



## Research Article

# Pharmacist's Insight into Pharmacovigilance: An Exploratory Study

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### ABSTRACT

Adverse drug reactions (ADRs) pose significant risks to public health, yet underreporting remains a major challenge in pharmacovigilance. Community pharmacists play a crucial role in detecting and reporting ADRs, but various barriers hinder their active participation. This study aimed to assess the knowledge, attitudes, and practices of community pharmacists in Kerala regarding ADR reporting, identifying key challenges and facilitators to improve reporting rates. A cross-sectional study was conducted among 313 community pharmacists in Kerala using a structured, validated questionnaire. Data were collected and analyzed using SPSS version 20. The findings revealed that while 90.4% of pharmacists recognized the importance of ADR reporting, only 74.4% knew where and how to report. Despite 83.4% acknowledging ADR reporting as a professional responsibility, only 45.4% had ever submitted a report. Key barriers included lack of awareness about reporting procedures (57.8%), absence of ADR reporting forms at workplaces (46%), and limited access to training programs (56.5%). These results highlight a positive attitude towards ADR reporting but also reveal significant gaps in knowledge and practice. Addressing these challenges through structured educational programs, streamlined reporting mechanisms, and improved accessibility to resources can enhance pharmacovigilance efforts in Kerala, ultimately improving patient safety and healthcare quality.

### INTRODUCTION

Adverse drug reactions (ADRs) are global problems and affects majority both children and adults causing both morbidity and mortality and

also a major impact on public health.[1] Post marketing surveillance is crucial for assessing the risks and benefits of pharmaceutical medicines after they are launched on the market.[2]

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Pharmacovigilance ensures the safety of medications and protects consumers from unwanted consequences. According to the definition provided by the World Health Organization, an ADR is any harmful, unintentional, and undesirable effect of a drug, which occurs at doses used in humans for prophylaxis, diagnosis, or therapy.[1] In clinical practice, the most commonly utilized technique for monitoring drug safety is spontaneous reporting of adverse drug reactions. Furthermore, spontaneous reporting of ADRs has played a most essential role in the detection of serious and atypical ADRs during marketing of the medicine in real practice on the market. This has led to the withdrawal of many drugs.[3] To translate the pharmacovigilance activities into practices for promoting patient safety, more ADR monitoring centres are being established around the country under India's pharmacovigilance initiative.[4] It can also help to prevent new medical disasters and raise the safety profile of pharmaceutical products. ADR reporting does not appear to be considered as a part of ordinary professional practice by health care professionals.[5] The ADR reporting rate in India is below 1% compared to the worldwide rate of 5%.[6] One of the reasons for low reporting rate in India may be a lack of knowledge and sensitization towards pharmacovigilance and ADR among health care professional.[6] Traditionally, pharmacists were responsible for preparing and administering medications ordered by physicians. Pharmacists now play a more comprehensive role in patient care. Roles include reporting adverse drug reactions (ADRs), improving patient health, and maximizing economic outcomes.[7] However, in many countries the knowledge of pharmacists about pharmacovigilance and ADR reporting is poor and the rate of reporting is low.[8] Assessing the knowledge, attitude and practice of community

pharmacists in spontaneous reporting of ADRs is very important.

### **1.1 Pharmacovigilance program of India**

The PvPI was founded with a wide purpose of improving patient safety for India's more than one billion inhabitants. In July 2010, the Central Drug Standard Control Organization, New Delhi, initiated a nationwide pharmacovigilance program under the aegis of the Ministry of Health and Family Welfare, Government of India, with the All India Institute of Medical Sciences (AIIMS), New Delhi as a National Coordinating Centre (NCC) to monitor ADR.[10,11] The Pharmacovigilance Programme of India (PvPI) is a national programme that aims to ensure the safe use of medicines and detect, assess, and prevent adverse effects or other possible drug-related problems. Launched in 2010 by the Indian Pharmacopoeia Commission (IPC) under the Ministry of Health and Family Welfare, PvPI monitors and collects data on adverse drug reactions (ADRs), analyses and evaluates ADR data, disseminates safety information to healthcare professionals and patients, and improves patient safety and well-being. The programme has a network of ADR monitoring centres across India, collaborating with international organizations like the World Health Organization (WHO) and the Uppsala Monitoring Centre (UMC). By promoting pharmacovigilance, PvPI ensures that medicines are used safely and effectively, identifying and mitigating potential risks. [10,11]

### **1.2 Importance of pharmacovigilance**

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems. Recently, its concerns have been widened to include:

- Herbals
- Traditional and complementary medicines
- Blood products



- Biologicals
- Medical devices

Pharmacovigilance is a system that monitors adverse drug reactions (ADRs) and potential drug-related issues to ensure patient safety, improve public health, and ensure regulatory compliance. It helps in drug development, promoting the rational use of medicines, and addressing post-marketing surveillance. Pharmacovigilance also reduces healthcare expenses associated with ADR treatment and drug-related hospitalization. It also promotes trust in the healthcare system, as it assures the public that drugs are constantly tested for safety.

