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Original Research Article

Knowledge Attitude Practice among Healthcare Workers for Adverse Drug Reaction Reporting at Tertiary Care Hospital in a Suburban Setting in North India

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Abstract

Background: Pharmacovigilance is essential for identifying, assessing and preventing adverse effects associated with medicines. Spontaneous adverse drug reaction (ADR) reporting remains a fundamental component of pharmacovigilance; however, substantial under-reporting persists worldwide. Knowledge and favourable attitudes towards ADR reporting do not necessarily translate into actual reporting behaviour.

Objectives: To assess the knowledge, attitude and practice (KAP) regarding pharmacovigilance and ADR reporting among healthcare workers; to identify factors associated with previous ADR-reporting experience; and to determine the correlations between knowledge, attitude and practice.

Methods: A cross-sectional questionnaire-based study was conducted among faculty members, postgraduate residents, senior residents and MBBS interns at Dr. Bhim Rao Ramji Ambedkar Government Medical Knowledge Kannauj Uttar Pradesh. A structured questionnaire assessed knowledge of pharmacovigilance and ADR reporting, attitudes towards reporting, reporting practices and perceived barriers. Categorical variables were summarized as frequencies and percentages. Associations were assessed using the χ^2 test or Fisher's exact test, as appropriate. Spearman's correlation coefficient was used to assess relationships between KAP domains. Statistical significance was set at $p<0.05$.

Results: Of 93 responses received, 90 participants consented and were included in the analysis, giving a response rate of 96.8%. Fifty-three (58.9%) were male and 37 (41.1%) female. Faculty members constituted 38 (42.2%), MBBS interns 24 (26.7%), postgraduate residents 23 (25.6%) and senior residents 5 (5.6%). Awareness of India's ADR reporting system was high [88/90, 97.8%; 95% CI 92.3–99.4]. The mean knowledge score was 15.96±2.06/18 (88.6%); 77 (85.6%) participants had good knowledge. The mean standardized attitude score was 70.62±9.75/100, with 77 (85.6%) demonstrating a positive attitude. Despite this, only 41 (45.6%; 95% CI 35.7–55.8) had previously reported a suspected ADR. The mean practice score was 3.00±0.87/4, with 66 (73.3%) classified as having favourable practice. Previous ADR-reporting experience was significantly associated with professional designation ($\chi^2=12.70$, df=3, $p=0.005$). Respondents with previous reporting experience had significantly higher knowledge scores than those without previous reporting experience (16.61±1.69 vs 15.41±2.25; $p=0.008$). Knowledge correlated positively with attitude ($\rho=0.302$, $p=0.004$) and practice ($\rho=0.316$, $p=0.002$), while attitude correlated positively with practice ($\rho=0.317$, $p=0.002$).

Conclusion: The study demonstrated high knowledge and generally favourable attitudes towards pharmacovigilance but substantially lower actual ADR-reporting experience. The findings indicate a persistent knowledge-to-practice gap. Interventions should therefore move beyond conventional awareness programmes towards practical, easily accessible and workflow-integrated ADR reporting, with particular emphasis on younger healthcare professionals and institutional barriers such as time constraints, uncertainty and perceived complexity of reporting systems.

Keywords: Pharmacovigilance; Adverse Drug Reaction; ADR Reporting; Spontaneous Reporting; Under-Reporting; Healthcare Professionals.

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Introduction

Medicines are indispensable to modern healthcare but may cause adverse drug reactions (ADRs), which can contribute to morbidity, mortality, prolonged hospitalization and increased healthcare expenditure. The safety profile of a medicine cannot be fully characterized before marketing because pre-marketing clinical trials generally involve selected populations, relatively limited sample sizes and restricted exposure periods. Continuous post-marketing safety surveillance is therefore essential.

