ISSN: 2320-9267

Indian Journal of Pharmaceutical and Biological Research (IJPBR)

Journal homepage: www.ijpbr.in

REVIEW ARTICLE

From Awareness to Action: A Systematic Review of Public Awareness, Reporting Barriers and Strategies to Strengthen Adverse Drug Reaction Reporting to Pharmacovigilance Systems

Gopinatha K[1]*, Shekar H S[1], Chandrika C[1].

ABSTRACT

Background: Spontaneous reporting is the cornerstone of post-marketing drug safety surveillance, but under-reporting limits what it can detect. Direct patient reporting, pharmacist involvement and hospital-based programmes have been introduced to widen and deepen reporting, yet the evidence on public awareness and on what improves reporting is scattered across study designs and reporter groups. **Objective:** To synthesise evidence on (i) public and patient awareness of adverse drug reaction (ADR) reporting systems, (ii) barriers to and facilitators of reporting by patients and professionals, and (iii) the effect of pharmacist-led and hospital-based strategies, and to establish whether urban–rural comparisons were available. **Methods:** The review followed the PRISMA 2020 statement. PubMed/MEDLINE, Embase, Web of Science, Scopus and the Cochrane Library were searched up to early 2026, supplemented by manual searches. Data were extracted into a standardised matrix, methodological limitations were appraised according to study design, and findings were synthesised narratively. **Results:** Twenty-five studies (23 primary studies and two narrative reviews) from 15 countries, published between 1989 and 2025, were included. Twelve examined public or patient awareness, knowledge or usability of reporting tools; five examined reporter groups or national system performance; four examined pharmacist-based reporting; and four evaluated hospital-based detection programmes. Awareness and knowledge were low wherever they were measured: 8% of respondents were aware of the national system in Malaysia, 8.5% had heard of the Yellow Card Scheme in Great Britain, only 4.3% of Saudi respondents had adequate knowledge, and 98.8% of Indian inpatients were unaware of the national programme, even though attitudes towards reporting were largely positive where assessed. Recurring barriers were complex reporting forms, uncertainty about whether a symptom was drug-related, reliance on healthcare professionals, limited time and weak institutional capacity. Educational intervention improved awareness (by 41.2% for the need for a hospital pharmacovigilance centre in Pakistan), pharmacist involvement facilitated patient reporting in Italy, and structured hospital programmes increased report numbers (from 0.4 to 20 per month in one programme). No included study reported urban–rural disaggregated data. **Conclusion:** Low awareness and practical barriers, rather than unwillingness alone, appear to limit ADR reporting. Simpler reporting tools, pharmacist-linked reporting, targeted education and structured institutional detection are the best-supported strategies. Future studies should use validated instruments, representative sampling and report results by place of residence.

Keywords: pharmacovigilance; adverse drug reaction reporting; patient reporting; public awareness; under-reporting; community pharmacist; systematic review

INTRODUCTION

Pharmacovigilance, 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 problem, is fundamental to post-marketing drug safety.1 Spontaneous reporting systems are a cornerstone of post-marketing surveillance because they can reveal safety signals linked to rare, delayed or idiosyncratic adverse drug reactions (ADRs) that pre-approval clinical trials may not detect.2,3 Their yield, however, is limited by under-reporting: a systematic review of 37 studies found a median under-reporting rate of 94% (interquartile range 82–98%).4 Factors associated with under-reporting by healthcare professionals include inadequate knowledge and negative attitudes towards reporting.[5]

To broaden the sources of ADR reports, regulators have established direct patient-reporting pathways. Directive 2010/84/EU requires European Union Member States to enable patients to report suspected adverse reactions to national competent authorities,6 and the US Food and Drug Administration's MedWatch programme has accepted voluntary reports since 1993.7 Reports from patients and from healthcare professionals have been compared systematically, showing both similarities and differences in reporter behaviour.[8]

© The Author(s). 2026 Open Access This article is distributed under the terms of the Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and non-commercial reproduction in any medium, provided you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license, and indicate if changes were made. The Creative Commons Public Domain Dedication waiver (http://creativecommons.org/publicdomain/zero/1.0/) applies to the data made available in this article, unless otherwise stated.

[1]Department of Pharmacy Practice, Visveswarapura Institute of Pharmaceutical Sciences Bengaluru, Karnataka, India

Corresponding author: Dr. Gopinatha K, Research scholar Department of Pharmacy Practice, Visveswarapura Institute of Pharmaceutical Sciences Bengaluru, Karnataka, India

How to cite this article: Gopinatha, K., Shekar, H. S., & Chandrika. From Awareness to Action: A Systematic Review of Public Awareness, Reporting Barriers and Strategies to Strengthen Adverse Drug Reaction Reporting to Pharmacovigilance Systems. Indian J. Pharm. Biol. Res. 2026;14(4):423-435

Conflict of Interest: None declared.

Source of Funding: Nil.

Received: 11.9.26 Revised: 20.10.26 Accepted: 31.10.26

Despite these mechanisms, patient awareness of reporting systems remains limited. A systematic review of patient reporting identified poor familiarity with reporting systems among the main barriers,9 and in Ghana only 3% of 491 surveyed participants were aware of the Food and Drugs Authority's Patient Reporting System.10 Awareness may also vary with place of residence: a multilevel analysis of national survey data from Nigeria found that urban residents were more likely than rural residents to know of the Pharmacovigilance Programme,11 and reviews of health literacy and eHealth literacy suggest that geographic and educational gradients may shape engagement with health information.12,13

Evidence on how to close the gap between experiencing an ADR and reporting it is dispersed across designs (population surveys, usability studies, database analyses, pharmacy-based interventions and hospital programmes) and across reporter groups (the public, patients, nurses, pharmacists and physicians). To our knowledge, no systematic review has brought these strands together in a single synthesis of awareness, barriers and strategies. This review therefore aimed to (i) synthesise evidence on public and patient awareness and knowledge of ADR reporting systems; (ii) identify barriers to and facilitators of reporting by patients and professionals; (iii) summarise the effect of pharmacist-led, educational and hospital-based strategies on reporting; and (iv) examine whether the available studies allowed a comparison between urban and rural populations.