### **1.3 The specific aims of pharmacovigilance are to:**

1. Improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions.
2. Improve public health and safety in relation to the use of medicines,
3. Contribute to the assessment of benefit, harm, effectiveness and risk of medicines,
4. Encouraging their safe, rational and more effective (including cost-effective) use, and
5. Promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public.
6. Pharmacovigilance has developed and will continue to develop in response to the special needs and according to the particular strengths of members of the WHO Programme and beyond. Such active influence needs to be encouraged and fostered; it is a source of vigour and originality that has contributed much to international practice and standards.

### **1.4 Role of Community Pharmacist**

Community pharmacists play a pivotal role in adverse drug reaction (ADR) reporting, as they are often the first point of contact for patients experiencing ADRs. Community pharmacists are well-positioned to identify and report ADRs, given

their frequent interactions with patients and knowledge of medications. A study found that community pharmacists can significantly contribute to ADR reporting, particularly for rare or unusual reactions. By identifying, reporting, and counselling patients about ADRs, community pharmacists can enhance patient safety and pharmacovigilance. Furthermore, a study emphasized the importance of community pharmacist involvement in ADR reporting, highlighting their role in improving medication safety and preventing harm. Overall, community pharmacists are essential in the detection and reporting of ADRs, and their contributions can significantly impact patient safety and pharmacovigilance. Community pharmacists are the most accessible healthcare providers to the general populace. They provide health/medical services and dispense drugs in accordance with legal and ethical guidelines, whether on prescription or over the-counter (OTC). They also serve as a bridge between doctors and patients, allowing for the most effective and sensible usage of medications. Community pharmacists provide a number of duties, including drug procurement and dispensing, patient counselling and education, health promotion, drug information, and advice to healthcare professionals on the judicious use of medications. In several affluent countries, pharmacists are regarded as one of the top three professions that benefit society. This recognition is given to pharmacists because of the professional services they provide to benefit public health. Many studies on public perception of pharmacists have been undertaken in many nations, and the results have varied. Brodie advocated that pharmacists give excellent drugs and appropriate guidance to patients about how to take their medications using their knowledge, understanding, judgment, procedures, and abilities. There were few studies in Kerala, done to analyse the knowledge, attitude, and practice



related to ADR reporting among community pharmacists. We provided ADR reporting guidelines which play a pivotal role in enhancing knowledge of community pharmacist. By providing clear instructions and structured frameworks, these guidelines support healthcare professionals in identifying, documenting, and communicating adverse drug reactions effectively. This ultimately contributes to improved patient safety, informed regulatory decisions, and the ongoing assessment of drug safety profiles.

### **1.5 Scope of the study**

This cross-sectional study aims to explore the adverse drug reaction (ADR) reporting practices among community pharmacists in Kerala, India. The scope of the study is to investigate the current practices, knowledge, and attitudes of community pharmacists in Kerala regarding ADR reporting. The study will focus on identifying the barriers and facilitators to ADR reporting among community pharmacists, as well as exploring the factors influencing their reporting practices. The study will also examine the awareness and knowledge of community pharmacists about the Pharmacovigilance Programme of India (PvPI) and the Indian Pharmacopoeia Commission (IPC), which are responsible for monitoring ADRs in India. Additionally, the study will investigate the role of community pharmacists in ADR reporting and their perceptions about the importance of ADR reporting in ensuring patient safety. The study will also explore the challenges faced by community pharmacists in reporting ADRs and identify potential strategies to improve ADR reporting practices among community pharmacists in Kerala. The findings of this study will contribute to the existing literature on ADR reporting and pharmacovigilance, providing valuable insights into the ADR reporting practices among community pharmacists in Kerala. Furthermore, the study's findings will be relevant to policymakers, healthcare professionals, and