Pharmacovigilance is defined by the World Health Organization (WHO) as the science and activities concerned with the detection, assessment, understanding and prevention of adverse effects or other medicine-related problems. It is an integral component of patient safety and rational use of medicines. The WHO Programme for International Drug Monitoring facilitates global sharing of individual case safety reports through the international pharmacovigilance network and VigiBase.[1]

Spontaneous reporting of suspected ADRs remains one of the principal methods of post-marketing safety surveillance. Healthcare professionals are often the first to recognize suspected medication-related harm and consequently have an important role in generating safety signals. In India, the Pharmacovigilance Programme of India (PvPI), coordinated by the Indian Pharmacopoeia Commission, provides a national spontaneous reporting framework through ADR Monitoring Centres and established reporting mechanisms.2 Healthcare professionals and patients can report suspected ADRs through the designated reporting system, including ADR reporting forms and digital/mobile mechanisms.[2]

Despite the importance of spontaneous reporting, under-reporting remains a major limitation of pharmacovigilance. A systematic review of factors associated with under-reporting found that knowledge deficits, uncertainty, lack of motivation, workload and misconceptions regarding reporting were recurrent determinants.[3] An updated systematic review similarly demonstrated that ignorance, lethargy, complacency, diffidence and insecurity remained common factors associated with under-reporting among healthcare professionals.[4]

Indian evidence has consistently demonstrated a discrepancy between awareness and actual reporting. An early study from a teaching hospital in North India found that although 77% of doctors knew the term pharmacovigilance, only 59% were aware of the national programme and only 23% had volunteered to report ADRs.[5] A subsequent South Indian study similarly demonstrated relatively favourable knowledge and attitudes but reported that only 22.8% of healthcare professionals had ever reported an ADR.[6]

A systematic review and meta-analysis specifically examining Indian healthcare professionals reported considerable heterogeneity in knowledge, attitudes and reporting practices across studies.[7] More recent Indian studies continue to indicate that under-reporting persists despite increasing awareness of pharmacovigilance.[8,9]

Importantly, knowledge, attitude and practice represent interconnected but distinct dimensions of pharmacovigilance behaviour. Knowledge facilitates recognition of ADRs and understanding of reporting procedures; attitude reflects willingness and perceived professional responsibility; and practice represents the translation of knowledge and intention into actual reporting. Evidence from educational intervention studies suggests that practical and repeated interventions can improve KAP and increase actual ADR reporting.[10]

Teaching hospitals provide a particularly important environment for strengthening pharmacovigilance because faculty members, residents and medical interns encounter diverse clinical conditions and medicines and participate at different levels in patient care. However, differences in clinical exposure and professional responsibility may influence reporting behaviour.

Although several Indian KAP studies have been conducted, substantial variation exists between institutions and professional groups. Furthermore, many studies have focused primarily on physicians or mixed healthcare professionals and have not simultaneously examined actual reporting experience, perceived barriers and correlations among knowledge, attitude and practice.

The present study was therefore undertaken in a tertiary care teaching hospital in North India to assess KAP regarding pharmacovigilance and ADR reporting among faculty members, postgraduate residents, senior residents and MBBS interns.

The study additionally examined factors associated with previous ADR-reporting experience, perceived barriers to reporting and relationships among the three KAP domains.

Aim: To assess the knowledge, attitude and practice regarding pharmacovigilance and adverse drug reaction reporting among healthcare professionals and medical trainees at a tertiary care teaching hospital in North India.

Objectives

1. To assess knowledge, attitudes, practice regarding ADR reporting among health care workers.
2. To assess actual ADR-reporting practice and previous reporting experience among health care workers.

Materials and Methods

Study Design and Setting: A cross-sectional questionnaire-based study was conducted among healthcare workers working at Dr. Bhimrao Ramji Ambedkar Government Medical College Kannauj.

Study Population: The study population consisted of faculty members, postgraduate residents, senior residents and MBBS interns working at Dr. Bhimrao Ramji Ambedkar Government Medical College Kannauj.

Inclusion and Exclusion Criteria: Participants belonging to the specified professional categories who provided informed consent were eligible for inclusion. Responses from participants who did not consent were excluded.

Study Instrument: A structured google form containing questions assessing participants' knowledge, attitude, and practice regarding pharmacovigilance and adverse drug reaction reporting was administered to the participants.[11] The questionnaire was completed by the participants during the study period from July 2024 to September 2024.
Questionnaire

Knowledge

1. Are you aware of suspected adverse reaction reporting system in India?
   a. Yes
   b. No

2. Who among the following can report adverse drug reaction?
   a. Doctors
   b. Pharmacist
   c. Nurses
   d. Patients
   e. Other Health Care Professional
   f. All of the above

