Arab American University
Faculty of Graduate Studies
Department of Administrative and Financial Sciences
Master Program in Quality Management in Health Institutions

Healthcare Providers Knowledge, Attitude and Practice in Relation to Adverse Drug Reactions Reporting in Oncology Departments in the West Bank

Rahaf Shaher Hilal Rimawi
202112792

Supervision Committee:
Dr. Shahenaz Najjar
Dr. Hani Shtaya
Dr Yousef Mimi

This Thesis Was Submitted in Partial Fulfilment of the Requirements for the Master Degree in Quality Management in Health Institutions

Palestine, July/ 2025

Arab American University

Faculty of Graduate Studies

Department of Administrative and financial sciences

Master Program in Quality Management in Health Institutions

Thesis Approval

Healthcare Providers Knowledge, Attitude and Practice in Relation to Adverse Drug Reactions Reporting in Oncology Departments in the West Bank

Rahaf Shaher Hilal Rimawi
202112792

This thesis was defended successfully on 22/ 07/2025 and approved by:

Thesis Committee Members:

Name	Title	Signature
1. Dr. Shahenaz Najjar	Main Supervisor	
2. Dr. Hani Shtaya	Member of Supervision Committee	
3. Dr Yousef Mimi	Member of Supervision Committee	

Palestine, July/2025

Declaration

I declare that, except where explicit reference is made to the contribution of others, this thesis is substantially my own work and has not been submitted for any other degree at the Arab American University or any other institution.

Student Name: Rahaf Shaher Hilal Rimawi
Student ID: 202112792
Signature: Rahaf Rimawi
Date of Submitting the Final Version of the Thesis: 08/11/2025

Dedication

I dedicate this work to Allah, my family, my friends and to my country, Palestine

Student Name: Rahaf Shaher Hilal Rimawi

Acknowledgments

I would like to express my deepest gratitude to Dr. Shahenaz Najjar, my supervisor, for her unwavering support, patient guidance, and insightful feedback throughout this journey. Her exceptional commitment to academic excellence and her meticulous attention to detail played a vital role in shaping this dissertation.

My sincere thanks also go to Arab American University and the Department of Administrative and Financial Sciences for equipping me with the knowledge, resources, and opportunities that made this work possible.

To my dear friends, thank you for your encouragement, presence, and kindness that carried me through the challenging moments.

To my beloved family and parents, your endless love, sacrifices, and steadfast support have been my foundation. Words will never fully capture how grateful I am for your strength and belief in me.

And to my companion, Osama — your quiet strength, unshakable faith in me, and boundless love turned every obstacle into a step forward. Thank you for being my anchor, my calm in every storm.

Healthcare Providers Knowledge, Attitude and Practice in Relation to Adverse Drug Reactions Reporting in Oncology Departments in the West Bank

Student Name: Rahaf Shaher Hilal Rimawi

Supervision Committee: Dr. Shahenaz Najjar, Dr. Hani Shtaya, Dr Yousef Mimi

Abstract

Background: Patient safety is a paramount concern in healthcare, with pharmacovigilance ensuring medication safety. Adverse drug reactions are especially alarming in oncology, as they affect 87% of patients. Although healthcare providers role is essential in pharmacovigilance, the underreporting of adverse drug reactions remains a global and local concern, especially in Palestine, where the pharmacovigilance infrastructure is still in its developmental stages.

Objective: This study aimed to examine healthcare providers' knowledge, attitudes, and practices toward pharmacovigilance and adverse drug reactions reporting in oncology departments across the West Bank, as well as to identify the barriers influencing ADR reporting behavior**.**

Methods: A descriptive cross-sectional study was conducted among 250 physicians, nurses, and pharmacists working in oncology departments of eight hospitals in the West Bank. Data were collected in April 2025 using a structured, self-administered questionnaire. Descriptive and inferential statistics were applied to analyze the data.

Results: Only 35.6% of participants achieved adequate knowledge, while over 91% of participants demonstrated favorable attitudes toward adverse drug reactions reporting. However, just 18.3% of participants satisfied the established criteria for adequate reporting practices. The most prevalent barriers mentioned were inadequate training, fear regarding potential legal consequences, deficient institutional reporting systems, and time limitations. Statistically significant correlations were identified between knowledge, attitudes, and practices levels and variables like profession, years of experience, prior training, and institutional support.

Conclusion: A significant gap exists in pharmacovigilance involvement among oncology healthcare practitioners in Palestine. Strengthening education, institutional frameworks, and integration of pharmacovigilance training into curricula is crucial to improving reporting behavior and ensuring safer oncology practice.

Keywords: Pharmacovigilance, Adverse Drug Reactions, Oncology, Healthcare Providers, Palestine.

Table of Contents

#	Title	Page

Declaration I
Dedication II
Acknowledgments III
Abstract IV
List of Tables IX
List of Figures XI
List of Appendices XII
List of Definitions of Abbreviations XIII
Chapter One: Introduction 1
1.1 Background 1
1.2 The Palestinian Healthcare and Oncology Context 2
1.2.1 Structure of the Healthcare System 2
1.2.2 The Rising Burden of Cancer 3
1.2.3 PV and ADR Reporting in Palestine 3
1.3 Problem Statement 5
1.4 Research Significance 6
1.5 Aim of the Study 6
1.6 Objectives of the Study 6
1.7 Research Questions 6
1.8 Research Hypothesis 7
1.9 Research Expected Outcome 8
1.10 Description of Thesis Chapters 8
Chapter Two: Literature Review 10
2.1 Introduction 10
2.2 Concept of ADRs 10
2.2.1 WHO Classification of ADRs 11
2.2.2 Clinical Significance and Impact on Patient Safety 11
2.3 Pharmacovigilance 12
2.3.1 Historical Development of PV 12
2.3.2 Objectives and Core Activities of PV 14

2.3.3 WHO-Uppsala Monitoring Centre and Global Systems 15
2.3.4 Spontaneous Reporting Systems and Their Significance 16
2.4 Role of HCPs in ADR Reporting 16
2.5 KAP of HCPs Toward ADR Reporting 17
2.6 Factors That Affect ADRs Reporting 20
2.7 Reporting Tools Found Around the World and How to Enhance Reporting 21
2.8 PV and ADR Reporting in Oncology 23
2.8.1 Importance of ADR Reporting in Oncology 23
2.8.2 Challenges and Opportunities in Oncology PV 24
2.8.3 KAP of HCPs in Oncology Toward PV and ADR Reporting 25
2.9 PV and ADR Reporting in Palestine 25
2.9.1 Development of PV in Palestine 26
2.9.2 PV Challenges in Palestine 27
2.9.3 Studies Cover PV in Palestine 28
2.10 Gaps in the Literature and Rationale for the Study 28
2.11 Conceptual Framework 29
2.12 Chapter Summary 32
Chapter Three: Materials and Methods 34
3.1 Introduction 34
3.2 Study Design 34
3.3 Study Setting 34
3.4 Population and Sample 35
3.4.1 Sampling Technique 36
3.4.2 Inclusion and Exclusion Criteria 36
3.4.3 Data Collection Instrument 36
3.5 Questionnaire Content Validity and Reliability 40
3.6 Data Collection 41
3.7 Data Processing 41
3.7.1 Survey Data Import and Initial Recoding 41
3.7.2 Demographic and Professional Variables 42
3.7.3 Final Variable Recoding and Transformation 43
3.7.4 Continuous-to-Categorical Banding 44
3.7.5 Rationale for Breakpoints 45
3.7.6 Category Merging and Rationale 45
3.7.7 Multi-Response Variables & Dummy Coding 46

3.7.8 KAP Domains and Binary Adequacy Thresholds 47
3.8 Statistical Analysis 50
3.8.1 One-Sample Proportion Tests (Hypotheses H1, H4, H6) 50
3.8.2 Logistic Regression Analyses (Hypotheses H2–H3, H5–H7, H–H14) 51
3.8.3 Firth's Penalized Logistic Regression 52
3.8.4 Predictor Specification and Factor Handling 52
3.8.5 Methodological Limitations 53
3.9 Ethical Consideration 53
3.10 Summary 54
Chapter Four: Results 55
4.1 Introduction 55
4.2 Internal Consistency of KAP Measures 55
4.2.1 Knowledge Subscale (α = 0.78, 14 items) 55
4.2.2 Attitude Subscale (α = 0.650, 10 items) 55
4.2.3 Practice Subscale (α = 0.66, 7 items) 56
4.2.4 Overall KAP Scale (α = 0.79, 31 items) 56
4.3 Sample Profile 57
4.4 Descriptive Statistics and Adequacy Rates for KAP domains 58
4.5 Descriptive Statistics for ADR Reporting Barriers 59
4.6 Suggestions for Improving ADR Reporting 60
4.7 Hypothesis Testing and Results 61
4.7.1 KAP Related Hypothesis 61
4.7.2 Barrier-Related Hypotheses (H_8–H_{12}): Impact on ADR-Reporting Practice 65
4.8 Univariate Firth-Penalized Logistic Regression Predicting Adequate ADR-Knowledge 70
4.9 Univariate Firth-Penalized Logistic Regression Predicting a Highly Positive Attitude 71
4.10 Univariate Firth-Penalized Logistic Regression Predicting Adequate ADR-Reporting Practice 73
4.11 Univariate Firth-Penalized Logistic Regression Predicting Adequate Overall KAP 75
4.12 Summary 76
Chapter Five: Discussion & Conclusion 77
5.1 Introduction 77
5.1.1 Summary of the Main Findings 77
5.2 A Reflection on the Highlights of the Demographic Data of the Study 78

5.3 KAP of HCPs Toward ADR Reporting in Oncology Departments 79
5.3.1 Reflection on the KAP Highlights 79
5.3.2 Reflection on Predictors of Adequate ADR KAP 81
5.3.3 The relationships between ADR reporting knowledge, attitudes, and practice among HCPs 85
5.3.3.1 HCP knowledge and their attitudes toward ADR reporting 85
5.3.3.2 HCP knowledge of PV and their ADR reporting practices 85
5.3.3.3 HCP attitudes toward ADR reporting and their reporting practices 86
5.4 Barriers to ADR reporting and Suggestions for improvement 86
5.5 Practical Implications and recommendations 89
5.6 Study Recommendations 90
5.7 Strengths and limitations of the study 92
5.7.1 Study Strengths 92
5.7.2 Study Limitations 92
5.8 Conclusion 93
5.9 Future Research 94
References 96
Appendices 103
ملخص 123

List of Tables

Table #	Title of Table	Page
Table 3.1	Study Population and Sample	35
Table 3.2	The Sources of the Questionnaire's Items	38
Table 3.3	Questionnaire Validation Experts Panel	41
Table 3.4	Demographic and Professional Variables after Recoding	43
Table 3.5	Continuous-to-Categorical Conversion Summary	44
Table 3.6	Category Merging and Rationale	46
Table 3.7	Multi-Response Variables & Dummy Coding	46
Table 3.8	Detailed Scoring Procedure for Practice Items (P3–P9)	48
Table 3.9	KAP Domain Composite Scores and Binary Adequacy Thresholds	50
Table 4.1	Internal Consistency of KAP Measures (Cronbach's Alpha)	56
Table 4.2	Demographic and Professional Characteristics of the Sample (N=180)	57
Table 4.3	Descriptive Statistics and Adequacy Rates for KAP Domains	59
Table 4.4	Descriptive Statistics for ADR Reporting Barriers	60
Table 4.5	Frequency and Percentage of Suggestions for Improving ADR Reporting	61
Table 4.6	KAP adequacy level hypothesis testing	64
Table 4.7	Associations Between KAP Dimensions	65
Table 4.8	Barrier-Related Hypotheses (H8–H12) Testing and Results	67
Table 4.9	Impact of Workload on ADR Reporting Practices	68
Table 4.10	Distribution of Routine Discussions (P6) (N = 180)	69
Table 4.11	Impact of Hospital Policies and Professional Culture on ADR Reporting Practices	70
Table 4.12	Predictors of Adequate ADR-Knowledge (≥ 80 % correct)	70
Table 4.13	Predictors of Highly Positive Attitude (mean ≥ 3.67)	72
Table 4.14	Predictors of Adequate Practice (score ≥ 12 / 23)	74
Table 4.15	Predictors of Adequate Overall KAP (≥ 60 % of maximum composite)	75
Table A1	Distribution of Knowledge, Attitude, Practice and Overall KAP Adequacy by Demographic and Professional Categories	119

Table A2	Annualized ADR Encounter Rates (×52) and Annual ADR Reporting by Practitioner Demographics and Professional Characteristics	121

List of Figures

Figure #	Title of Figure	Page
Figure 2.1	Conceptual framework	30

List of Appendices

Appendix #	Title of Appendix	Page
Appendix 1	Study Questionnaire	103
Appendix 2	Arabic questionnaire	109
Appendix 3	AAUP IRB Approval	115
Appendix 4	MoH Hospitals Approval	116
Appendix 5	IAH Ethical Approval	117
Appendix 6	NNUH Approval Letter	118
Appendix 7	Table A1	119
Appendix 8	Table A2	121

List of Definitions of Abbreviations

Abbreviations	Title
ADR	Adverse Drug Reaction
EMA	European Medicines Agency
EPV	Events per Variable
EU	European Commission
FAERS	FDA Adverse Event Reporting System
GDP	General Directorate of Pharmacy's
GI	Gastrointestinal
GVP	Good Pharmacovigilance Practices
H_{0X}	Null Hypothesis
HCPs	Healthcare Professionals
IAH	Istishari Arab Hospital
ICSRs	Individual Case Safety Reports
IRB	Institutional Review Board
JCI	Joint Commission International
KAP	Knowledge, Attitudes, and Practices
KHCC	King Hussein Cancer Centre
KSA	Kingdom of Saudi Arabia
LMICs	Low- and Middle-Income Countries
MAH	Marketing Authorization Holders
MoH	Ministry of Health
MRAEs	Medication-Related Adverse Events
NDA	New Drug Application

NGOs	Non-Governmental Organizations
NNUH	An-Najah National University Hospital
PI	Prescribing Information
PID	Pharmaceutical Information Department
PIDM	Program for International Drug Monitoring
PNCCP	Palestinian National Cancer Control Programme
PV	Pharmacovigilance
R	R Statistical Software
REMS	Risk Evaluation and Mitigation Strategies
RMP	Risk Management Plans
SmPC	Summary of Product Characteristics
SRSs	Spontaneous reporting systems
UK	United Kingdom
UMC	Uppsala Monitoring Centre
UNRWA	The United Nations Relief and Works Agency for Palestine Refugees
US	United States
WHO	World Health Organization

Chapter One: Introduction

1.1 Background

Patient safety has always been a main concern in healthcare practice, with medication safety playing a central role in protecting patients from preventable harm. Pharmacovigilance (PV), as defined by the World Health Organization (WHO), is "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems"(World Health Organization, 2002) It is a critical component in ensuring the safe and effective use of medicines across their entire life cycle.