2. METHODS

2.1 Protocol and reporting standards:

This systematic review was conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 statement.14 The protocol for this review was not prospectively registered.

2.2 Information sources and search strategy:

Five electronic databases (PubMed/MEDLINE, Embase, Web of Science, Scopus and the Cochrane Library) were searched from inception to early 2026. Medical Subject Headings (MeSH) and free-text terms were combined with Boolean operators and adapted to each database. The core strategy for PubMed was:

("Pharmacovigilance"[Mesh] OR "Adverse Drug Reaction Reporting Systems"[Mesh] OR "adverse drug reaction reporting" OR "patient reporting" OR "consumer reporting" OR "spontaneous reporting" OR "under-reporting") AND ("Awareness"[Mesh] OR "Health Literacy"[Mesh] OR "Health Knowledge, Attitudes, Practice"[Mesh] OR "knowledge" OR "attitude" OR "barriers" OR "pharmacist" OR "educational intervention")

Reference lists of included articles and documents from the WHO and national regulatory and monitoring bodies were also searched manually. The full database-specific search strategies are available from the authors on request.

2.3 Eligibility criteria:

Studies were eligible if they (i) were peer-reviewed full-text articles published in English; (ii) addressed awareness, knowledge, practice, barriers or facilitators of ADR reporting, or evaluated a strategy, programme or system intended to improve ADR reporting; and (iii) involved the general public, patients or consumers, or healthcare professionals and institutions that report ADRs. Original studies of any design (cross-sectional, qualitative, mixed-methods, database analyses, intervention and programme evaluations) and review articles that bore directly on ADR reporting were considered; review articles were retained to provide context and were not used in any quantitative description. Editorials, conference abstracts without a full methodology and studies of drug adherence, self-medication or drug utilisation that did not assess ADR reporting were excluded. Whether a study reported data stratified by urban or rural residence was recorded as a secondary extraction item and was not an inclusion requirement.

2.4 Study selection and data extraction:

Two reviewers independently screened titles and abstracts and then full texts against the eligibility criteria; disagreements were resolved by discussion. Data were extracted into a standardised matrix recording first author, year, country and World Bank income setting, study design, sample size or data source, principal findings relating to ADR reporting, and any urban–rural stratification.

2.5 Methodological appraisal:

Because the included studies used different designs, methodological quality was appraised in a design-appropriate way. The Newcastle–Ottawa Scale adapted for cross-sectional studies15 served as the reference framework for the survey studies, with attention to sample representativeness, sample size, response rate, validity of the measurement tool and statistical reporting. For qualitative, database-based, interventional, programme-evaluation and review designs, principal strengths and limitations were recorded narratively. No study was excluded on the basis of quality.

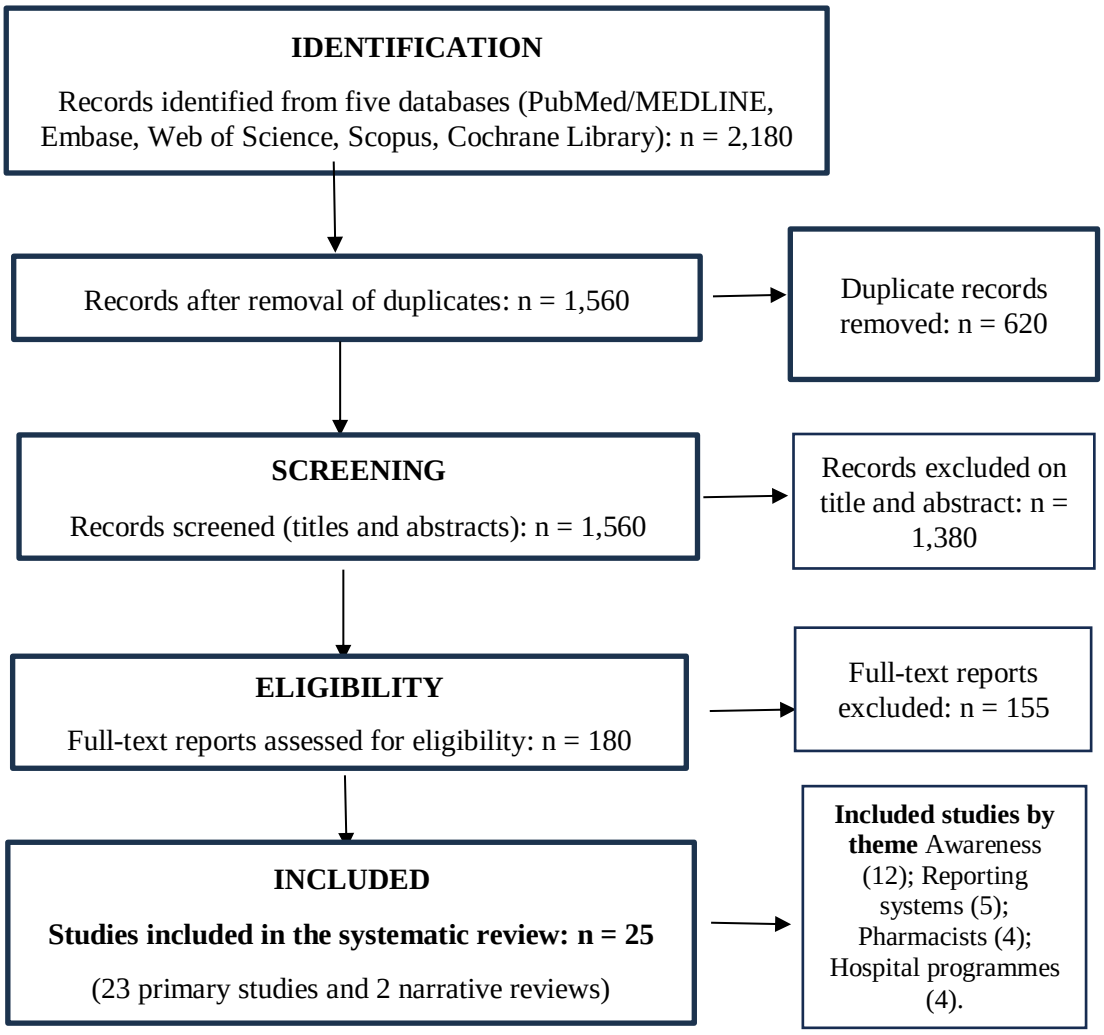
2.6 Data synthesis:

