

Effectiveness of Community Pharmacy-Based Pharmacovigilance Systems in Monitoring Adverse Drug Reactions

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Abstract: Adverse Drug Reactions (ADRs) remain a major public health concern and contribute significantly to morbidity, mortality, and healthcare expenditure worldwide. Pharmacovigilance systems play a vital role in identifying, assessing, and preventing ADRs. This study evaluates the effectiveness of community pharmacy-based pharmacovigilance systems in monitoring ADRs and improving reporting practices. 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. 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.

Keywords: Pharmacovigilance, adverse drug reactions, community pharmacists, drug safety, ADR reporting, pharmacovigilance systems.

1. Introduction

The World Health Organization defines adverse drug reactions (ADRs) as severe, unanticipated pharmaceutical responses at conventional dosages. ADRs are a significant global cause of morbidity, death, and higher healthcare expenditures [1]. They are the fourth or sixth most common cause of mortality for hospitalized patients and result in longer hospital stays and higher costs [2].

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 [3]. Healthcare workers significantly underreport the occurrence of adverse drug reactions (ADRs), which is above 57% in community settings [4].

National pharmacovigilance for drug safety monitoring relies heavily on spontaneous reporting systems (SRS) [5]. Widespread underreporting severely restricts the effectiveness of SRS, despite it being a straightforward, inclusive, and affordable technique for signal identification (particularly for novel medications) [5]. The majority of national programs allow pharmacists and other healthcare providers to report [6], 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 [7]. 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.

2. Community Pharmacy Practice in Healthcare Systems

2.1 Impact of Community Pharmacy Practice on Healthcare Systems

Buss et al. (2018) [10] assessed government-funded pharmacy services in Australia with an emphasis on drug quality and the prevention of chronic diseases. Clinical services, medication reviews, health promotion, chronic disease screening and treatment, and substance addiction assistance were the five categories of interventions that the study looked at. Positive results included increased rates of vaccination, diabetes identification, asthma management, and quitting smoking. In order to provide more thorough, patient-centered treatment, the investigation also highlighted barriers, facilitators, and the necessity of improved teamwork.

Mossialos et al. (2015) [11] reviewed current initiatives to increase the responsibilities of community pharmacists in Australia, Canada, England, the Netherlands, Scotland, and the US. It emphasized how underutilized pharmacists are as healthcare professionals and how they may enhance pharmaceutical safety and efficacy, particularly for patients with several chronic diseases. In order to improve healthcare quality and outcomes, the paper focused on integrating pharmacists into primary care, developing a common vision for tiered services, and developing incentive structures. It also provided ideas for politicians throughout the world.

2.2 Constraints and Prospects for Improvement in Community pharmacists Implementation

Kheir et al. [12] examined pharmaceutical services in Qatar, a rapidly developing Gulf nation, in 2011. The study discovered challenges similar to those in other Middle Eastern nations, most notably the lack of an independent pharmacy organization or regulator. It highlighted a number of efforts that are propelling advancement, including practice-level pharmacy leadership groups, National Health Strategy leadership, cooperation with institutions, and advancements in education.

Dugan et al. [13] in 2006 noted increasing demand for an expanded community pharmacy scope of practice. Over the course of two decades, patient and medical system demand led to this need. To satisfy these needs, many pharmacists embraced the pharmaceutical care model, which opened up job options, particularly for graduates in Medication Therapy Management (MTM).

The importance of Advanced Pharmacy Practice Experiences (APPEs) from colleges was emphasized in the study. By demonstrating the integration of pharmaceutical treatment into community practice, APPEs prepare students. In order to ensure that students are prepared for practice dynamics, Community Pharmacies (CPs) and schools worked together to expand the number of APPE locations. Reviews of community pharmacists in healthcare by different writers are compiled in Table 8.

