

Knowledge, Attitude, and Practice of Adverse Drug Reaction Reporting among Community Pharmacists in India: A Review

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ABSTRACT

Adverse Drug Reaction (ADR) reporting plays a vital role in pharmacovigilance and patient safety. This review synthesizes published Indian studies examining the Knowledge, Attitude, and Practice (KAP) of community pharmacists regarding ADR reporting and their role within the Pharmacovigilance Programme of India (PvPI). While pharmacists generally acknowledge the importance of ADR reporting and express positive attitudes toward participating, significant gaps remain in knowledge of pharmacovigilance systems and actual reporting practices. Barriers such as limited awareness, inadequate training, perceived time constraints, and fear of legal consequences persist. Evidence from educational interventions suggests that structured training significantly improves knowledge and willingness to report. Strengthening training systems, simplifying reporting processes, and enhancing collaborative structures between community pharmacies and PvPI are essential to improving ADR reporting practices. Overall, empowering community pharmacists can enhance postmarketing drug safety surveillance and reduce preventable medication-related harm.

Keywords: ADR Reporting, Community Pharmacists, KAP, Pharmacovigilance, PvPI.

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INTRODUCTION

According to the World Health Organization (WHO), pharmaceutical companies are legally required in all countries to test their drugs on both healthy volunteers and patients before making them widely available. These clinical trials determine the efficacy of a drug for a specific disease and assess potential harms; however, such trials offer limited information about broader, untested populations that may differ in age, gender, health status, or ethnic background.

WHO further emphasizes that, especially for complex medicinal products, safety monitoring must continue beyond the manufacturing phase. Ongoing medicine safety requires systematic patient monitoring and continued scientific data collection, a process referred to as postmarketing surveillance. The organization notes that the effectiveness of national postmarketing surveillance systems is critically dependent on the active participation of healthcare professionals. Since physicians, pharmacists, nurses, and dentists are uniquely positioned to observe patients in routine care, WHO recommends that they

report all suspected Adverse Drug Reactions (ADRs) even when uncertainty exists regarding the causal relationship between the drug and the reaction (World Health Organization).

Pharmacovigilance, defined as the science and practice of detecting, assessing, understanding, and preventing adverse effects or other medicine or vaccine-related problems, is a vital component of modern healthcare systems (World Health Organization, n.d.). Healthcare professionals occupy a pivotal position in pharmacovigilance by detecting, documenting, and reporting adverse drug reactions, educating patients, ensuring data quality, and contributing to risk communication and policy development. Their active engagement is indispensable for strengthening drug safety surveillance and ensuring patient protection.

The Pharmacovigilance Programme of India (PvPI) is India's national drug safety monitoring program, launched in 2010 by the Ministry of Health and Family Welfare, to collect and analyze reports of ADRs and medication safety issues to protect patient safety and welfare (Pharmacovigilance Programme of India, n.d.).

In many countries, including India, the scope of ADR reporting has been expanded beyond physicians to include hospital pharmacists, community pharmacists, nurses, and even patients, in an effort to enhance reporting rates. Given their frequent interactions with the public and their involvement in dispensing



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over-the-counter medications, community pharmacists are well-positioned to identify potential ADRs. Consequently, they can play a pivotal role in the detection, management, and reporting of ADRs, thereby making a significant contribution to the PvPI (Selvam *et al.*, 2024).

Despite many initiatives aimed at strengthening pharmacovigilance, underreporting of ADRs continues to pose a significant global challenge. In the context of community pharmacy practice, underreporting is frequently linked to a poor understanding of the concept and procedures of ADR reporting, which limits pharmacists' active participation in the pharmacovigilance systems. Lack of adequate training, uncertainty regarding the causal relationship between a drug and a reaction, and limited awareness of reporting mechanisms further contribute to this problem (M S and R, 2018).

