

Pharmacovigilance Barriers for Healthcare Providers: A cross-sectional study

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Abstract:

Background: Pharmacovigilance is an essential area of public health, involving the detection, assessment, understanding, and prevention of adverse reactions to drugs and medication-related problems.

Methods: The study has been conducted in a period of six months extending from 10 /10/ 2024 to 1 /3/ 2025 in Mosul hospitals. Probability (simple random sample) was selected for the present study. A sample of Health care workers in Mosul hospitals. (166 Health care workers). The subject's acceptance to participate in the study was through the use of a specialized consent form.

Results: The study shows that most of the sample participating in the study amounted to 166 health care workers, that most of the study sample was from 20 to 29 years old, at a rate of 74.7%, and that the sample of female was higher than that of male by (59%), 47.6% of the sample whose residence was institution, Most of the sample was workplace (surgical), with moderate percentage (28.3%).

Conclusion: The data indicate that healthcare providers face moderate to significant barriers in reporting ADRs, with responses fairly split on several key issues.

Key words: Pharmacovigilance, Barriers, Healthcare Providers.

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Introduction

Healthcare providers, including doctors, nurses, pharmacists, and other clinical staff, are the first line of defense in identifying, reporting, and managing adverse drug reactions (ADRs). Their understanding and attitudes toward pharmacovigilance directly impact their ability to detect and report ADRs in a timely and effective manner⁽¹⁾. A study assessing their barriers can provide insights into whether HCPs are adequately trained to recognize potential drug safety issues and manage them appropriately. ⁽²⁾ Effective pharmacovigilance systems rely on active reporting of adverse drug reactions by healthcare providers. However, studies have shown that underreporting of ADRs is a common issue in many healthcare settings. By assessing the knowledge and attitudes of healthcare providers, this study can identify gaps in reporting behaviors, such as lack of awareness of the importance of reporting, fear of legal consequences, or perceived lack of time. Identifying these barriers is crucial in enhancing reporting systems and, ultimately, improving patient safety⁽³⁾. Pharmacovigilance is an essential area of public health, involving the detection, assessment, understanding, and prevention of adverse reactions to drugs and medication-related problems.⁽⁴⁾ Adverse drug reactions (ADRs) are defined as any unintended noxious response to a drug that occurs at doses used normally in humans for prophylaxis, diagnosis, or therapy or to modify physiological function⁽⁵⁾. The aim of the study to assess the barriers of healthcare giver towards pharmacovigilance.

Methods and Materials:

Study Design:

A descriptive study that conducted during the period of 10 /10/ 2024 to 1 /3/ 2025 in Mosul hospitals .

Study Setting:

The present study was conducted at Nineveh Governorate. It is a governorate in northern Iraq, with Mosul as its capital. Mosul is Iraq's second largest city, located 465 kilometers north of Baghdad. The sample was collected from Health care workers in mosul hospitals.

Data Collection Period:

The study has been conducted in a period of six months extending from 10 /10/ 2024 to 1 /3/ 2025 in Mosul hospitals.

Sample of the Study:

Probability (simple random sample) was selected for the present study. A sample of Health care workers in Mosul hospitals. (166 Health care workers). The subject's acceptance to participate in the study was through the use of a specialized consent form.

Steps of the study:

The interview was conducted to fill out the questionnaire with in Health care workers in Mosul hospitals included and each one of them needed approximately (15-20) minutes to complete the interviewing and answering the questionnaire.

Data collection Instrument:

The information of data was collected through a questionnaire used to assess the knowledge and attitudes of healthcare providers towards pharmacovigilance. The instruments of the study were composed of (2) parts,

Part One: Demographic characteristics that include (ages, class, gender, martial status, and residence).

Part Two: To assess the Barriers of healthcare providers towards pharmacovigilance. It consisted of (8) multiple choice questions, in two answer(Yes, No).

Statistical Analysis:

The Statistical Package for Social Sciences (SPSS) version 26 was used to analyze the statistical results. A descriptive approach was applied. Using percentages and frequencies to calculate student's demographic description characteristics⁽⁵⁻¹¹¹⁾.

Results:

Table (1): Distribution of Demographical Characteristics of sample (166)

Variables		Frequency	Percentage
Age	20-29	124	74,7
	30-39	28	16,9
	40-49	9	5,4
	50- more	5	3,0
<u>Total</u>		166	100,0
Gender	Male	68	41,0
	Female	98	59,0
<u>Total</u>		166	100,0
Academic achievement	Master's	4	2,4
	Bachelor's	76	45,8
	Institution	79	47,6
	Nursing preparatory	7	4,2
<u>Total</u>		166	100,0
Experience	Less than one year	62	37,3
	1-3	53	31,9
	3-5	16	9,6
	5-10	13	7,8
	10 years or more	22	13,3
<u>Total</u>		166	100,0
Workplace	Surgery	47	28,3
	Internal Medicine	20	12,0
	Adult Intensive Care Unit	11	6,6
	Pediatrics	9	5,4
	Pharmacy	52	31,3
	Emergency Department	12	7,2
	Other	15	9,0
<u>Total</u>		166	100,0
Hospitals	Mosul General	53	31,9
	Ibn-sina	57	34,3
	Al-jumhuri	56	33,7
<u>Total</u>		166	100,0
Specialty	Doctors	32	19,3
	Nursing	69	41,6
	Pharmacy	65	39,1
<u>Total</u>		166	100,0

