Assessing Knowledge and Attitudes Healthcare Professionals Towards Adverse Drug Reaction of Reporting in Primary Healthcare Centers of AL-Madinah Region, Saudi Arabia

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Abstracts

Background: Adverse drug responses (ADRs), often known as drug-related adverse events, are adverse outcomes resulting from medications. Adverse drug reactions can have a significant impact on patients' quality of life and increase the burden on the healthcare system. As medications become more complex to treat a variety of conditions in older adults, adverse drug reactions will continue to be a serious public health concern. It is one of the main causes of illness and death in general.

Objective: The study aimed to evaluate the knowledge and attitudes of health care workers towards reporting adverse drug reactions and to explore potential areas for improvement in primary health care centers in Medina.

Methodology: A cross-sectional survey was conducted using a questionnaire on September 2022 in primary healthcare centers in Medina for two months. A self-administration questionnaire consist of two parts was distributed to the participants. The questionnaire was distributed to randomly selected professionals such as physicians, pharmacists and nurses. Of the 253 questionnaire a total of 220 professionals responded with a response rate of 86.9 %. Professionals categorize involved in study were (69) physicians, (58) pharmacists and (93) nurses. The data was analyzed using SPSS program.

Results: The results revealed a satisfactory level of knowledge regarding reporting of ADRs among healthcare workers with significant variation (p value <0.05), where the majority of participants agreed (104) (47.27) or strongly agreed (79) (35.9) that they are familiar with reports of adverse drug reaction and they can deal with them. It was also found that there is awareness of adverse effects of drugs and potential risks associated with herbal/traditional medicines. The majority of participants agreed (90) (40.09) or strongly agreed (106) (48.18) That the education and training for helps in reporting ADRs. Moreover, the majority of participants agreed (75) (34.09) or strongly agreed (118) (53.63) that reporting ADRs is part of their professional responsibility and obligation.

Furthermore, the results indicated a positive attitude towards reporting ADRs, as participants considered it their responsibility and recognized the benefits of professional training in this area. However, a preference for reporting only severe or life-threatening drug reactions was

also noted.

Keywords: Adverse drug responses (ADRs), healthcare system.

1. Introduction

The prevalence of adverse drug reactions (ADRs) in health organizations is one of the concerns that has gained attention, as 5-10% of patient's experience ADRs upon admission to the hospital or during their stay (Coleman & Pontefract, 2016). Epidemiological studies have indicated the varying impact of adverse drug reactions on patients, which is due to clinical and personal factors (Smith, Seidl & Cluff, 1966). In addition to medical errors, despite their potential benefits, they are one of the leading causes of morbidity and mortality worldwide (Hodkinson et al., 2020).

It is an unexpected and unpleasant reaction to a drug or drug that occurs at levels generally used to diagnose, prevent, treat disease, or alter physiological functions (Abdel Latif and Abdel Wahab, 2015). Adverse drug reactions can have adverse effects on patients, including extended hospitalization, higher mortality rates, and financial burdens. Furthermore, adverse drug reactions are a leading cause of hospital admission, underscoring their impact on patients' health and healthcare resources (Sales et al., 2017).

Previous studies have focused on the economic effects caused by harmful drug interactions due to their consequences, such as extended hospital stays and the complexity of mortality and morbidity. International studies in the United States (US) have shown that ADR-associated hospital admissions have increased significantly from 1% to 16%, with an incidence of 6.7% and some cases proving fatal (Formica et al., 2018).

The annual ADR incidence rate continues to rise, reaching critical levels. Healthcare systems worldwide witness an increase in cases suffering from ADRs, resulting in higher fatality percentages (Hussain et al., 2018). The Kingdom of Saudi Arabia's healthcare system is not exempt from this issue, as reporting and underreporting of drug-related problems coexist with the mortality rate linked to ADRs in the Kingdom's hospitals. Numerous obstacles, such as quick demographic shifts, an ageing population, and a rise in sedentary behavior, beset the Saudi healthcare system, these challenges have led to a high rate of drug use in Saudi Arabia.

Given the significance of understanding and addressing the challenges posed by ADRs in healthcare settings, this study aims to analyze the reporting of Adverse Drug Reactions in Primary Healthcare Centers (PHCs) in the Al-Madinah region, Saudi Arabia.

1.1 Research Problem

ADRs are preventable medical errors that can harm patients and potentially result in inappropriate medication, particularly when administered by healthcare professionals' (Khoja et al., 2011). The Institute of Medicine in Saudi Arabia has identified three types of behaviors that lead to ADRs in patients: overuse (prescribing when treatment is not warranted), underuse (failure to prescribe when treatment is possible and would likely be beneficial), and misuse (actual mistakes or errors) (Qureshi et al., 2011). The underreporting of ADRs and failure to

prescribe necessary medication in the kingdom jeopardize quality and patient safety of healthcare (Haider & Mazhar,2017). A higher proportion of ADR underreporting (94%) has been reported, with more serious effects on patients (Hazell & Shakir, 2006).

The Food and Drug Authority has established guidelines, which stipulate that all health professionals' bear the responsibility of reporting adverse drug interactions that are discovered during the performance of their duties. However, misconceptions about reporting adverse drug reactions persist in healthcare settings in Saudi Arabia.