Clinical and methodological heterogeneity precluded meta-analysis. Findings were therefore synthesised narratively, grouping studies into four themes defined a priori from the review objectives: (1) awareness, knowledge and usability among the public and patients; (2) reporter groups, report characteristics and national system performance; (3) pharmacist involvement; and (4) hospital-based detection and reporting programmes. Proportions are reported as given in the original articles, and studies are presented in chronological order of publication within each theme.

3. RESULTS

3.1 Study selection:

Figure 1. PRISMA 2020 study selection flow diagram.



3.2 Characteristics of the included studies:

The 25 included studies were published between 1989 and 2025 (five before 2000, nine between 2005 and 2014, and eleven between 2018 and 2025) and were conducted in 15 countries in Asia, Africa, Europe and North America. Of the 25, 14 were from high-income countries, two from upper-middle-income countries, eight from low- and middle-income countries and one from a mixed group of three Arab countries (Table 1). Twelve studies examined public or patient awareness, knowledge or the usability of reporting tools; five examined reporter groups or national system performance; four examined pharmacist involvement; and four evaluated hospital-based programmes (Table 2). Twenty-three were primary studies and two were narrative reviews. The sample sizes of the eleven population surveys ranged from 172 to 2,028 participants.

Methodological observations:

The survey studies were mostly single-setting or non-probability designs: three were conducted in hospital or tertiary settings, one in primary healthcare centres, two used online self-administered questionnaires (one with convenience and snowball sampling), and one used a national telephone omnibus survey (Table 1). The usability study enrolled 40 participants, and in one observational study only 88 of 152 accepted post-discharge questionnaires were returned. The programme evaluations from 1989 to 1990 were single-institution, uncontrolled evaluations of professional reporting rather than of patient reporting. The two review articles were narrative and were not appraised for risk of bias.

Urban–rural data:

None of the 25 studies reported results disaggregated by urban or rural residence, so a pooled or stratified comparison could not be made. This was treated as a finding of the review rather than as an analytical gap to be filled by inference.

Table 1. Characteristics and principal findings of the included studies (n = 25)

No.	Study (first author, year)	Country / income setting	Design	Sample / data source	Principal findings relevant to ADR reporting
1	Keith et al., 1989 [16]	United States / HIC	Multidisciplinary hospital ADR detection and evaluation programme (concurrent chart review, pharmacist assessment, committee review)	Not reported; reporting rate evaluated	Nurse-led chart screening, pharmacist follow-up, causality assessment and multidisciplinary review raised reports from 0.4 to 20 per month; the previous voluntary system yielded fewer than one report a month.
2	Gilroy et al., 1990 [17]	United States / HIC	Hospital ADR surveillance programme coordinated by pharmacists to encourage physician reporting	249 reports in total; 175 from house staff over 12 months	Pharmacist–physician interaction, feedback, promotion and a US$5 payment per report were used. House-staff reports rose from about 4 voluntary reports a year to 175 in the 12-month evaluation.
3	Johnston et al., 1990 [18]	United States / HIC	Hospital monitoring programme with computerised ADR reporting, concurrent chart review and multidisciplinary evaluation	340 ADRs reported in the first 9 months	Quality-assurance nurses reviewed charts every three days; pharmacists and hospital committees evaluated identified ADRs. The programme facilitated rapid detection and trend analysis; 15 reports were submitted to the FDA. Newsletters and targeted education supported the programme.

