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Medication safety reporting in Indian hospitals: Systems, barriers, pharmacist involvement, and opportunities for improvement

Shubham Kumar Vohra*
M.M. College of Pharmacy, Mullana, Ambala, Haryana, India
Corresponding Author: Shubham Kumar Vohra
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Abstract
Medication-safety reports allow hospitals to identify preventable harm and learn from failures in the medication-use process. In India, however, suspected adverse drug reactions (ADRs), medication errors, near misses, and other safety incidents are often handled through separate reporting routes. This structured narrative review examined openly accessible Indian literature on reporting arrangements, barriers, pharmacist participation, and practical options for improvement. PubMed was searched to 21 June 2026 using one broad medication-safety strategy and a second strategy focused on reporting barriers and pharmacists. The two searches returned 281 records. After 42 duplicates were removed, 239 unique records were screened and 43 full-text publications were included. Most of the evidence came from single-centre observational studies and questionnaire surveys. Frequently reported obstacles were uncertainty about what and where to report, difficulty judging causality, heavy workload, limited time, complicated forms, fear of blame or legal consequences, lack of anonymity, and poor feedback. Educational programmes usually improved knowledge and attitudes in the short term, although increases in actual reporting were less consistent. Better practice was reported when education was supported by simple confidential reporting routes, active surveillance, pharmacist coordination, and feedback to staff. Pharmacists contributed to detection, medication review, causality and preventability assessment, documentation, trend review, and service redesign. Indian hospitals need a coordinated learning system that connects ADRs, medication errors, near misses, and unsafe conditions while protecting reporters, defining a pharmacist coordination role, returning timely feedback, and reducing duplicate documentation through interoperable digital systems.

Keywords: Adverse drug reaction reporting systems; incident reporting; pharmacovigilance; patient safety; medication errors

Introduction

Medication-related harm covers suspected ADRs, preventable errors, near misses, and unsafe conditions in medication use. Problems may occur during prescribing, transcription, dispensing, administration, monitoring, or transfer between care settings. A systematic review of Indian hospital studies reported a median medication-error incidence of 34.11% among incidence studies and a pooled frequency of 26.74%, although estimates differed widely according to setting and detection method [1]. These findings make reporting valuable not simply as a surveillance activity, but as a way to locate repeated weaknesses in care processes and guide corrective action.

Suspected ADRs can be reported nationally through the Pharmacovigilance Programme of India (PvPI) and its ADR Monitoring Centres (AMCs). Medication errors and broader clinical incidents, by contrast, are usually managed through local quality, pharmacy, nursing, or patient-safety systems. Indian priority-setting work has called for stronger pharmacovigilance, greater patient involvement, implementation research, and technology-supported medication safety [2]. Yet the presence of a formal channel does not mean that clinicians use it. In a systematic review and meta-analysis, 55.6% of Indian healthcare professionals were unaware of the national programme and 74.5% had never submitted an ADR report [3].

The central problem is therefore not the absence of forms. Reporting must be straightforward, safe for the reporter, useful to clinical teams, and followed by visible action. ADR reporting and medication-error reporting have different regulatory purposes, but the information from both should contribute to a shared hospital medication-safety programme.

The present review brings together freely accessible evidence from Indian hospitals to describe current reporting arrangements, explain persistent barriers, assess the contribution of pharmacists, and outline an integrated model that hospitals could adapt locally.

Methods

A structured narrative review was conducted. PubMed was searched up to 21 June 2026 with two complementary strategies. The first combined terms for medication errors, medication incidents, ADRs, pharmacovigilance, and near misses with terms for reporting, under-reporting, hospitals, and India. The second concentrated on barriers, knowledge, attitudes, safety culture, and pharmacist involvement in ADR or medication-error reporting. Both search strings are reproduced in Appendix 1.

English-language publications were eligible when they concerned Indian hospitals or hospital-linked pharmacovigilance activities and examined reporting performance, barriers or facilitators, professional knowledge or practice, educational or workflow interventions, digital systems, pharmacist roles, patient participation, or medication-error surveillance relevant to reporting-system design. Drug-specific ADR studies were included only when they also described how a hospital reporting system functioned or what it produced. Case reports, non-hospital

studies, and vigilance topics unrelated to medicines were excluded.