1.2 Research Objectives

The main objective of this study is to analyze the reporting of adverse drug reactions in (PHCs) in the Medina region, Saudi Arabia. From this main objective, the following sub-objectives branch out:

1. To evaluate the knowledge of healthcare professionals regarding reporting adverse drug reactions in Primary Healthcare Centers in Al-Madinah Al-Munawarah.

2. To evaluate the attitudes of healthcare professionals towards reporting adverse medication reactions in Al-Madinah Al-Munawarah Primary Healthcare Centers.

3. To evaluate the knowledge of medical professionals' regarding ADR and their relationship with professionals' education, motivation, technological advancements, and policy interventions.

1.3 Research Questions

The current study asks: What is the current situation of the Adverse Drug Reactions reporting in PHCs in the Al-Madinah region, and what factors may affect the reporting system?

Sub-questions:

1. What is the level of knowledge among health professionals' regarding ADRs reporting in (PHCs)in Al-Madinah Al-Munawarah?

2. What are the attitudes of health professionals towards adverse drug reactions reporting in Primary Healthcare Centers in Al-Madinah Al-Munawarah?

3. Is there a statistically significant relationship between professionals' education, motivation, technological advancements, policy interventions and the knowledge of health professionals regarding ADRs reporting in Primary Healthcare Centers in Al-Madinah Al-Munawarah?

1.4 Research Variables

To thoroughly evaluate the attitudes and knowledge of healthcare professionals' towards reporting ADRs in PHCs in the Al-Madinah region, Saudi Arabia, this study will focus on the following research variables:

Independent Variables:

professionals' education, motivation, technological advancements, and policy interventions. The knowledge and attitudes of healthcare professionals about ADR reporting may be affected by this factors.

Dependent Variables:

A. Knowledge of reporting adverse drug reactions: This variable assesses knowledge of adverse drug reactions, reporting procedures, and the importance of reporting for patient safety and improving health care quality among health care professionals'.

B. Attitudes toward reporting adverse drug reactions: This variable assesses healthcare professionals' perceptions and beliefs about reporting ADRs, including their willingness to report adverse drug reactions, perceived barriers to reporting, and their perceived role in the reporting process.

1.5 Research Significance

The significance of this study lies in promoting patient safety by enhancing the knowledge of ADR reporting, ultimately reducing the likelihood of ADR events in primary care settings. The practical implications of the study are evident in the development of accurate knowledge and attitudes among professionals', which will improve prescribing efficiency and minimize the unintended consequences of ADRs in the form of morbidity and mortality.

This research contributes to a better understanding of the current condition of ADR reporting in the Al-Madinah region of Saudi Arabia by analyzing the knowledge and attitudes of healthcare workers towards ADRs reporting and its association with professionals' education, motivation, technological advancements, and policy interventions.

1.6 Research hypothesis

1. The study assumes a sufficient level of knowledge among healthcare professionals
2. The study assumes a sufficient level of attitudes among healthcare professionals
3. The study assumes the existence of a statistically significant relationship between the professionals' education, motivation, technological advancements, and policy interventions and professional's knowledge toward ADRs reporting.

1.7 Research methodology

This study adopts a quantitative research design and an employed a cross-sectional research design to investigate the factors affecting ADR reporting in healthcare settings. A quantitative approach was used for data analysis. The study utilized a validated and self-administered questionnaire to collect the data. The study population consists of 500 health care professionals, including doctors, pharmacists, and nursing. Data was analyzed using the statistical package for social science and the research was conducted in strict compliance with ethical principles to prevent any legal or ethical issues during the study.

1.8 Delimitations of the study

The study was conducted in PHCs in the Al-Madinah region of Saudi Arabia. The study population consists of 500 health care professionals, including doctors, pharmacists, and nursing.

This study aims to provide insights into the current state of ADR reporting and identify variables that may have an impact on the reporting by evaluating healthcare professionals' knowledge and attitudes regarding ADR reporting and investigating its relationship with professionals' education, motivation, technological advancements, and policy interventions.

1.9 Research structure

The topic of the study is Assessing Knowledge and Attitudes Healthcare Professionals Towards Adverse Drug Reaction of Reporting in Primary Healthcare Centers of AL-Madinah Region, The main objective of this study is to analyze the reporting of adverse drug reactions in (PHCs) in the Medina region, Saudi Arabia .This study aims to provide insights into the current state of ADR reporting and identify variables that may have an impact on the reporting by evaluating healthcare professionals' knowledge and attitudes regarding ADR reporting and investigating its relationship with professionals' education, motivation, technological advancements, and policy interventions.

2. Literature Review

ADRs pose a significant threat to patient safety, as they have been identified as the primary cause of mortality and morbidity in hospital admissions. A noxious and unexpected reaction (ADR) is described as occurring at dosages usually used for disease prevention, diagnosis, treatment, or alteration of physiological function (Coleman & Pontefract, 2016).

ADRs are the main contributor to morbidity, death, and subpar treatment results. As a result, pharmacovigilance is crucial for keeping track on the hazards and advantages of pharmaceutical goods after they have been released on the market (Krishnan, 2020) However, health professionals underreporting of ADRs continues to be a major obstacle in increasing pharmaceutical safety (Siraj et al., 2022).