No.	Study (first author, year)	Country / income setting	Design	Sample / data source	Principal findings relevant to ADR reporting
4	Koch, 1990 [19]	United States / HIC	Hospital ADR monitoring using standardised screening procedures and spontaneous reporting	298 ADRs identified in the first 7 months	Standardised screening identified 149 ADR reports. Screening of laboratory results, antidote orders and tracer drugs improved detection relative to voluntary reporting alone; physicians reported infrequently, mostly serious or unexpected reactions.
5	Taras-Zasowski and Einarson, 1999 [20]	Canada / HIC	Literature review of pharmacist involvement in ADR reporting and hospital ADR incidence	Not applicable (review)	Pharmacists can contribute to ADR recognition, evaluation and reporting; about 17% of hospital patients in the cited Canadian studies developed an ADR. The time needed for reporting may deter pharmacist participation.
6	van Grootheest et al., 2005 [21]	Netherlands / HIC	Descriptive analysis of patient reports versus doctor and pharmacist reports in the first year of direct patient reporting	276 patient reports; 3,131 doctor and pharmacist reports	Patient reports generally contained sufficient medical information and more often described serious suspected ADRs; the system was continued after the first year.
7	van Grootheest and de Jong-van den Berg, 2005 [22]	Netherlands / HIC	Literature overview of the roles of hospital and community pharmacists	Not applicable (review)	Hospital pharmacists can identify serious ADRs associated with hospital care; community pharmacists contribute substantially to the number and quality of reports.
8	Carleton et al., 2007 [23]	Canada / HIC	Retrospective analysis of paediatric suspected ADR reports to Health Canada (January 1998–May 2002)	1,193 reports	61% of reports were serious and 41 deaths were recorded. The authors highlighted insufficient ADR reporting and recommended more detailed reports and trained surveillance personnel.
9	Jarernsiripornkul et al., 2009 [24]	Thailand / UMIC	Six-month observational study at a tertiary teaching hospital comparing doctors' ADR records, patients' reported symptoms and formal reporting	203 inpatients; 152 post-discharge questionnaires accepted, 88 returned	Patients reported 249 post-discharge symptoms, of which 190 (76%) were judged probable or possible ADRs by pharmacists. Doctors documented only five symptoms on formal ADR forms, and the Thai FDA received four reports for the 13 studied drugs, none from the hospital.

No.	Study (first author, year)	Country / income setting	Design	Sample / data source	Principal findings relevant to ADR reporting
10	Anderson et al., 2012 25	United Kingdom / HIC	Qualitative usability study (think-aloud observation of paper and internet reporting; telephone reporting)	40 participants	Difficulties completing forms and with the usability of online reporting.
11	Conforti et al., 2012 26	Italy / HIC	Retrospective analysis of the Italian pharmacovigilance database (January 2004–December 2010); nurse versus hospital physician reports	1,403 nurse reports	Serious ADRs made up 22.9% of nurses' reports versus 44.9% of physicians' reports; probable ADRs were more frequent in nurses' reports (76% vs 67%).
12	Fortnum et al., 2012 27	Great Britain / HIC	Cross-sectional telephone omnibus survey	2,028 respondents	Low awareness of the Yellow Card Scheme: 8.5% had heard of it.
13	Leone et al., 2013 28	Italy / HIC	Four-month community-pharmacy intervention promoting patient ADR reporting (Veneto region)	52,495 customers interviewed; 4,949 reported a suspected ADR; 2,311 forms received; 1,794 entered in the national database	Pharmacist involvement facilitated patient reporting. 9.4% of customers reported a suspected ADR and 46.7% of these submitted a form. Patient reports were generally of good quality and complemented those of general practitioners.
14	Parretta et al., 2014 29	Italy / HIC	Community-pharmacist intervention promoting direct patient ADR reporting (Campania region)	18,677 patients interviewed; 10.88% reported experiencing an ADR	54.32% of forms were entered in the Italian spontaneous reporting system after quality control; patient reports reached about 7% of spontaneous reports. Pharmacist involvement facilitated reporting; patients mainly reported non-serious (91.28%) and expected (94.62%) ADRs.
15	Hariraj and Aziz, 2018 30	Malaysia / UMIC	Cross-sectional public survey	860 respondents	Only 8% (69/860) were aware of the national ADR monitoring system; 60% felt confident to report. Ease of completing the reporting form was the strongest predictor of confidence (OR 18.45; 95% CI 10.55–32.25).
16	Jacobs et al., 2018 10	Ghana / LMIC	Quantitative survey with qualitative interviews	572 participants	Low awareness of formal channels for reporting ADRs.

No.	Study (first author, year)	Country / income setting	Design	Sample / data source	Principal findings relevant to ADR reporting
17	Adisa and Omitogun, 2019 31	Nigeria / LMIC	Questionnaire-guided cross-sectional survey in 10 primary healthcare centres	360 patients (80 health workers surveyed separately)	Awareness of pharmacovigilance among patients was 8.6%; 18.6% had reported ADRs they had previously experienced.
18	Patel et al., 2019 32	India / LMIC	Cross-sectional study; investigator-administered questionnaire among hospital inpatients	820 inpatients	98.8% were unaware of the Pharmacovigilance Programme of India; 32.2% did not know that medicines could cause adverse effects.
19	Thadani et al., 2019 33	India / LMIC	Cross-sectional questionnaire-based study at a tertiary care hospital (Lucknow)	172 participants	54.2% were uncertain whether symptoms were caused by medicines; knowledge of reporting procedures was incomplete and patients relied on healthcare professionals.
20	Garashi et al., 2022 34	Jordan, Oman and Kuwait / mixed	Mixed-methods study: document review, semi-structured interviews and a questionnaire based on WHO pharmacovigilance indicators	56 key informants; questionnaire completed by the Omani and Kuwaiti national centres	Inadequate or absent regular funding and staffing, weaknesses in reporting rates and reporter awareness, and limited signal-detection performance.
21	Rehman et al., 2022 35	Pakistan / LMIC	Pre- and post-intervention cross-sectional survey (health-promotion brochure and counselling)	423 participants	Limited baseline awareness and knowledge of pharmacovigilance; awareness of the need for a hospital pharmacovigilance centre improved by 41.2% after the intervention.
22	Binu KM et, 2023 36	India / LMIC	Questionnaire-based consumer survey with an educational intervention	375 pre-interventions; 100 post-interventions	Low baseline awareness of ADRs and of reporting systems.
23	Alshehri et al., 2024 37	Saudi Arabia / HIC	Cross-sectional study, self-administered online questionnaire	1,098 respondents	Only 4.3% of respondents had adequate knowledge of pharmacovigilance, whereas 83.4% had a positive attitude and 34.5% had good practice.
24	Iffat et al., 2025 38	Pakistan / LMIC	Cross-sectional online questionnaire; convenience and snowball sampling	384 respondents	Low awareness of the national ADR reporting form and reluctance to report ADRs.