Adverse drug reaction (ADR) reporting is one significant area of PV. According to the WHO, an ADR is 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". (World Health Organization, 2002)While clinical trials provide initial safety data, the importance of ADR reporting arises after medication approval to evaluate the post-marketing toxicity and to evaluate the risks and benefits of the new medication. Healthcare professionals (HCPs), physicians, pharmacists, and nurses have a vital PV role regarding ADR reporting. Their clinical proximity to patients places them in a unique position to identify, document, and report ADRs, particularly in a sensitive area such as oncology. (World Health Organization, 2002)

Spontaneous ADR reporting is the major source for monitoring and investigating adverse reactions of marketed drugs. The ADR reporting rate "Total number of reports received per million population per year" is one of the WHO PV indicators that measure the health of the PV program in the country. (World Health Organization, 2015) However, low- and middle-income countries (LMICs) usually have low reporting rate. For example, a global analysis found that Malaysia and the Philippines report only 0.86 and 0.01 ADRs per million population, respectively, while higher-income countries such as Denmark and the Netherlands exceed 400 reports per million.(Worakunphanich et al., 2022) These differences underline the significant development needed in the PV infrastructure, awareness, and engagement across LMICs.

In oncology field, new medications, different, complex and updated regimens are continuously being used. Studies indicate that up to 87% of oncology patients experience at least one ADR during treatment, with many experiencing multiple reactions due to polypharmacy and overlapping toxicities. (Saini et al., 2015) Moreover, ADR-related hospitalizations account for approximately 21.5% of admissions in cancer patients and 35.8% of emergency admissions. (Lavan et al., 2019a) Therefore, Effective PV including ADRs reporting is a great need for the clinical practice to monitor and assess the toxicity and the appropriateness of the therapies used.

1.2 The Palestinian Healthcare and Oncology Context

1.2.1 Structure of the Healthcare System

The State of Palestine, a lower middle-income country, has around 5.3 million people living in the West Bank and Gaza, the Palestine's healthcare system consists of four main sectors: the public sector (led by the Ministry of Health), the private sector, non-governmental organizations (NGOs), and the United Nations Relief and Works Agency for Palestine Refugees (UNRWA). The Palestinian Ministry of Health (MoH) is responsible of the health system to provide comprehensive high-quality services. (Ministry of Heath, 2024)

Even with constant improvement, the system still has continuing issues. These include financial limitations that impact the workforce, infrastructure, and supply chain, as well as political instability and restrictions on movement. A small number of large hospitals provide the majority of oncology services, only six out of 18 MoH hospitals have oncology departments and these facilities frequently lack specialized, trained staff and up-to-date therapeutic resources. (Ministry of Heath, 2024) PV practices are more challenging to implement in oncology units because medical staff frequently oversee complicated medication regimens without integrated safety monitoring systems. These systemic and infrastructural constraints not only limit access to specialized oncology care but also contribute to the growing cancer burden in Palestine, as discussed in the following section.

1.2.2 The Rising Burden of Cancer

In 2023, cancer accounted for 16.5% of all recorded deaths in Palestine, making it the second leading cause of death. The most prevalent types of cancer are breast, colorectal, and lung cancers in adults, whereas leukaemia and lymphoma among children. Each year, there is a 5.3% increase of cancer cases in 2023.Moreover, the mortality rates showed no improvement in the last years. Therefore, much work must be done to decrease the incidence and mortality of cancer in Palestine. (Ministry of Health, 2023)

In order to address the rising cancer burden in Palestine, the Ministry of Health and the World Health Organization collaborated to develop the Palestinian National Cancer Control Programme (PNCCP) 2024–2034, a strategic national framework. The plan seeks to strengthen cancer prevention, early detection, diagnosis, treatment, palliative care, and cancer surveillance over a ten-year period. It highlights systemic issues like the need for multidisciplinary and standardized care, shortages of necessary medications, and restricted access to oncology services. (Ministry of Health, 2023)

Despite its comprehensive nature, the PNCCP does not explicitly address PV or the incorporation of ADR reporting into oncology care. While the strategy highlights recurrent shortages of cancer medications and the lack of trained oncology pharmacists, it leaves out important details about post-marketing surveillance, medication safety systems, and institutional mechanisms for tracking drug-related harm. This absence represents a substantial gap because oncology treatments are high-risk and often involve complicated and toxic regimens. (Ministry of Health, 2023)Addressing this rising cancer burden and ensuring the safe use of oncology medications requires a strong pharmacovigilance framework, which remains underdeveloped in the Palestinian healthcare system

1.2.3 PV and ADR Reporting in Palestine

In 2015, the national PV program was initiated by the Ministry of Health (MOH) under the General Directorate of Pharmacy's (GDP) responsibility by the Pharmaceutical Information Department (PID). This program was to institutionalize pharmaceutical

safety through clear ADR monitoring and reporting mechanisms in different health care settings.

In 2017, the MOH issued the official PV Guidelines, which formalized PV operations. These recommendations highlighted the responsibilities of patients, pharmaceutical firms, HCPs, and drug agents and created the legal and procedural basis for ADR reporting. (Palestinian Ministry of Health, 2017)

Despite the efforts to develop PV infrastructure, Palestine has not yet attained membership in the WHO Program for International Drug Monitoring, coordinated by the Uppsala Monitoring Centre (UMC). This presents a major obstacle to the advancement of PV in the country. This membership provides access to PV tools and services especially the VigiBase, the largest global database for post-marketing drug safety surveillance, it also offers technical support through scientific activities related to various drug-related problems such as detection, assessment and prevention and additional PV capacity building. Without this support the local PV system most likely will stay immature and hinder medication safety efforts in Palestine. (WHO Uppsala Monitoring Centre, 2025)

Recent information from the Ministry of Health showed that from 2022 to 2024, a total of 2,846 ADR reports were submitted to PID. This number of reports was from pharmaceutical firms and marketing authorization holders (MAH), and very few submissions were from HCPs. This indicates considerable underreporting and lost opportunity to assess and enhance patient safety.

According to MoH documentation, only head of public hospital pharmacists have received a formal lecture on PV Guidelines and ADR reporting after their official publication in 2017. There has no official PV training to HCPs nor ADR reporting educational session conductions in MoH. These findings point to the need for stronger national commitment to patient safety.

Finally, PV is absent from most Palestinian medical, pharmacy, and nursing curricula. As a result, HCPs frequently start their careers lacking a robust understanding of medication safety or risk reporting. The gap in education and practice obstructs the establishment of a culture of accountability and PV. Collectively, these challenges underscore the urgent need to assess healthcare providers' readiness, awareness, and practices regarding ADR reporting—forming the basis for the present study.

1.3 Problem Statement

ADRs are a predominant cause of morbidity and mortality globally. They are considered to account for 5–10% of all hospital admissions and occur in around 10% of outpatient settings. Between ten and twenty percent of hospitalized patients may experience at least one ADR, potentially prolonging hospitalizations and significantly increasing medical costs. (Montané & Santesmases, 2020)

ADR reporting is a cornerstone of PV and essential for ensuring patient safety, especially in oncology, where treatment regimens are complex, toxic and high-risk. (Lavan et al., 2019b) However, it remains inadequately addressed in Palestine. PV is not integrated in the national cancer control strategy and ADR reporting is not systematically practiced in Palestinian hospitals.

The underreporting issue of ADRs is a global issue and appear to be higher in oncology due to several factors associated with the cancer patient ant the treatment regimen. (Baldo et al., 2018) HCPs involved in direct patient care are primarily responsible for identifying and reporting suspected ADRs. Thus, their competence in PV—reflected in their knowledge, attitudes, and practices (KAP)—is essential for ensuring patient safety and effective pharmacotherapy.

In Palestine, no prior study has comprehensively assessed HCPs' KAP toward ADR reporting in oncology departments without a comprehensive understanding of the current state of ADR reporting among these professionals, particularly within oncology departments where medication safety is paramount, efforts to strengthen PV systems will remain constrained. (Montané & Santesmases, 2020) Given the increasing cancer burden, the growing complexity of anticancer agents, and the absence of real-time safety data, addressing this issue has become an urgent priority.

This study aimed to fill this gap and assess the KAP of HCPs toward ADR reporting in oncology departments across the West Bank. The findings are expected to inform national and institutional strategies for improving PV infrastructure, policy implementation, and educational interventions tailored to oncology care.

1.4 Research Significance

At the time this study was conducted, no research in Palestine had specifically addressed the KAP of hospital-based HCPs regarding ADR reporting. This study is the first to investigate KAP toward ADR reporting among HCPs in oncology departments across the West Bank. The findings will serve as a foundational baseline for future research and policy-making, contributing to the development of targeted interventions and strategies aimed at enhancing ADR reporting systems within the national PV framework. Ultimately, this will support safer medication practices and improve patient safety among cancer patients in Palestine.

1.5 Aim of the Study

This study aimed to assess the unmet needs related to PV and ADR reporting within oncology departments across the West Bank. Specifically, it aimed to examine HCPs' KAP toward PV and ADR reporting in oncology departments across the West Bank, as well as to identify the barriers and influencing factors associated with ADR reporting behavior.

1.6 Objectives of the Study

This study sought to achieve the following objectives:

- Assess the KAP of HCPs toward PV and ADR reporting within oncology departments in the West Bank.
- Identify barriers that impede effective ADR reporting in oncology settings in the West Bank.
- Examine the relationships between HCPs' demographic characteristics, clinical experience, institutional policies, safety culture, workload and other relevant factors and their KAP levels concerning ADR reporting.

1.7 Research Questions

This study sought to answer the following research questions:

- What is the level of KAP of HCPs toward PV and ADR reporting in oncology departments in the West Bank?
- What are the main barriers to ADR reporting in oncology departments in the West Bank?
- What is the association between HCPs' demographic characteristics, clinical experience, hospital policies, safety culture, workload and other factors and their KAP toward ADR reporting in oncology departments across the West Bank?

1.8 Research Hypothesis

The following hypotheses have been formulated to be empirically tested in the course of this study. As outlined earlier, both the study and its hypotheses are specifically designed to be examined in oncology departments across the West Bank of Palestine.

Knowledge-Related Hypotheses:

H_{01}: HCPs in oncology departments in the West Bank possess sufficient knowledge about ADR reporting.

H_{02}: There is no significant association between HCPs' level of knowledge and their attitudes toward ADR reporting.

H_{03}: There is no significant association between HCPs' knowledge of PV and their ADR reporting practices.

Attitude-Related Hypotheses:

H_{04}: HCPs in oncology departments have favorable attitudes toward their role in ADR reporting.

H_{05}: There is no significant association between HCPs' attitudes toward ADR reporting and their reporting practices.

Practice-Related Hypotheses:

H_{06}: HCPs in oncology departments regularly report ADRs.

H_{07}: Training on PV and ADR reporting has no effect on ADR reporting frequency.

Barrier-Related Hypotheses:

H_{08}**:** Lack of knowledge about reporting rules does not affect ADR reporting practices.

H_{09}**:** Time constraints are not associated with ADR reporting practices.

H_{010}**:** Lack of feedback on ADR reports does not affect future reporting practices.

H_{011}**:** Fear of legal consequences does not influence ADRs reporting practices.

H_{012}**:** Institutional ADR reporting systems do not influence reporting practices.

Workload & Institutional Factors:

H_{013}: Workload is not associated with ADR reporting frequency.

H_{014}: Hospital policies and professional culture are not associated with ADR reporting.

1.9 Research Expected Outcome

This study is expected to reveal gaps in HCPs' KAP related to ADR reporting in oncology departments in the West Bank. It will identify key barriers and influencing factors, thereby providing evidence-based recommendations to improve PV systems. Ultimately, the study aims to support initiatives that enhance patient safety in oncology care.

1.10 Description of Thesis Chapters

This thesis is structured as follows:

- Chapter two: Provides a comprehensive literature review on PV, ADR reporting, HCPs' KAP, the context in Palestine, the gap led to this research and finally the conceptual framework including variables and operational definitions.
- Chapter Three: Describes the research methodology including study design, setting, population, data collection instrument, validity and reliability testing, data analysis procedures and ethical considerations.

- Chapter Four: Presents the results, including descriptive statistics, correlational analysis and hypotheses testing.
- Chapter Five: Discusses the findings in relation to the existing literature, provides conclusions, outlines recommendations for practice and policy, and highlights limitations and suggestions for future research.

Chapter Two: Literature Review

2.1 Introduction

This chapter provides a comprehensive review for the latest published literature relevant to adverse drug reactions (ADRs) and pharmacovigilance (PV). It begins by defining and emphasizing the concepts of ADRs, PV, ADR reporting. It then reviews healthcare providers' (HCPs) knowledge, attitude and practice KAP in relation to ADR reporting both in general healthcare settings and specifically within oncology departments. The chapter further examines the major factors that affect ADRs reporting and explores strategies proposed in the literature to enhance reporting behavior. This chapter discusses the context of PV and ADR reporting in Palestine, highlighting national efforts and existing challenges. Finally, the chapter identifies the research gap that led to the present study and presents the conceptual framework outlining the study variables.

2.2 Concept of ADRs

In the literature, there are different definitions of ADR that have evolved over the years. The most common and agreed -upon definition that is simplified is the following "a nonpreventable adverse drug event occurring with usual use of medication", according to this definition ADRs are not linked to the presence of medication errors. (Lee et al., 2022) On the other hand, an adverse drug event is "Any untoward medical occurrence that may present during treatment with a pharmaceutical product, but which does not necessarily have a causal relationship with this treatment." These definitions lead that an adverse event that has a direct link to a medication is called an ADR. (Kommu et al., 2024) Others add the harm caused from dependence, abuse and misuse to the definition of ADR, and even though the definition of ADR was simplified to ¨any noxious and unintended response to a medicinal product. (Montané & Santesmases, 2020)The first definition mentioned is the one will be adopted in this research.