3. Are you aware of regional center of ADR reporting
   a. Yes
   b. No

4. The following are commonly associated with ADRs:
   a. Old age Yes No
   b. Multiple co-morbidities Yes No
   c. Poly-pharmacy Yes No
   d. Patients in ICU Yes No
   e. Children aged 1–4 yrs Yes No

5. Following are essential information while reporting an ADR
   a. Patients initials Yes No
   b. Date of start of reaction Yes No
   c. Suspected medication Yes No
   d. Outcome of the event Yes No
   e. Name of reporter Yes No

6. Are you aware of any drug withdrawn from market due to safety reason?
   a. Yes
   b. No

7. ADR reporting is required in following circumstances:
   a. When it is caused by herbal medicine Yes No
   b. When it is not certain that drug has caused the reaction Yes No
   c. When it is caused by OTC drugs Yes No
   d. When it is caused by topical agents Yes No

ATTITUDE

1. Do you agree that ADR reporting system would benefit patient care?
   a. Strongly agree
   b. Agree
   c. Neutral
   d. Disagree
   e. Strongly disagree

2. Would you suspect ADRs when drug is administered in normal dose?
   a. Strongly agree
   b. Agree
   c. Neutral
   d. Disagree
   e. Strongly disagree

3.Do you think reporting of seemingly insignificant ADRs is required?
   a. Strongly agree
   b. Agree
   c. Neutral
   d. Disagree
   e. Strongly disagree

4. Reporting of all ADRs for a new drug is essential?
   a. Strongly agree
   b. Agree
   c. Neutral
   d. Disagree
   e. Strongly disagree

5. Reporting of ADR is the duty of all health care professionals?

a. Strongly agree
b. Agree
c. Neutral
d. Disagree
e. Strongly disagree

6. Factors that encourage you to report ADRs

a. Seriousness of event: i) Strongly agree ii) Agree iii) Neutral iv) Disagree v) Strongly disagree
b. Unusual reaction. i) Strongly agree ii) Agree iii) Neutral iv) Disagree v) Strongly disagree
c. Reaction to new drug: i) Strongly agree ii) Agree iii) Neutral iv) Disagree v) Strongly disagree
d. Certainity that the reaction is an ADR: i) Strongly agree ii) Agree iii) Neutral iv) Disagree v) Strongly disagree

7. Reasons for not reporting ADRS:

a. Apprehension about sending inappropriate forms: i) Strongly agree ii) Agree iii) Neutral iv) Disagree v) Strongly disagree
b. Busy Schedule to fill the form: i) Strongly agree ii) Agree iii) Neutral iv) Disagree v) Strongly disagree
c. Non-remuneration for reporting: i) Strongly agree ii) Agree iii) Neutral iv) Disagree v) Strongly disagree
d. Concern that extra work is required to fill & send the report: i) Strongly agree ii) Agree iii) Neutral iv) Disagree v) Strongly disagree
e. Not sending one report may not contribute a lot to patient care: i) Strongly agree ii) Agree iii) Neutral iv) Disagree v) Strongly disagree
f. Busy practice to look actively for ADR: i) Strongly agree ii) Agree iii) Neutral iv) Disagree v) Strongly disagree
g. Difficult to diagnose ADR in clinical practice: i) Strongly agree ii) Agree iii) Neutral iv) Disagree v) Strongly disagree
h. Non-availability of reporting form at work place: i) Strongly agree ii) Agree iii) Neutral iv) Disagree v) Strongly disagree
i. Feeling that reporting of previously known ADR is not required: i) Strongly agree ii) Agree iii) Neutral iv) Disagree v) Strongly disagree

8. The CDSCO suspected adverse drug reaction reporting form is complex to use:

a. Strongly agree
b. Agree
c. Neutral
d. Disagree
e. Strongly disagree

9. Do you agree that reporting of ADRs should be made compulsory?

a. Strongly agree
b. Agree
c. Neutral
e. Disagree
f. Strongly disagree

PRACTICE

1. **Have you reported any suspected adverse drug?**
   Yes
   No
2. **Have you attended any CME on ADR reporting?**
   Yes
   No
3. **If serious an adverse drug reaction occur what needs to be done with the suspected drug?**
   a.Stopped immediately
   b.Dose tapered and stopped
   c.Depends upon the drug & ADR
4. **Are you willing to implement adverse drug reactions reporting in your daily practice?**
   Yes
   No
5. **How do you prefer to send adverse drug reactions?**
   Yes
   No

Statistical Analysis: Categorical variables were expressed as frequencies and percentages. Continuous variables were expressed as mean ± standard deviation; median values were also reported where appropriate. Associations between categorical variables were evaluated using the Pearson χ^2 test or Fisher's exact test when expected cell frequencies were small.

