, accessible technology, and patient participation should reinforce one another. A balanced performance framework can monitor report volume, completeness, timeliness, follow-up requirements, reporter type, and training or feedback coverage. These indicators should be interpreted together and in context, because stimulated reporting may increase report counts without indicating a change in underlying ADR frequency. [15,18,25,41,51–62]

XI. CONCLUSION

Underreporting and incomplete documentation remain important challenges for pharmacovigilance. The supplied literature identifies a recurring gap between knowledge or positive attitudes and actual reporting practice. Uncertainty about causality, limited awareness of reporting procedures, inadequate practical training, workload, complex systems, fear of blame, and limited feedback are commonly described barriers. Strengthening ADR reporting requires coordinated practical education, accessible and simplified reporting pathways, institutional leadership, a non-punitive safety culture, meaningful feedback, multidisciplinary participation, and patient-friendly reporting options. Digital tools can support this work when designed with usability, privacy, interoperability, and human oversight in mind. Future evaluations should use transparent methods and predefined outcomes, and all source-reported numerical findings should be verified before submission.

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