Specifically, this review aims to identify the current level of awareness and understanding of ADR reporting among community pharmacists, assess their attitudes toward pharmacovigilance activities, and examine their reporting practices. Furthermore, the review seeks to highlight the barriers and challenges that hinder effective ADR reporting and to explore the potential role of community pharmacists in strengthening the PvPI. As a final step, this review intends to provide evidence-based recommendations to enhance the participation of community pharmacists in ADR reporting, thereby contributing to the overall improvement of drug safety in the country.

This review adopted a narrative approach, synthesizing published studies found in electronic databases such as PubMed and Google Scholar, covering the period between 2012 and 2025. The selection criteria focused on studies specifically assessing the knowledge, attitude, and/or practice of ADR reporting among community pharmacists in India. Eight articles were selected, published between 2012 and 2024 (Table 1). Six studies were cross-sectional questionnaire-based surveys, while two studies used interventional approaches to assess the impact of education on awareness and practices. The total number of pharmacists participating across all included studies was 3,417, with individual study sample sizes varying significantly from 49 to 2,205 participants. Diploma in Pharmacy (DPharm) holders consistently represented most participants across most studies, with proportions ranging from 78% to nearly 98%.

Knowledge of Community Pharmacists Regarding ADR Reporting

Knowledge levels were found to be variable and often inadequate, as illustrated in Figure 1 and Table 2.

ADR Definition and Drug Safety

While a high proportion of pharmacists in one study (Article 7) reported knowing what an ADR is (91.4%), the ability to correctly define it was low in others (e.g., 37.5% in Article 4 and 14.7% in Article 3). Furthermore, a substantial percentage in some studies (e.g., 58.6% in Article 7) incorrectly believed that all dispensed or marketed drugs are completely safe, highlighting a fundamental misconception about the need for pharmacovigilance.

Table 1: Study characteristics of included articles.

ART	Study design	Study place	Duration
Article 1	Cross-sectional questionnaire-based study (Prakasam <i>et al.</i> , 2012).	Hyderabad, India	9 months (August 2011 to April 2012)
Article 2	Cross-sectional survey (Ahmad <i>et al.</i> , 2013).	Nationwide (India)	3 months (May 2012 to July 2012)
Article 3	Prospective and questionnaire-based survey (Ravinandan <i>et al.</i> , 2015).	Davangere city, Karnataka	6 months (December 2013 to May 2014)
Article 4	Prospective cross-sectional study (Srikanth <i>et al.</i> , 2015).	NA	NA
Article 5	Cross-sectional questionnaire-based study (Sah <i>et al.</i> , 2017).	West Delhi, India	4 months (June 2016 to September 2016)
Article 6	Interventional study (M S and R, 2018).	Rural areas of Mysuru district, Karnataka	NA
Article 7	Single-group, pre–post interventional trial	Anantapur district, Andhra Pradesh	NA
Article 8	Cross-sectional observational study (Selvam <i>et al.</i> , 2024).	Nationwide (India)	10 months (May 2021 – February 2022)

Abbreviations: ART: Articles. Table 1 summarizes the study characteristics of the eight selected articles that assessed the KAP of community pharmacists in India regarding ADR reporting.

Awareness of PvPI

Familiarity with the PvPI was notably limited. Awareness of the national ADR monitoring system ranged from a low of 9% in one study (Article 5) to 36.2% in another (Article 7), and 73.2% of pharmacists in one study (Article 4) were unaware of any existing pharmacovigilance program.

Training: Only 19.6% of pharmacists in one study (ART 3) felt adequately trained in ADR reporting, indicating a major obstacle to correct identification and reporting.

Attitude of Community Pharmacists Toward ADR Reporting

In contrast to the knowledge gaps, the attitude toward ADR reporting was predominantly positive and supportive, as illustrated in Figure 2 and Table 3.

Role and Responsibility

A clear majority of pharmacists across studies recognized ADR reporting as an essential professional duty, with agreement ranging from 72.4% (Article 7) to 93.4% (Article 1).