To address this issue, it is crucial to explore the barriers that healthcare professionals face in reporting ADRs, such as poor of awareness, time constraints, and inadequate training.

2.1 Factors that Influence Reporting of ADRs

The literature has found a number of characteristics that affect how ADRs are reported by healthcare professionals, frequently resulting in a significant amount of underreporting. The attitude and behavior of the individual reporter and professional and personal circumstances can be broadly divided into two groups (Haider & Mazhar, 2017). Uncertainty on which ADRs to report and ignorance of reporting guidelines and protocols are a few of the factors mentioned (Fadare & Enwere, 2011).

Factors related to healthcare professionals include their experience, knowledge, and attitudes towards ADRs reporting. Limited knowledge about ADRs and their reporting procedures, lack of awareness about the importance of reporting, fear of litigation, and low motivation can result in underreporting of ADRs (Gupta & Udupa, 2011). Patient factors such as gender, age, and health literacy may also contribute to ADRs reporting. Patients' knowledge and awareness about

ADRs and their willingness to report them can significantly influence the reporting of ADRs (Lorimer et al., 2012). Practitioner Knowledge

In a review of 45 studies that satisfied the inclusion criteria, Lopez-Gonzalez et al. (2009) discovered that the professional trait most closely linked to underreporting was a medical specialty. Personal and professional characteristics had little impact, but a significant number of studies suggested that health professionals' attitudes and knowledge were strongly associated with reporting. In a study carried out in the Klang region of Malaysia, unsatisfactory knowledge was observed in 57.2% of respondents, with higher qualifications associated with significantly better knowledge (Agarwal et al., 2013). According to Guner and Ekmekci (2019), the primary cause of underreporting is professional's insufficient pharmacovigilance knowledge. To increase pharmacovigilance efforts, training initiatives that are tailored to HCPs' requirements and references should be carried out, as should close follow-up by authorities.

2.1.2 Practitioner Attitude

Following complacency, "fear of investigations or litigation" against the practitioners who report ADRs may deter them from reporting. This fear can stem from concerns about potential professional consequences, legal repercussions, or damage to their reputation (Biriell and Edwards, 1997). Additionally, that might have endangered a patient" may cause reluctance to report ADRs, as healthcare professionals may feel responsible for the adverse event and worry about the impact on their professional relationships or patient trust (Morrison-Griffiths and Pirmohamed, 2000).

2.1.3 Professional and Personal Factors

The literature suggests that there is a clear situation of underreporting by healthcare professionals due to various professional and personal factors. Personal factors that are patient-related, such as age and acquired knowledge, can directly influence ADR reporting (Kiguba et al., 2014).

2.2 Previous Studies

The factors influencing healthcare professionals reporting of adverse drug reactions (ADRs) and methods for increasing reporting rates are discussed in this section. These studies have been conducted in different countries and focus on various aspects of ADR reporting, providing a comprehensive understanding of the challenges and potential solutions in this area.

2.2.1 Strategies to Increase the Reporting of ADRs

Numerous studies have examined various tactics that can encourage healthcare professionals to report ADRs, enabling hospitals and practitioners to take action to address the problem of underreporting (Abdel-Latif & Abdel-Wahab, 2015). These strategies can be classified into professionals' education, motivation, technological advancements, and policy interventions.

2.2.2 Professional's Education

Continuous education is an approach by which professionals can develop their abilities during their clinical practice. Improved knowledge can lead to better recognition of medical issues, increasing the reporting rate and service quantity (Jimeno-Demuth et al., 2012). Tailored

educational programs focusing on ADR identification, reporting processes, and the importance of reporting can help bridge the knowledge gap among healthcare professionals (Aldryhim et al., 2019).

2.2.3 Motivation

Incentivizing healthcare professionals to report ADRs can play a critical role in increasing the reporting rate. This can include non-financial incentives such as recognition, positive feedback, and support from peers and supervisors (Johansson, Hägg, and Wallerstedt, 2011). Financial incentives, such as bonuses or rewards for reporting ADRs, may also be considered, although this approach may raise ethical concerns and should be implemented with caution (Backstrom et al., 2006).

2.2.4 Technological Advancements

The adoption of technological advancements in ADR reporting can streamline the process and make it more accessible for healthcare professionals. Electronic reporting systems, such as online portals or mobile applications, can simplify the reporting process and allow healthcare professionals to report ADRs directly and efficiently (Emmendorfer et al., 2012). Integrating ADR reporting tools within electronic health records can further facilitate reporting by auto-populating relevant information, minimizing the time and effort required to submit a report (Tagne et al., 2022).

2.2.5 Policy Interventions

Policy interventions, such as mandatory reporting of specific ADRs or the implementation of penalties for non-reporting, can potentially increase reporting rates (Alsaleh et al., 2017). However, these measures should be balanced against the risk of over-reporting or the creation of a punitive culture that may discourage open communication and transparency among healthcare professionals.

Literature Gap

The Primary Healthcare Centers play a crucial role in providing primary care services to the population and serve as the first point of contact for patients seeking medical attention.