The Mann–Whitney U test was used to compare knowledge scores between respondents who had and had not previously reported an ADR. Spearman's rank correlation coefficient (ρ) was used to determine associations between knowledge, attitude and practice scores. Two-sided $p<0.05$ was considered statistically significant. For descriptive proportions, approximate 95% confidence intervals were calculated using the Wilson method.

Ethical Considerations: Participation was voluntary and based on informed consent. Confidentiality and anonymity of participants were maintained. Ethical approval details should be inserted before submission: Ethics approval: [REC/GMCK/2024/06.]

Results

A total of 93 responses were received, of which 90 respondents consented to participate and were included in the final analysis. Two respondents did not consent and one response was ambiguous with respect to consent. Among the 90 respondents, 53 (58.9%) were male and 37 (41.1%) were female. Faculty members constituted 38 (42.2%) respondents, followed by MBBS interns (24, 26.7%), postgraduate residents (23, 25.6%) and senior residents (5, 5.6%).

Table 1: Sociodemographic and professional characteristics of participants (n=90)

Characteristic	N	%	Approx. 95% CI
Sex			
Male	53	58.9	48.6–68.5
Female	37	41.1	31.5–51.4
Professional designation			
Faculty	38	42.2	32.5–52.5
MBBS intern	24	26.7	18.6–36.6
Postgraduate resident	23	25.6	17.7–35.4
Senior resident	5	5.6	2.4–12.4

Knowledge regarding pharmacovigilance and ADR reporting: The respondents demonstrated a high level of knowledge regarding pharmacovigilance and adverse drug reaction (ADR) reporting. Awareness of the ADR reporting system in India was reported by 88 (97.8%) respondents.

Seventy-two (80.0%) correctly recognized that ADRs could be reported by all relevant healthcare professionals, while 73 (81.1%) were aware of regional ADR monitoring centres. Knowledge regarding important risk factors for ADRs was high, particularly multiple comorbidities (97.8%), polypharmacy (96.7%) and children aged 1–4 years (96.7%). Suspected medication was recognized as essential information in an ADR report by all respondents (100%), followed by date of onset of the reaction (94.4%), patient initials (93.3%) and outcome of the event (92.2%). Recognition of the reporter's name as essential information was comparatively lower (77.8%).

Knowledge regarding the circumstances in which ADRs should be reported was comparatively weaker. Only 58 (64.4%) respondents recognized that ADRs associated with herbal medicines should be reported, while 68 (75.6%) recognized that reporting is appropriate even when causality is uncertain. Overall, the mean knowledge score was 15.96 ± 2.06 out of 18 (88.6%), with a median of 17. Seventy-seven respondents (85.6%) had good knowledge, whereas 13 (14.4%) had moderate knowledge and none had poor knowledge.

Table 2: Knowledge regarding pharmacovigilance and ADR reporting (n=90)

Knowledge item	Correct response, n (%)	Approx. 95% CI
Awareness of ADR reporting system in India	88 (97.8)	92.3–99.4
ADRs can be reported by relevant healthcare professionals	72 (80.0)	70.6–87.0
Awareness of regional ADR Monitoring Centres	73 (81.1)	71.8–87.9
Multiple comorbidities recognized as ADR risk factor	88 (97.8)	92.3–99.4
Polypharmacy recognized as ADR risk factor	87 (96.7)	91.0–98.8
Children aged 1–4 years recognized as risk group	87 (96.7)	91.0–98.8
Suspected medication recognized as essential report information	90 (100.0)	95.9–100.0
Date of onset recognized as essential information	85 (94.4)	87.6–97.8
Patient initials recognized as essential information	84 (93.3)	86.2–96.9
Outcome recognized as essential information	83 (92.2)	84.8–96.2
Reporter name recognized as essential information	70 (77.8)	68.4–81.9
ADRs associated with herbal medicines should be reported	58 (64.4)	54.2–73.6
Reporting appropriate when causality is uncertain	68 (75.6)	65.8–83.3
Mean knowledge score	15.96±2.06/18	—

Attitude towards ADR reporting: Overall, attitudes towards ADR reporting were favourable. Eighty-eight (97.8%) respondents agreed or strongly agreed that ADR reporting benefits patient care. Reporting all ADRs associated with a new drug was considered essential by 84 (93.3%), and 83 (92.2%) agreed that ADR reporting is the responsibility of all healthcare professionals. Seriousness of the event was considered an important stimulus for reporting by 89 (98.9%), while an unusual reaction was considered a reporting stimulus by all respondents (100%).