2.2.1 WHO Classification of ADRs

ADRs are classified by the WHO primarily into Type A and Type B reactions. Type A (augmented) reactions are ADRs that occur as the result of known pharmacological properties of the drug. Usually, they are common and less severe. On the other hand, Type B (bizarre) reactions are ADRs that occur when the known pharmacological properties of the drug do not predict the reaction, typically immune-mediated or idiosyncratic, and can be fatal. (Kommu et al., 2024)

More recent classifications have expanded this scheme to include additional types: (Montané & Santesmases, 2020; Schatz & Weber, 2015)

- Type C (chronic): related to long-term use and the accumulation of doses such as tolerance or organ toxicity that develops gradually (e.g., corticosteroid-induced osteoporosis).
- Type D (delayed): effects that appear after prolonged latency, sometimes months or years later, such as carcinogenesis and teratogenesis.
- Type E (end-of-treatment): symptoms that occur when treatment is withdrawn, often due to physiological adaptation to the drug, for instance adrenal insufficiency after abrupt corticosteroid discontinuation or withdrawal symptoms from benzodiazepines.
- Type F (failure): Unexpected failure of therapy, which may result from drug resistance (e.g., antibiotics or anticancer agents).

2.2.2 Clinical Significance and Impact on Patient Safety

Worldwide, ADRs are a leading cause of morbidity and mortality. They are thought to account for 5–10% of all hospital admissions and occur in roughly 10% of outpatient settings. Ten to twenty percent of hospitalized patients may have at least one ADR, which can lengthen hospital stays and dramatically raise medical expenses. ADRs are one of the leading causes of death in the United States alone, where they are thought to be responsible for over 100,000 deaths per year. (Montané & Santesmases, 2020)

In clinical settings, the most frequent ADRs among inpatients include GI bleeding, renal impairment, electrolyte disturbance, and hematologic disorders. On the other hand, skin reactions, dizziness, and GI disturbances are more common in the outpatient

settings. Several factors increase ADR risk, such as advanced age, female gender, polypharmacy, renal or hepatic dysfunction, and genetics. (Montané & Santesmases, 2020) In cancer patients and according to a study titled “Adverse Drug Reactions in an Oncological Population: Prevalence, Predictability, and Preventability”, more than 21% of the admissions are caused by ADRs, which are caused by systemic anticancer therapies “53.3%” and non-cancer specific medications. The majority are predictable which means they can be prevented. And to be noted cancer patients have high prevalence of multimorbidity and polypharmacy and this expose them more for ADRs and require critical care. (Lavan et al., 2019b).

2.3 Pharmacovigilance

The European Commission (EU) has defined PV as the “Process and science of monitoring the safety of medicines and taking action to reduce the risks and increase the benefits of medicines”. (Fornasier, Francescon, et al., 2018) This definition resembles the World Health Organization (WHO)’s which focus on the identification, evaluation, comprehension, and avoidance of adverse effects or any other issue relating to drugs. This has made PV a key element of modern healthcare systems, intended to improve patient safety and quality of life by tracking the risks associated with medication use.

2.3.1 Historical Development of PV

In a historical overview of PV, the mid-19th century saw the first known cause of drug safety surveillance; Hannah Greener, a young girl, died in 1848 following a minor surgical procedure under chloroform anaesthesia. This incident sparked widespread concerns about the safety of anaesthetics and prompted The Lancet journal to initiate a review of anaesthesia-related deaths. This was one of the first initiatives to systematically gather safety data relevant to medication use. (Fornasier, Francescon, et al., 2018)

In the early 20th century, several devastating events stressed the need for drug regulation. In the United States, the 1937 Sulfanilamide tragedy, which resulted in 107 deaths due to the use of diethylene glycol as a solvent, highlighted the risks of inadequate safety evaluation. As a result, the Federal Food, Drug, and Cosmetic Act of 1938 was implemented, which mandated that pharmaceutical companies demonstrate pre-

marketing safety approval. Subsequent observations, including the gastrointestinal toxicity of aspirin (acetylsalicylic acid), further illustrated the necessity of long-term medication monitoring. (Fornasier, Francescon, et al., 2018)

The thalidomide tragedy in 1961 marked the most important turning point in the history of PV. Thousands of cases of severe congenital malformations have been linked to the drug, which was widely utilized as a sedative and antiemetic during pregnancy. Clinicians like Dr. McBride in Australia and Dr. Lenz in Germany were among the first to issue warnings. Drug safety laws underwent significant changes as a result of the tragedy's worldwide repercussions. It led to changes in the US that require safety and efficacy information, including testing for teratogenicity in animal models, prior to approving a drug. It resulted in the creation of EC Directive 65/65 in Europe in 1965, which laid the foundation for the regulatory framework of the European Union. (Fornasier, Francescon, et al., 2018)

The Yellow Card program, a standardized form for the spontaneous reporting of ADRs, was first implemented in the UK in 1964 and quickly became a model for other countries. To coordinate international efforts in ADR detection, the World Health Organization (WHO) established the Programme for International Drug Monitoring (PIDM) in 1968, with ten member nations at first. This program later evolved to include the Uppsala Monitoring Centre (UMC) in Sweden, which manages *VigiBase*, the global ADR database. (Fornasier, Francescon, et al., 2018)

PV infrastructure was formalized and expanded 2.3.3 Objectives and Core Activities of PV significantly in the 1990s and 2000s. The European Medicines Agency (EMA) was established in 1995, followed by the EudraVigilance database in 2001 to centralize ADR data across the EU. In 2012, Directive 2010/84/EU, which revised the legal definition of ADRs and required increased patient involvement and enhanced transparency. The PV Risk Assessment Committee (PRAC) was a significant reform established within EMA. This legislation also introduced the concept of “additional monitoring” for newly approved or high-risk drugs.(Fornasier, Francescon, et al., 2018)

Overall, the history of PV reflects a growing global recognition of the need for robust post-marketing drug surveillance systems. From individual case reports to coordinated international networks, the field has evolved significantly, achieving major

progress in protecting public health today, and to identify the challenges that lie ahead in PV in future years. (Beninger, 2018)

2.3.2 Objectives and Core Activities of PV

To ensure the safety of pharmaceutical products throughout their lifecycle, PV encompasses a diverse range of activities, extending from early-phase clinical trials to post-marketing surveillance. These activities reflect a commitment to both patient safety and the optimization of the product's benefit-risk profile. Safeguarding human subjects in clinical trials is an essential aspect of PV, rooted in historical ethical violations. This includes data monitoring committees, institutional review boards, and rigorous informed consent processes. PV professionals contribute expertise to these processes, ensuring that safety data is accurately collected, conveyed, and integrated into essential control documents. (Beninger, 2018)Another core objective of PV is the effective sharing of safety information to stakeholders. This requires adhering to formats for essential materials, including Investigational's, Investigational New Drug (IND) Supplements, New Drug Applications (NDA), New Drug Applications (NDA) Supplements, Prescribing Information (USPI), Summary of Product Characteristics (EU SmPC), Patient Package Inserts, and ClinicalTrials.gov. All these are vital resources for clinical investigators, healthcare practitioners, pharmacists, and patients, including crucial information on indications, dose, pharmacology, and safety profiles. (Beninger, 2018)

PV efforts also include post-market active surveillance involving case management, signal identification, and benefit-risk assessment. Underlying signal management activities are aggregating and analysing adverse event reports from many sources, including HCPs, consumers, literature reviews, data extraction, manufacturer complaints, patient registries, and research mandated by regulatory agencies. (Beninger, 2018)

For PV, particularly with regard to upstream material procurement, the manufacturing process, and downstream operations, control of safety-related concerns concerning the produced product takes first importance. This includes running hazard assessments for manufacturing variances, reviewing consumer complaints, and maintaining integrity of drug supply chains. (Beninger, 2018)

Risk management is central to PV, which is involved in the development and implementation of Risk Evaluation and Mitigation Strategies (REMS) and Risk Management Plans (RMP). These strategies aim to minimise the risks associated with drug use while ensuring that the benefits outweigh the risks. PV experts have to keep inspection ready as well, guaranteeing regulatory compliance and helping with training programs. (Beninger, 2018)

Finally, PV plays an important role in the analysis of advertising and promotion strategies since it guarantees that promotional materials fairly depict the safety profile of the product. Further areas where PV knowledge is appreciated are medical information and due diligence. (Beninger, 2018) By including these many actions, PV hopes to maximise the benefit-to-risk ratio of pharmacological drugs throughout their lifetime and enhance patient safety.

2.3.3 WHO-Uppsala Monitoring Centre and Global Systems

The Uppsala Monitoring Centre (UMC) in Sweden, an independent, non-profit foundation, collaborated with the WHO for more than 45 years to coordinate global PV activities through the WHO Program for International Drug Monitoring PIDM. UMC main activities include developing and promoting tools for various PV activities such as signal detection and causality assessment. It also collaborates with national PV centres around the world by providing training programs to support their capacity building. The UMC conducts research to better understand ADR reporting barriers and how to overcome them and enhance PV methods. The most crucial role for UMC is managing VigiBase, the world's largest global database of individual case safety reports (ICSRs), contributed by around 150 national PV centres. (Uppsala Monitoring Centre, n.d.)

VigiBase facilitates early signal detection and the global dissemination of drug safety issues. This allows member countries to gain insights from extensive data, frequently uncovering unusual or delayed ADRs that may not appear in pre-marketing testing. UMC also creates systems such as VigiAccess (for public access to safety data) and VigiLyze (for professional signal detection), which improve transparency and international collaboration.

Other significant global systems include the European Medicines Agency's EudraVigilance, the US FDA Adverse Event Reporting System (FAERS), and Spain's

FEDRA system, all of which feed into the broader international PV framework. (Montané & Santesmases, 2020)

2.3.4 Spontaneous Reporting Systems and Their Significance

Spontaneous reporting systems (SRSs) constitute the foundation of PV, offering a cost-effective, readily accessible, and flexible method for detecting potential safety issues. These systems rely on voluntary reporting from patients, physicians, and pharmaceutical companies to gather information regarding potential ADRs (Montané & Santesmases, 2020)

Despite the advances in reporting tools, spontaneous reports remain the most widely used tool for signal generation in PV due to their ability to uncover unexpected, rare, or delayed ADRs. A major constraint in spite of their simplicity is underreporting, which can postpone the discovery of developing safety signals. (Montané & Santesmases, 2020)

Regulatory bodies emphasize that spontaneous reporting is crucial for severe and unexpected reactions, particularly with newly released pharmaceuticals. Continuous initiatives are essential to educate HCPs about the significance of ADR reporting and to utilize technological improvements such as electronic health records and artificial intelligence for anticipatory signal detection. Patient-reported outcomes and digital platforms, including web-based reporting portals, are being integrated to improve participation and boost detection capabilities. (Montané & Santesmases, 2020)

2.4 Role of HCPs in ADR Reporting

HCPs play a pivotal role in PV, significantly contributing to the detection, documentation, and reporting of ADRs. Due to their direct patient interaction and clinical competence, physicians, pharmacists, and nurses serve as primary reporters of ADRs, identifying potential drug-related problems that could otherwise remain unnoticed. The effective function of ADR reporting systems and, hence, the protection of patient safety depend on their contributions. (Phougat et al., 2024)

Being prescribers and diagnosticians, physicians are generally the first to identify potential ADRs in their patients. Their clinical experience assists in analysing the

relationship between a suspected substance and the patient's signs and symptoms. Their responsibility goes beyond only handling the ADR to include documenting and reporting the occurrence to the relevant PV regulatory agencies or systems. (Phougat et al., 2024)

Complementing the role of physicians, pharmacists, as medication experts, play a critical role in detecting ADRs. They can detect potential ADRs through medication reviews, patient counselling, and tracking drug utilization patterns. Pharmacists are equipped to inform patients and other HCPs about ADRs, fostering awareness and advocating for reporting. Moreover, pharmacists are the leaders to the formulation and execution of institutional policies and procedures that enhance PV, thereby reinforcing the entire drug safety infrastructure. (Lee et al., 2022; Phougat et al., 2024)

In addition, nurses, as primary caregivers, are the first to observe any abnormality in a patient's status, which may indicate an ADR. Their vigilance about patient symptoms and accurate recording is critical for detecting possible drug-related adverse effects. Nurses play a crucial role in transferring patient concerns to physicians and pharmacists, thus enabling timely evaluation and management of ADRs. (Phougat et al., 2024)

The responsibility of HCPs to report ADRs extends beyond national borders. Their participation in global PV initiatives is crucial for guaranteeing that all patients, irrespective of their geographical location, receive comprehensive pharmaceutical safety oversight. Ethical considerations, including the responsibility to prevent injury and the commitment to promote public health, highlight the significance of ADR reporting by HCPs. Ignoring declaration of suspected ADRs may lead to serious consequences, such as delaying the identification of important safety signals and jeopardizing the health of other patients. (Phougat et al., 2024)

2.5 KAP of HCPs Toward ADR Reporting

Literature from different healthcare settings around the globe has studied KAP of HCPs regarding ADR reporting to reveal barriers and opportunities within PV systems. They illustrated that underreporting is often associated with limited awareness, uncertainty about causality, and inadequate training. This section reviews existing literature on KAP among physicians, pharmacists, and nurses, highlighting key findings, underreporting causes, and areas requiring educational and systemic improvement.

In a cross-sectional study involved 192 doctors and nurses in Nepal to detect the knowledge and practice of ADR reporting. The population of the study have had good knowledge of ADR reporting. However, the actual reporting is insufficient and there is a gap in training and experience on ADR reporting systems. (Shah et al., 2021) Similar results were found after interviewing 13 physicians from four public hospitals in Pakistan a Lower Middle-Income Country (LMIC). The majority of the physicians had good knowledge and positive attitude toward ADR reporting and its importance. However, many of them confessed that they have never reported any ADR. (Hussain et al., 2020a)

In Ghana 259 doctors were surveyed from 23 hospitals to assess ADR reporting rate, knowledge of the reporting system and attitudes to spontaneous ADR. Doctors agreed that it is their responsibility to report ADR and had positive attitude toward reporting. On the other hand, the majority had faced suspected ADR in the past one year but minority had reported it by completing the ADR reporting form. (Sabblah et al., 2014)

In 2015 in India, the functional rate of 90 ADR-monitoring centers was only 56.45%. This was stated in a retrospective observational, cross-sectional prospective analysis to detect the factors responsible for underreporting of ADRs one of the major factors was the lack of knowledge and awareness about PV. (Tandon et al., 2015)

In September 2010, a study held in a developed country, Sweden, to investigate the awareness of nurses regarding their role as reporters of ADRs and factors that may influence their reporting. More than half of the study population were aware of their new role as reporters of ADRs, but few of the responding nurses had reported an ADR. (Ekman et al., 2012)

In the Middle Eastern region, several studies have examined healthcare providers' knowledge, attitude, and practice toward ADR reporting and pharmacovigilance, revealing similar patterns of limited ADR reporting regardless of knowledge level and despite generally positive attitudes.