No.	Study (first author, year)	Country / income setting	Design	Sample / data source	Principal findings relevant to ADR reporting
25	Jhaj et al., 2025 39	India / LMIC	Cross-sectional study at a tertiary healthcare centre	203 participants	Awareness of the consumer reporting form was 6.4%.

ADR, adverse drug reaction; FDA, Food and Drug Administration; HIC, high-income country; LMIC, low- and middle-income country; UMIC, upper-middle-income country.

Table 2. Distribution of the included studies by theme.

Theme	n	Studies	Principal designs
1. Awareness, knowledge and usability among the public and patients	12	10, 25, 27, 30–33, 35–39	Cross-sectional surveys (including online, telephone and hospital-based), qualitative usability study, pre–post educational interventions
2. Reporter groups, report characteristics and system performance	5	21, 23, 24, 26, 34	Mixed-methods system assessment, retrospective database analyses, descriptive and observational comparisons
3. Pharmacist involvement	4	20, 22, 28, 29	Two community-pharmacy interventions; two narrative reviews
4. Hospital-based detection and reporting programmes	4	16–19	Single-institution programme evaluations

Percentages and counts of studies are based on the 25 included studies.

3.3 Theme 1: Awareness, knowledge and usability among the public and patients:

Awareness of reporting systems was low in every study that quantified it. In Great Britain, 8.5% of 2,028 adults had heard of the Yellow Card Scheme.[27] In Malaysia, only 8% of 860 respondents were aware of the national ADR monitoring system,[30] and in Ghana awareness of formal reporting channels was low.[10] Awareness of pharmacovigilance among patients attending primary healthcare centres in Nigeria was 8.6%,[31] and 98.8% of Indian hospital inpatients were unaware of the national Pharmacovigilance Programme.[32] Baseline awareness and knowledge were limited in Pakistan[35] and in an Indian consumer survey with an educational component.[36] In Saudi Arabia, only 4.3% of 1,098 respondents had adequate knowledge of pharmacovigilance, although 83.4% had a positive attitude and 34.5% reported good practice.[37] Awareness of the national reporting form was low in Pakistan[38] and was 6.4% for the consumer reporting form in a tertiary centre in India.[39]

Knowledge of ADRs themselves was also incomplete, and reporting in practice was uncommon. Among patients in Nigeria, 18.6% had reported ADRs they had previously experienced.[31] In Indian hospital surveys, 32.2% of inpatients did not know that medicines could cause adverse effects[32] and, in another, 54.2% were uncertain whether their symptoms were caused by medicines.[33]

Usability and confidence emerged as a distinct barrier. Think-aloud testing of paper, internet and telephone reporting in the United Kingdom identified difficulties in completing forms and in using the online route.[25] In Malaysia, ease of completing the reporting form was the strongest predictor of confidence to report (odds ratio 18.45; 95% confidence interval 10.55–32.25).[30] Indian patients relied on healthcare professionals and had incomplete knowledge of reporting procedures,[33] and reluctance to report accompanied low awareness in Pakistan.[38] Educational intervention was associated with improvement: awareness of the need for a hospital pharmacovigilance centre rose by 41.2% after a brochure and counselling intervention in Pakistan.[35]

3.4 Theme 2: Reporter groups, report characteristics and system performance:

Patient reports were informative. In the first year of direct patient reporting in the Netherlands, 276 patient reports were compared with 3,131 reports from doctors and pharmacists; patient reports generally contained sufficient medical information and more often described serious suspected ADRs, and the system was continued.[21] In a Thai teaching hospital, patients described 249 post-discharge symptoms, of which pharmacists judged 190 (76%) probable or possible ADRs, yet doctors documented only five symptoms on formal ADR forms

and the national authority received four reports for the 13 studied drugs, none from the hospital.[24] By contrast, patients reporting through a community-pharmacy intervention in Campania, Italy, mainly described non-serious (91.28%) and expected (94.62%) ADRs,[29] which may reflect differences in how reporting was solicited.

Professional reports showed their own gaps and strengths. An analysis of 1,193 paediatric reports to Health Canada found that 61% were serious and 41 deaths were recorded, and the authors concluded that reporting was insufficient and that dedicated, trained surveillance personnel were needed.[23] Nurses contributed 1,403 reports to the Italian database; their reports included a lower proportion of serious ADRs than physicians' reports (22.9% vs 44.9%) but a higher proportion of probable ADRs (76% vs 67%), suggesting that nurses extend detection beyond the most severe events.[26]

At system level, a mixed-methods assessment of three Arab countries using WHO pharmacovigilance indicators identified inadequate or absent regular funding and staffing, weaknesses in reporting rates and reporter awareness, and limited signal-detection performance.[34]

3.5 Theme 3: Pharmacist involvement:

Two narrative reviews described the contribution of pharmacists. A Canadian review concluded that pharmacists can contribute to ADR recognition, evaluation and reporting, while noting that the time required may discourage participation.[20] A later overview described complementary roles: hospital pharmacists can identify serious ADRs associated with hospital care, and community pharmacists contribute substantially to the number and quality of reports.[22] Two Italian regional interventions then engaged community pharmacists to promote patient reporting. In Veneto, 4,949 of 52,495 customers interviewed (9.4%) reported a suspected ADR, 2,311 forms were received (46.7% of those reporting) and 1,794 were entered in the national database after quality control; patient reports were generally of good quality and complemented those of general practitioners.[28] In Campania, 10.88% of 18,677 interviewed patients reported experiencing an ADR, 54.32% of forms were entered after quality control, and patient reports reached about 7% of spontaneous reports.[29] Both studies concluded that pharmacist involvement facilitated patient reporting.