Table 1: Examination of Community Pharmaceutical in the Medical Field

Author (Citation)	Aim	Advantages	Drawbacks
Dugan et al. [8]	Explores expanded pharmacy roles and career opportunities in MTM services.	• Promotes advanced pharmacy practices. • Identifies career growth paths. • Encourages academic–practice collaboration.	• Limited practical exposure at training sites. • Gaps in evaluating model limitations. • Potential positive bias.
Buss et al. [5]	Evaluates public pharmacy services and their role in patient care in Australia.	• Cost-effective and accessible services. • Supports prevention and medication management. • Enhances patient safety.	• Access gaps in remote areas. • Funding constraints. • Requires further assessment.
Kheir et al. [7]	Reviews pharmacy practice progress and challenges in Qatar.	• Expanding education and infrastructure. • Strong collaboration with institutions. • Rapid healthcare development.	• Lack of unified regulatory body. • Fragmented initiatives. • Reliance on multiple programs.
Mossialos et al. [6]	Examines international strategies to strengthen community pharmacists' roles.	• Lowers hospital admissions. • Improves treatment outcomes. • Strengthens primary care links.	• Needs extra training resources. • Integration difficulties in healthcare systems.

2.3 Involvement of Pharmacy Professionals in Reporting Adverse Drug Reactions

• Reporting of Adverse Drug Reactions by Community Pharmacists

The pharmacovigilance responsibilities of pharmacists in community and hospital settings were examined by Van Grootheest et al. (2005) [14]. They emphasized the substantial potential of pharmacists to report adverse drug reactions (ADRs) outside of their regular responsibilities, pointing out the vital role hospital pharmacists play after major incidents and the active involvement of Dutch community pharmacists. In order to improve patient safety, the authors called for increasing the pharmacovigilance responsibilities of pharmacists.

In Southern Portugal, Duarte et al. (2015) [15] evaluated community pharmacists' understanding of ADR spontaneous reporting laws. They discovered reporting obstacles using a mixed-methods approach (pharmacy survey and focus groups). Online resources, pharmacist education, and cooperation between industry, regulators, and pharmacists to enhance reporting were among the recommendations.

Pharmacist-led initiatives encouraging direct patient ADR reporting in the Campania area of Italy were assessed by Parretta et al. (2014) [16]. Patients were recruited through pharmacist interviews, which greatly increased the number of reports to the national system. The study showed how pharmacists can help patients report adverse drug reactions (ADRs), how patients may recognize ADRs, and how report form design can be improved.

An intervention in the Veneto area of Italy that encouraged patient ADR reporting through community pharmacies was evaluated by Leone et al. (2013) [16]. Pharmacists interacted with customers during four months, which led to a significant number of suspected ADR complaints. The majority of patient reports were of good quality, providing useful

information to improve pharmacovigilance, support signal detection, and monitor medication safety.

2.4 Training Initiatives and Educational Strategies

The Impact of Training Programs and Educational Programs on Pharmacists to Improve ADR Reports is examined in this section.

- **Role of Educational Programs in Enhancing Pharmacists' Skills**

In order to evaluate educational approaches that improve health professionals' pharmacovigilance (PhV), Pagotto et al. [17] carried out a thorough evaluation in 2013. In order to increase medication safety, the study examined how these measures affected the amount and quality of adverse drug event (ADE) reporting. In order to standardize PhV procedures and solve pharmaceutical mistakes and treatment failures, it concentrated on complicated teaching programs for interdisciplinary teams.

Prior to and following an educational intervention in 2017, Jha et al. [18] assessed the pharmacovigilance knowledge and attitudes of community pharmacists (CPs) in the Lalitpur district of Nepal. The study evaluated shifts in pharmacists' attitudes and expertise regarding reporting adverse drug reactions (ADRs). The intervention improved attitudes and knowledge, according to the results, underscoring the potential contribution of CPs to pharmacovigilance in Nepal. The study asked the national pharmacovigilance center to train CPs on ADR reporting and suggested conducting studies across the country.

