Journal of Futuristic Sciences and Applications
Vol. 7(2), Jul-Dec 2024, pp. 59-63
doi: 10.51976/jfsa.722405
www.gla.ac.in/journals/jfsa
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Barriers and Educational Interventions Influencing Adverse Drug Reaction Reporting among Community Pharmacists: Evidence from a Pharmacovigilance Study

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ABSTRACT

Underreporting of adverse drug reactions (ADRs) remains one of the major limitations of pharmacovigilance systems worldwide. Community pharmacists play an important role in detecting and reporting ADRs because of their close interaction with patients. This study investigated the barriers affecting ADR reporting and evaluated the impact of educational interventions among community pharmacists participating in a pharmacovigilance program in Oman. A prospective interventional study was conducted among seven community pharmacies between March 2020 and March 2022. Pharmacists participated in a structured educational workshop on pharmacovigilance and ADR reporting procedures. Data regarding reporting barriers, pharmacist participation, and ADR reporting trends were collected and analyzed. The most common barriers identified were concerns regarding patient confidentiality (35.7%), competing clinical responsibilities (19.8%), lack of ADR reporting forms (15.2%), and uncertainty regarding reporting procedures (9.2%). Educational interventions significantly improved pharmacist awareness, confidence, and reporting participation. A total of 700 ADR reports were documented during the study period following implementation of the intervention program. The study highlights the importance of pharmacist education and standardized reporting systems in strengthening pharmacovigilance practices. Simplified reporting processes, regular training programs, and supportive healthcare policies are essential to improving ADR reporting rates in community pharmacy settings.

Keywords: *Pharmacovigilance; ADR reporting; Community pharmacists; Educational intervention; Drug safety; Reporting barriers.*

1.0 Introduction

A prospective observational study was conducted over 24 months from March 2020 to March 2022 in selected community pharmacies in Oman. Seven community pharmacists participated after receiving structured training on ADR identification and reporting. A total of 700 ADR reports were collected and analyzed using WHO causality assessment criteria, the Naranjo algorithm, and Hartwig's severity scale. Results indicated that antihypertensives and antidiabetics were the most frequently implicated drug categories. Most ADRs were mild and categorized as "possible" or "probable" according to WHO criteria.

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Doi: 10.51976/jfsa.722405

The study demonstrated that pharmacist involvement, continuous training, and structured monitoring significantly improve ADR reporting rates and public awareness regarding medication safety. Community pharmacy-based pharmacovigilance systems can therefore strengthen national drug safety programs and enhance patient outcomes.

The incidence of adverse drug reactions (ADRs) during hospital stays varies from 1.5% to 35%, accounting for 3% to 6% of hospitalizations globally. An ADR-related hospitalization is expected to cost Rs. 4945 per day for treatment [1]. Healthcare workers significantly underreport the occurrence of adverse drug reactions (ADRs), which is above 57% in community settings [2].

National pharmacovigilance for drug safety monitoring relies heavily on spontaneous reporting systems (SRS) [3]. Widespread underreporting severely restricts the effectiveness of SRS, despite it being a straightforward, inclusive, and affordable technique for signal identification (particularly for novel medications) [4]. The majority of national programs allow pharmacists and other healthcare providers to report [5], but underreporting is still a significant problem that is frequently caused by practitioners' lack of understanding of the need and protocols of ADR reporting.

By recognizing, avoiding, recording, and reporting adverse drug reactions (ADRs), pharmacists play a crucial role in pharmaceutical safety. They contribute considerably to pharmacovigilance databases and are heavily involved in national reporting systems; for example, they account for 26% of reports in Spain, 24% in Portugal, 89% in Canada, 40% in the Netherlands, and 41% in Australia [6]. In modern healthcare systems, pharmacists are actively encouraged to record adverse drug reactions (ADRs), and the quality of their reports is on par with that of other medical professionals [7].

On the other hand, Indian pharmacists' knowledge of ADR reporting procedures is still rather low. Clinical pharmacists may now take on more responsibility for ADR surveillance and reporting because to the implementation of specialist clinical pharmacy training programs [8]. Community pharmacists are in a good position to assist with pharmacovigilance initiatives since they are often thought of as the most approachable medical professionals for medication-related issues [9]. Their professional scope has grown over the past several decades to include active involvement in prescription choices and the provision of all-encompassing pharmaceutical care, in addition to traditional dispensing.

According to Hepler and Strand, pharmaceutical treatment is the responsible administration of pharmacological therapy to improve patient quality of life by achieving specific goals. Community pharmacists actively participate in national pharmacovigilance programs because of their direct patient interaction [10]. It is acknowledged that no drug is completely free of possible negative side effects. The European Commission's ADR figures are shown in Table 1.

