

# Questionnaire-based survey on awareness of adverse drug reaction reporting for antihypertensive drug by community pharmacists in Amravati district

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## ABSTRACT

**Introduction:** Drug-related effects may lead to hospitalization, patient suffering, and economic burden. Adverse drug reaction (ADR) monitoring and reporting system help in the detection and prevention of the reoccurrence of some common and also rarest ADRs. The objective of this study was to create awareness among the selected community pharmacists and to improve their level of understanding about monitoring and reporting ADRs to the pharmacovigilance center around the facility. **Aim:** The study aimed to monitor ADRs associated with antihypertensive drugs through community pharmacists. The study was conducted in Amravati district with the help of different pharmacists. The study was conducted by one-to-one interaction with pharmacists using a questionnaire-based ADR monitoring form related to antihypertensive drugs. **Objectives:** The study was conducted to examine awareness about ADRs in drug-treated hypertensive patients. The objectives of the present study were to create awareness among select community pharmacists about ADRs reporting. **Conclusion:** The pharmacists need to upgrade knowledge and should be aware about all the aspects of ADR.

**Keywords:** Community pharmacist, Adverse drug reaction, Anti-hypertensive drugs, Adverse drug reaction reporting, Creating awareness

## Introduction

An adverse drug reaction (ADR) is “an unpleasant and unexpected response to a medication that occurs at doses usually used in humans for the prevention, diagnosis, and treatment of illness, or for change of physiological function,” according to the World Health Organization (WHO).<sup>[1]</sup> Another definition of an ADR is “an appreciably detrimental or unpleasant reaction occurring from an intervention related to the use of a pharmaceutical product, which predicts danger from future administration and necessitates avoidance, specific therapy, dose regimen modification, or product withdrawal.”<sup>[2]</sup> In India, ADRs are among the leading causes of morbidity and death. Approximately 6% of hospital admissions are estimated to be the result of ADRs, and 6–15% of hospitalized patients have a major ADR.<sup>[3]</sup> The whole adverse event

profile of a new treatment may not be known when it is authorized for commercialization by the food and drug administration<sup>[4]</sup> due to the limits of pre-approval clinical studies. Depending on the sort of study and the final type of data you intend to collect, survey methodologies might be qualitative or quantitative.<sup>[5,6]</sup> For instance, using Form plus, you can design and manage an online survey that enables you to gather statistical data from respondents.<sup>[7,8]</sup> Face-to-face interviews or focus groups may be set up for qualitative research.<sup>[9]</sup>

## Role of pharmacists in preventing ADRs

Fundamental to pharmaceutical care is making sure that medications are utilized safely. The engagement of pharmacists in patient care should aid in the early identification and prevention of ADRs.<sup>[9]</sup> According to studies, the intervention of pharmacists has prevented a significant number of possible negative effects.<sup>[10]</sup> Pharmacists may make sure that prescription is as safe and appropriate as feasible using their understanding of the relevant patient and pharmaceutical aspects.<sup>[11]</sup> In addition, pharmacists are in a unique position to spot ADRs brought on by medication interactions.<sup>[12]</sup>

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## Reporting of ADRs in India

Clinical pharmacy is still in the early stages of development and pharmacists are a medical specialty that is underused.<sup>[13]</sup> As a National Coordinating Center, the Department of Pharmacology at AIIMS oversees the ADR monitoring program, which was launched in 1982 under the direction of the Drug Control General of India.<sup>[14]</sup> When medications are made available for widespread societal usage, the primary goal of pharmacovigilance is to assure their safe and responsible use. There are relatively few studies regarding ADR reporting in community settings in India.<sup>[15]</sup> Community pharmacists are restricted to trade because to a lack of understanding of their professional responsibility. The reporting mechanism will be strengthened if community pharmacists are sufficiently motivated.<sup>[16]</sup> As a result, community pharmacists need to establish and execute an ADR reporting system.<sup>[17]</sup>