3.6 Theme 4: Hospital-based detection and reporting programmes:

Four single-institution programmes from 1989 to 1990 showed that active, structured detection raised reporting. A multidisciplinary programme using nurse-led chart screening, pharmacist follow-up and committee review raised monthly reports from 0.4 to 20, compared with fewer than one a month under the previous voluntary system.[16] A pharmacy-coordinated programme that combined close pharmacist–physician interaction, feedback, promotion and a small payment per report increased house-staff reports from about four a year to 175 in 12 months.[17] A computerised monitoring programme identified 340 ADRs in nine months, but only 15 reports were submitted to the FDA, illustrating the distance between internal detection and external reporting.[18] Standardised screening of laboratory results, antidote orders and tracer drugs improved detection compared with voluntary reporting alone, whereas physicians reported infrequently and tended to report serious or unexpected reactions.[19]

3.7 Barriers and facilitators

The barriers and facilitators recurring across the four themes are summarised in Table 3.

Table 3. Barriers to and facilitators of ADR reporting identified in the included studies.

Domain	Barriers	Facilitators or strategies	Supporting studies
Awareness and knowledge	Unawareness of national reporting systems and forms; not knowing that medicines can cause adverse effects; uncertainty about whether a symptom is drug-related	Educational intervention with brochure and counselling; educational programmes targeting low baseline awareness	10, 27, 30–33, 35, 36, 39
Reporting tools and usability	Complex reporting forms; difficulty using online reporting	Forms that are easy to complete (the strongest predictor of confidence to report)	25, 30
Reporter attitudes and behaviour	Reluctance to report; reliance on healthcare professionals; time required; infrequent and selective reporting by physicians	Feedback, promotion and incentives within programmes; involvement of nurses and pharmacists as reporters	17, 19, 20, 26, 33, 38

Domain	Barriers	Facilitators or strategies	Supporting studies
Health-system and institutional capacity	Inadequate funding and staffing; weak signal detection; insufficient trained surveillance personnel; large gap between observed ADRs and formal reports	Pharmacist-supported reporting; standardised screening; multidisciplinary review; computerised monitoring; regular education	16, 18, 19, 22–24, 28, 29, 34

Numbers in the final column refer to the reference list.

4. DISCUSSION

4.1 Principal findings:

This systematic review of 25 studies suggests that the limited contribution of patients and many professionals to ADR reporting reflects, in large part, low awareness, uncertainty about causality and practical barriers, rather than an unwillingness to report. Awareness of national reporting systems was low across settings and decades. The most consistent strategies associated with higher reporting were simpler tools, educational intervention, pharmacist involvement and structured, multidisciplinary detection within institutions.

4.2 Comparison with existing evidence:

The finding of low awareness is consistent with an earlier systematic review of patient reporting, which listed poor familiarity with reporting systems among the principal barriers,[9] and with the very high estimates of under-reporting in the wider literature.[4] Our synthesis adds quantified awareness figures from several health systems and shows that the gap is not confined to settings that adopted patient reporting recently: it was also evident in Great Britain, where patient reporting has been accepted since 2005.[27] The observation that ease of completing the form was the strongest predictor of confidence to report in Malaysia[30] aligns with the usability problems documented in the United Kingdom,[25] and suggests that simplifying reporting tools is a modifiable target in its own right.

Patient reports appear to add value, but their character depends on context. Dutch patient reports more often described serious ADRs than professional reports,[21] whereas the Italian pharmacy-based interventions captured mainly non-serious and expected reactions.[29] Taken together with the comparison of reporter groups in the wider literature,[8] this indicates that patient reporting is complementary and that its profile is shaped by the way reporting is promoted. The Thai observation that clinicians recorded few of the symptom's patients described[24] reinforces the rationale for patient reporting, and the Italian nurse data[26] support a broader reporter base within healthcare teams, in line with the evidence that knowledge and attitudes influence professional reporting.[5]

The pharmacist-based studies showed that reporting can be mobilised at the point of dispensing,[28,29] and the narrative reviews describe complementary hospital and community roles while noting time constraints.[20,22] The hospital programmes demonstrate that active detection, feedback and multidisciplinary review can raise report numbers substantially,[16,17] but they also illustrate a limit: detection within an institution does not guarantee that reports reach the regulator.[18] These programmes are three decades old and concern professional rather than consumer reporting, so their findings should be regarded as proof of principle rather than as a template for current systems. National capacity is a further determinant: funding, staffing and signal-detection limitations were reported in three Arab countries.[34]

4.3 Urban–rural differences: an evidence gap:

None of the 25 included studies disaggregated results by urban or rural residence. Indirect evidence suggests that residence may matter: urban residents were more likely than rural residents to be aware of the national programme in a multilevel analysis from Nigeria,[11] and a systematic review found that most studies reported higher health literacy in urban than in rural populations, although rurality alone did not explain the difference and sociodemographic factors played important roles;[12] a separate review addressed the digital divide in eHealth literacy among underserved populations in the United States.[13] Because these sources do not address ADR reporting directly or compare reporting behaviour across settings, we cannot conclude that urban–rural differences exist in the included evidence. Future survey studies should record and report place of residence, education and digital access so that this question can be answered directly.

4.4 Implications for practice and policy:

The evidence supports four practical measures: (i) simplifying reporting forms and offering more than one reporting channel, since ease of use predicted confidence and online use was difficult for some participants;[25,30] (ii) integrating pharmacists into reporting, with attention to the time burden;[20,28,29] (iii) delivering educational interventions, which improved awareness where tested;[35] and (iv) strengthening national and institutional capacity through staffing, funding, feedback and structured detection.[16,17,19,34] These are supported by the reviewed

studies, but none of them was tested here in a controlled comparison across settings.