Eighty (88.9%) supported making ADR reporting compulsory. Despite these favourable attitudes, substantial barriers to reporting were identified. Apprehension regarding submission of an inappropriate report and a busy schedule for completing the reporting form were the most frequently identified barriers, reported by 61 (67.8%) respondents each. Sixty percent felt that previously known ADRs did not necessarily require reporting.

Non-availability of reporting forms at the workplace was reported by 56.7%, while 54.4% considered the CDSCO ADR reporting form complex to use. These findings indicate that practical and system-related barriers persist despite adequate awareness and favourable attitudes. The mean standardized attitude score was 70.62 ± 9.75 out of 100.

Table 3: Attitude towards ADR reporting

Attitude/barrier item	n (%)	Approx. 95% CI
ADR reporting benefits patient care	88 (97.8)	92.3–99.4
Reporting ADRs associated with a new drug is essential	84 (93.3)	86.2–96.9
ADR reporting is responsibility of all healthcare professionals	83 (92.2)	84.8–96.2
Seriousness of reaction is a stimulus for reporting	89 (98.9)	94.0–99.8
Unusual reaction is a stimulus for reporting	90 (100.0)	95.9–100.0
Support making ADR reporting compulsory	80 (88.9)	80.7–93.9
Apprehension about submitting an inappropriate report	61 (67.8)	57.6–76.5
Busy schedule/time constraints	61 (67.8)	57.6–76.5
Previously known ADRs do not necessarily require reporting	54 (60.0)	55.7–62.8
Reporting forms not available at workplace	51(56.7)	50.3–64.2
CDSCO ADR reporting form considered complex	49 (54.4)	44.2–64.3
Mean standardized attitude score	70.62±9.75/100	—

Practice of ADR reporting: The practice domain demonstrated a substantial gap between willingness and actual ADR reporting. Only 41 (45.6%) respondents had previously reported a suspected ADR, despite 65 (72.2%) having attended a CME related to ADR reporting.

Seventy-seven (85.6%) indicated that a serious ADR should be managed by immediately stopping the suspected drug, and almost all respondents (90, 100%) expressed willingness to implement ADR reporting in their daily clinical practice.

The most preferred route for ADR reporting was through an ADR Monitoring Centre (44.4%), followed by mobile applications and toll-free numbers (17.8% each).

The mean practice score was 3.00 ± 0.87 out of 4, and 66 (73.3%) respondents had a favourable practice score.

Table 4: Practice of pharmacovigilance and ADR reporting (n=90)

Practice indicator	n (%)	Approx. 95% CI
Previously reported a suspected ADR	41 (45.6)	35.7–55.8
Attended CME related to ADR reporting	65 (72.2)	62.2–80.4
Would immediately stop suspected drug in serious ADR	77 (85.6)	76.8–91.4
Willing to implement ADR reporting in routine practice	90 (100.0)	95.9–100.0
Preferred ADR Monitoring Centre as reporting route	40 (44.4)	40.4–48.9
Preferred mobile application	16 (17.8)	11.2–26.9
Preferred toll-free number	16 (17.8)	11.2–26.9
Mean practice score	3.00±0.87/4	
Favourable practice	66 (73.3)	63.4–81.4

Factors associated with ADR-reporting practice: Previous ADR-reporting experience was significantly associated with professional designation (χ^2=12.70, df=3, p=0.005). Previous reporting was most frequent among senior residents (100%), followed by faculty (52.6%) and postgraduate residents (47.8%), whereas only 20.8% of MBBS interns had previously reported an ADR. Because of the small number of senior residents, this finding should be interpreted cautiously.