researchers interested in ADR reporting and pharmacovigilance, providing a comprehensive understanding of the factors influencing ADR reporting among community pharmacists in Kerala. The study will also provide insights into the current infrastructure and resources available for ADR reporting among community pharmacists in Kerala, including the availability of reporting forms, access to internet facilities, and training programs on ADR reporting. Additionally, the study will examine the relationship between community pharmacists' knowledge, attitudes, and practices regarding ADR reporting, and their demographic characteristics, such as age, gender, and years of experience. Overall, this study has the potential to make a significant contribution to the improvement of patient safety and healthcare quality in Kerala, and its findings will be relevant to a wide range of stakeholders, including policymakers, healthcare professionals, and researchers. The study's findings will also have implications for the development of policies and programs aimed at improving ADR reporting practices among community pharmacists in Kerala, and will provide a foundation for future research on ADR reporting and pharmacovigilance in India.

### **1.6 Need of the study**

The reporting of Adverse Drug Reactions (ADRs) is crucial for ensuring patient safety, yet underreporting remains a significant concern in India. Community pharmacists play a vital role in healthcare delivery, and their participation in ADR reporting is crucial for identifying potential safety issues with medications. Despite their importance, community pharmacists in Kerala have limited knowledge and awareness about ADR reporting, which can hinder their participation in ADR reporting. Furthermore, there is a lack of studies exploring the current practices and barriers to ADR reporting among community pharmacists in Kerala, highlighting the need for a study to address



this knowledge gap. This study aims to explore the current practices, knowledge, and attitudes of community pharmacists in Kerala regarding ADR reporting, with the objectives of assessing their knowledge and awareness about ADR reporting, exploring the current practices and barriers to ADR reporting, and identifying the facilitators and strategies to improve ADR reporting practices. By addressing the gaps in current knowledge and practice, this study will provide valuable insights into the ADR reporting practices among community pharmacists in Kerala, ultimately contributing to improved patient safety and healthcare quality. The findings of this study will help to identify the barriers and facilitators to ADR reporting among community pharmacists, informing the development of targeted interventions to improve ADR reporting practices. Additionally, this study will contribute to the existing literature on ADR reporting, providing a better understanding of the factors influencing ADR reporting among community pharmacists in Kerala. Overall, this study has the potential to make a significant contribution to the improvement of patient safety and healthcare quality in Kerala, and its findings will be relevant to policymakers, healthcare professionals, and researchers interested in ADR reporting and pharmacovigilance. Moreover, the study's findings will also inform the development of educational programs and training initiatives aimed at improving community pharmacists' knowledge and awareness about ADR reporting. By exploring the current practices, knowledge, and attitudes of community pharmacists in Kerala regarding ADR reporting, this study will provide a comprehensive understanding of the factors influencing ADR reporting among community pharmacists in Kerala, ultimately contributing to improved patient safety and healthcare quality.

## **MATERIALS AND METHOD**

### **Study period**

The study was conducted over a period of 3 months.

### **Study population and study centre**

The study was conducted among 313 community pharmacists (randomly selected) in and around Kerala, India.

### **Study design**

It was a cross sectional study conducted among community pharmacist from Kerala.

### **Inclusion criteria**

All community pharmacists with qualification as registered pharmacist and a minimum of 3 months' professional experience were included in the study.

### **Exclusion criteria**

Pharmacy technicians and assistants with no eligible qualification and experience were excluded.

### **Study tool**

A self-administered questionnaire was made using evidence and careful examination from the literature survey and features used in former research studies. It was then validated by three experts, with experience in drug use research, to evaluate the clarity, relevance and conciseness of matter incorporated in the questionnaire. Their observations and comments were taken in to the account and final questionnaire was prepared. The KAP questionnaire consisted of a total of twenty two questions. Section A included six questions on demographic details. Section B comprised of six questions related to basic knowledge and information about ADR reporting (five closed ended questions and one open ended question) Section C consisted of five questions (closed ended) related to pharmacist's attitude. Section D has five questions (four closed ended and one open ended) related to practice / perception regarding ADR reporting.

### **Data analysis**



The response to the questionnaire was analysed by performing descriptive statistics using Microsoft Excel 2010.