The primary search identified 229 records and the supplementary search 52. Removal of 42 duplicates left 239 unique records for screening. Sixty-three reports appeared potentially relevant; 43 were freely available in full text and met the eligibility criteria. Information was extracted on setting, design, participants, reporting domain, barriers, interventions, pharmacist activity, and outcomes. Publications were treated as direct evidence when they assessed reporting behaviour, barriers, interventions, reporter groups, or system implementation; as contextual evidence when they described hospital ADR or medication-error surveillance; and as background evidence when they were reviews, priority-setting studies, or protocols. The included literature ranged from cross-sectional surveys and qualitative studies to programme evaluations, prospective surveillance, retrospective analyses, and reviews. Because these designs and outcomes were not sufficiently comparable, the findings were synthesised narratively rather than statistically pooled. Formal risk-of-bias scoring was not undertaken because the review aimed to map implementation evidence across heterogeneous study types. Figure 1 summarises selection.

The author completed screening, eligibility assessment, data extraction, and narrative synthesis. All 43 full-text reports assessed for eligibility were included.

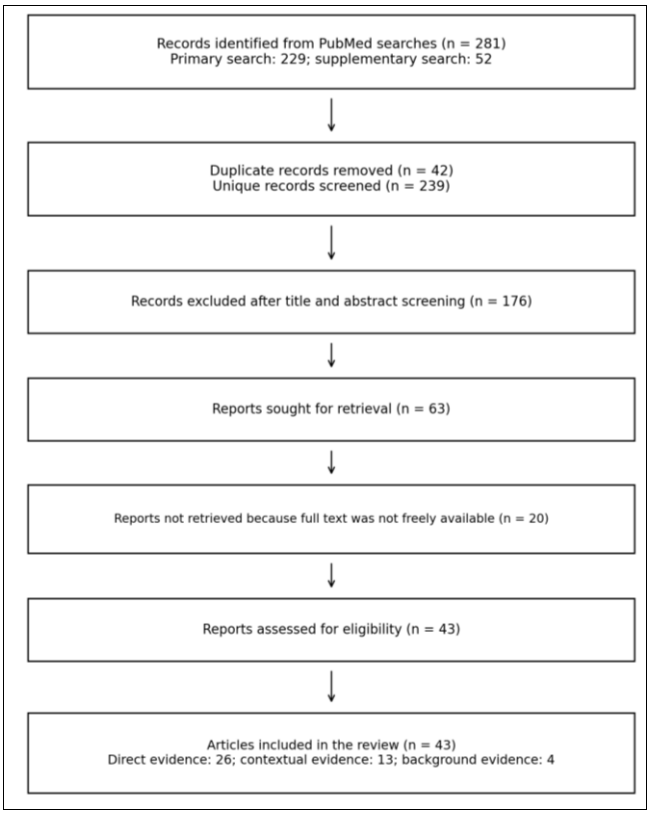

Fig 1: Flow of literature identification, retrieval, and inclusion.

Results and Discussion

Profile of the Evidence Base

The 43 publications were issued between 2007 and 2026[43]. Twenty-six directly investigated reporting behaviour, barriers, interventions, reporter groups, or implementation. Thirteen provided contextual information from hospital ADR or medication-error surveillance, and four were reviews, national priority-setting studies, or a digital-surveillance protocol. Most primary studies were single-centre investigations in tertiary teaching hospitals. Doctors and nurses were studied most often; pharmacists, patients, students, and hospital-wide reporter groups received much less attention.

Across settings, the literature repeatedly identified similar practical obstacles. Far less evidence was available on comparisons between reporting technologies, multicentre effectiveness, cost, long-term sustainability, or reductions in preventable harm.

Current Reporting Architecture and Performance

PvPI is the main national route for suspected ADR reports through AMCs and VigiFlow. From 2011 to 2021, public-sector partners supplied 55.1% of individual case safety reports and private partners 44.9%. Public-sector reports were more complete, indicating that wider participation must be accompanied by data-quality support [4]. An earlier AMC study also found that active surveillance generated many more reports than spontaneous methods and that contributions differed sharply between departments and professional groups [5].

Hospital incident systems capture a wider range of events. In a 2026 survey from a quaternary hospital, medication-related incidents formed the largest reported category, but reporting patterns varied among doctors, nurses, and allied health professionals. Staff still described fear of punishment, concern that their identity could be traced, and inadequate anonymity [6]. Another tertiary-hospital study found that only 22 of 80 healthcare professionals had ever reported an ADR. Reported barriers included poor understanding of the process (52%), low motivation (36%), time burden (31%), fear of legal liability (22%), and a complicated form (16%) [7].