Gender was not significantly associated with previous ADR reporting (Fisher's exact p=0.520). Similarly, attendance at a CME on ADR reporting was not significantly associated with previous reporting (χ^2=1.20, p=0.274).

Respondents who had previously reported an ADR had a significantly higher mean knowledge score than those who had never reported an ADR (16.61 ± 1.69 versus 15.41 ± 2.25; Mann–Whitney U, p=0.008). This suggests that although knowledge alone does not fully explain reporting behaviour,

greater knowledge may contribute to actual reporting practice.

Correlation between KAP domains: Spearman correlation analysis demonstrated significant positive correlations between all three KAP domains. Knowledge was positively correlated with attitude (ρ=0.302, p=0.004) and practice (ρ=0.316, p=0.002). Attitude was also positively correlated with practice (ρ=0.317, p=0.002). These findings indicate that improvements in knowledge and attitudes may be accompanied by improvements in reporting-related practices, although the modest correlation coefficients demonstrate that factors beyond individual knowledge and attitude are also important determinants of ADR reporting.

Discussion

The present study demonstrates that doctors working in a tertiary-care setting possess a high level of knowledge and generally favourable attitudes towards pharmacovigilance and ADR reporting. However, a considerable gap exists between knowledge, willingness and actual reporting behaviour. While 85.6% of respondents had good knowledge and an equal proportion had a positive attitude, fewer than half (45.6%) had actually reported a suspected ADR. Most strikingly, all respondents expressed willingness to incorporate ADR reporting into their routine practice. This discrepancy between willingness and actual behaviour suggests that under-reporting is unlikely to be explained solely by lack of awareness.

The high knowledge score observed in this study is encouraging and indicates substantial awareness of the principles of pharmacovigilance among healthcare professionals. Despite the high knowledge score in our study, important specific gaps remained. Only 64.4% recognized that ADRs associated with herbal medicines should be reported, and 75.6% understood that reporting remains appropriate when causality is uncertain. These findings are important because pharmacovigilance encompasses not only conventional pharmaceutical medicines but also herbal and complementary products. WHO explicitly recognizes pharmacovigilance as encompassing medicines including herbal and complementary remedies.[12]

The attitude findings were encouraging. More than 90% recognized the importance of ADR reporting for patient care and its responsibility among healthcare professionals. Almost 99% regarded serious reactions as an important stimulus for reporting, and all participants considered unusual reactions a reporting stimulus. Nevertheless, only 45.6% had previously reported an ADR. This discrepancy closely resembles the pattern reported internationally. A 2024 systematic review of healthcare-professional pharmacovigilance studies found that the proportion of professionals with experience reporting an ADR varied widely, from approximately 12% to 61%, despite considerable variation in attitudes and awareness.[13] A recent international systematic review similarly identified low reporting practice despite generally favourable attitudes and highlighted lack of time, uncertainty and lack of knowledge about where to report as recurrent barriers.[14]

The most important finding was the discrepancy between willingness and actual reporting. Although 100% of respondents were willing to implement ADR reporting in daily practice, only 45.6% had previously reported an ADR. This knowledge–practice gap is consistent with the broader phenomenon of under-reporting in pharmacovigilance, in which healthcare professionals may recognize the importance of reporting but fail to submit reports because of workload, uncertainty, procedural difficulties or misconceptions about which reactions are reportable.

Recent Indian evidence reinforces this interpretation. A 2025 tertiary-care hospital study from Tamil Nadu reported that only 22 of 80 healthcare professionals had previously reported an ADR; lack of understanding of the reporting mechanism, time consumption, fear of legal liability and perceived complexity of the reporting form were identified as important barriers.[15] These findings are strikingly similar to those observed in our population.

All three KAP domains were significantly and positively correlated. Knowledge correlated with attitude (ρ=0.302), knowledge with practice (ρ=0.316), and attitude with practice (ρ=0.317). These results suggest a coherent relationship in which greater knowledge is associated with more favourable attitudes and better practice.

Nevertheless, the relatively modest correlation coefficients are important. They suggest that pharmacovigilance behaviour is not determined by a linear knowledge-to-practice pathway. This interpretation is consistent with previous Indian evidence. In a study among healthcare professionals involved in India's malaria control programme, knowledge was positively correlated with attitude, but the authors emphasized the need for targeted in-service education and hands-on training to improve real-time pharmacovigilance.[16]

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