A cross-sectional survey study was conducted among 313 community pharmacists in Kerala, India, to assess Adverse Drug Reaction (ADR) reporting practices. The study began with a thorough literature review, followed by the design of the survey. The sample size was calculated using Cochran's Formula, A self-administered questionnaire was developed based on the literature review and expert input. The survey was conducted in community pharmacies through face-to-face interviews, and responses were collected using Google Forms. Additionally, a hard copy of guidelines was provided to each community pharmacist, and the importance of ADR reporting was discussed to improve awareness. The collected data was analysed using descriptive

statistics with Microsoft Excel 2010. The findings provided insights into ADR reporting practices, knowledge, and attitudes among community pharmacists, identifying factors influencing reporting and areas for improvement. Finally, conclusions were drawn, and recommendations were made to enhance ADR reporting practices among community pharmacists.

## RESULT AND DISCUSSION

### Demographics of The Participants

Our study population consisted of 59.4% female and 40.6% male community pharmacist. The average age of the participants was 26.03 years. Majority 78.9% were D Pharm, 20.4% were B Pharm, 0.3% were M Pharm and 0.3% were Pharm D graduates. The majority (77.3%) of pharmacists were employed in independent pharmacy and (22.7%) in chain pharmacy. (95.2%) of community pharmacy have internet service.

**Table I: Demographics of the participants**

VARIABLES	CATEGORY	n(%)
Mean age		
Gender	Female Male	186 (59.4%) 127 (40.6%)
Education	D pharm B pharm M pharm Pharm D	247 (78.9%) 64 (20.4%) 1 (0.3%) 1 (0.3%)
Experience	0 – 5 years 6-10 years 11-15 years >20 years	203 (64.9%) 73 (23.3%) 28 (9.9%) 09 (2.9%)
Availability of internet service	Yes No	298 (95.2%) 15 (4.8%)
Category of pharmacy	Independent Chain pharmacy	242 (77.3%) 71 (22.7%)

## 2. Community pharmacist knowledge about ADR reporting

There were five questions to evaluate the knowledge of community pharmacist regarding ADR reporting (Table II). Among the 313 respondents, 90.4% (n=283) were aware that all ADRs of allopathic medications need to be reported. 74.4% community pharmacists said

that they were aware about how and where to report an ADR. Those who said they were aware about such reporting were asked whether they knew the regulatory body responsible for collecting and monitoring ADR in India. Answers were given by community pharmacists that included pharmacovigilance (30%), Indian Pharmacopoeia commission (15%), CDSCO



(15%), WHO(5%), National coordination committee (NCC-5%), Drug control department (10%), Pharmacy council of India (PCI 5%), ADR monitoring centre (AMC-5%) and Pharmacy and Therapeutic Committee (PTC-5%) . 74.1%

respondents believed that ADR should be reported only when they are severe and cause danger to life. However about 17.6% of pharmacists did not know that they could report ADR through an online system.

**Table II: Community pharmacist knowledge about ADR reporting**

S.no.	Questions	Response			
		Yes		No	
		n	%	n	%
1	Do you think all ADRs of allopathic medications need to be reported as it is extensively studied during clinical trials?	283	90.4%	30	9.6%
2	Do you think that ADRs associated with herbal products also need to be reported?	276	88.2%	37	11.8%
3	Do you know how and where to report an ADR?	233	74.4%	80	25.6%
4	Do you think ADR need to be reported only when they are severe and cause danger to life?	232	74.1%	81	25.9%
5	Can community pharmacist submit adverse drug reactions by electronic (online) reporting in India?	258	82.4%	55	17.6%

### 3. Community pharmacist Attitude towards ADR reporting

There were five questions related to attitude of pharmacists towards ADR reporting (Table III). 83.4%% pharmacist felt that community pharmacist should be involved in ADR reporting. Most of the pharmacists (83.4%%) felt that reporting ADR is their professional responsibility.

84.7%% respondents believed that serious ADR encouraged them to report it to the relevant authority. 80.8% participants felt that ADR reporting should be made compulsory for all practicing pharmacist. 80.5% of community pharmacist were interested in participating in the reporting system. Table 3 summarizes attitude of community pharmacist towards ADR reporting.

**Table III: Community pharmacist Attitude towards ADR reporting.**

S.no.	Questions	Response			
		Yes		No	
		n	%	n	%
1	Do you think community pharmacist should be involved in ADR reporting?	261	83.4%	52	16.6%
2	Do you think ADR reporting is professional responsibility of a pharmacist?	261	83.4%	52	16.6%
3	Do you think serious ADR encourage pharmacist to report it to the relevant authority?	265	84.7%	48	15.3%
4	Do you think ADR reporting should be made compulsory for all practicing pharmacist?	253	80.8%	60	19.2%
5	Are you interested in participating in the ADR reporting system?	252	80.5%	61	19.5%

### 4. Community pharmacist practice towards ADR reporting

There were five questions regarding practice of respondents towards ADR (Table 4). 46% of



pharmacists replied that reporting form of ADR are not available at their work place. 60.1% have observed ADR cases during their practice. Only 45.4% reported that they are sending a suspected ADR report to the manufacturer. Only 43.5% have attended any ADR workshop or training. About question regarding reasons for not reporting ADR by pharmacist, majority of participants (57.8%)

replied that they are not aware about method of reporting of ADR. Other reasons include, most ADR were minor (3.2%%). 11.2% responded that they don't have enough time for reporting and 7.3% participants feared facing legal problems while reporting and 17.3% were about other reasons.