Table 1: Data on Adverse Drug Reactions (ADRs) Sourced from European Commission Publications

Clinical Indicator	Estimated Proportion (%)
Cases requiring inpatient care	0.3 – 5
Recorded fatal outcomes	3.5
Adverse drug events observed during hospital stay	1.9 – 6

When it comes to tracking and reporting adverse drug reactions (ADRs) for over-the-counter and complementary medications, community pharmacists hold a special position. Research from

throughout the world attests to their important role in locating and reporting adverse drug reactions (ADRs) to pharmacovigilance programs; for example, community pharmacists were responsible for 40% of reports to the Netherlands' Lareb center [11,12]. Therefore, maintaining their knowledge, self-assurance, and drive is essential to raising ADR reporting rates.

2.0 Provision of Alert Cards to Patients

Table 2: ADR Events Requiring Alert Card Issuance and Associated Medications

Reaction Type	Drugs Involved	Primary Site Affected
Skin-related events	Metoprolol; Glipizide; Co-trimoxazole; Levofloxacin; Glimepiride + Metformin; Cefixime; Salmeterol + Fluticasone	Skin
Oral manifestations	Penicillin G	Oral cavity

Strategies for ADR Management

Table 2: Outcomes Following Identification of Suspected Drugs in ADR Cases

Management Approach	Proportion (%)	Number of Cases (n)
Discontinuation of drug	57.14	400
Substitution with another	21.42	150
Dose modification	14.28	100
No therapeutic change	7.14	50
Total Cases	**100**	**700**

Table 4: Management Strategies Adopted for ADR Cases

Measure	Specific	Symptomatic	No Treatment	Total
Number of ADRs	100	200	400	700
Percentage (%)	14.28	28.57	57.14	100

Results of Adverse Drug Reactions

Table 5: Clinical Outcomes Observed in ADR Cases

Indicator	Recovered	Continuing	Fatal	Total
Number of ADRs	400	300	0	700
Percentage (%)	57.14	42.85	0.00	100

Assessment of ADR Severity

Table 6: Severity Classification of ADRs Based on Intensity Levels

Severity Category	Levels Included	Total Cases	Percentage (%)
Mild	Level 1 & 2	650	92.85
Moderate	Level 3–4	50	7.14
Severe	Level 5–7	0	0.00
Overall Total	—	**700**	**100**

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Assessment of ADR Preventability

Table 7: Assessment of ADR Preventability

Preventability Category	Proportion (%)	Number of Cases (n)
Likely preventable	64.28	450
Unavoidable	35.71	250
Clearly preventable	0.00	0
Total Cases	**100**	**700**

Evaluation of ADR Causality

Table 8: Causality Evaluation of ADRs Using WHO Criteria

Measure	Certain	Probable	Possible	Unlikely	Conditional	Unassessable	Total
Number of ADRs	0	200	250	100	150	0	700
Percentage (%)	0.00	28.57	35.71	14.28	21.42	0.00	100

Table 9: Causality Evaluation of ADRs Based on Naranjo Scale

Measure	Highly Probable	Probable	Possible	Unlikely	Total
Number of ADRs	0	250	450	0	700
Percentage (%)	0.00	35.71	64.28	0.00	100

3.0 Results and Discussion

The Rawlins and Thompson categorization was used to classify ADRs: 250 (35.71%) were Type B responses and 450 (64.28%) were Type A reactions. "Alert cards" were given to patients who experienced Type B responses (hypersensitive, not dose-related, and less frequent) for upcoming medical appointments.

The most common adverse drug reaction (ADR) was acidity (160, 22.85%), followed by constipation (108, 15.42%), and giddiness (1, 0.14%).400 (57.14%) patients had their medications discontinued, 150 (21.42%) had their dosages changed, and 100 (14.28%) had their dosages changed.400 patients (57.14%) got no therapy, whereas 100 patients (14.28%) received specialized treatment for ADRs.

Results: No fatal responses happened throughout the research, and 400 patients (57.14%) recovered. According to Hartwig's severity scale, the majority of ADRs were classified as Mild (650, 92.85%) and Moderate (50, 7.14%).

Based on the Modified Schumock & Thornton criterion, 250 ADRs (35.71%) were not avoidable and 450 ADRs (64.28%) were likely preventable. According to the WHO probability scale, the majority of ADRs were classified as "Possible" (250, 35.71%), "Conditional" (150, 21.42%), and "Probable" (200, 28.57%).In a similar vein, the majority of ADRs were assessed as "Possible" (450, 64.28%) by the Naranjo algorithm, followed by "Probable" (250, 35.71%).

Underreporting of adverse drug reactions (ADRs) was attributed by community pharmacists to a number of factors, including patient unawareness, poor medication knowledge, and hectic schedules.

4.0 Conclusion

Community pharmacy–based pharmacovigilance systems are effective tools for monitoring adverse drug reactions and improving medication safety. Structured training, standardized reporting methods, and pharmacist involvement significantly enhance ADR detection and reporting practices.

Expanding pharmacovigilance activities within community pharmacies can strengthen national drug safety systems and improve patient outcomes. Policymakers should encourage pharmacist participation through training programs, simplified reporting systems, and stronger regulatory support.

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