## Hypertension

The classic definition of hypertension is an extended rise in blood pressure (BP) of 140/90 mm Hg, a criteria that define a subset of people with a high enough risk of cardiovascular disease (CVD) associated with hypertension to need medical treatment.<sup>[18]</sup> The lowest risk of both fatal and non-fatal CVD in adults is related with systolic BP (SBP) of 120 mm Hg and diastolic BP (DBP) of 80 mm Hg; greater SBP and DBP increase both risks.<sup>[19]</sup> Up to one billion individuals may be affected by hypertension, which is estimated to cause 7.1 million fatalities annually.<sup>[20]</sup> The WHO states that there is minimal difference in the incidence of CVD and ischemic heart disease among men and women when suboptimal BP (>115 mmHg SBP) is present.<sup>[21]</sup> In addition, the greatest cause of mortality worldwide is excessive BP.<sup>[22]</sup> ADR costs have been expected to be taken into account due to the extension of hospital stays, in addition to the suffering of patients who are really experiencing one or more ADRs.<sup>[23]</sup> To reach BP objectives, two or more antihypertensive medications (AHAs) are commonly needed; however, adding additional AHAs to a regimen may have even more negative side effects.<sup>[24]</sup> ADRs are considered to be the fourth leading cause of mortality, after only pulmonary illness, AIDS, accidents, and traffic fatalities.<sup>[25]</sup>

### Primary hypertension

It is also known as essential hypertension. Hypertension occurs when you have abnormally high BP that is not the result of a medical condition.<sup>[24,25]</sup>

### Secondary hypertension

It may be defined as a type of hypertension with an underlying, potentially correctable cause.<sup>[24,25]</sup>

## Methodology

This study's design called for it to be observational, prospective, and survey-based. Among order to raise awareness of ADRs or reporting ADR linked to antihypertensive medicines, this prospective survey research was undertaken for 1 month in 100 chosen authorized community pharmacists in Amravati city. A self-designed survey that

was created and validated included all pertinent information, such as the name of the pharmacy, the pharmacist's name, their registration number, and whether or not the community pharmacist was aware of ADRs, adverse events, or reporting ADR related to AHA. These questionnaires include a pre-questionnaire to determine whether the pharmacist is familiar with terms such as ADRs, adverse events, and pharmacovigilance, and a post-questionnaire to determine whether the pharmacist has ever received an ADR from a patient who is taking an antihypertensive medication or reported an ADR to a reporting center. The survey also included information that may be used to gauge a pharmacist's level of expertise, including information on ADRs, how to report ADRs, where to get ADR forms, and a survey to gauge the pharmacist's attitude toward ADR reporting. Using the paper survey technique and the face-to-face communication survey method, we established specified requirements for this questionnaire. The questionnaire that is used in this particular survey type is shown in the chart Tables 1 and 2.

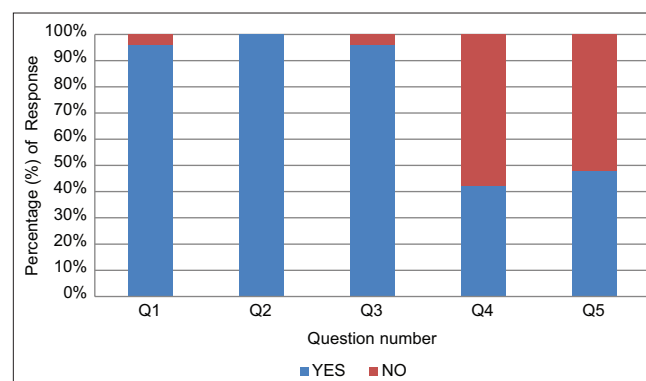
This was a prospective survey study, conducted for 1 month in 100 selected approved community pharmacies in Amravati city to create awareness of ADRs. Among the two chain pharmacies were selected.