There are insufficient studies examining and analyzing the factors that influence reports of ADRs among healthcare professionals. Investigating the factors influencing ADRs reporting in this setting is of particular importance, as it allows for a better understanding of the challenges faced by healthcare professionals on the frontline of patient care.

By focusing on PHCs in the Al-Madinah region, this study aims to provide insights into the factors that influence ADRs reporting in a healthcare setting where patient safety and effective pharmacovigilance are of utmost importance.

3. Research Methodology

This chapter will explain the research environment, its procedures, and the method of collecting and analyzing data. The chapter also reviews the reliability and validity of the data collected, and statistical methods for analyzing the data. The chapter also addresses an explanation of the research community and how to select the sample.

3.1 Research Design

This study adopts a quantitative research design to provide an in-depth understanding of the issues faced by healthcare service providers in relation to ADRs reporting. The quantitative method enables the collections of numerical data and the application of statistical analysis to find patterns, trends, and correlations between variables. A descriptive design is particularly useful in this context, as it enables the researcher to describe and summarize the current state of ADRs reporting in PHCs, as well as the factors influencing it.

To assess the factors that affect ADR reporting in PHCs, a cross-sectional sampling strategy was employed. This method, which involves gathering data at a single moment in time, is appropriate for this study since it attempts to provide a comprehensive overview of the situation of ADR reporting in the Al-Madinah area at the time of the study. The cross-sectional design is a useful tool for examining the occurrence and distribution of ADRs as well as for locating possible relationships between different variables and reporting practices.

3.2 Research Setting

The study was conducted in PHCs in the Al-Madinah region of Saudi Arabia. These healthcare facilities play a crucial role in providing primary care services to the population and serve as the first point of contact for patients seeking medical attention. Investigating the factors influencing ADRs reporting in this setting is of particular importance, as it allows for a better understanding of the challenges faced by healthcare professionals on the frontline of patient care.

By focusing on PHCs in the Al-Madinah region, this study aims to provide insights into the factors that influence ADRs reporting in a healthcare setting where patient safety and effective pharmacovigilance are of utmost importance. The development of focused interventions and initiatives to improve reporting practices can be influenced by an understanding of the variables causing the complexity and hurriedness of ADRs reporting in this setting. This will eventually improve patient safety and the standard of care offered in these institutions.

3.3 Study Population and Sample

The study population consists of 500 health care professionals, including doctors, pharmacists, and nursing staff, who work in primary health care centers in the Medina region in a random manner, focusing on (20) that were accredited by the Central Council for Accreditation of Health Care Institutions (CBAHI) to ensure compliance. With quality standards. Using a sample size calculator, a minimum sample size of 218 participants was chosen to ensure a representative sample, taking into account a confidence level of 95%, a response distribution rate

of 50%, and a margin of error of 5%. The sample size was generated using the Raosoft website (http://www.raosoft.com/samplesize.html).

STAFF	POPULATION	%	SAMPLE
Doctors	174	34.8	69
Pharmacists	103	20.6	58
Nursing	223	44.6	93
TOTAL	500	100%	220

3.4 Data Collection Instrument

The study utilized a validated and self-administered questionnaire, adapted from Adisa & Omitogun (2019), as the primary data collection instrument. The questionnaire was created to evaluate ADR reporting at primary healthcare facilities (PHCs), assess healthcare professionals' familiarity with ADR reporting, and the factors that affect the recording of ADRs.

The questionnaire was structured in alignment with the study's objectives and consisted of two main dimensions.

The first dimension aimed to assesses knowledge of adverse drug reactions, reporting procedures, and the importance of reporting for patient safety and improving health care quality among health care professionals', while the second dimension sought to recorded participants' attitudes about reporting ADRs and their comprehension of the duty of doing, in addition to the factors that affect the recording of ADRs.

The questionnaire's reliability was established by conducting a pilot study, and the reference for the questionnaire is Adisa & Omitogun (2019). After validation, the questionnaire was electronically distributed to the selected sample for this study (Appendix II. Questionnaire).

3.5 Procedures for data collecting

Data were collected after designing an electronic questionnaire that was distributed to the selected study sample using (WhatsApp). Participants received a WhatsApp link to the survey, a brief description of the study's objectives, and instructions for completing the questionnaire.

The questionnaire was sent to 253 healthcare professionals and the number of respondents was 220 participants with a participant rate of 86.9 percent.

The electronic distribution of the questionnaire allowed for efficient, cost-effective, and environmentally friendly data collection. The online survey platform ensured that participants could complete the questionnaire at their convenience, using their preferred electronic devices. Furthermore, the platform facilitated real-time monitoring of responses and the option to send automated reminders to non-responders, increasing the response rate.

3.6 Reliability Analysis and T-Test

To evaluate the consistency of the participants' responses, Cronbach's Alpha, a measure of internal consistency, was employed.

3.7 Data Security

The confidentiality of the collected data was ensured through the questionnaire design and data handling procedures. It was made sure that the anonymity of the participants and the confidentiality and privacy of the data obtained were both maintained.

Analysis of data

The statistical package for social science was employed due to its robust capabilities in handling large datasets and its extensive range of statistical analysis techniques. This software allowed the researcher to perform descriptive and inferential statistical analyses to examine the relationships between variables and test the research hypotheses.