In a descriptive cross-sectional study in King Fahd Hospital in the Kingdom of Saudi Arabia (KSA) between April 2015 and April 2016, it included 331 HCPs. Most of them were unaware of the term PV hence ADR reporting was low. (Almandil, 2016)Another study conducted in the KSA to assess KAP of 150 HCPs toward ADR reporting in public hospitals, revealed that the HCPs have insufficient knowledge and practices despite their positive attitude toward ADR reporting. (Daghriri et al., 2024)

Additional study employing the Theory of Planned Behavior explores hospital pharmacists' intentions toward ADR reporting in Saudi Arabia. It documents that attitudes, subjective norms, and perceived behavioral control significantly influence intention to report. The authors emphasize that although many pharmacists recognize ADR reporting as a professional responsibility, structural and motivational barriers (e.g. system complexity, perceived workload, low incentives) dampen actual reporting behavior. (Barr & Alsulami, 2025)

Similar results found among hospital pharmacists in Kuwait, Alsaleh et al. (2017) conducted a survey of pharmacists working in secondary and tertiary governmental hospitals, and found that although most respondents had moderate-to-good knowledge of pharmacovigilance concepts, actual ADR reporting was very low. (Alsaleh et al., 2017)

In an earlier study conducted in Qatar, Wilbur (2013) distributed a 27-item web-based survey to pharmacists, with a 25% response rate (116 pharmacists). While basic knowledge of ADR terminology and purpose of reporting was high, only 29.3% had ever submitted a suspected ADR report despite their high attitude. The study also showed that hospital pharmacists were about seven times more likely to report than nonhospital pharmacists. (Wilbur, 2013)

In the United Arab Emirates (UAE), a nationwide survey among hospital pharmacists (n = 342) revealed strong knowledge: 93.3% correctly defined pharmacovigilance and 86.8% understood ADR definitions. Yet, despite 71.1% having noticed ADRs in the previous year, only 53.2% actually reported them. The most commonly cited barrier was lack of training in ADR reporting (median score 4 out of 5), followed by lack of awareness about the national reporting system. (Shanableh et al., 2023)

In Romania in 2013 after assessing the perception of 532 doctors towards PV activities and ADRs reporting. The reporting of ADRs in Romania was accidental, doctors are less or not at all informed about PV activities, even though they have a favorable attitude towards reporting ADRs. (PAVELIU et al., 2013)

The same results were concluded from a KAP study in Northeast Ethiopia, which performed on 114 health care professionals about ADR reporting and the associated factors. The majority of health care professionals had a positive attitude, but they had

inadequate knowledge and poor practice towards ADR reporting. (Kassa Alemu & Biru, 2019)(Kassa Alemu & Biru, 2019) The outcome of a systematic review of 13 studies in Ethiopia confirmed these results; the KAP of health care professionals towards ADR reporting were low. (Hailu & Mohammed, 2020)

Another Systematic review by Salehi et al. in 2021 which reviewed 23 studies from January 2010 to October 2020 to assess KAP among nurses in relation to ADR reporting. In spite of that nurses have positive attitude and knowledge regarding PV activities and ADRs reporting the actual reporting was infrequent. (Salehi et al., 2021)

When analyzing the previous results, it is noticed that almost all these studies to measure KAP in HCPs are centered in developing countries. Because there is a shift of ADR reporting from the prescriber to the consumer or patient in developed countries. (Hussain et al., 2020a)

Among all healthcare practitioners, including doctors and nurses, pharmacy professionals stand out in the knowledge level and awareness of PV and ADR significance. (Almandil, 2016; Daghriri et al., 2024; Kassa Alemu & Biru, 2019)

There is a huge gap between developed and developing countries regarding KAP in relation to PV and reporting ADRs. Meanwhile, developing countries are studying the awareness of their HCPs regarding ADR reporting. Developed countries are on another level of working on improving the reporting process through electronic tools and patient involvement in the process. Thus, there is an urgent need to raise the KAP level in developing countries toward ADR reporting.

2.6 Factors That Affect ADRs Reporting

There is consensus on the factors that affect the reporting of ADRs by HCPs in the various studies and reviews. Lack of training and medical education regarding PV activities including ADRs reporting and ADRs reporting systems was found to be the main reason behind poor reporting of ADRs in several studies. (Hussain et al., 2020a; PAVELIU et al., 2013; Sabblah et al., 2014; Salehi et al., 2021; Shah et al., 2021; Tandon et al., 2015)

Other factors that discourage ADRs reporting are work overload, lack of communication, fear of legal liability, lethargy, indifference, insecurity, complacency, lack of feedback from hospital management or regulatory authorities, fear that reporting ADRs could negatively reflect on one's competence, fear of complaints from a patient's family. Fearing to report, uncertainty about the ADR, concern about reporting generating extra work, nonavailability of reporting forms, and that the physician responsible did not regard the reaction necessary to report. All were stated reasons for underreporting. (Baldo et al., 2018; Ekman et al., 2012; Hailu & Mohammed, 2020; Hussain et al., 2020a; PAVELIU et al., 2013; Tandon et al., 2015)

On the other hand, many factors considered important to encourage ADR reporting such as the severity of the ADR and if the reaction occurred to a newly approved drug.(Ekman et al., 2012) The easiness of reporting using an online platform, the periodic information and the training about all adverse reactions reported by doctors and the measures taken to deal with them. (PAVELIU et al., 2013)

2.7 Reporting Tools Found Around the World and How to Enhance Reporting

The surveillance of Medication-related adverse events (MRAEs) in health care including ADRs relies on three methods: incident reporting, direct surveillance, and computerized methods for reporting as emphasized in a narrative overview about the current knowledge of MRAEs in health care. (Laatikainen et al., 2022)

Incident reporting, mainly voluntary, is the primary method used and has been implemented for a long time in healthcare organisations worldwide. The most significant limitations for this method, as previously mentioned, is underreporting, even when it is encouraged within healthcare personnel. Therefore, using this method alone is not trustworthy.

Direct surveillance is usually performed as real-time chart reviews or patient interviews. It is an accurate and reliable method but it is time-consuming and costly; requires trained personnel for every unit.

Computerized methods include global trigger tool-type real-time alert-system. One well-established trigger tool system can cover data from the entire organization, but it

requires expert assessment for actions to triggers to face all technical errors that might arise.

The recommendations arising from studies included in the review are focused on developing and applying these three methods, or combining them. (Laatikainen et al., 2022)

As the first issue about under-reporting is lack of education and training; providing educational programs, training courses and presentations to HCPs on PV activities was the leading enhancing method. (Almandil, 2016; Baldo et al., 2018; Ekman et al., 2012; Hailu & Mohammed, 2020; Jha et al., 2014; Rabayah et al., 2019; Salehi et al., 2021) Furthermore, national PV centers should publicize their activities among physicians (Hussain et al., 2020b)

Patient involvement is also essential for improving knowledge, attitudes, and perceptions about ADRs and increasing the numbers of ADR reports. (Almandil, 2016) Routledge et al. (2023) highlighted that engaging patients through educational initiatives and accessible electronic reporting systems enhances their awareness and participation in pharmacovigilance. Although most existing interventions focus on healthcare professionals, the study emphasized that empowering patients to actively report ADRs can significantly enrich safety data and strengthen overall pharmacovigilance systems. (Routledge & Bracchi, 2023a)

A clinical pharmacist should be in charge of medicine safety issues in the wards, as they are more educated and trained on that particular issue, their active involvement has been shown to reduce medication errors and improve ADR detection and reporting rates. (Baldo et al., 2018; Hussain et al., 2020a)

Physicians in developing countries have recommended to establish an online reporting system to facilitate reporting. (Hailu & Mohammed, 2020; Hussain et al., 2020a; Rabayah et al., 2019) On the other hand, developed countries are working on interventions to facilitate the use of their electronic reporting systems and increase their efficiency. (Ribeiro-Vaz et al., 2016)

All the mentioned strategies are supported and proven to be effective in increasing ADR reporting by HCPs. In a systematic review of 13 papers published from 01 July 2010 to 17 June 2019 to investigate the impact of strategies used to improve ADR

reporting. Electronic reporting tools such as applications integrated into electronic health records have demonstrated the potential to substantially increase ADR reporting, in some cases yielding more than a 13-fold rise. Multifaceted strategies, which combine digital tools with active interventions like education and feedback, show the most significant promise, reaching a 14-fold increase in one study. These findings underline that improving ADR reporting requires technological facilitation, ongoing professional engagement, and system-level support to guarantee sustainability and high-quality reporting. (Li et al., 2020)

2.8 PV and ADR Reporting in Oncology

PV, which is focused on monitoring medication safety, is critical in oncology due to the built-in toxicity of antineoplastic medicines, their narrow therapeutic windows, and the high doses with strict scheduling of treatment protocols. Such therapies can lead to a wide range of ADRs, which may be severe or life-threatening. Effective ADR reporting ensures patient safety, improves therapeutic outcomes, and informs clinical decision-making. (Baldo et al., 2018)

2.8.1 Importance of ADR Reporting in Oncology

Cancer patients are more vulnerable to adverse medication reactions owing to factors such as polypharmacy, comorbidities, and the severity of oncological treatments. (Lavan et al., 2019b) The advent of targeted therapies and immunotherapies has complicated the ADR landscape, as these treatments can provoke unique and unanticipated side effects not often linked to traditional chemotherapies. A study revealed that real-world ADRs associated with targeted therapies are often not recorded in clinical trials, highlighting the need for stringent post-marketing surveillance. (Fornasier, Taborelli, et al., 2018)

Moreover, PV depends on spontaneous ADR reporting, which produces essential information that can help to identify rare or unexpected side effects. In cancer, where the balance between therapeutic efficacy and toxicity is sensitive and quick detection of ADRs can significantly affect patient outcomes, this is particularly important. (Tuccori et al., 2015)

2.8.2 Challenges and Opportunities in Oncology PV

In a systematic review of 54 studies to identify the main issues in carrying out an effective PV activity in oncology, eight critical issues were detected; These issues pertain to: terminology in classifying ADRs; the wide range of anti-cancer therapies; the emergence of targeted therapy and immunotherapy; chemoradiotherapy combination; the growing usage of generic drugs and biosimilars in oncology; polypharmacy and drug interactions, special patient categories that require special consideration such as pregnant women, elderly and children; and finally under-reporting of ADRs. (Baldo et al., 2018)

The last issue mentioned in PV activity implementation in oncology was under-reporting of ADRs, where there are more causes of under-reporting; the underlying clinical conditions of cancer patients could be confused with ADRs. Furthermore, the toxicity of anticancer drugs is often considered “normal” and almost all systemic medications have a narrow therapeutic window. Ageing and co-morbidities increase the complexity of the problem, making interactions among drugs more likely to occur. Moreover, the assignment of causality of an adverse effect to a particular drug or pre-existing risk factor is difficult (Baldo et al., 2018) HCPs frequently face obstacles, including excessive workload, time constraints, and inadequate understanding of the PV system, resulting in the underreporting of ADRs. (Rabayah et al., 2019)

On the other hand, there are opportunities to enhance PV practices in oncology. Scientific and developed societies are showing great productivity in the establishment of guidelines, tools and platforms for the reporting of ADRs in clinical trials and in oncology research. While the reasons for under-reporting are well known, lack of knowledge can no longer be used as an excuse to avoid ADR reporting, even in oncology. (Baldo et al., 2018)

Therefore, implementing educational programs to raise awareness among HCPs about the significance of ADR reporting can improve reporting rates. Additionally, presence of clinical pharmacists in the oncology care teams has impact on increasing ADR detection and reporting. This was emphasized in a study where the involvement of clinical pharmacists led to a 124.3% increase in spontaneous ADR reports, highlighting their essential role in PV activities. (Fornasier, Taborelli, et al., 2018)

2.8.3 KAP of HCPs in Oncology Toward PV and ADR Reporting

Taking a cross-sectional KAP study held in King Hussein Cancer Centre, Jordan, as a model of a cancer centre in a developing country to focus on ADR reporting. All 307 health-care providers who participated in the study had a highly positive attitude toward PV and ADR reporting. However, filling in an ADR reporting form, assessing the severity of ADRs, and differentiating between ADRs and adverse events were low. The main barriers to ADR reporting were considered to be a lack of training and understanding of reporting rules. No associations were found with age, gender, years of experience, attitude, or knowledge.(Rabayah et al., 2019)

A recent cross-sectional study by Alkofide et al. (2024) examined the awareness, attitudes, and practices of HCPs in oncology settings in Saudi Arabia regarding PV and barriers to efficient ADR reporting. The study revealed that the majority of HCPs reported ADRs internally, while only 38.5% were aware of the formal ADR review methods. On the other hand, most of them have a positive perspective regarding PV. Underreporting causes illustrated in this study resonate with previous literature, including lack of feedback, legal concerns, doubts regarding the value of reporting, and cancer treatment complexities. The authors underscored the necessity for focused educational interventions, more explicit institutional protocols, and the incorporation of PV content into ongoing professional development to improve ADR reporting in oncology. They also stressed the need for technology deployment in PV practices to facilitate precise and prompt reporting. (Alkofide et al., 2024)

In conclusion, comprehensive PV methods are vital in oncology to address the unique requirements of cancer therapies and ensure patient safety. By tackling present challenges and utilizing available opportunities, healthcare systems can enhance ADR reporting methods, resulting in better therapeutic outcomes for cancer patients.

2.9 PV and ADR Reporting in Palestine

Significant steps have been taken towards developing a national PV system in Palestine. The process began in 2015, when the Ministry of Health (MOH) launched the national PV program, and has since continued to strengthen the PV infrastructure to

enhance Palestinian patient safety. Comprehensive information regarding the advancement of PV in Palestine can be found below.

2.9.1 Development of PV in Palestine

By the end of 2015, under the General Directorate of Pharmacy's (GDP) of MoH, the Pharmaceutical Information Department (PID) initiated the national PV program. Through the establishment of clear ADR monitoring and reporting mechanisms across different health care settings, the initiative aimed to institutionalize that pharmaceutical safety in Palestine.

In 2017, the Palestinian MoH in cooperation with the Jordanian FDA and the WHO and depending on the Guideline on good pharmacovigilance practices (GVP) For Arab Countries issued the official PV Guidelines, this formalized PV operations and provided recommendations to highlight the responsibilities of patients, pharmaceutical firms, HCPs, and drug agents and created the legal and procedural basis for ADR reporting. (Palestinian Ministry of Health, 2017)

Based on international best practices, the MoH introduced the "yellow card" system to promote spontaneous ADR reporting. These standardized forms are accessible through hospitals, professional syndicates, and the Ministry's website and can be filled out by HCPs, patients, or caregivers. They are required to document a range of ADRs, including those brought on by prescription, over-the-counter, herbal, and medication errors. (Palestinian Ministry of Health, n.d.)