## Result and Discussion

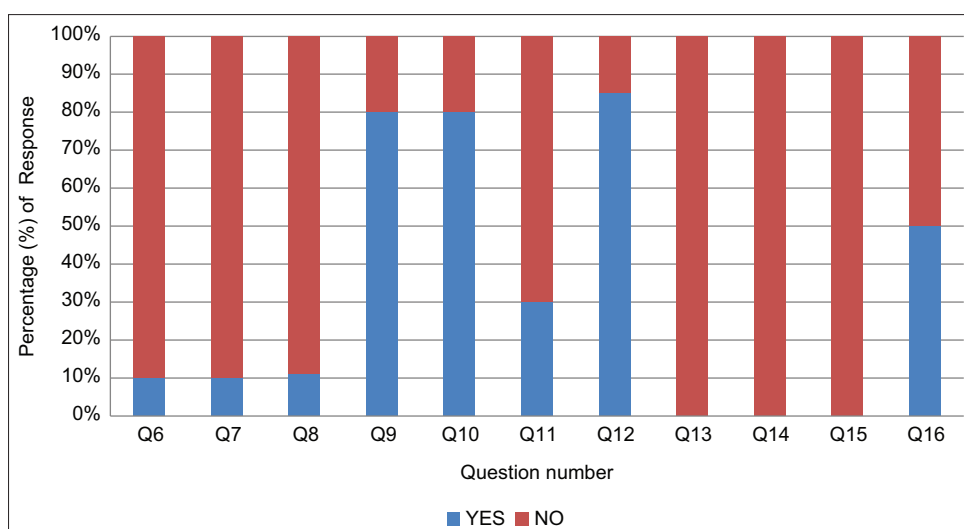
The present prospective study was conducted among 100 community pharmacists for 1 month in and around Amravati city to create awareness among community pharmacists about ADR related to antihypertensive drugs. The results of questionnaire are represented as Figure 1 and 2.

After asking questions to pharmacist, we got response as, 96% of community pharmacist well known about pharmacovigilance and 4% did not aware about it. All the pharmacist were found known about ADRs but when asked about adverse event, 4% were known about it and remaining 96% were unknown to this term. Only 42% pharmacist found aware about reporting ADR to authorized person. About 48% pharmacist found aware about identification of ADR.

Second question set found response as, only 10% come across patients experiencing ADRs related to antihypertensive drugs and remaining did not notice any ADR. About 11% community pharmacist found



**Figure 1:** Response of common questions asked to community pharmacist in Amravati (Question set 1)



**Figure 2:** Response of common questions asked to community pharmacist in Amravati (Question set 2)

**Table 1: Common questions asked to community pharmacist in Amravati (Question set 1)**

S.No	Common questions	Yes	No
Q1	Do you know about pharmacovigilance?	96%	04%
Q2	Do you know about ADRs?	100%	0%
Q3	Do you know about adverse events?	96%	4%
Q4	Do you know how to report ADRs to authorize person of office?	42%	58%
Q5	Do you know how to identify ADRs?	48%	52%

ADRs: Adverse drug reactions

**Table 2: Questions asked to community pharmacist related to antihypertensive drug in Amravati (Question set: 2)**

S. No	Questions related to antihypertensive drug	Yes	No
Q6	Did you ever come across patients experiencing ADRs related to antihypertensive drugs?	10%	90%
Q7	Did you report an ADR?	10%	90%
Q8	Have you ever observed any ADR that cause Hospitalization A life-threatening situation A congenital anomaly Death of patients?	11%	89%
Q9	Do you think reporting ADR increases patient safety?	80%	20%
Q10	Do you think reporting ADR is mandatory?	80%	20%
Q11	ADR reporting helps to compare ADR for drugs in similar therapeutic class?	30%	70%
Q12	ADR reporting enables the safe drug to be identified?	85%	15%
Q13	Have you observed about sodium intake of the patient?	0%	100%
Q14	Are you involved in the treatment of ADR?	0%	100%
Q15	Have you ever sodium intake?	0%	100%
Q16	Does ADR of antihypertensive are dose-dependent?	50%	50%

ADRs: Adverse drug reactions

hospitalization, a lifethreatening situation, a congenital anomaly, death of patients, etc. as a result of ADR. According to 80% of community,

pharmacist reporting ADR increases patient safety as well as it is reporting ADR is mandatory and remaining 20% had no response on it. ADR reporting helps to compare ADR for drugs in similar therapeutic class, this statement supported by only 30% pharmacist and remaining 70% said that it does not depend on therapeutic class of drug. About 85% pharmacist said that ADR reporting enables the safe drug to be identified. No pharmacist found to say that they ask patients about sodium intake. No pharmacist found included in ADR treatment. About 50% pharmacist said that ADR of antihypertensive is depend on dose.

## Conclusion

This study concludes that community pharmacist of Amravati district is known about general concept of ADR but when thought about its specificity, it found that more awareness is necessary about ADR, its reporting, its identification, its causes, etc. as they all are connected to public health.

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