Impact on Patient Safety

Pharmacists strongly believed that ADR reporting benefits patients and improves patient safety, with the highest agreement reaching 95% (Article 2).

Time Constraints: Despite the positive attitude, a majority of pharmacists in one study (Article 7: 67.3%) found the process time-consuming. However, only a small minority (Article 3: 16.6%) felt it was time-consuming “with no outcome,” suggesting they generally recognize the value.

Table 2: Topics and sample questions used to assess knowledge of community pharmacists on Adverse Drug Reaction (ADR) reporting.

Sl. No.	Topics	Questions
1	ADR	Do you know what ADRS are? Do you think reporting of ADR is necessary?
2	pharmacovigilance	What is pharmacovigilance and its main purpose?
3	PvPI	Are you aware of the PvPI?
4	ADR Monitoring Centres	Do you know where the nearest ADR Monitoring Centre is located?
5	ADR reporting forms	Are you aware of the ADR reporting form used in India?
6	Eligibility to Report	Who can report ADRS?
7	Reporting Procedure	Do you know how to fill out and submit an ADR reporting form?
8	Information Required to Report an ADR	What details are essential in an ADR report?
9	International PV System	Are you aware of the international ADR monitoring system (WHO–UMC, Sweden)?
10	Safety of Marketed Drugs	Are all marketed drugs completely safe, or can they still cause ADRS?

Abbreviations: ADR: Adverse Drug Reaction; PvPI: Pharmacovigilance Programme of India.

Table 3: Topics and sample questions used to assess the attitude of Community Pharmacists toward Adverse Drug Reaction (ADR) reporting.

Sl. No.	Topics	Questions
1	Role of Pharmacists in ADR Reporting	Is ADR reporting an essential role of the pharmacist?
2	Impact of ADR reporting	Will ADR reporting benefit the patient? How does ADR reporting benefit patients?
3	Legal Concerns in ADR Reporting	Do you worry about legal issues when considering ADR reporting?
4	Time Constraints in ADR Reporting	Do you think the ADR reporting process is time-consuming?
5	Importance of Training	Do you think pharmacovigilance should be taught in detail to community pharmacists?
6	Inclusion of Pharmacovigilance in Pharmacy Curriculum	Do you think pharmacovigilance must be taught as part of pharmacy education?
7	Encouraging Pharmacists and Financial Incentives to Report ADRS	Do you think incentives or recognition programs would increase ADR reporting among pharmacists?

Abbreviations: ADR: Adverse Drug Reaction.

ADR Reporting Practices of Community Pharmacists

Actual reporting practices revealed a significant disconnect between the positive attitude and implementation, as illustrated in Figure 3 and Table 4.

Encountering ADRs

A substantial proportion of community pharmacists reported having encountered ADRs in their practice, ranging from 39.7% (Article 7) to 79.8% (Article 8).

Actual Reporting Rates

Despite frequent encounters, actual reporting rates to pharmacovigilance or monitoring centers were low, ranging from 20% (Article 4) to 42.4% (Article 8). Crucially, only 4.08% (Article 6) reported ADRs frequently. Awareness of where and how to report was also limited (30.8% in Article 1).

Table 5 highlights the main barriers preventing community pharmacists from participating in ADR reporting. The most common issue was being unaware of the national ADR reporting system, mentioned in five studies (Articles 2, 3, 6, Articles 7, 8). Lack of time was another major challenge, reported in four studies. Other factors, such as fear of legal issues and limited promotion by authorities, also contributed to underreporting.

Figure 4 illustrates the major barriers faced by pharmacists in reporting ADRs. The most frequently cited obstacle was the concern that ADR reporting might damage their professional image (77% in Article 5). Lack of awareness about the ADR

reporting system was another significant barrier, reported by up to 42.16% of participants (Article 3). Time constraints (up to 43.1% in Article 7) and fear of facing legal issues (31.1% in Article 7) were also commonly mentioned challenges.