Nevertheless, the Ministry of Health has continued its efforts to enhance PV awareness among HCPs and MAHs. These include conducting awareness meetings and coordinating with MoH hospital pharmacists and MAHS. The PID also constantly reminds HCPs of the necessity of ADR reporting within all department circulars.

In an overview of PV systems in 22 Arab countries, Palestine is still in the early stages of PV development compared to other Arab countries. While nations such as Morocco, Tunisia, Saudi Arabia, Egypt, and Jordan have established mature PV systems supported by full membership in the WHO Program for International Drug Monitoring, Palestine is not yet a member of this global network. These countries benefit from robust governmental support, specialized national centers, and efficient reporting infrastructures. In Saudi Arabia, tens of thousands of ADR reports are submitted

annually, reflecting strategic awareness campaigns and regulatory demands. Conversely, Palestine's system encounters considerable resource limitations, insufficient public awareness, and a deficit of qualified personnel. This underscores the urgent necessity for capacity enhancement, regional cooperation, and international assistance to elevate photovoltaic (PV) development in Palestine to the standards seen in more advanced Arab nations. (Alshammari et al., 2019)

Data from the MoH shows that 2846 reports were submitted to the MoH from pharmaceutical companies and marketing authorisation holders from 2022 to 2024, as follows: 1700 reports in 2022, 891 reports in 2023, and only 255 reports in 2024. These numbers indicate a decrease in reporting over the years, which is mainly related to COVID-19 vaccination and treatment in 2022 and early 2023. The 255 reports in 2024 are around 80 reports per million \ year in the West Bank, which is lower than the WHO benchmark for reporting rate of 200 per million\ year. (Khan & Karatas, 2022) On the other hand, only 20 reports from HCPs were submitted in the same period of time, which also highlights the lack of HCPs' involvement in ADR reporting in the West Bank.

2.9.2 PV Challenges in Palestine

In spite of the efforts to develop PV infrastructure, Palestine, due to political and financial challenges, couldn't become a member in the WHO Program for International Drug Monitoring, coordinated by the Uppsala Monitoring Centre (UMC). (Uppsala Monitoring Centre, 2025) This is a significant barrier to the improvement of PV in the country, which limits international collaboration and access to global drug safety data and may be associated with a reduced ADR reporting rate. (Wiwan Worakunphanich, 2022)

Other structural challenges hindering progress are the absence of a national ADR safety database, limited integration with international PV networks, and the shortage of trained PV personnel.

In addition to the previous PV structural limitations, the suspected barriers to ADR reporting include limited awareness about PV and reporting procedures due to insufficient training opportunities for healthcare workers, heavy workloads and time constraints in clinical settings, and a lack of feedback mechanisms that could encourage ongoing participation. (Alshammari et al., 2019)

Without assessing the immediate impact of these challenges, strategies to support the local PV system will most likely remain immature, and medication safety efforts in Palestine will be in vain.

2.9.3 Studies Cover PV in Palestine

In 2016, Khdour et al. evaluated the knowledge and attitudes of 270 community and hospital pharmacists toward PV and ADR reporting in a cross-sectional study in the West Bank. The study revealed significant gaps in pharmacists' knowledge and involvement in PV initiatives. Only 12.2% of respondents had ever reported an ADR, and just 11.9% could accurately define PV. Despite these low reporting rates, over 90% of participants believed that reporting ADRs was a professional obligation. They were interested in participating in the national PV program in Palestine. (Khdour et al., 2016)

Hospital pharmacists reported ADRs more frequently than community pharmacists, most likely due to their closer collaboration with other HCPs. The major barriers for ADR reporting included a lack of knowledge about how to report, inadequate patient information, and the perception that some ADRs were too trivial to report. These results raised the public and policymakers' alert about the nature of PV in Palestine, and thus, there is a need for improved training and systemic intervention to strengthen PV culture in Palestine. (Khdour et al., 2016)(Khdour et al., 2016)

No further studies in Palestine cover KAP of hospital HCPs toward ADR reporting, nor do they cover PV in oncology.

Without a thorough understanding of the current status of ADR reporting among HCPs, particularly in oncology departments where drug safety is especially critical, efforts to improve patient safety and enhance PV systems will be limited.

2.10 Gaps in the Literature and Rationale for the Study

Despite the growing interest in PV in Palestine, there is a significant deficiency of studies explicitly targeting oncology healthcare workers. Current research has predominantly neglected high-risk areas like oncology, where the intricacy and toxicity of treatments amplify the significance of ADR reporting. Furthermore, there is a notable absence of studies evaluating the KAP of HCPs in this domain. This study seeks to fill

these gaps by assessing the KAP of oncology practitioners in the West Bank, producing data to guide targeted interventions, bolster PV systems, and ultimately improve patient safety in oncology environments.

2.11 Conceptual Framework

The conceptual framework guiding this study is based on the Knowledge–Attitude–Practice (KAP) model, which posits that individuals must first acquire knowledge, develop a positive attitude, and then translate these into practice. This model is commonly used in health behavior research to evaluate readiness for behavioral change and compliance. (Sharma, 2024) Within this study, the KAP framework provides a structure for understanding how healthcare providers' knowledge and attitudes toward pharmacovigilance and adverse drug reaction (ADR) reporting affect their actual reporting practices in oncology departments.

To effectively explore these gaps and guide the study's design, a conceptual framework was developed to illustrate the relationship between HCPs' demographics and their KAP levels. It also illustrates the barriers suspected to affect ADR reporting. The study was limited to the HCPs who have direct contact with adult cancer patients in the West Bank, including doctors, pharmacists and nurses working in oncology departments of the West Bank hospitals. This framework provides the foundation for understanding how these variables interact and influence PV behaviour in high-risk clinical settings.

According to Sharma (2024), KAP surveys aim to explore what is *known* (knowledge), *believed* (attitude), and *done* (practice) by individuals in a given context. In this study: (Sharma, 2024)

- Knowledge refers to the capacity to acquire, retain, and apply information about ADRs, pharmacovigilance concepts, and reporting mechanisms.
- Attitude represents a learned predisposition to respond favorably or unfavorably toward ADR reporting, reflecting motivation, beliefs, and perceptions regarding its importance.

- Practice denotes the application of knowledge and attitude through actual reporting behaviors, including identifying, documenting, and submitting ADR reports.

These constructs are interrelated, where increased knowledge is expected to foster positive attitudes, which then translate into improved reporting practices.

The conceptual framework and variables of the study are as illustrated in the figure.1

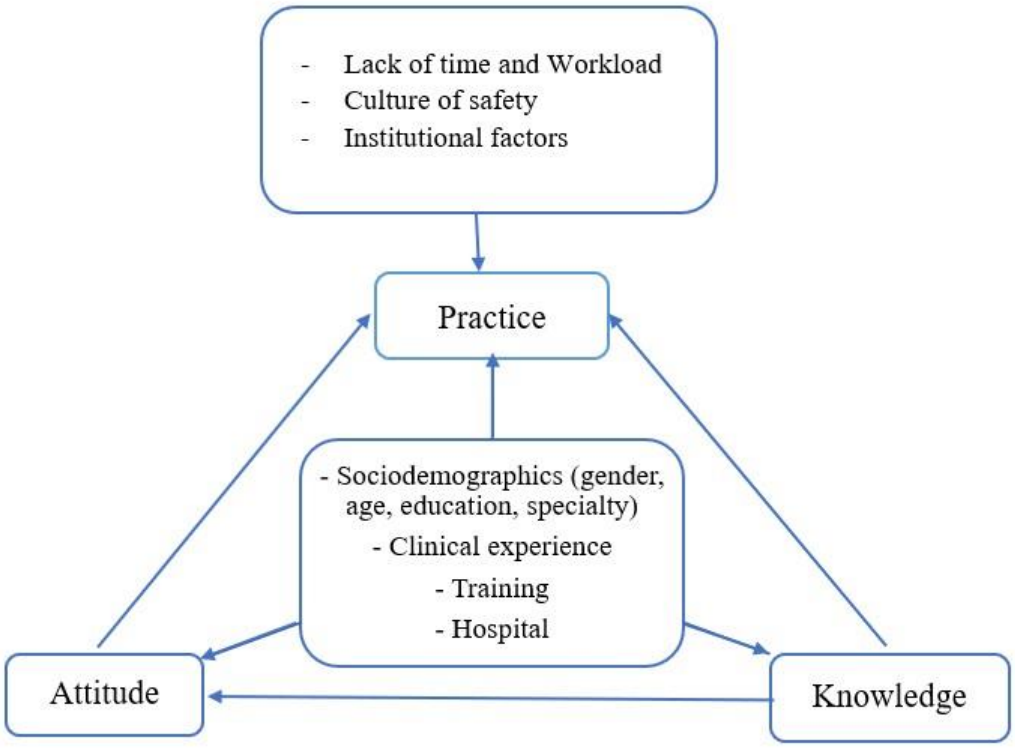

Figure 2.1 Conceptual framework

In addition to these three core constructs, several sociodemographic and institutional factors are proposed to influence pharmacovigilance behavior. Variables such as profession, years of experience, prior pharmacovigilance training, and type of hospital (public or private) are expected to shape knowledge and attitudes, thereby indirectly influencing ADR reporting practices. These factors act as predictors or moderators within the framework and are essential for understanding the determinants of healthcare providers' reporting behavior.

The study variables shown in the conceptual framework and as they appear in the questionnaire are the following:

1) The sociodemographic data
    a) Gender: participant's gender, a nominal close ended question (male, female), gender in the study is an independent variable.
    b) Age: participant's age in years, a numeric open-ended question which was recoded as ordinal (20–29, 30–39, 40 -49, 50+), age in the study is an independent variable.
    c) Profession: the participant specialty, a nominal close ended question (Pharmacist; Doctor of Pharmacy; Physician (Consultant); Physician (Fellow); Physician (Resident); Physician (Service physician); Daycare Nurse; Medical Nurse), profession in the study is an independent variable.
    d) Level of education: measures the highest level of education completed, a nominal close ended question (Diploma degree; Bachelor's degree; Master's degree; Residency program; Specialist), level of education in the study is an independent variable.
2) Years of experience: participant's total and oncology specific experience in years, ordinal close ended question (<1 year, 1–3 years, 3–5 years, 5–10 years, >10 years), experience in the study is an independent variable.
3) Attending training on PV and ADR reporting: a nominal close ended question (Yes, No) attending training in the study is an independent variable.
4) Hospital: the hospital the participant is currently working in, a nominal close ended question (Al-Hussein; Al-Watani; An-Najah; Dura; Istishari; Khalil Suleiman; Palestine Medical; Thabet Thabet), hospital in the study is an independent variable.
5) Lack of time and workload: Weekly work hours, Patients seen per day, both are continuous open-ended questions which were converted to ordinal, as for working hours coded (≤40=1, 41–59=2, ≥60 = 3), as for Patients Seen Daily coded (≤10=1, 11–19= 2, ≥20= 3). workload in the study is an independent variable.

6) Culture of safety: it is measured based on three questions (the availability of routine discussions on ADRs an open-ended question, and the choose of Fear from legal responsibility and ADR reporting negatively affect professional image among ADR reporting barriers)**,** Culture of safety is in the study is an independent variable.
7) Institutional factors as a choice among ADR reporting barriers (My institution does not have a reporting system), institutional factors in the study are independent variable.
8) Knowledge: the participant knowledge of PV and ADR reporting, 14 close-ended questions (Yes, No, I don't know), where 14 × (0 = incorrect, 1 = correct) then categorized to Low (0–7); Intermediate (8–10); High (11–14), knowledge is a dependent variable in relation to the previous variables mentioned, on the other hand it is an independent variable when measuring the association with attitude and practice.
9) Attitude: the participant attitude toward ADR reporting measured by 10 (1-5) Likert items, which were categorized to Negative (< 2.34); Moderate (2.34–3.66); Highly Positive (≥ 3.67), attitude is a dependent variable in relation to the previous variables mentioned, on the other hand it is an independent variable when measuring the association with practice.
10) Practice: the participant practices regarding ADR reporting, ten mixed method close-ended and open-ended with short answers (including the frequency of encountering ADRs, documentation practices and procedures, and expectations) questions that are coded then categorized into Poor (< 12); Moderate (12–16); Good (≥ 17), practice is a dependent variable in relation to the previous variables mentioned

2.12 Chapter Summary

This chapter has presented a comprehensive review of recent literature concerning ADRs, the principles and evolution of PV, and the critical role of ADR reporting in clinical practice. It explored the KAP of HCPs with respect to ADR reporting, both in general and within oncology departments, where the risk and complexity of drug-related

harm are particularly high. Factors that affect ADR reporting, as well as the measures to enhance reporting, were also covered.

The chapter also provides a review of the context in Palestine regarding PV and ADR reporting, highlighting the gap in literature and practices that led to this research to study the KAP of oncology HCPs toward PV and ADR reporting in the West Bank. Finally, it illustrates the conceptual framework of the study that guided the study design and methodology, which will be covered in the next chapter.

Chapter Three: Materials and Methods

3.1 Introduction

This chapter presents the methodology of this research used to achieve the study objectives. It includes the study design, setting, population and sample, instrument, data collection and analysis, and ethical considerations.

3.2 Study Design

A hospital-based descriptive cross-sectional study design was implemented. This study follows a quantitative approach with supplementary qualitative elements using a structured self-administered questionnaire to collect data on knowledge, attitude and practice (KAP) of selected health care providers (HCPs). The questionnaire mainly included closed-ended questions, which ensured structured and quantifiable responses, facilitating statistical analysis. On the other hand, open-ended questions allow participants to elaborate, offering deeper and more comprehensive insights.

This study is a KAP investigation designed to assess the prevalence of HCPs' knowledge, attitudes, and practices about ADR reporting. The cross-sectional methodology was used because it offers a snapshot of KAP levels at a single time point, making it an efficient and suitable tool for prevalence investigations. (Salazar et al., 2015) Further information regarding the study tools and data collection will be presented throughout this chapter.