Frontline workers also described substantial non-reporting, especially in solo practice, nursing homes, and public hospitals. They linked unsafe medication use to fear of punitive action, absent reporting mechanisms, staff shortages, inadequate training, poor communication, and missing standard procedures [8]. National ADR reporting and local incident reporting therefore address related but distinct safety needs, and both depend on effective implementation within hospitals.

Knowledge-Practice Gap and Reporting Barriers

Surveys from several regions showed a persistent gap between supportive attitudes and actual reporting. Resident doctors and nurses generally agreed that ADR reporting was necessary, yet few had reported and many asked for simpler channels, feedback, workshops, and continuing education [9]. At an AMC-linked teaching hospital, only 19.1% of doctors reported spontaneously; inadequate risk perception, fear, uncertainty, limited training, and poor awareness contributed to non-reporting [10]. In a northern Indian hospital, more than 60% of participants did not know how or where to submit an ADR report [11].

The same pattern appeared elsewhere. At one southern tertiary hospital, 64.4% of respondents had encountered an ADR but only 22.8% had ever reported one, and only around half had received training [12]. In Sikkim, 79% did not know that their hospital was linked to an AMC and 87% said that they were not submitting completed forms [13]. At an institution of national importance, 64.15% of doctors

named lack of procedural knowledge as the principal barrier, while only 8.5% had ever reported or published an ADR [14].

Studies involving younger professionals likewise found limited awareness, with lack of time and knowledge repeatedly mentioned [15]. Comparisons among physicians, nurses, and pharmacists showed weak overall knowledge, attitudes, and practices [16]. Focus-group research added organisational concerns: staff were unsure which events were reportable, feared blame, struggled with competing duties, and often could not see a clear reporting pathway or receive useful follow-up [17].

These barriers operate at several levels. At the individual level, staff may lack knowledge, confidence, or certainty about causality and preventability. Workflow problems include time pressure, documentation burden, high workload, and inaccessible forms. Cultural barriers arise from blame, hierarchy, fear, and reluctance to implicate colleagues. At the organisational level, weak leadership, limited confidentiality, poor feedback, fragmented responsibility, and failure to act on reports reduce trust in the system.

Educational and Implementation Interventions

Training generally improved knowledge and attitudes. Educational programmes for resident doctors increased knowledge, confidence, and reporting competence [18]. A one-hour session for doctors and nurses produced measurable gains in both groups and confirmed poor awareness as a major obstacle [19]. Postgraduate training also improved scores, although participants continued to report weak motivation and insufficient practical experience [20].

Changes in behaviour were clearer when education continued beyond a single session. One hospital programme doubled the number of ADR reports submitted by doctors and nurses [21]. Another study found better knowledge and attitudes after training but little correction of neglectful reporting behaviour [22]. Education alone is therefore unlikely to be enough. It needs to be accompanied by accessible tools, local champions, reminders, time to report, feedback, and evidence that reports lead to improvement.

Hospital monitoring programmes illustrate this combined approach. In a Mumbai teaching hospital, stimulated spontaneous reporting, chart review, reminders, and readily available forms supported ADR detection [23]. A clinical pharmacist-coordinated programme in secondary care showed that systematic monitoring was feasible and also described the clinical and financial burden of ADRs [24]. At a government teaching hospital, a simple system that included an ADR drop box collected 265 reports over 15 months [25].

Pharmacist Involvement

Pharmacists work across several stages of medication use and can connect clinical review with safety reporting. A national survey found that pharmacists were interested in pharmacovigilance but had important gaps in knowledge and practice; performance was better among those with higher qualifications, supporting competency-based training [26]. Their contribution can extend beyond submitting ADR forms to medication reconciliation, prospective review, detection of errors and near misses, causality and preventability assessment, completion and follow-up of reports, data-quality checks, trend analysis, feedback, and coordination of corrective actions.

One implementation study examined an open, anonymous, stand-alone, non-punitive medication-error programme initiated by pharmacists. Among 20,256 hospitalised patients, 1,310 errors were identified (6.4%). Administration and prescribing or transcription errors were most common, and distraction, workload, and communication problems were frequent contributing factors [27]. The study shows how pharmacists can coordinate a reporting programme rather than act only as individual reporters.

Pharmacist leadership should nevertheless remain multidisciplinary. A medication-safety committee should include medicine, nursing, quality staff, information technology, pharmacy, and hospital administration. Pharmacy can lead medication-specific classification and analysis, while responsibility for corrective action is shared across departments.