Prior to data analysis, the dataset underwent a thorough data cleaning process to identify and address any issues such as missing, inconsistent, or duplicate responses. This process ensured the accuracy and reliability of the data for analysis.

3.7 Ethical Considerations

The research was conducted in strict compliance with ethical principles to prevent any legal or ethical issues during the study

The Institutional Review Board (IRB) and the Ethical Committee of the Directorate of Health Affairs in Al-Madinah Al-Munawwarah provided official clearance number 22-086 and date 10/09/2022 before to the study's start. All participants were invited to participate willingly after being fully informed of the study's aims and methods.

4. Data Analysis and Findings

4.1 Introduction

In this chapter the findings will be discussed in addition to analyzing the study results for a comprehensive understanding of the factors that influence reports of ADRs. Demographic characteristics and their impact on professional's knowledge will also be discussed. In addition to providing a comprehensive overview of the knowledge and attitudes of professionals and their impact on ADRs reports in light of the results reached. Moreover, this chapter will evaluate the relationship between the study variables and the extent of their relationship to the knowledge and attitudes of healthcare professionals.

4.2 Demographic Characteristics

The frequency method was used to fully comprehend the sociodemographic features of the subjects. A thorough presentation of these characteristics can be found in Table 1. It was observed that the majority of the participants were male, accounting for 83.6%, while female

participants comprised 16.4%. In terms of age, more than half of the participants (55%) belonged to the 31–40 years old, while 24.55% were between the ages of 41–50. In contrast, only 5% of participants were over the age of 50, while 15.45% of participants were between the ages of 20 and 30.

Focusing on the participants' educational background, 42.27% held undergraduate degrees, 40.45% possessed diplomas or certificates, and a minority of 17.27% had attained postgraduate degrees. The table below shows that (58.64%) have more than 10 years of experience, 25.45% reported that they have less than 5 years of professional experience in the field, and 15.91% reported that their practical experience was between 5 and 10 years of experience.

Table 4-1: Socio and Demographic Characteristics of the Participants

Variables	Frequency	Percent
Gender		
Female	36	16.4
Male	184	83.6
Age		
from 20 -30	34	15.45
from 31 -40	121	55.00
from 41 -50	54	24.55
More than 50 years	11	5.00
Level of study		
Undergraduate	93	42.27
Diploma/Certification	89	40.45
Postgraduate	38	17.27
Years of Experience		
Less than 5 years	56	25.45
from 5- 10	35	15.91
More than 10years	129	58.64

4.3 Reliability Analysis and T-Test

To evaluate the consistency of the participants' responses, Cronbach's Alpha, a measure of internal consistency, was employed. Table 2 presents the reliability test results for the knowledge and attitude criteria. With a Cronbach's Alpha value greater than 0.7 for the knowledge criteria, the data indicates a high level of consistency among the responses for each statement within this

domain. This suggests that the participants' answers are reliable and can be used for further analysis.

Table 4-2: Reliability test for the selected criteria

	Cronbach's Alpha	N of Items
Knowledge	0.792	13
Attitudes	0.661	8

The one-sample t-test results for the first criterion (Knowledge) are displayed in Table 3. The findings reveal a significant difference in the mean value of each statement within the Knowledge criterion, as evidenced by the p-value for each statement being less than 0.05. This statistical significance suggests that the respondents' knowledge levels differ across the various statements, warranting further examination of these disparities.

4.4 Knowledge of health workers towards adverse drug reactions reporting in Primary Healthcare Centers in Al-Madinah Al-Munawar

Table 5 indicates that a large percentage of participants (40.90%) or strongly agreed (40.45%) with the first statement, and this confirms that an adverse drug interaction is considered a common side effect that occurs when taking medication. The mean value of 4.04 for responses indicates that participants, on average, largely agree with the idea of side effects of drug interactions.

The results indicate, regarding the second statement, that a professionals familiar with reports of adverse drug reaction and can deal with it. The percentage of those who agreed with this was 47.27% of the participants, and 35.9% strongly agreed. The mean value of 4.12 indicates that 37.3% of participants agreed with the statements regarding possible drug interaction, 29.5% strongly agreed, and 19.1% were neutral. The mean value of 3.78 shows the overall agreement between participants.

The fourth statement indicates that a harmful drug interaction has the same side effect, as 31.36% of participants agreed, 24.54% strongly agreed, and 20% did not agree. The average value of 3.4 shows that most participants tend to agree on average. The fifth statement from the survey, which claims that only patients taking conventional medicines could be at risk. 38.63% of the sample agreed, and the average value of 2.78 indicates that most of the sample disagreed with this statement.

The sixth statement, which addresses the possibility of experiencing an adverse drug reaction by patients using herbal/traditional medicines, garners agreement from 46.81% of participants and strong agreement from 40%, while only 3.17% disagree. The mean value of 4.2 signifies high agreement among participants that adverse drug reactions can result from using herbal/traditional medicines. In relation to the seventh statement, which postulates that all ADRs be known before using the drug on the market, 29.09% of participants agree, and 18.18%

disagree. The mean value of 3.58 reveals that the average participant is inclined to agree that adverse drug reactions are known before a drug becomes available for use.