3.3 Study Setting

The study was conducted in all hospitals with oncology departments in the West Bank, Palestine. There are eight hospitals in the West Bank that provide oncology services; six of them are governmental, which are Thabet Thabet Hospital in Tulkarm, Al-Hussein Hospital in Beit Jala, Bethlehem, Al-Watani Hospital in Nablus, Palestine Medical Complex in Ramallah, Khalil Sulaiman Hospital in Jenin, and Dura Hospital in Hebron. Furthermore, there are two private hospitals, both are Joint Commission

International (JCI) accredited, Istishari Arab Hospital (IAH) and AnNajah National University Hospital (NNUH). All eight centers have chemotherapy daycare departments where cancer patients get their treatment as outpatients. Just three hospitals, Al-Hussein, IAH, and NNUH, have inpatient oncology departments. Given the presence of both outpatient and inpatient oncology care across these institutions, they represent appropriate settings for assessing ADR reporting practices.

3.4 Population and Sample

The study's target population comprises HCPs who have direct contact with adult cancer patients in the West Bank, including nurses, physicians, and pharmacists from oncology departments in the participating hospitals. "Direct contact" was defined as actively involved in the prescribing, dispensing, administering, or monitoring of adult cancer patients. The individual HCP is the unit of data collection and analysis. he total target population, shown in Table 3.1 below, represents the sample included in the study. Information regarding the number of HCPs in each department was obtained from the heads of the respective departments where data collection took place.

Table 3.1: Study target Population and Sample

Hospital	Nurses	Physicians	Pharmacists	Total
Jenin	4	4	5	13
Tulkarem	3	3	9	15
Al-Watani	10	5	7	22
An-Najah	94	20	3	117
Palestine Medical Complex	4	5	2	11
Istishari Arab Hospital	16	11	3	30
Beit Jala	17	13	2	32
Dura	4	5	1	10
Total	152	66	32	250

3.4.1 Sampling Technique

A total population sampling technique was employed in this study. This strategy involves incorporating all individuals from the population who fit the inclusion criteria. (Etikan et al., 2015) Considering the relatively small number of HCPs in oncology departments throughout the West Bank, and the significant role in ADR reporting they have, all (n=250) were invited to participate in the study. Therefore, engaging the entire target population seemed both practical and methodologically appropriate. This method guarantees thorough data collection and improves the applicability of the results within this particular healthcare setting.

3.4.2 Inclusion and Exclusion Criteria

- Inclusion criteria: HCPs who are nurses, physicians, including residents, fellows, and consultants, and pharmacists of oncology departments in the West Bank who have direct contact with adult cancer patients, meaning they are actively involved in the prescribing, dispensing, administering, or monitoring of adult cancer patients.
- Exclusion criteria: None

3.4.3 Data Collection Instrument

A structured self-administered questionnaire was used; this tool is reasonable in cross-sectional studies that aim to measure a certain phenomenon, which in our case, is the KAP level at a single time point. The questionnaire was developed by modifying tools from other similar studies as illustrated in table 3.2, and in a way that fits oncology departments and Palestine.

The questionnaire was divided into three sections that cover the participant demographics, the KAP level toward ADR reporting, and the barriers that hinder HCPs from reporting as follows:

1. Section one, Demographic Data contains 10 questions asking about the HCP's gender, age in years, academic qualification and specialty, type of contract (full-

time or part-time), number of work hours per week, number of cancer patients seen daily, current hospital, and finally, the HCP's experience, showing total experience and oncology experience**.**

2. Section two, KAP questionnaire:

2.1. Knowledge questions: ten close-ended questions, with answers ranging from Yes, No, and I don't know, were used to measure each participant's knowledge level regarding PV and ADR definitions, the timing for ADR reporting, the procedure of ADR reporting, and whether there is an ADR reporting centre in Palestine.

2.2. Attitude questions which were ten close-ended questions following five-point Likert scale where the participant is to choose among Strongly Agree, Agree, Neutral, Disagree, Strongly Disagree to measure the level of the HCPs attitude and beliefs toward ADR reporting regarding its importance, what should be reported, incorporation of PV in education curriculum, assessment of their institution reporting system and form, their redenies to report, if reporting should be mandatory and the need for patient counselling regarding ADRs.

2.3. Ten practice questions, mixed close-ended and open-ended with short answers, were asked to explore the participants' practices related to ADR reporting, including the frequency of encountering ADRs, documentation practices and procedures, and expectations.

3. Section three, Barriers to ADR reporting and Suggestions for improvement.
   This section had two questions; the first one was a multiple-choice question where the participants could choose all the factors that hinder their reporting and the second question was an open-ended question where the participants could provide suggestions for improving ADR reporting.

The questionnaire was mainly taken from the questionnaire used in a similar study titled "Assessing KAP of health-care providers toward PV and ADR reporting at a comprehensive cancer centre in Jordan", the validated questionnaire was sent by the researcher Abeer Ahmad Al Rabayah as a consent to be utilized and modified. (Rabayah et al., 2019) Then the tool was modified using other studies' instruments. (Bakhsh et al., 2016; Gidey et al., 2020; Rehan et al., 2012)(Bakhsh et al., 2016; Gidey et al., 2020; Rehan et al., 2012) Further modifications were made through the validation process. Table 3.2 illustrates the questionnaire used and the source for each question. The full questionnaire is available as appendix A.

Table 3.2: The Sources of the Questionnaire's Items

#	Item	Source
	Knowledge	
1)	Pharmacovigilance covers both adverse drug reactions and other drug related problems such as medication errors	(Rabayah et al., 2019)
2)	Adverse drug reaction (ADR) definition a) ADR is any noxious or undesired effect of drug occurring at normal dose, during normal use b) ADR is adverse health outcomes associated with inappropriate drug use c) ADR is harm resulting from the use of substandard/counterfeit drugs d) ADR is harm caused by drug overdose e) All can define ADR.	(Gidey et al., 2020)
3)	The difference between ADR and adverse events is clear to me	(Rabayah et al., 2019)
4)	Healthcare provider should report ADR within maximum one working day	New/ added by researcher based on feedback during validation
5)	Once I report an ADR, I forward it to the pharmacy department	(Rabayah et al., 2019)
6)	I know how to fill the institution ADR reporting form	(Rabayah et al., 2019)
7)	I know how to assess the severity of reported ADRs	(Rabayah et al., 2019)
8)	ADR documentation using the institution system is well understood	(Rabayah et al., 2019)
9)	All serious ADRs are known before a drug is marketed	(Gidey et al., 2020)
10)	Is there any center/ADR reporting system in Palestine?	(Gidey et al., 2020)
	Attitude	
1)	I believe ADR Reporting is necessary for improving clinical practice	(Rabayah et al., 2019)
2)	An ADR database can serve as a trigger for research projects	(Rabayah et al., 2019)
3)	I believe only serious ADRs that results in life-threatening conditions should be reported	(Rabayah et al., 2019)

4)	Pharmacovigilance should be taught in detail to all health care providers	(Rabayah et al., 2019)
5)	Reporting of ADRs is necessary for well recognized adverse drug reactions	(Rabayah et al., 2019)
6)	I believe in ADR documentation using institution system	(Rabayah et al., 2019)
7)	The institution ADR reporting form is comprehensive and captures required information for further assessment	(Rabayah et al., 2019)
8)	I am adequately prepared to report ADRs	(Rabayah et al., 2019)
9)	I believe ADR reporting should be mandatory for all Healthcare Providers (HCPs)	(Gidey et al., 2020)
10)	I believe patient should be counselled about adverse drug reactions before dispensing or administering the medications	New/ added by researcher based on feedback during validation
	Practice	
1)	How many ADR cases do you encounter in your practice per week?	(Rabayah et al., 2019)
2)	How many ADR cases have you actually reported in the last year?	(Rabayah et al., 2019)
3)	I document reported ADRs in patients' medical file	(Rabayah et al., 2019)
4)	I do document only severe adverse reactions	(Rehan et al., 2012)
5)	Have you ever been trained on pharmacovigilance and ADR reporting? If yes, can you please specify the type of attended training and year?	(Rabayah et al., 2019)
6)	Is there any routine discussion on ADRs in your hospital? Explain.	(Rehan et al., 2012)
7)	How often do you give advice to your patients on possible ADRs you prescribed, dispensed or administered	(Gidey et al., 2020)
8)	Where did you send the last reported ADRs?	(Rabayah et al., 2019)
9)	How do you report? (Reporting mode)	(Bakhsh et al., 2016)
10)	What do you expect from the submitted ADRs? Feedback, publication, nothing? Explain.	(Rehan et al., 2012)
	Barriers to ADR reporting and Suggestions for improvement	
1)	Which among the following factors discourage you from reporting Adverse Drug Reactions:	(Rabayah et al., 2019)

	a) Do not know reporting rules	(Rabayah et al., 2019)
	b) Lack of time to report Adverse Drug Reactions	(Rabayah et al., 2019)
	c) Fear from legal responsibility	New/ added by researcher based on feedback during validation
	d) A single unreported case may not affect clinical practice	(Rabayah et al., 2019)
	e) Difficult to decide whether Adverse Reaction has occurred or not	(Rabayah et al., 2019)
	f) Lack of feedback about previously reported Adverse Drug Reactions	(Rabayah et al., 2019)
	g) ADR reporting form is not easily accessible	(Rabayah et al., 2019)
	h) It is not my responsibility to report	(Rabayah et al., 2019)
	i) I haven't been trained to report ADRs	(Rabayah et al., 2019)
	j) ADR reporting negatively affect professional image	(Rehan et al., 2012)
	k) My institution does not have a reporting system	New/ added by researcher based on feedback during validation
2)	What are your suggestions to improve ADRs reporting at your hospital?	(Rabayah et al., 2019)

3.5 Questionnaire Content Validity and Reliability

The questionnaire was mainly derived from validated questionnaires. (Bakhsh et al., 2016; Gidey et al., 2020; Rabayah et al., 2019; Rehan et al., 2012) Then seven academic experts from different Palestinian universities validated the final developed version. The panel of validation experts is emphasised in Table 3.3. Subsequently, the questionnaire was translated into Arabic to enhance comprehension, and a back-translation was conducted to ensure accurate translation. The Arabic questionnaire that was distributed can be found in Appendix 2. The questionnaire was also pilot-tested before being used on seven participants who fulfilled the criteria of the target population. They were asked about the clarity of the questions and the time needed to fill out the

questionnaire. Revisions were made where needed based on their feedback. The internal consistency reliability of the questionnaire was assessed using Cronbach's alpha coefficient.

Table 3.3 Questionnaire Validation Experts Panel

Name	Position
Dr. Shahenaz Najjar	Faculty of graduate's studies, Arab American University, Palestine
Dr. Yousef Mimi	Faculty of Graduate Studies, Health sciences department, Arab American University, Palestine
Dr. Lina Adwan	Dean of Pharmacy and Health sciences, Birzeit University, Palestine
Dr. Abdallah Abu Khalil	Faculty member, Pharmacy department, Birzeit University, Palestine
Dr. Maher Khdour	Faculty member, Pharmacy department, Al-Quds University, Palestine
Dr. Hussain Hallaq	Faculty member, Pharmacy department, Al-Quds University, Palestine
Dr. Rawa'a Ramahi	Faculty member, Pharmacy department, Al-Najah University, Palestine

3.6 Data Collection

Data collection was finished on April 1st to May 1st, 2025. The study required each participant to fill out the questionnaire once within 10-15 minutes. The principal investigator, Rahaf Rimawi, carried out the data collection process, which involved distributing the questionnaire to HCPs at the selected hospitals. The distribution was conducted through two modes: printed copies delivered in person and an online version shared via a Google Form. This dual approach was employed to maximize participation and accommodate the preferences and availability of the target population. (Baruch & Holtom, 2008)

3.7 Data Processing

3.7.1 Survey Data Import and Initial Recoding

The dataset was imported into R (version 4.4.3) using the readxl package. Initial data standardization involved systematically converting all categorical variables from their original Arabic labels into standardized English-labeled factors, preserving the original response categories precisely. Recoding was conducted using clearly defined mapping via functions such as dplyr: recode () and conditional recoding using case_when () for clarity, consistency, and transparency.

3.7.2 Demographic and Professional Variables

Three demographic items initially recorded as free-text required structured and rigorous processing prior to analysis:

- Hospital name: Participants specified their institution by name. Responses were carefully matched against a predefined list of eight known West Bank oncology centers. Each exact match was recoded explicitly to a corresponding English-labeled factor. Following initial recoding, the hospital variable was further condensed into four analytically meaningful groups: three hospitals with sufficient response frequency were retained individually, while all other hospitals (initially individually recoded) were collectively merged into a single "Other" category. This approach ensured sufficient subgroup sizes for robust statistical analysis, specifically to facilitate stable logistic regression modeling.
- Weekly work hours: Responses displayed substantial heterogeneity, including numerals written in Arabic (e.g., "٤٠"), numerals written in English, numeric ranges (e.g., "40–45"), and textual descriptions (e.g., "forty"). To achieve uniform numeric interpretation, we employed a structured parsing pipeline:
    - ✓ Unified Arabic-to-Latin digit conversion (using the *stringi* package).
    - ✓ Extraction of the numeric component via the *readr* package's parsing functionality (*parse_number()*).
    - ✓ Validation checks for logical plausibility (0–100 hours per week). Subsequently, the numeric responses were categorized into three practically relevant intervals: standard (≤40 hrs), extended (41–59 hrs), and excessive work schedules (≥60 hrs), thus ensuring sufficient group sizes for analytical clarity and interpretability.

- Patients seen per day: Similar complexity characterized responses about daily patient volume, ranging from numeric ranges and approximate descriptions to direct numeric entries. These were systematically processed by:
    - ✓ Standardizing numeric formats from Arabic to Latin numerals.
    - ✓ Extracting numeric values, using midpoints for ranges.
    - ✓ Flagging and reviewing outliers (above plausible daily patient volumes, e.g., >100).
    - ✓ The final numeric data were categorized into three workload categories: light (≤10 patients/day), moderate (11–19), and heavy (≥20), ensuring robust analytical cells.

3.7.3 Final Variable Recoding and Transformation

Seven key categorical demographic and professional variables were systematically recoded into English-labeled factors. Each variable was accompanied by a numeric code assigned for computational convenience during statistical modeling. The final recoding scheme for these variables is presented in Table 3.4.

