



# ADVERSE DRUG REACTION REPORTING AND MONITORING IN COMMUNITY PHARMACIST: AN OVERVIEW

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## ABSTRACT:

ADRs, or adverse drug reactions, are unforeseen side effects of taking medication that can cause hospitalizations or even fatalities. For the sake of drug monitoring, research, and patient safety, authorities must receive ADR reports in a timely manner. One of the main factors contributing to morbidity, mortality, and rising healthcare costs is adverse medication reactions. Community pharmacists worldwide have a crucial role in monitoring and reporting ADRs to their respective national Pharmacovigilance programmes because the prevalence of ADRs is greater than 50% in community settings. Yet, community pharmacists have not yet begun to practise in India because of the attitude of traders. They made to the Indian Pharmacovigilance programme (PvPI).

**KEY WORDS:** ADR

## INTRODUCTION:

Medications are utilised to cure diseases because they have the power to alter the body's altered physiological systems. Yet, they always carry the risk of adverse drug events, which are undesirable or unanticipated outcomes brought on by a variety of predisposing variables. Every unfavourable and unplanned medical occurrence that coincidentally manifests while receiving therapy with a medication but does not necessarily have a causal connection to this treatment is referred to as an adverse event (AE). It covers all unfavourable events or responses brought on by medications as well as any other occurrences that are believed to be unrelated to reactions. Not all adverse drug reactions (AEs) are caused by medications; some can be the result of a patient's sickness or condition, genetic or environmental variables, food, or other factors.<sup>1</sup>

## FACTORS IMPACTING THE RISK OF A DRUG SIDE EFFECT:

Pharmacodynamic variables:

1. Variations in receptor sensitivity

Pharmacokinetic aspects include:

1. Distribution, metabolism, excretion, absorption, and metabolism
2. Co-occurring illness Kidney function impairment; liver function impairment; heart failure  
Interactions between drugs
3. Physiological state, age, pregnancy, obesity, lifestyle variables, alcohol consumption, and smoking
4. Variability of genetic components. Compliance with recommended therapy  
Medication errors.<sup>2,3</sup>

## IMPORTANCE OF ADR MONITORING AND REPORTING:

In clinical trials, medications are typically tested on a small number of patients for a short period of time in a controlled environment. The drug's safety profile with various co-morbid conditions and unique populations has not been fully established with various co-morbid diseases and distinct populations. The elderly, the very young, and patients with co-morbidities are occasionally excluded from these trials, even though the approval procedure includes comprehensive safety assessment. Those using various medications as well as those with impaired liver and kidney function are frequently excluded. Any potential ADRs in this patient cohort won't be caught when they are monitored during research investigations. Clinicians have a very tough time predicting patients' prescription behaviour.<sup>4,5</sup>

## BENEFITS OF ADR MONITORING:

1. Provide information on the drug's risk profile.
2. Coordinates risk-management initiatives and works to reduce drug-related issues.
3. Evaluate the safety profile of medications, particularly freshly approved medications.
4. Calculate the incidence rate of ADR.
5. Raising patient and healthcare professional awareness of potential medication-related issues and monitoring them to report adverse drug reactions (ADRs).
6. Evaluation of the economic costs associated with ADRs and methods to reduce them by evaluating their seriousness and preventability.<sup>6,7</sup>

## KAP studies of Community Pharmacists Regarding ADR Reporting: International Situation

Jimmy Jose and colleagues conducted a cross-sectional pilot study in the Sultanate of Oman in 2012 to evaluate community pharmacists' knowledge, attitudes, and behaviours regarding features of harmful medication reactions. They created the questionnaires by consulting prior literature and the factors that were assessed as part of the study. Mostly three sections make up the questionnaire, which has 21 questions overall. There are nine questions in Section One to gauge pharmacists' knowledge of drug safety, and there are questions in Section Two to gauge community pharmacists' attitudes and knowledge about reporting adverse drug reactions (ADRs) and how they behave when confronted with ADR-related issues. Mahmoud MA et al. carried out a different study to evaluate community pharmacists' knowledge, actions, and experiences about reporting adverse medication reactions in Saudi Arabia in 2013. Surveys were sent out to a convenience sample of 147 community pharmacists working in Riyadh.

The poll has received responses from about 104 pharmacists (70.7%). Only 22% of respondents, according to the study's findings, were aware of the ADR reporting procedure, and only 20% were aware that pharmacists may submit ADR reports online. Nonetheless, the majority of participants (91%) had never reported an ADR.<sup>8</sup>

## Drug Abuse Reported by Community Pharmacists

Community pharmacists' reporting of ADRs can produce valuable information about the drug's safety profile. Using this information will make it easier to create community-wide ADR prevention initiatives.<sup>9</sup>

### Solutions for Community Pharmacists to Enhance ADR Reporting:

1. Improving the awareness about importance of Pharmacovigilance and role of pharmacists in strengthening the same through organising workshops on adverse drug reaction reporting and monitoring
2. Awareness on adverse drug reactions to consumers or general population.
3. Set up of the ADR drop boxes at the community pharmacy.
4. ADR Reporting should be made mandatory for community pharmacist.
5. Providing incentives to the community pharmacists for quality reports.
6. Creating consumers awareness in reporting ADRs.
7. Periodic meetings between community pharmacists and nearest ADR monitoring centre coordinator to improve the quality of reports.
8. Implement the data base system in community pharmacy setting which includes patient characteristics with respective treatment and physician details.
9. Awareness on important ADRs to the community.<sup>8,9</sup>

## CONCLUSION

Community pharmacists are better suited to report adverse events to Pharmacovigilance programmes because they have a greater understanding of patient needs, their struggles with medications, and their professional qualifications. Several research findings indicate that personal barriers to reporting and a lack of knowledge about where to report and how to disclose can be addressed via ongoing education and motivation.

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