Regarding the eighth statement, which states that all ADRs experienced by a patient using the medication must be documented, 28.63% of participants agreed with it. On average, most participants also show a high level of agreement. For the ninth statement, which asserts that only unbearable reactions to a drug must be reported, 30.9% of participants disagreed, while the average participant agreed with the statement. In the case of the tenth statement, which states that an ADR may not be reported if the patient is adequately counseled about such a reaction, 40.45% of participants agreed, while 14.54% believed that an ADR may still be recorded if the patient is appropriately counseled.

For the eleventh statement, which posits that the best way for addressing adverse effects is to recommend another drug, 36.36% of participants agree, and only 13.63% disagree. In response to the twelfth statement, which claims that there is no require to report an ADR already documented in the drug literature insert, 31.81% of participants disagree. Similarly, for the thirteenth statement, which emphasizes the importance of reporting and documenting adverse drug reactions, 69.54% of the participants strongly agree that reporting and documentation of adverse drug reactions are crucial. The standard deviation values for each of the statements range from 0.8 to 1.3, indicating minimal variation in overall responses. The cumulative results demonstrate that a sufficient level of knowledge exists among health workers concerning adverse drug reaction reporting in Primary Healthcare Centers in Al-Madinah Al-Munawarh.

In summary, the survey results highlight the general agreement among health workers on various aspects of adverse drug reactions and their reporting. Participants showed strong agreement on the importance of reporting and documenting adverse drug reactions, regardless of whether they stemmed from orthodox or herbal/traditional medicines. Additionally, most participants agreed that all adverse drug reactions should be reported and documented, even if the patient has been counseled appropriately on the potential reaction. These findings emphasize the need for continued education and training for health workers to ensure the proper reporting and management of adverse drug reactions in Primary Healthcare Centers.

Table 4-5: Knowledge assessment of health workers towards adverse drug reactions reporting in Primary Healthcare Centers in Al-Madinah Al-Munawarh

Statement	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Mean	Std. Dev.
Adverse drug interaction is one of the expected side effects when a patient takes medication	89 (40.45)	90 (40.90)	12 (5.45)	18 (8.188)	11 (5)	4.04	1.11
I am familiar with reports of adverse drug reaction and I can deal with it.	79 (35.9)	104 (47.27)	23 (10.45)	12 (5.45)	2 (0.9)	4.12	0.87
An ADR is an expected effect of a drug	65 (29.5)	82 (37.3)	42 (19.1)	22(10.0)	9 (4.1)	3.78	1.1

An adverse drug interaction means a side effect of a drug	54 (24.54)	69 (31.36)	31 (14.09)	44 (20)	22 (10)	3.4	1.32
The patient can only experience a negative effect when taking traditional medicines	26 (11.81)	44 (20)	35 (15.9)	85 (38.63)	30 (13.63)	2.78	1.25
It is expected that patients will experience adverse drug interactions when taking herbal/traditional medicines	88 (40)	103 (46.81)	18 (8.18)	7 (3.18)	4 (1.81)	4.2	0.86
All harmful drug interactions can be known before the drug is distributed on the market for use	66 (30)	64 (29.09)	36 (16.36)	40 (18.18)	14 (6.36)	3.58	1.26
It is important to report all adverse drug reactions to which the patient is exposed while taking the medication and ensure that they are documented	147 (66.81)	63 (28.63)	7 (3.18)	2 (0.9)	1 (0.45)	4.6	0.64
Only unexpected drug reactions should be reported	55 (25)	55 (25)	14 (6.36)	68 (30.9)	28 (12.72)	3.19	1.43
If the patient has been adequately counseled about an ADR, there is no require to document such a reaction	47 (21.36)	89 (40.45)	37 (16.81)	32 (14.54)	15 (6.81)	3.55	1.18
The preferred way to limit adverse effects is to take or recommend another medication	48 (21.81)	80 (36.36)	49 (22.27)	30 (13.63)	13 (5.9)	3.55	1.15
If adverse drug reactions are documented, there is no need to report them in the drug literature appendix	24 (10.9)	40 (18.18)	27 (12.27)	70 (31.81)	59 (26.81)	2.55	1.35
Reporting and documenting adverse drug reactions is important	153 (69.54)	54 (24.54)	9 (4.09)	1 (0.45)	3 (1.36)	4.6	0.72

1= Strongly Agree, 2=Agree, 3=Neutral, 4=Disagree, 5= Strongly Disagree

Table 6 presents the associations between participants' demographic characteristics and their knowledge of the subject matter. A significant relationship is observed for individuals possessing a postgraduate degree (OR=0.385, p-value=0.009), demonstrating that this particular characteristic is statistically associated with their knowledge criteria. In contrast, the remaining demographic factors analyzed in this study do not exhibit any significant associations with the knowledge criteria. Thus, it appears that holding a postgraduate degree plays a crucial role in participants' knowledge, while other demographic characteristics seem to have a negligible impact.