4.5 Strengths and limitations:

Strengths of this review include its use of PRISMA 2020,[14] a search of five databases, extraction into a standardised matrix and a thematic structure that links awareness, barriers and interventions. Limitations should be considered. First, heterogeneity of designs, populations and outcomes precluded meta-analysis, and awareness estimates are not directly comparable between studies. Second, several surveys used single-site, online or convenience samples, which may limit generalisability.[32,33,37–39] Third, the hospital programmes were evaluated three decades ago and addressed professional reporting. Fourth, two of the 25 studies were narrative reviews, which were used for context and not for quantitative description. Fifth, restriction to English-language, published literature may have introduced language and publication bias. Finally, no study provided urban–rural data, so that comparison could not be made.

5. CONCLUSION

Across 25 studies from 15 countries, awareness of ADR reporting systems was low wherever it was measured, and reporting was hindered by complex tools, uncertainty about causality, limited time and constrained institutional capacity. Simpler and multichannel reporting tools, pharmacist-linked reporting, targeted education and structured institutional detection are the best-supported strategies for strengthening reporting. Well-designed, representative studies that use validated instruments and report outcomes by place of residence are needed to determine whether, and by how much, awareness and reporting differ between urban and rural populations.

DECLARATIONS

Ethics approval: Not applicable; this review used published literature only.

Conflict of interest: The authors declare no conflict of interest.

Funding: This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Author contributions: All authors contributed to the conception and design of the review, literature search, study selection, data extraction, synthesis and drafting of the manuscript, and approved the final version.

Data availability: All data analysed in this review were extracted from the published articles cited in Table 1.

Abbreviations: ADR, adverse drug reaction; FDA, Food and Drug Administration; HIC, high-income country; LMIC, low- and middle-income country; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; UMIC, upper-middle-income country; WHO, World Health Organization.

REFERENCES

1. World Health Organization. The importance of pharmacovigilance: safety monitoring of medicinal products. Geneva: World Health Organization; 2002. 48 p.
2. Brewer T, Colditz GA. Postmarketing surveillance and adverse drug reactions: current perspectives and future needs. JAMA. 1999;281(9):824–9.
3. Desai M. Pharmacovigilance and spontaneous adverse drug reaction reporting: challenges and opportunities. Perspect Clin Res. 2022;13(4):177–9. doi: 10.4103/picr.picr_169_22
4. Hazell L, Shakir SAW. Under-reporting of adverse drug reactions: a systematic review. Drug Saf. 2006;29(5):385–96. doi:10.2165/00002018-200629050-00003
5. García-Abeijon P, Costa C, Taracido M, Herdeiro MT, Torre C, Figueiras A, et al. Factors associated with underreporting of adverse drug reactions by health care professionals: a systematic review update. Drug Saf. 2023;46(7):625–36. doi:10.1007/s40264-023-01302-7
6. European Parliament and Council. Directive 2010/84/EU of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use. Off J Eur Union. 2010; L348:74–99.
7. Kessler DA. Introducing MEDWatch: a new approach to reporting medication and device adverse effects and product problems. JAMA. 1993;269(21):2765–8.
8. Inch J, Watson MC, Anakwe-Umeh S. Patient versus healthcare professional spontaneous adverse drug reaction reporting: a systematic review. Drug Saf. 2012;35(10):807–18.
9. Al Dweik R, Stacey D, Kohen D, Yaya S. Factors affecting patient reporting of adverse drug reactions: a systematic review. Br J Clin Pharmacol. 2017;83(4):875–83. doi:10.1111/bcp.13159
10. Jacobs TG, Ampadu HH, Hoekman J, Dodoo ANO, Mantel-Teeuwisse AK. The contribution of Ghanaian patients to the reporting of adverse drug reactions: a quantitative and qualitative study. BMC Public Health. 2018;18(1):1384. doi:10.1186/s12889-018-6285-9
11. Alo OD, Akinyemi JO, Akpa MO, Yusuf OB, et al. Level and determinants of pharmacovigilance programme awareness in Nigeria: a multilevel