Impact of Intervention

The two interventional studies (Articles 6 and 7) demonstrated a significant positive impact from educational programs. Postintervention results showed considerable improvement, including a greater ability to correctly define ADRs (77.55% in Article 6) and increased willingness to report (75.51% in Article 6). This suggests that targeted, practical education is an effective tool to bridge the identified gaps.

Recommendations for Training

To promote ADR reporting, training initiatives should be designed to address both perceptual and practical barriers. They should emphasize that ADR reporting is an essential ethical and professional responsibility that directly contributes to patient safety, while also focusing on practical skills for identifying, documenting, and assessing suspected reactions. Training must provide clear guidance on reporting procedures, including how to accurately complete official forms and use appropriate submission channels such as the toll-free PvPI helpline or the nearest ADR Monitoring Centre. Additionally, it should reinforce the importance of reporting all suspected ADRs—whether new, known, serious, or nonserious to dispel misconceptions that only rare or severe reactions warrant reporting.

Table 4: Topics and sample questions used to assess the Adverse Drug Reaction (ADR) reporting practices of Community Pharmacists.

Sl. No.	Topics	Questions
1	Observation of ADR Cases	Did you observe any ADR cases in your practice?
2	Availability of the ADR Reporting System	Is the ADR reporting form available at your workplace?
3	Experience with ADR Reporting	Have you ever reported an ADR to the pharmacovigilance center?
4	Documentation of ADR	Do you keep records of ADR?
5	Knowledge of the ADR Reporting Process	Do you know how to report ADR?
6	Awareness of Training in Pharmacovigilance	Do you feel that you are adequately trained in ADR reporting?

Abbreviations: ADR: Adverse Drug Reaction.

Table 5: Key barriers to Adverse Drug Reaction (ADR) reporting identified in included studies.

Sl. No.	Barriers reported	Articles
1	Lack of Information Provided by the patient	Article 2
2	Lack of Time	Article 7, Articles 1, 2, 3
3	Unaware of the Existence of a National ADR Reporting System	Articles 2, 3, 6, Articles 7, 8
4	Unaware of the need to Report an ADR	Articles 1, 2
5	ADR Reporting is not Widely Promoted by the Relevant Authorities	Articles 2, 6
6	Fear of Facing Legal Problems	Articles 2, 3, 5

Abbreviations: ADR: Adverse Drug Reaction.