Expanding the Reporter Base

The reporter base can be widened to include trainees and patients. After sensitisation and structured clinical exposure, undergraduate medical students produced ADR reports of broadly similar quality to physician reports [28]. Patients were generally receptive to participating, but only 10% knew about PvPI and 37.7% had considered reporting an ADR [29]. Partnerships between public and private institutions can expand national coverage, although common training and quality controls are needed [4].

Hospitals should offer more than one route for reporting, including staff reporting, confidential near-miss reporting, patient or caregiver reports, and active surveillance. These streams can feed a single local learning process while suspected ADRs continue to follow the regulatory requirements of PvPI.

Medication-Error Reporting Beyond Adr Surveillance

Medication-error reporting is less standardised than ADR reporting. A study covering several Indian regions found uneven understanding of medication errors and reporting among healthcare personnel, supporting the need for common definitions and structured training [30]. In a public teaching hospital, 34% of reviewed patients had at least one prescribing error; the investigators recommended a hospital reporting system with clinical-pharmacist involvement [31].

Reported error rates also depended on how events were detected. Review of 6,705 critical-care charts identified 410 errors (6.11%), mainly transcription and prescribing errors, and highlighted the checkpoint role of clinical pharmacists [32]. An anonymous voluntary ICU system recorded 292 errors among 5,137 admissions (5.6%), with administration errors most frequent and workload, fatigue, and communication commonly implicated [33]. A broader tertiary-care study found 557 errors among 3,798 patients (14.6%) and recommended computerised prescribing, barcode-assisted administration, closed-loop medication management, and regular audit [34].

A national systematic review of 40 Indian studies found wide variation in incidence, frequency, detection methods, and severity classification [1]. Such variation makes comparisons difficult and supports the development of shared definitions, a minimum dataset, and rates based on clear denominators.

Learning from Hospital Adr Datasets

Hospital ADR databases can identify clinically relevant patterns, although most published reports describe the events collected rather than evaluate the reporting process itself. Studies from Raipur, Patna, Faridabad, and central India reported low or variable submission rates, differences between departments, frequent involvement of antimicrobials, and continued need for better awareness and case capture [35-38].

Other hospital studies described cutaneous ADRs, compared causality methods, examined ADRs associated with polypharmacy, or evaluated antidepressant safety [39-42]. These analyses are useful, but report volume alone does not show whether a system is improving care. Hospitals should also record whether reports lead to prescribing alerts, formulary restrictions, protocol changes, staff education, or fewer repeated events.

Digital Opportunities

Electronic records, pharmacovigilance databases, computerised order entry, barcode administration, and closed-loop systems may reduce repeated documentation and support active case finding. A current multistudy protocol is assessing electronic medical records and pharmacovigilance databases for surveillance of antimicrobial use, resistance, and ADRs in Indian hospitals [43]. Digital tools should fit clinical workflow, protect confidentiality, communicate with existing systems, and avoid creating another isolated data-entry task.

Automated triggers may flag high-risk laboratory changes, antidote use, sudden drug discontinuation, or other possible harm signals. These tools require clinical validation rather than automatic reporting. Pharmacists can review the trigger, determine whether the event is more consistent with an ADR or a medication error, and direct it to the appropriate local or national pathway.

Proposed Integrated Reporting and Learning Model

The evidence supports a practical hospital model built around the following elements:

- **Unified governance:** create a multidisciplinary medication-safety committee with executive support, defined authority, and a pharmacist serving as coordinator.
- **Comprehensive scope:** include suspected ADRs, errors in prescribing, dispensing, administration and monitoring, near misses, unsafe conditions, and concerns raised by patients, while retaining PvPI requirements for regulatory ADR reports.
- **Psychological safety:** state clearly that reporting is confidential and primarily non-punitive; allow anonymous reports where appropriate and keep improvement review separate from disciplinary action except in cases of deliberate unsafe conduct.
- **Low-burden reporting:** begin with a short initial report available on ward-based, mobile, and desktop routes, followed by structured completion by trained safety staff when further information is required.
- **Pharmacist-led triage and analysis:** use pharmacists to verify medication details, classify the event, assess causality, preventability and severity, identify recurring patterns, and coordinate follow-up.
- **Feedback and visible learning:** acknowledge reports, return unit-level feedback, share de-identified lessons, and document the corrective and preventive actions that follow.
- **Standardised measurement:** agree on definitions and denominators, and monitor report rates, near-miss capture, completeness, time to feedback, completion of actions, recurrence, and harm outcomes.
- **Digital interoperability:** link incident-reporting software with electronic medical records, pharmacy systems, and AMC or VigiFlow processes to reduce duplicate entry.
- **Continuous competency development:** combine induction training with repeated case discussion, simulation, local champions, and periodic assessment instead of relying on a single lecture.
- **Patient and trainee engagement:** provide simple reporting options for patients and caregivers, include ADR and medication-error reporting in clinical education, and treat reports from trainees as an additional source of safety information.