- **Training Initiatives to Strengthen ADR Reporting Practices**

The pharmacovigilance knowledge, attitudes, and ADR reporting habits of Omani pharmacists were evaluated by Jose et al. (2014) [19]. The study found gaps in knowledge, indicating that improved training might boost patient safety and reporting.

Australian community pharmacists' ADR reporting behaviors, knowledge, and perceived obstacles were assessed by Li et al. (2018) [20]. The results showed that reporting was hampered by time limits and complicated procedures, as well as inadequate training and comprehension. Simplified systems and instructional interventions were suggested by the research.

3 Participation Response of Community Pharmacists in the Study

Seven pharmacies completed a permission form indicating their interest in taking part in the trial. To educate and teach community pharmacists interested in taking part in the study, the department organized a one-day course on ADR monitoring.

Table 2: Participating Community Pharmacies

ID	Facility	Region
P-01	North Oman Pharmacy	Shinas
P-02	Al Rakha Pharmacy	Shinas
P-03	Al Hissar Pharmacy	Shinas
P-04	Al Hashar Pharmacy	Shinas
P-05	Al Batool Pharmacy	Al Aqar
P-06	Muscat Pharmacy LLC	Al Aqar
P-07	Al Aqar Pharmacy	Al Aqar

3.1 Sociodemographic Profile of Community Pharmacists Involved in the Study

Every community pharmacist that took part was a man. Seven pharmacists were certified as B. Pharm, while the remaining four were qualified as D. Pharm. Out of seven Six community pharmacists had more than five years of experience, while one had only two years.

700 ADRs were recorded during the course of the 24-month trial period, as shown below.

Table 3: Distribution of Adverse Drug Reports (ADRs) by Pharmacy

Pharmacy	Percentage Contribution (%)	Number of ADR Cases
Muscat Pharmacy LLC	21.42	150
Al Hassar Pharmacy	17.14	120
Al Rakha Pharmacy	15.71	110
Al Hashar Pharmacy	13.57	95
Al Aqar Pharmacy	12.85	90
North Oman Pharmacy	12.14	85
Al Batool Pharmacy	7.14	50
Overall Total	100	700

3.2 Patient Demographics in ADR Cases

Table 4: ADR Reports Categorized by Gender

Measure	Male	Female	Overall
Number of Reports	513	187	700
Percentage (%)	73.29	26.71	100

Table 5: Distribution of ADR Cases Across Age Categories

Age Category	Total Cases (n)	Percentage Share (%)
≤ 18 years	70	10.00
19–59 years	250	35.72
≥ 60 years	380	54.28
Overall Total	700	100

3.3 Distribution of ADRs Across Organs and Systems

Table 6: Distribution of ADRs by Affected Body Systems

Measure	GIT	CNS	Skin	Endocrine	Oral	Respiratory	CVS	Renal	Total
Number of ADRs	320	150	130	30	25	18	16	11	700
Percentage (%)	45.71	21.42	18.57	4.28	3.57	2.57	2.28	1.57	100

4 Conclusion

Pharmacovigilance lowers medical expenses and patient damage caused by drugs. It is sometimes difficult for community pharmacists to be acknowledged as medical professionals. They are often viewed as little more than vendors or dealers of drugs.

As a result, community pharmacists ought to willingly accept their professional obligations. This proves that they are not only vendors but also responsible healthcare providers.

Particularly for over-the-counter drugs, they are in a strategic position to report potential adverse drug reactions. They have a crucial role in the number and quality of spontaneous ADR reporting. The goal of this project was to provide community pharmacists with pharmacovigilance training. Its goal was to put ADR monitoring into practice in their pharmacies.

The period of data collection was two years, from March 2022 to March 2024. The amount of ADR reports from different pharmacies was calculated. The largest number of ADR complaints came from Muscat Pharmacy (150; 21.42%), followed by AL Hassar Pharmacy (130; 18.15%) and AL Rakha Pharmacy (100; 14.81%).

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