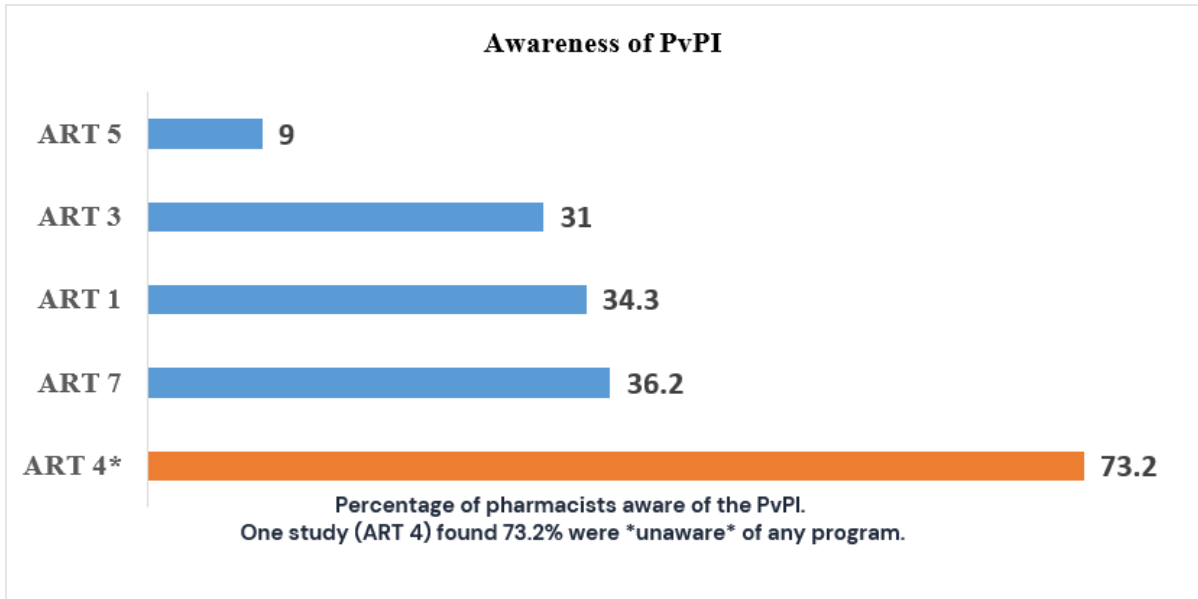


Figure 1: Knowledge of Community Pharmacists on Adverse Drug Reaction (ADR) reporting.

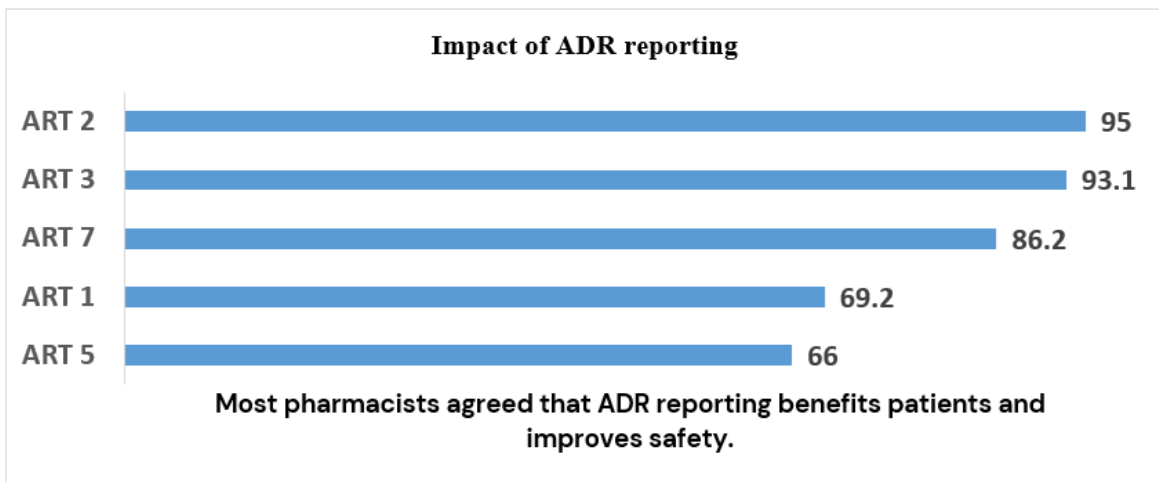
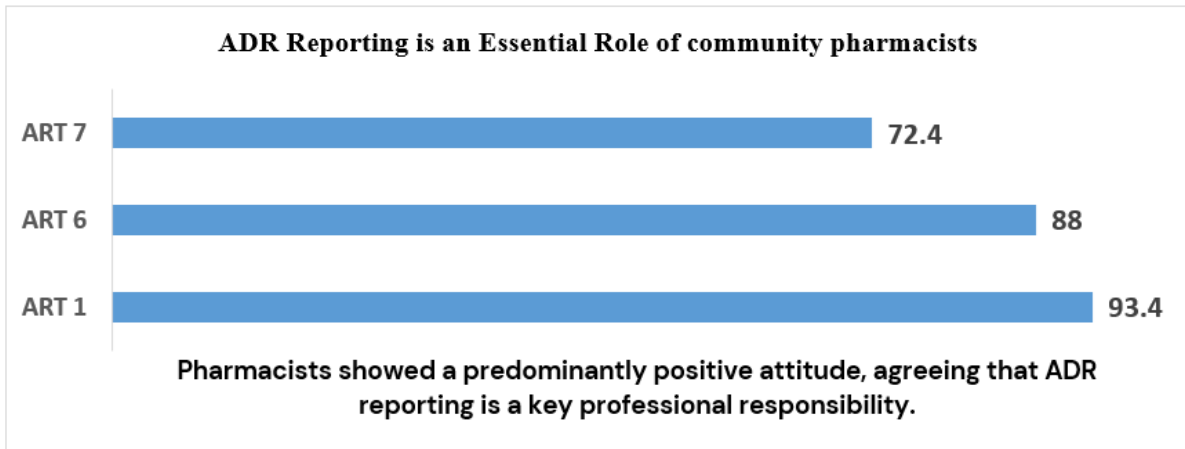