analysis. Afr J Pharm Pharmacol. 2017;11 (29):342–8.
12. Aljassim N, Ostini R. Health literacy in rural and urban populations: a systematic review. Patient Educ Couns. 2020;103(10):2142–54.
13. Chesser A, Burke A, Reyes J, Rohrberg T. Navigating the digital divide: a systematic review of eHealth literacy in underserved populations in the United States. Inform Health Soc Care. 2016;41(1):1–19. doi:10.3109/17538157.2014.948171
14. Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. Int J Surg. 2021; 88:105906. doi: 10.1016/j.ijsu.2021.105906
15. Wells G, Shea B, O'Connell D, Peterson J, Welch V, Losos M, et al. The Newcastle–Ottawa Scale (NOS) for assessing the quality of nonrandomised studies in meta-analyses. Ottawa: Ottawa Hospital Research Institute; 2000.
16. Keith MR, Bellanger-McCleery RA, Fuchs JE Jr. Multidisciplinary program for detecting and evaluating adverse drug reactions. Am J Hosp Pharm. 1989;46(9):1809–12.
17. Gilroy GW, Scollins MJ, Gay CA, Harry DJ, Giannuzzi DF. Pharmacy-coordinated program that encourages physician reporting of adverse drug reactions. Am J Hosp Pharm. 1990;47(6):1327–33.
18. Johnston PE, Morrow JD, Branch RA. Use of a database computer program to identify trends in reporting of adverse drug reactions. Am J Hosp Pharm. 1990;47(6):1321–7.
19. Koch KE. Use of standardized screening procedures to identify adverse drug reactions. Am J Hosp Pharm. 1990;47(6):1314–20.
20. Taras-Zasowski KM, Einarson TR. Review of Canadian pharmacist involvement in adverse drug reaction reporting. Can J Hosp Pharm. 1999. PMID: 10318271.
21. van Grootheest AC, Passier JL, van Puijenbroek EP. [Direct reporting of side effects by the patient: favourable experience in the first year]. Ned Tijdschr Geneeskd. 2005;149(10):529–33. Dutch.
22. van Grootheest AC, de Jong-van den Berg LT. The role of hospital and community pharmacists in pharmacovigilance. Res Social Adm Pharm. 2005;1(1):126–33. doi: 10.1016/j.sapharm.2004.12.009
23. Carleton BC, Smith MA, Gelin MN, Heathcote SC. Paediatric adverse drug reaction reporting: understanding and future directions. Can J Clin Pharmacol. 2007;14(1):e45–57.
24. Jarernsiripornkul N, Kakaew W, Loalukkana W, Krska J. Adverse drug reaction monitoring: comparing doctor and patient reporting for new drugs. Pharmacoepidemiol Drug Saf. 2009;18(3):240–5. doi:10.1002/pds.1708
25. Anderson C, Gifford A, Avery A, Fortnum H, Murphy E, Krska J, et al. Assessing the usability of methods of public reporting of adverse drug reactions to the UK Yellow Card Scheme. Health Expect. 2012;15(4):433–40.
26. Conforti A, Opri S, D'Incau P, Sottosanti L, Moretti U, Ferrazin F, et al. Adverse drug reaction reporting by nurses: analysis of Italian pharmacovigilance database. Pharmacoepidemiol Drug Saf. 2012;21(6):597–602.
27. Fortnum H, Lee AJ, Rupnik B, Avery AJ. Survey to assess public awareness of patient reporting of adverse drug reactions in Great Britain. J Clin Pharm Ther. 2012;37(2):161–5.
28. Leone R, Moretti U, D'Incau P, Conforti A, Magro L, Lora R, et al. Effect of pharmacist involvement on patient reporting of adverse drug reactions: first Italian study. Drug Saf. 2013;36(4):267–76. doi:10.1007/s40264-013-0028-8
29. Parretta E, Rafaniello C, Magro L, Coggiola Pittoni A, Sportiello L, Ferrajolo C, et al. Improvement of patient adverse drug reaction reporting through a community pharmacist-based intervention in the Campania region of Italy. Expert Opin Drug Saf. 2014;13 Suppl 1: S21–9. doi:10.1517/14740338.2014.939582
30. Hariraj V, Aziz Z. Patient reporting of adverse drug reactions (ADRs): survey of public awareness and predictors of confidence to report. Ther Innov Regul Sci. 2018;52(6):757–63. doi:10.1177/2168479017745025
31. Adisa R, Omitogun TI. Awareness, knowledge, attitude and practice of adverse drug reaction reporting among health workers and patients in selected primary healthcare centres in Ibadan, southwestern Nigeria. BMC Health Serv Res. 2019;19(1):926. doi:10.1186/s12913-019-4775-9
32. Patel JJ, Shah MK, Patel PP, Gandhi AM, Desai MK. Knowledge, attitude and practice among consumers about adverse drug reaction reporting. Int J Basic Clin Pharmacol. 2019; 8:1776–82.
33. Thadani A, Abidi A, Qadeer F, Bhagchandani D, Rizvi D. Evaluation of knowledge and awareness of adverse drug reaction reporting among patients visiting a tertiary care hospital in northern India. Asian J Pharm Pharmacol. 2019;5(2):310–5. doi:10.31024/ajpp.2019.5.2.14
34. Garashi H, Steinke D, Schafheutle E. Strengths and weaknesses of the pharmacovigilance systems in three Arab countries: a mixed-methods study using the WHO

pharmacovigilance indicators. Int J Environ Res Public Health. 2022;19(5):2518. doi:10.3390/ijerph19052518

35. Rehman AU, Khalid SN, Zakar R, Hani U, Zakar MZ, Fischer F. Patients' perception of the pharmacovigilance system: a pre-diagnostic and post-interventional cross-sectional survey. Front Pharmacol. 2022; 13:936124.
36. Binu KM, Mukthar Rifan CM, Sumayya, Patil A, Verma T, Doddayya H, et al. Impact of educational intervention on adverse drug reaction reporting: a consumer-centered cross-sectional survey. Asian J Pharm Health Sci. 2023;13(3):2847-2855.
37. Alshehri H, Alharbi A, Alqethami N, Alnuhait M, Alshammari A, Alotaibi AS. Knowledge, attitude, and practice regarding pharmacovigilance and barriers to reporting adverse drug reactions among the general population in Saudi Arabia. Risk Manag Healthc Policy. 2024; 17:2557–72. doi:10.2147/RMHP.S484223
38. Iffat W, Shakeel S, Nesar S, Qamar A, Huma Z, Rehman H, et al. Assessment of public awareness and perspectives towards adverse drug reaction reporting system in Karachi, Pakistan. PLoS One. 2025;20(2): e0318139.
39. Jhaj R, Shukla AK, Khasbage SU, Chaudhary D, Ahmed SN. An analysis of awareness and acceptability of the Medicines Side Effect Reporting Form for Consumer and the quality of data entered by consumers – an Indian perspective. Indian J Pharmacol. 2025;57(6):401–8. doi: 10.4103/ijp.ijp_464_24.