Table 4-6: Multivariate logistic regression analysis of association between demographic factor and Knowledge of health workers

Factor	Odds ratio	95% confidence interval of odds ratio	P value
Gender			
Female	0.713	0.398-1.156	0.391
Male	1.291	0.615-2.709	0.5
Age			
from 20 -30	1.168	0.541-2.52	0.692
from 31-40	1.321	0.621-2.60	0.631
from 41-50	0.842	0.469-1.489	0.748
Older than 51	0.578	0.397-1.847	0.692
Level of study			
Undergraduate	1.007	0.58-0.175	0.979
Diploma	1.301	0.612-2.47	0.614
Postgraduate	0.385	1.88-0.788	0.009
Years of Experience			
Less than 5 years	1.401	0.733-2.677	0.308
from 5- 10	1.007	0.479-2.166	0.986
from 11-20	1.286	0.602-2.688	0.564
More than 21years	0.762	0.434-1.341	0.346

4.5 Attitudes of health workers towards adverse drug reactions reporting in Primary Healthcare Centers in Al-Madinah Al-Munawarh

Table 6 provides a comprehensive overview of health workers' attitudes towards ADRs reporting in Primary Healthcare Centers in Al-Madinah Al-Munawarh. A majority of participants (57.72%) strongly agreed that they would report all encountered ADRs, while only 3% disagreed. The mean value of 4.46 suggests that, on average, most participants highly agreed with reporting all ADRs. Furthermore, 53.63% strongly agreed and 34.09% agreed that reporting ADRs is their responsibility, yielding a mean value of 4.38, which indicates a high level of agreement among participants.

In terms of the impact of training healthcare professionals on ADR reporting, 52.72% strongly agreed that it would be beneficial, with only 1% disagreeing. When considering the effectiveness of pharmacovigilance training in identifying and reporting ADRs, 48.18% strongly agreed and 40.9% agreed, resulting in a mean value of 4.36, suggesting strong support for the training. Additionally, 59.09% strongly agreed and 32.72% agreed that ADR reporting is part of their professional obligation. The majority of participants (58.63%) also agreed, and 31.81% strongly agreed that pharmacovigilance concepts should be incorporated into healthcare workers' training. When it comes to reporting life-threatening or severe ADRs, 24.54% agreed that they would likely do so, but 19.54% disagreed. Most participants (29.54%) strongly disagreed that tolerable, mild ADRs need to be reported, whereas 16.36% agreed that they would report such reactions. The standard deviation values indicate limited variation in responses. The overall mean values for each statement exceed 3, signifying a positive attitude among health workers towards ADR reporting in Primary Healthcare Centers in Al-Madinah Al-Munawarh.

Table 4-7: Attitudes assessment of health workers towards adverse drug reactions reporting in Primary Healthcare Centers in Al-Madinah Al-Munawarh

Statements	1	2	3	4	5	Mean	Std. Dev
All ADR I experienced were reported	127 (57.72)	73 (33.18)	16 (7.27)	3 (1.36)	1 (0.45)	4.46	0.73
It is my responsibility as a healthcare professional to report harmful cases	118 (53.63)	75 (34.09)	21 (9.54)	4 (1.81)	2 (0.9)	4.38	0.8
Training for healthcare professionals helps in reporting adverse drug reactions	116 (52.72)	87 (39.54)	16 (7.27)	1 (0.45)	0	4.45	0.65
Enrolling in pharmacovigilance training programs helps me to record ADRs.	106 (48.18)	90 (40.9)	21 (9.54)	3 (1.36)	0	4.36	0.71

It is a professional obligation to report ADR	130 (59.09)	72 (32.72)	15 (6.81)	2 (0.9)	1 (0.45)	4.49	0.71
The concept of pharmacovigilance should be part of the training of healthcare workers	2 (0.9)	70 (31.81)	129 (58.63)	19 (8.63)	0	4.47	0.73
I will likely only report life threatening/sever ADR.	66 (30)	54 (24.54)	32 (14.54)	43 (19.54)	25 (11.36)	3.42	1.39
It is important to document potentially and moderately harmful ADRs.	34 (15.45)	36 (16.36)	19 (8.63)	66 (30)	65 (29.54)	2.58	1.45

1- Strongly Agree 2-Agree 3 - Neutral 4 –Disagree 5 - Strongly Disagree

Furthermore, Table 8 presents the associations between the demographic characteristics of the participants and their attitudes towards adverse drug reaction (ADR) reporting in Primary Healthcare Centers in Al-Madinah Al-Munawarh. Interestingly, the results of this study reveal no significant associations between the various demographic characteristics of the participants and their attitudes towards ADR reporting.

5. Discussion

In this chapter, the results of the study are discussed in the light of theoretical frameworks, previous studies, and field studies, with an attempt to highlight the points of agreement and difference between the previous studies and the current study.

Beginning with a comparison and contrast of the findings with earlier studies in the field, this chapter will explore the information on health workers' understanding of ADR reporting in PHCs.

5.1 Knowledge of health workers towards adverse drug reactions reporting in Primary Healthcare Centers

The majority of participants agreed (104) (47.27) or strongly agreed (79) (35.9) that they are familiar with reports of adverse drug reaction and they can deal with them., including the necessity of recording and reporting ADRs, the likelihood that ADRs may occur with both conventional and herbal/traditional treatments, and the requirement to report all ADRs, regardless of their severity. The growing amount of research on the subject of healthcare workers' knowledge of ADR reporting is supported by and expanded upon by these findings.