Figure 2: Attitude of Community Pharmacists toward Adverse Drug Reaction (ADR) reporting.

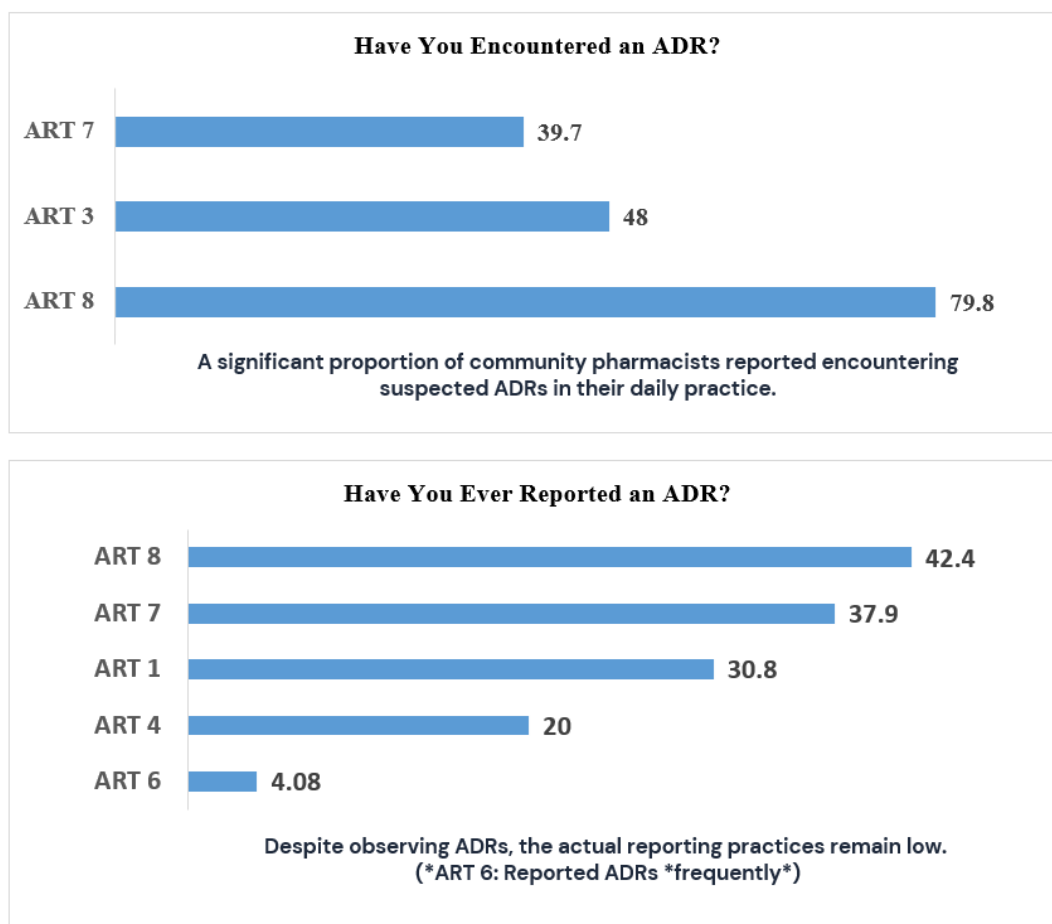


Figure 3: Practice of Community Pharmacists toward Adverse Drug Reaction (ADR) reporting.