**Table IV: Community pharmacist practice towards ADR reporting.**

S.no.	Questions	Response			
		Yes		No	
		n	%	n	%
1	Is reporting form of ADR available at your place of work?	144	46%	169	54%%
2	Have you observed ADR cases during your practice?	188	60.1%	125	39.9%
3	Do you report ADR that you come across?	142	45.4%	171	54.4%
4	Have you attended any ADR workshop or training ?	136	43.5%	177	56.5%
5	What are the reasons for not reporting an ADR?				
	I. Lack of awareness about the method of reporting	181	57.8%		
	II. Pharmacist doesn't have enough time.	35	11.2%		
	III. Most ADR are minor and should not be reported	10	3.2%		
	IV. All ADRs are familiar and already reported	10	3.2%		
	V. Fear of facing legal problems	23	7.3%		
	VI. Other	54	17.3%		

## DISCUSSION

Community pharmacists play a pivotal role in pharmacovigilance, especially in the reporting of adverse drug reactions (ADRs). This study highlights their potential to significantly enhance patient safety while also identifying barriers that hinder their full participation. Despite widespread acknowledgment of the importance of ADR reporting, with 90.4% of pharmacists understanding the need for it, knowledge gaps persist. While 74.4% knew where and how to report ADRs, a substantial number remained unaware of electronic reporting systems, with 17.6% not knowing such tools existed. This lack

of awareness suggests the need for targeted educational interventions to bridge operational and procedural knowledge gaps.

The attitudes of community pharmacists towards ADR reporting are overwhelmingly positive, as evidenced by over 80% believing that it is their professional responsibility and advocating for it to be made mandatory. Additionally, most respondents showed a strong interest in participating in reporting systems, with many citing their willingness to engage if systems were improved. However, this positive outlook is not fully reflected in their practices. While 60.1% of pharmacists reported observing ADR cases, only

45.4% submitted reports, indicating a significant gap between awareness and action.

Several barriers contribute to this discrepancy. For instance, only 43.5% of pharmacists had attended workshops or training sessions on ADR reporting, demonstrating a clear need for structured and accessible training programs. Administrative hurdles, such as the unavailability of reporting forms at 46% of workplaces and the complexity of reporting processes, further discourage participation. Fear of legal consequences, reported by 7.3% of pharmacists, adds to the reluctance. These factors collectively highlight the necessity of simplifying the reporting process, increasing the availability of resources, and ensuring pharmacists feel supported and protected when fulfilling their pharmacovigilance responsibilities. Demographic factors also play a role in shaping pharmacists' engagement with ADR reporting. The study population was predominantly young and female, with 64.9% having less than five years of professional experience. This emphasizes the importance of integrating pharmacovigilance education into undergraduate pharmacy curricula and offering early-career training programs to ensure these professionals are well-equipped to contribute to patient safety. A critical issue identified is the lack of feedback mechanisms. Many pharmacists expressed frustration at not receiving updates or acknowledgment for their contributions, which diminishes their motivation to report ADRs. Establishing feedback loops that inform pharmacists about the impact of their reports can foster a sense of ownership and accomplishment, encouraging consistent participation.

The findings align with global trends, where knowledge gaps and underreporting are common challenges in pharmacovigilance. Lessons from countries with well established systems, such as the UK and Netherlands, can provide valuable insights for improving India's framework.

Strategies like mandatory pharmacovigilance training, enhanced digital tools for reporting, and campaigns to raise awareness among healthcare professionals and the public are crucial.

In conclusion, community pharmacists are well-positioned to strengthen pharmacovigilance efforts, but systemic barriers must be addressed to unlock their full potential. By bridging knowledge gaps, streamlining processes, and fostering a supportive environment, policymakers can enhance pharmacists contributions to ADR reporting, ensuring safer medication use and better healthcare outcome.

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