Table 3.4: Demographic and Professional Variables after Recoding

Variable	Type	Category Label	Category Value
Gender	Factor (nominal)	Female	0
		Male	1
Age Category	Ordered Factor (ordinal)	20–29	1
		30–39	2
		40–49	3
		50+	4
Contract Type	Factor (nominal)	Full time	1
		Part time	0
Hospital	Factor (nominal)	Al-Watani Governmental Hospital (Nablus)	1
		An-Najah National University Hospital (Nablus)	2
		Istishari Arab Hospital (Ramallah)	3
		Other	4
Oncology Experience		<1 year	1
		1–3 years	2

	Ordered Factor (ordinal)	3–5 years	3
		5–10 years	4
		>10 years	5
Patients Seen Daily category	Ordered Factor (ordinal)	≤10	1
		11–19	2
		≥20	3
Qualification	Ordered Factor (ordinal)	Diploma/Bachelor	1
		Master	2
		Residency/Specialist	3
Specialty	Factor (nominal)	Physician	1
		Pharmacist	2
		Nurse	3
Total Experience	Ordered Factor (ordinal)	<1 year	1
		1–3 years	2
		3–5 years	3
		5–10 years	4
		>10 years	5
Working Hours Category	Ordered Factor (ordinal)	≤40	1
		41–59	2
		≥60	3

3.7.4 Continuous-to-Categorical Banding

Continuous demographic measures were grouped into analytically relevant categories using left-closed, right-open intervals. This procedure optimized interpretability and ensured sufficient cell counts for stable statistical tests (χ^2 and logistic regression). Table 3.5 summarizes these final categorical breakdowns.

Table 3.5: Continuous-to-Categorical Conversion Summary

Variable	Original Scale	Final Scale	Category Label	Code	n (%)
Age	Years (numeric)	Factor	20–29	1	67 (37.2%)
			30–39	2	66 (36.7%)
			40–49	3	23 (12.8%)
			≥ 50	4	12 (6.7%)
Work Hours/week	Hours (numeric)	Factor	≤ 40 hrs	1	55 (30.6%)

			41–59 hrs	2	112 (62.2%)
			≥ 60 hrs	3	13 (7.2%)
Patients/day	Count (numeric)	Factor	≤ 10	1	45 (25%)
			11–19	2	62 (34.4%)
			≥ 20	3	73 (40.6%)

3.7.5 Rationale for Breakpoints

- Age intervals reflect clinically and professionally meaningful early-career, mid-career, and late-career stages.
- Weekly work hours reflect practical distinctions between standard, extended, and excessive workloads.
- Daily patient volume differentiates manageable (≤10), moderate (11–19), and high patient-load (≥20) scenarios, directly relevant to professional practice and quality of care.

These categorizations ensure a minimum sample size per cell (>10–15 cases), promoting robust statistical modeling and clear interpretability.

3.7.6 Category Merging and Rationale

Prior to analysis, several categorical variables with sparse cells or closely related levels were collapsed to ensure stable estimation and meaningful interpretation. Specifically, age bands of 50–59 and ≥ 60 years were combined into a single "50+" category (only 1 participant ≥ 60), and the four smallest-sample hospitals (< 9 % each) were aggregated as "Other" beside the three largest sites. Diploma and Bachelor's degree holders were merged into a "Diploma/Bachelor" group, and Residency-program participants and Specialists into "Residency/Specialist," to avoid tiny cells (< 5 cases) and reflect shared professional training levels. Finally, the eight specialty labels were distilled into three core roles; "Physician" (all medical doctors), "Nurse" (daycare and internal-department nurses), and "Pharmacist", capturing distinct scopes of practice

while eliminating sub-role sparsity. Category merging and the rationale for categorization is summarized in table 3.6.

Table 3.6: Category Merging and Rationale

Variable	Original Categories	Final Categories	Rationale
Hospital	Al-Hussein; Al-Watani; An-Najah; Dura; Istishari; Khalil Suleiman; Palestine Medical; Thabet Thabet	Al-Watani; An-Najah; Istishari; Other	The four largest sites each had ≥ 10 % of sample; the remaining four (each < 9 %) were combined into "Other" for stability.
Qualification	Diploma degree; Bachelor's degree; Master's degree; Residency program; Specialist	Diploma/Bachelor; Master; Residency/Specialist	Diploma and Bachelor had similar KAP profiles and small counts when separate; likewise, Residency and Specialist were combined to ensure adequate group sizes.
Specialty	Pharmacist; Doctor of Pharmacy; Physician (Consultant); Physician (Fellow); Physician (Resident); Physician (Service physician); Daycare Nurse; Medical Nurse	Pharmacist; Physician; Nurse	All physician roles collapsed into "Physician," nursing roles into "Nurse," and pharmacy roles into "Pharmacist" to reflect three distinct professional functions.

3.7.7 Multi-Response Variables & Dummy Coding

Two items allowed multiple selections: the 12-barrier checklist and the reporting mode (P9). Table 3.7 below emphasized how each barrier was expanded into a binary dummy variable and reporting mode responses were recoded into six ordered levels reflecting increasing channel complexity (0 = never, 1 = verbal, …, 5 = verbal + paper + electronic).

Table 3.7: Multi-Response Variables & Dummy Coding

Variable	Original Options	Final Levels & Codes
Barriers	12 fixed choices (e.g., "Don't know rules"; "Lack time"; … "No system")	12 binaries (1 = endorsed; 0 = not)

Reporting Modes (P9)	Verbal; Paper form; Electronic form; any combination; Never	0 = Never; 1 = Verbal; 2 = Single form; 3 = Verbal+form; 4 = Paper+Electronic; 5 = All three

3.7.8 KAP Domains and Binary Adequacy Thresholds

To enable meaningful interpretation and robust statistical analyses, we dichotomized the KAP domains into binary indicators ("adequate" vs. "not adequate"). This decision was informed by careful consideration of the empirical distributions observed in our data, theoretical insights from established PV literature, and the statistical necessity of ensuring sufficient case counts to produce stable logistic regression models. The justifications and thresholds for each domain are presented below:

Knowledge Domain

Participants' knowledge was measured using 14 dichotomous (correct/incorrect) items, generating composite scores ranging from 0 to 14. To classify respondents as possessing "adequate knowledge," we selected a threshold of at least 11 correct answers (≈79%). This cut-off is consistent with the commonly cited WHO standard (~80%) indicative of "satisfactory knowledge". (World Health Organization, 2015) Empirically, it produced a balanced distribution of "adequate" cases (n = 64, 35.6%), ensuring an adequate number of events per variable (EPV) for stable logistic modeling (Peduzzi et al., 1996).

Attitude Domain

Attitude was measured using 10 Likert-scale items (range: 1–5), yielding continuous composite scores from 10 to 50 (mean scores from 1.00 to 5.00). Given the substantial clustering of responses at the positive end (91.7% "positive," 8.3% "moderate," and 0% "negative"), we defined "adequate attitude" as having a mean score of at least 3.67 out of 5 (≈73%), corresponding closely to the WHO's recommended benchmark (≥75%) indicative of a strong positive PV culture. (World Health Organization, 2015) This threshold ensured sufficient cases (n = 165 positive, 91.7%) while maintaining statistical validity and clear interpretability.

Practice Domain

The Practice domain, as illustrated in table 3.8, was operationalized through seven behavior-oriented items (P3–P9) chosen explicitly due to their direct relevance to

observable PV practices and ADR reporting behaviors. The selection of these specific items was guided by their ability to clearly and comprehensively represent the multifaceted nature of PV practices, avoiding reliance on estimations or retrospective self-assessments (e.g., weekly encounters or annual reporting frequency in items P1 and P2). Consequently, items P1 and P2, while valuable descriptively, were excluded from the composite score to enhance clarity, interpretability, and statistical stability.

Responses to the selected seven items ranged from structured Likert-type scales to qualitative open-ended responses, necessitating thematic content analysis. Items were carefully scored as outlined below, yielding a composite Practice score with a maximum achievable total of 23 points.

Table 3.8: Detailed Scoring Procedure for Practice Items (P3–P9)

Item	Description	Original Format	Scoring Methodology	Final Scale
P3	Documentation frequency of reported ADRs in medical records	Structured Likert-type scale	Direct recoding (Always = 4, Mostly = 3, Sometimes = 2, Rarely = 1, Never = 0).	Ordinal (0–4)
P4	Documentation limited to severe ADR cases only	Structured Yes/No binary response	Reverse-coded to reflect positive practice (Yes = 0 negative practice, No = 1 positive practice).	Binary (0–1)
P5	Receipt of formal PV training	Structured Yes/No binary response	Direct binary coding (Yes = 1, No = 0).	Binary (0–1)
P6	Presence and regularity of hospital-based ADR discussions	Qualitative open-ended text	Inductive thematic content analysis (0 = None; 1 = Rarely; 2 = Departmental discussions only; 3 = Regular meetings; 4 = Formal lectures/workshops).	Ordinal (0–4)

P7	Frequency of advising patients about potential ADRs	Structured Likert-type scale	Direct recoding (Always = 3, Usually = 2, Sometimes = 1, Never = 0).	Ordinal (0–3)
P8	Destination(s) for sending ADR reports	Qualitative open-ended text	Hierarchical thematic analysis (0 = Never sent; 1 = Verbally; 2 = Pharmacy department; 3 = Quality department; 4 = Both Pharmacy and Quality; 5 = Electronic form submission).	Ordinal (0–5)
P9	Mode of ADR reporting used	Qualitative open-ended text	Hierarchical thematic coding based on reporting complexity (0 = Never reported; 1 = Verbal only; 2 = Single form, paper or electronic; 3 = Verbal plus one form; 4 = Paper plus electronic forms; 5 = Verbal and both forms).	Ordinal (0–5)

The final Practice domain score, calculated as the sum of these seven items (P3–P9), ranged from 0 (minimal practice) to 23 (optimal practice). Respondents were originally categorized as "Poor" (0–11 points), "Moderate" (12–16 points), or "Good" (≥17 points). However, data revealed a highly skewed distribution, with only one respondent (0.6%) achieving the original "Good" threshold (≥17 points). To address this sparsity, the "Moderate" and "Good" categories were pragmatically merged into a single "Adequate Practice" category, using ≥12 points (~52%) as the cut-off criterion. This approach generated sufficient statistical power (33 respondents; 18.3%) to enable stable and interpretable analytical results. The chosen threshold also represented a pragmatically meaningful criterion, reflecting routine implementation of at least half of the essential PV practices.

Overall KAP Score

An overall KAP score was computed by summing knowledge (0–14), attitude (mean × 10; range 10–50), and practice scores (0–23), resulting in a possible total of 87 points. Based on our empirical distribution—no participants were classified as "high," with most clustered in the lower two categories—we defined "adequate overall KAP" as obtaining at least 60% of the maximum possible score (≥52.2 out of 87 points). This threshold provided a statistically adequate number of positive cases (n = 148, 82.2%) to facilitate robust analyses while reflecting a conceptually meaningful level of integrated competence across all three domains.

By applying these carefully derived pragmatic thresholds, our approach effectively balanced theoretical grounding from PV literature, statistical feasibility (sufficient event counts and avoidance of sparse cells), and practical interpretability for informing actionable healthcare recommendations. Table 3.9 summarizes the KAP Domains and Binary Adequacy Thresholds.

Table 3.9: KAP Domain Composite Scores and Binary Adequacy Thresholds

Domain	Composite Range	Adequacy Threshold	Adequate Cases n (%)
Knowledge	0–14	≥ 11 (≈79%)	64 (35.6%)
Attitude	1–5 (mean by ×10)	≥ 3.67 (≈73%)	165 (91.7%)
Practice	0–23	≥ 12 (≈52%)	33 (18.3%)
Overall KAP	0–87	≥ 52.2 (≈60%)	148 (82.2%)

3.8 Statistical Analysis

Statistical analyses were conducted using R (version 4.4.3), leveraging packages including *tidyverse*, *broom*, *logistf*, and *lmtest*.

3.8.1 One-Sample Proportion Tests (Hypotheses H1, H4, H6)

One-sample proportion tests were employed to assess whether the observed proportions meeting predefined adequacy thresholds significantly fell below established

benchmarks: knowledge adequacy (≥ 80%), positive attitude (≥ 75%), and adequate practice (≥ 50%). Given the directional hypotheses anticipating insufficient performance, one-sided proportion tests (alternative = "less") were utilized to maximize statistical power to detect deficits (Newcombe, 2012). The proportion tests were implemented in R as follows:

```
prop.test(x = n_adequate, n = N, p = benchmark, alternative = "less")
```

Where:

- *x* — number of respondents with adequate knowledge
- *n* — total number of respondents (sample size)
- *p* — benchmark proportion used for comparison
- *alternative = "less"* — indicates a one-tailed test to assess whether the observed proportion is significantly lower than the benchmark value

3.8.2 Logistic Regression Analyses (Hypotheses H2–H3, H5–H7, H–H14)

Logistic regression was employed to test associations among knowledge, attitudes, practice, barriers, and demographic variables. Effect sizes were reported as odds ratios (OR) accompanied by 95% confidence intervals (CI), providing clinically meaningful interpretations.

Standard Logistic Regression

For hypotheses examining direct relationships between KAP domains (e.g., adequate knowledge predicting positive attitude), training, and specific barriers (H2–H3, H5–H7, H8–H12, H14), standard logistic regression models (*glm*) were used:

```
glm(outcome ~ predictor(s), data = df1, family = binomial)
```

Univariate Analysis

Each KAP predictor on its specified binary outcome to quantify effect sizes, and each barrier dummy separately to assess its impact on practice adequacy.

Multivariate Analysis

Applied for hypothesis H14 to assess the simultaneous independent effects of institutional factors (routine discussions, fear of legal repercussions, and concern about professional image) on adequate practice, as well as, for hypothesis H13, to examine the

joint effect of daily patient load and weekly work hours after standardizing them (z-scores) using *scale()* which allows the ORs to be interpreted as the change in odds of adequate reporting per one standard deviation increase in each workload measure.

Likelihood ratio tests (*lmtest::lrtest*) and information criteria (*AIC* and *BIC*) were utilized for model comparisons and selection.

3.8.3 Firth's Penalized Logistic Regression

Due to the presence of small sample sizes and sparsity in some demographic categories, Firth's penalized logistic regression (*logistf*) was implemented to provide unbiased estimates and stable confidence intervals (Heinze & Schemper, 2002). Two analytical strategies were conducted:

Univariate Analysis

Each demographic predictor was analyzed separately to identify significant associations with KAP outcomes.

Multivariate Analysis

All demographic variables were simultaneously entered into the model to obtain adjusted odds ratios, accounting for inter-variable relationships and confounding effects.

Penalized-model coefficients, Wald-type p-values, and profile-likelihood confidence intervals were obtained via a custom *broom* method.

3.8.4 Predictor Specification and Factor Handling

- Continuous and ordinal predictors (e.g., working hours per week, patients seen daily, routine discussion) were entered on their original scales.
- Categorical predictors were converted to factors with meaningful reference levels. Rare factor levels were collapsed using *forcats::fct_collapse()* to ensure at least 10–15 observations per category, preserving model stability.