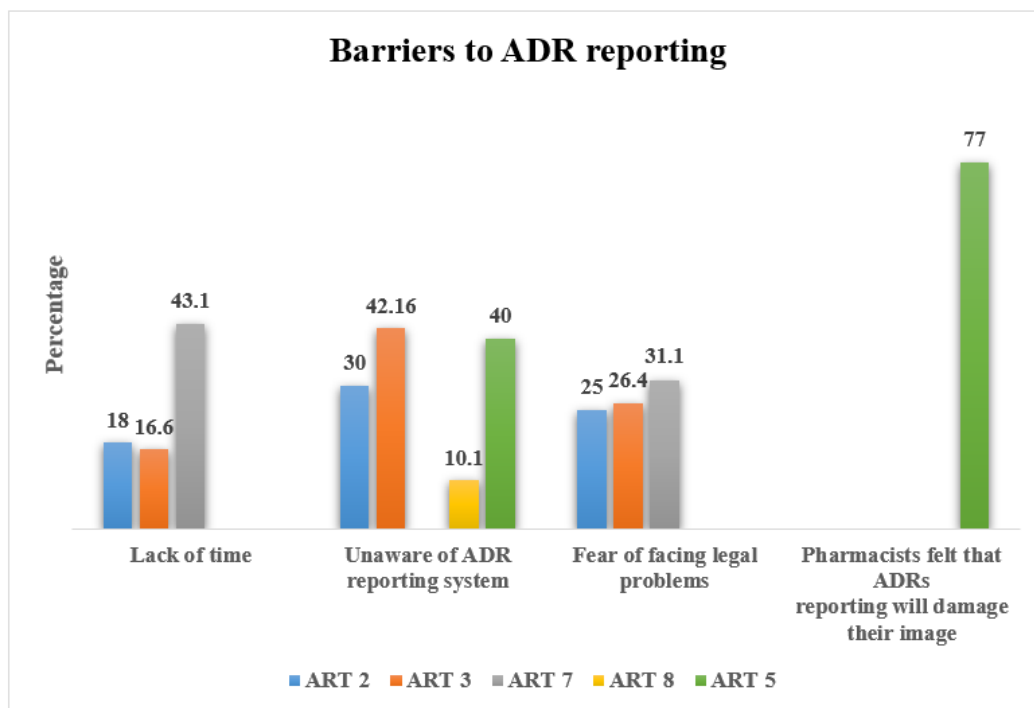


Figure 4: Major barriers faced by pharmacists in reporting Adverse Drug Reactions (ADRs).

CONCLUSION

Community pharmacists in India exhibit a positive attitude toward ADR reporting, overwhelmingly recognizing it as an essential professional duty that contributes to patient safety. However, this positive attitude is undermined by significant knowledge gaps, particularly a lack of awareness of the national PvPI system and inadequate training leading to suboptimal reporting practices. The primary barriers are a lack of awareness of the reporting system, a lack of time, and concerns about legal issues or professional image.

The evidence strongly suggests that regular and ongoing educational intervention programs are the crucial strategy for strengthening pharmacovigilance by improving pharmacists' knowledge, confidence, and adherence to reporting procedures.

ACKNOWLEDGEMENT

None.

ABBREVIATIONS

ADR: Adverse Drug Reaction; **ART:** Articles; **CNS:** Central Nervous System; **DPharm:** Diploma in Pharmacy; **KAP:** Knowledge, Attitude, and Practice; **PvPI:** Pharmacovigilance Programme of India; **UMC:** Uppsala Monitoring Centre; **WHO:** World Health Organization.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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