Table No. 1 shows that most of the sample participating in the study amounted to 166 health care workers, that most of the study sample was from 20 to 29 years old, at a rate of 74.7%, and that the sample of female was higher than that of male by (59%), 47.6% of the sample whose residence was institution ,Most of the sample was workplace (surgical), with moderate percentage (28,3%).

Table(2): Barriers to Reporting Adverse Drug Reactions Among Healthcare Providers

Variables		Frequency	Percentage
Q1: I have not been trained to report adverse drug reactions.	Yes	77	46.4
	No	89	53.6
Total		166	100.0
Q2: I am not aware of the rules for reporting adverse drug reactions.	Yes	65	39.2
	No	101	60.8
Total		166	100.0
Q3: Lack of time to report adverse drug reactions.	Yes	83	50.0
	No	83	50.0
Total		166	100.0
Q4: Lack of feedback on previously reported adverse drug reactions.	Yes	74	44.6
	No	92	55.4
Total		166	100.0
Q5: It is difficult to determine whether a drug has adverse effects or not.	Yes	79	47.6
	No	87	52.4
Total		166	100.0
Q6: The reporting form for adverse drug reactions is not easily accessible.	Yes	97	58.4
	No	69	41.6
Total		166	100.0
Q7: One unreported case might not affect clinical practice.	Yes	55	33.1
	No	111	66.9
Total		166	100.0
Q8: It is not my responsibility to report.	Yes	36	21.7
	No	130	78.3
Total		166	100.0

Barriers to reporting pharmacovigilance were moderate between yes and no.

Discussion:

The majority of respondents were in the 20-29 age group (74.7%), followed by 30-39 (16.9%), and progressively smaller proportions in the older age brackets. This suggests that younger healthcare workers are more prevalent in this sample, which may reflect general trends in the workforce where younger generations dominate the healthcare profession. Study Insight: Studies have shown that younger healthcare professionals tend to be more adaptable to new concepts and technologies. Their higher presence in the sample might reflect greater openness to pharmacovigilance initiatives, though their lower levels of experience could also limit their understanding. The gender distribution is skewed towards females (59%), which is consistent with the global trend in nursing and healthcare sectors where

women are the majority .Study Insight: The predominance of female workers in healthcare is well-documented. Research by the World Health Organization (WHO) indicates that women make up around 70% of the global health workforce, which might influence pharmacovigilance attitudes and practices, given their strong involvement in patient care. Academic Achievement: A substantial proportion (45.8%) had completed a bachelor's degree, followed by a significant group with nursing preparatory training (47.6%).A high percentage of respondents (83.7%) correctly identified that pharmacovigilance covers adverse drug reactions and medication errors. Most (77.1%) were aware of the difference between drug side effects and adverse events.Nearly half (46.4%) of respondents felt they had not been trained to report ADRs, and 39.2% were unaware of the rules for reporting. These gaps are significant barriers to effective pharmacovigilance. Study Insight: Lack of training is a well-recognized barrier to ADR reporting. A study by Otero et al. (2018) found that healthcare workers in many settings reported receiving inadequate formal education on pharmacovigilance. Training is critical for improving both knowledge and motivation to report ADRs.Half of the respondents (50%) cited a lack of time as a barrier, and 58.4% found the ADR reporting form not easily accessible. These logistical issues are frequently cited in the literature as major challenges in pharmacovigilance reporting ⁽¹¹²⁻¹²⁰⁾.Study Insight: Time constraints and difficulties in accessing reporting systems are common barriers to ADR reporting. Research by Hazell et al. (2010) found that time pressure is a major concern for healthcare workers, particularly in busy clinical settings, which can lead to a reduction in the reporting of ADRs, even when the adverse events are recognized.A significant minority (21.7%) felt that reporting ADRs was not their responsibility, which highlights an attitudinal barrier to the reporting culture.Study Insight: The perception of ADR reporting as a shared or administrative task is common, especially when healthcare workers believe that pharmacovigilance is primarily the responsibility of pharmacists or specialized staff. Studies indicate that fostering a culture of shared responsibility is essential for improving pharmacovigilance reporting (Lazarou et al., 2018).

Conclusion:

The data indicate that healthcare providers face moderate to significant barriers in reporting ADRs, with responses fairly split on several key issues.

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