A study by Palaian et al. (2011) similarly found a relatively high level of knowledge among healthcare professionals regarding ADR reporting in Nepal. The researchers suggested that this may be attributable to the ongoing training and education programs offered to healthcare professionals in the region. However, it is essential to note that despite the adequate knowledge, underreporting of ADRs remains an issue in many healthcare settings, highlighting the need for continued efforts to address this gap (Seid et al., 2018).

In contrast, a study conducted by Thakkar et al. (2017) found that healthcare practitioners in India had less understanding about ADR reporting. The authors placed the blame for this on a lack of knowledge and inadequate training in pharmacovigilance, highlighting the demand for organized education and training programs to increase healthcare personnel' understanding and reporting habits. This shows that there may be geographical disparities in ADR reporting expertise, necessitating additional research and focused interventions.

The results of the current study are consistent with the findings of the study by Olsson et al. (2010), which emphasized the value of pharmacovigilance training in enhancing healthcare professionals understanding of attitudes towards ADR reporting. In the current study, participants showed a substantial support for pharmacovigilance training, with 48.18% strongly agreeing and 40.9% agreeing that such training helps in recognizing and reporting ADRs.

The positive attitude and adequate knowledge among healthcare professionals in Al-Madinah Al-Munawarh's Primary Healthcare Centers provide a promising basis for continued improvements in patient safety and care quality. However, it is crucial to consider that knowledge alone may not translate to optimal ADR reporting practices (Lopez-Gonzalez et al., 2009). As such, healthcare organizations and policymakers must continue to invest in education and training initiatives that address potential knowledge gaps and emphasize the importance of ADR reporting, thereby fostering a culture of continuous learning and growth within healthcare settings.

5.2 Attitudes of health workers towards adverse drug reactions reporting in Primary Healthcare Centers

The findings of the study revealed that medical staff members at Primary Healthcare Centers in Al-Madinah Al-Munawarh typically had a good attitude towards reporting ADRs. This is consistent with results from other research carried out in other areas, which also showed the significance of positive attitudes among health staff for efficient ADR reporting and management. (Hadi et al., 2017).

The majority of participants agreed (75) (34.09) or strongly agreed (118) (53.63) that reporting ADRs is part of their professional responsibility and obligation, supporting the findings of Alshakka et al. (2021), who reported that healthcare professionals in Yemen similarly exhibited a strong sense of responsibility for reporting ADRs. This shared attitude underscores the importance of fostering a sense of responsibility among health professionals for ensuring patient safety and improving the overall quality of care.

Additionally, the study revealed that participants believed in the effectiveness of pharmacovigilance training in identifying and reporting ADRs. This agreement with the results

of a study conducted by Pagotto et al. (2013), which demonstrated that targeted training in pharmacovigilance led to an increase in ADR reporting among healthcare professionals in Brazil. These findings collectively emphasize the significance of continuous education and training in enhancing healthcare professional's attitudes and skills in ADR reporting.

Despite the overall positive attitudes towards ADR reporting, the study's results also indicated some variation in participants' perspectives on reporting tolerable, mild ADRs where most of the participants (29.54%) strongly disagreed that tolerable, mild ADRs need to be reported, whereas 16.36% agreed that they would report such reactions. This finding contrasts with the study by Figueroa's et al. (2006), which found that healthcare professionals in Spain tended to report mild ADRs more consistently. This difference highlights the importance of addressing potential misconceptions or knowledge gaps among health workers regarding the reporting of all types of ADRs, including mild ones.

6. Conclusion and Recommendation

6.1 Conclusion

The study examined ADRs in PHCs in the Al-Madinah region of Saudi Arabia. The main objectives of this study were to evaluate healthcare workers' knowledge and attitudes regarding ADR reporting in PHCs in Al-Madinah Al-Munawarh.

A questionnaire survey was employed for data collection, involving 218 participants, and the data was analyzed using the SPSS. The findings revealed that healthcare workers had adequate knowledge about ADRs.

Regarding attitudes, healthcare workers displayed a positive outlook towards their responsibility for ADR reporting. They strongly agreed that training for healthcare professionals could enhance ADR reporting.

6.2 Limitations of the Study

This study may not be generalized to the population because it was confined to PHCs in Al-Madinah region, and future studies could investigate ADR across different hospitals and Centers in Saudi Arabia to have generalized results.

6.3 Recommendation

Based on this study findings, the following recommendations may be beneficial for healthcare professionals to consider:

Emphasizing professional education and training can help healthcare professionals develop and improve their clinical practice abilities. Enhanced knowledge will aid in identifying medical issues such as adverse drug reactions and increase the ADR reporting rate. Moreover, it is recommended to increase the significance of reporting through measures such as notifications, brochures, and mobile apps that inform and notify professionals about reporting and potential errors. Implementing these practices can promote ADR reporting. The study suggests continuing

to increase knowledge about ADR reporting and ensuring adherence to ADR standards, which can improve quality and safety in PHCs.

Although the study revealed positive knowledge and attitudes regarding ADRs, it does not guarantee actual reporting practices. Therefore, healthcare systems should adopt programs that are user-friendly and cutting-edge, as well as establish and maintain ongoing intervention programs managed by staff members with expertise in pharmacovigilance, to motivate practitioners to report.

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