Table 1: Priority actions for strengthening medication-safety reporting in Indian hospitals.

Level	Priority action	Lead responsibility	Suggested indicator
Hospital governance	Adopt a confidential, non-punitive medication-safety policy and establish one coordinating committee	Hospital leadership and quality unit	Meeting regularity; action closure; staff safety-culture score
Reporting process	Provide a short initial report through confidential ward, mobile, and desktop routes	Quality, information technology, and pharmacy	Time to submit; near-miss proportion; range of reporter groups
Clinical analysis	Use pharmacist-led validation, classification, follow-up, and review of recurring patterns	Clinical pharmacy and AMC	Completeness; validation time; rate of repeated events
Learning and feedback	Acknowledge reports, return unit feedback, and circulate de-identified safety lessons	Medication-safety committee	Feedback within 14 days; CAPA completion; recurrence after action
Digital systems	Connect incident software with electronic records, pharmacy systems, and PvPI processes	Information technology, pharmacy, and AMC	Duplicate entry avoided; trigger yield; uptime and usability
Workforce development	Repeat case-based training and assess practical reporting competence	Medical, nursing, and pharmacy education leads	Training coverage; competence; reports per trained unit
National alignment	Use a shared taxonomy, minimum dataset, and denominator-based measures	IPC/PvPI, accreditation bodies, and professional organisations	Benchmark participation; standardised completeness and reporting rates

Abbreviations

AMC, ADR Monitoring Centre; CAPA, corrective and preventive action; EMR, electronic medical record; IPC, Indian Pharmacopoeia Commission; IT, information technology; PvPI, Pharmacovigilance Programme of India.

Research priorities

- Compare reporting systems across public and private hospitals, accredited and non-accredited institutions, and secondary and tertiary care settings.
- Test anonymous versus identified reporting, shorter forms, digital channels, feedback dashboards, and pharmacist-coordinated models using controlled designs.
- Measure whether reporting interventions reduce recurrence, preventable harm, length of stay, cost, or poor safety culture, rather than relying mainly on knowledge scores.
- Develop and validate a national minimum dataset and a medication-incident taxonomy that can be used across Indian hospitals.
- Evaluate staffing requirements, workflow effects, cost, and long-term sustainability before wider implementation.
- Study patient reporting, automated triggers, natural-language processing, and practical links between hospital incident systems and PvPI.

Limitations

This review has several limitations. Only PubMed was searched, and eligibility was restricted to reports that were freely available in full text. Subscription-only articles, studies outside indexed databases, and grey literature may therefore have been missed. The evidence was heterogeneous and largely consisted of single-centre cross-sectional surveys and descriptive surveillance, which limits causal inference and national generalisability. Studies used different knowledge and attitude instruments, denominators, and detection methods, so reporting rates were not directly comparable. No formal risk-of-bias assessment or meta-analysis was undertaken. The findings should therefore be read as an implementation-focused map of the available evidence rather than a complete estimate of effectiveness. Screening and data extraction were performed by one reviewer, which may have introduced selection or extraction error.

Conclusion

Under-reporting in Indian hospitals cannot be explained by lack of knowledge alone. It is also shaped by workload, uncertainty, professional hierarchy, fear of blame, weak confidentiality, fragmented responsibilities, and limited feedback. Training can prepare staff to report, but lasting improvement requires changes to the reporting system itself. Hospitals should bring ADRs, medication errors, near misses, and unsafe conditions into a confidential learning process, give pharmacists a defined coordinating and analytical role, return feedback promptly, and link local improvement work with national pharmacovigilance. Future studies should test these approaches across multiple hospitals and determine whether they reduce repeated errors and preventable harm.

Declarations

Ethics approval: Not applicable. The review used published literature and did not involve human participants or animals.

Conflicts of interest: None declared.

Data availability: All information synthesised in this review is available in the cited publications.

Author contribution: Shubham Kumar Vohra designed the review, developed the search strategy, screened the records, selected the literature, extracted and synthesised the findings, drafted and revised the manuscript, and approved the final version.

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