3.8.5 Methodological Limitations

Binarization inherently loses granularity. Sensitivity analyses using the original 3-level variables were conducted to verify robustness (not reported here). Barrier analyses (H8–H12) could not adjust for confounders due to sample size constraints. The H14 test used discussion frequency as a proxy for institutional policies, reflecting data availability limitations.

The analytic strategy prioritized hypothesis-aligned operationalization of outcomes, evidence-based thresholds, and clinically interpretable effect sizes. This approach balances methodological rigour with translational relevance for PV improvement initiatives.

3.9 Ethical Consideration

Before conducting the study, IRB approval from the ethical review committee at Arab American University was secured with the code number "R-2024/A/154/N". Then, the ethics committee at the Ministry of Health approved conducting the study at governmental hospitals. IRB committees' approval at Istishari Arab Hospital and An-Najah National University Hospital were obtained to perform the study in these hospitals, too. The approvals are found in Appendix 3, 4, 5, and 6.

Informed consent was obtained from all the participants in the study. The consent form provided detailed information about the significance of the study, objectives, methods, and procedures, as well as the investigator's contact information. Participation in this study is voluntary, and participants are allowed to withdraw at any time. There was no personal information taken from the participants to protect confidentiality. Information collected in this study is to be used for the purpose of scientific research only, to be kept confidential, and its access permitted only to the research team responsible for the study.

3.10 Summary

This research employed a descriptive, cross-sectional design aimed at assessing the KAP related to PV and ADR reporting among HCPs in oncology departments across hospitals in the West Bank, Palestine. The study population included HCPs—physicians, nurses, and pharmacists—actively involved in patient care within oncology settings. Data were collected using a structured, self-administered questionnaire encompassing demographic characteristics, knowledge (14 items), attitude (10 Likert-scale items), practice indicators (7 items), and perceived barriers (12 items).

A total population sampling technique was employed in this study. This method guarantees thorough data collection and improves the applicability of the results within this particular healthcare setting. Ethical approval was secured before data collection commenced, and confidentiality and anonymity were strictly upheld throughout the process.

Chapter Four: Results

4.1 Introduction

This chapter presents the study's results, beginning with the construct reliability of the instrument employed, followed by a description of the sample characteristics, descriptive analysis of the KAP level and barriers of ADR reporting among HCPs and their suggestions to improve reporting. Lastly, the results of the hypothesis testing are revealed.

4.2 Internal Consistency of KAP Measures

To gauge the reliability of our KAP, and overall KAP scales, we computed Cronbach's α for each subscale and the complete 31-item instrument. Cronbach's α is a measure of internal consistency—how closely related a set of items is as a group—and values above 0.70 are generally considered acceptable for research purposes (Nunnally & Bernstein, 1994). However, values above 0.60 may be deemed adequate in exploratory studies (Streiner, 2003).

4.2.1 Knowledge Subscale (α = 0.78, 14 items)

The 14 dichotomous items assessing PV and ADR-related knowledge yielded a Cronbach's α 0.777. This indicates good internal consistency: respondents who answered one knowledge item correctly were relatively likely to answer other items correctly. An α in the high 0.70s suggests that, as a group, these 14 questions form a coherent scale without excessive redundancy (Streiner, 2003). In practical terms, the knowledge subscale reliably distinguishes between participants with higher vs. lower PV understanding.

4.2.2 Attitude Subscale (α = 0.650, 10 items)

The attitude scale, ten 5-point Likert items capturing beliefs about the importance of ADR reporting, returned an α of 0.65. Although this falls slightly below the

conventional 0.70 threshold, it remains within an acceptable range for exploratory survey research (Nunnally & Bernstein, 1994).

4.2.3 Practice Subscale (α = 0.66, 7 items)

The seven practice-related indicators (frequency of documentation, selective reporting of severe events, training, discussion, patient counselling, destination of reports, and reporting mode) coalesced into a subscale with α = 0.66. This moderate internal consistency is again acceptable in exploratory KAP studies (Streiner, 2003) and reflects the practice dimension's multi-faceted nature. Unlike knowledge items, which uniformly probe factual recall, "practice" items encompass distinct behaviors: whether one documents in the medical record; whether one limits reporting to severe ADRs; whether one participates in routine discussions; etc. The α value of 0.66 suggests that while these practices share an underlying PV theme, they do not function as a tightly unitary construct. In applied terms, the practice subscale is reliable enough to justify combining its items into a single total practice score, but the spread of behaviors indicates that specific practice components may benefit from independent examination in future work.

4.2.4 Overall KAP Scale (α = 0.79, 31 items)

When all 31 items - combining knowledge, attitude, and practice - are aggregated, Cronbach's α reaches 0.79. This high internal consistency confirms that the entire KAP questionnaire collectively forms a reliable composite measure of PV competence. A near-0.80 α suggests that despite heterogeneity across domains, the total KAP instrument satisfies accepted psychometric standards for multi-dimensional health-behaviour surveys (DeVellis, 2016). Thus, researchers and decision-makers can confidently interpret the overall KAP score as a robust indicator of an individual's readiness to engage in ADR reporting. Table 4.1 summarizes the Internal Consistency of KAP Measures found in the study questionnaire.

Table 4.1 Internal Consistency of KAP Measures (Cronbach's Alpha)

Construct	No. of Items	Cronbach's Alpha
Knowledge	14	0.78

Attitude	10	0.65
Practice	7	0.66
Overall KAP	31	0.79

4.3 Sample Profile

The study sample comprised 250 oncology HCPs, with a response rate of 72% (n=180), table 4.2 presents the final analytic respondents. Gender was nearly balanced (Male = 51.1%, Female = 48.9%). The majority fell into the 20–29 (37.2%) and 30–39 (36.7%) age brackets, with smaller proportions aged 40–49 (12.8%) and 50+ (6.7%). Almost all respondents worked full-time (98.3% vs. 1.7% part-time).

Among hospital sites, An-Najah National University Hospital (46.7%), Istishari Arab Hospital (13.9%), and Al-Watani Governmental Hospital (10.6%) were most represented; the remaining five hospital appeared under "Other" (28.9%). Oncology-specific experience spanned < 1 year (22.8%), 1–3 years (23.3%), 3–5 years (18.3%), 5–10 years (22.8%), and > 10 years (12.8%). Daily patient load was categorized as ≤ 10 (25.0%), 11–19 (34.4%), and ≥ 20 (40.6%) patients. Qualifications distributed across Diploma/Bachelor (67.8%), Master (18.3%), and Residency/Specialist (13.9%). Specialty roles were Nurse (62.8%), Physician (22.8%), and Pharmacist (14.4%). Overall professional tenure followed a five-level pattern from < 1 year (6.7%) to > 10 years (34.4%), and weekly work hours fell into ≤ 40 hours (30.6%), 41–59 hours (62.2%), and ≥ 60 hours (7.2%).

Table 4.2 Demographic and Professional Characteristics of the Sample (N = 180)

Variable	Category Label	n (%)
Gender	Female	88 (48.9%)
	Male	92 (51.1%)
Age Category	20–29	67 (37.2%)
	30–39	66 (36.7%)
	40–49	23 (12.8%)
	50+	12 (6.7%)
	Missing	12 (6.7%)
Contract Type	Full time	177 (98.3%)

	Part time	3 (1.7%)
Hospital	Al-Watani Governmental Hospital (Nablus)	19 (10.6%)
	An-Najah National University Hospital (Nablus)	84 (46.7%)
	Istishari Arab Hospital (Ramallah)	25 (13.9%)
	Other	52 (28.9%)
Oncology Experience	<1 year	41 (22.8%)
	1–3 years	42 (23.3%)
	3–5 years	33 (18.3%)
	5–10 years	41 (22.8%)
	>10 years	23 (12.8%)
Patients Seen Daily category	≤10	45 (25%)
	11–19	62 (34.4%)
	≥20	73 (40.6%)
Qualification	Diploma/Bachelor	122 (67.8%)
	Master	33 (18.3%)
	Residency/Specialist	25 (13.9%)
Specialty	Physician	41 (22.8%)
	Pharmacist	26 (14.4%)
	Nurse	113 (62.8%)
Total Experience	<1 year	12 (6.7%)
	1–3 years	34 (18.9%)
	3–5 years	26 (14.4%)
	5–10 years	46 (25.6%)
	>10 years	62 (34.4%)
Working Hours Category	≤40	55 (30.6%)
	41–59	112 (62.2%)
	≥60	13 (7.2%)

4.4 Descriptive Statistics and Adequacy Rates for KAP domains

As seen in table 4.3, knowledge scores (0–14) averaged 9.3 (SD = 3.2; range: 0.0–14.0). With our cut-off of ≥11 correct items, 35.6% of participants (n = 64) demonstrated

adequate knowledge. Attitude ratings (rescaled to 10–50) averaged 41.7 (SD = 3.6; range: 30.9–46.4); using a threshold of a mean score ≥3.67, 91.7% (n = 165) were classified as having a positive attitude. Practice scores (0–23) had a mean of 8.3 (SD = 3.5; range: 1.0–17.0); only 18.3% (n = 33) reached the "adequate practice" threshold of ≥12. Finally, the overall KAP index (0–87) averaged 59.4 (SD = 7.6; range: 35.5–73.4), with 82.2% (n = 148) meeting our combined adequacy criterion of ≥52.2.

Table 4.3: Descriptive Statistics and Adequacy Rates for KAP Domains

Domain	Mean (SD)	Maximum score	Range	Adequate n (%)
Knowledge	9.3 (3.2)	14	0.0–14.0	64 (35.6%)
Attitude	41.7 (3.6)	50	30.9–46.4	165 (91.7%)
Practice	8.3 (3.5)	23	1.0–17.0	33 (18.3%)
Overall KAP	59.4 (7.6)	87	35.5–73.4	148 (82.2%)

Appendix 7, Table A1 presents a detailed distribution of knowledge, attitude, practice, and overall KAP adequacy levels across demographic and professional variables.

Further description of actual ADR encounters and reporting behavior as reported by the participants by subgroups is shown in Appendix 8, table A2 which shows P1 and P2 descriptive analysis.

4.5 Descriptive Statistics for ADR Reporting Barriers

As shown in Table 4.4, the two most commonly endorsed barriers to ADR reporting were lack of familiarity with reporting procedures and uncertainty about whether an event truly constituted an ADR, each cited by 37.8% of respondents (n = 68). Insufficient training on how to report and lack of time were also frequently mentioned, by 35.0% (n = 63) and 28.9% (n = 52) of participants, respectively. Approximately one quarter of the sample (25.6%, n = 46) reported not receiving feedback on prior submissions, while one in five found the reporting form difficult to access (20.6%, n = 37). Fewer respondents indicated the absence of an institutional system (18.3%, n = 33) or fear of legal liability (15.6%, n = 28). Notably, 11.1% of participants (n = 20) perceived no barriers at all. The least frequently reported obstacles were concern for professional image (8.9%, n = 16), the sense that reporting did not fall under one's

responsibility (7.2%, n = 13), and the belief that omitting a single case would not affect practice (5.0%, n = 9).

Table 4.4: Descriptive Statistics for ADR Reporting Barriers

Barrier	n (%)
Unaware of ADR reporting procedures	68 (37.8%)
Difficulty determining occurrence of ADRs	68 (37.8%)
Insufficient training on ADR reporting	63 (35.0%)
Lack of time to report ADRs	52 (28.9%)
Lack of feedback on prior ADR reports	46 (25.6%)
Inaccessibility of the ADR reporting form	37 (20.6%)
Absence of an institutional reporting system	33 (18.3%)
Fear of legal repercussions	28 (15.6%)
No perceived barriers to reporting	20 (11.1%)
Concern about impact on professional image	16 (8.9%)
Perception that reporting is not my responsibility	13 (7.2%)
Single unreported case perceived as inconsequential	9 (5.0%)

4.6 Suggestions for Improving ADR Reporting

Overall, the most frequently proposed improvement (22.8%, n = 41) was to provide regular training and continuing-education sessions on ADR reporting, underscoring a perceived need for ongoing skill development. The second most common recommendation (17.2%, n = 31) was to establish or enhance a formal reporting system, whether electronic or paper-based, indicating that ease of access and system reliability are key concerns. Far fewer participants suggested timely feedback (2.2%, n = 4), standardized protocols (0.6%, n = 1), awareness campaigns (1.7%, n = 3), or legal protections and confidentiality assurances (1.1%, n = 2), suggesting these areas may warrant attention but are not yet widely perceived as priorities. Oncology HCPs suggestions for Improving ADR Reporting are listed in table 4.5.

Table 4.5: Frequency and Percentage of Suggestions for Improving ADR Reporting

Suggestion Type	n (%)
"Regular training workshops and continuing-education sessions on ADR reporting"	41 (22.8%)
"Implementation or enhancement of a formal ADR-reporting system (electronic or paper)"	31 (17.2%)
"Timely, structured feedback to reporters on their submitted ADRs"	4 (2.2%)
"Clear, standardized reporting protocols and step-by-step procedures"	1 (0.6%)
"Ongoing awareness campaigns (posters, reminders, educational materials)"	3 (1.7%)
"Legal protections and confidentiality assurances for ADR reporters"	2 (1.1%)

Note: Categories are not mutually exclusive; percentages reflect the proportion of respondents whose suggestions fell into each category.

4.7 Hypothesis Testing and Results

4.7.1 KAP Related Hypothesis

One-sample proportion tests were used to test the adequacy KAP levels among health care providers are emphasized in table 4.6, while Binary logistic regression as appears in table 4.7 was used to test the associations between KAP dimensions:

H_{01}: HCPs in oncology departments in the West Bank possess sufficient knowledge about ADR reporting.

We tested whether at least four-fifths of oncology professionals met the knowledge-mastery standard (≥ 11/14 correct). A one-sample proportion test showed that only 35.6% of respondents reached this cut-off, well below the 80% workforce benchmark, $\chi^2(1, N = 180) = 219.45$, $p < .001$. Accordingly, the null hypothesis of "sufficient knowledge" was rejected, demonstrating a substantial PV knowledge gap that warrants targeted training.

H_{02}: There is no significant association between HCPs'level of knowledge and their attitudes toward ADR reporting

A binary logistic regression model was employed to examine whether adequate knowledge of ADR reporting (≥11/14 correct) increases the odds of exhibiting a positive attitude (mean Likert score ≥3.67). Adequate attitude was coded as the outcome variable, with knowledge adequacy as the sole predictor (Hosmer, Lemeshow, & Sturdivant, 2013). The analysis yielded a non-significant effect: Wald $\chi^2(1) = 1.64$ (equivalently Wald $z = 1.28$), $p = .20$, odds ratio (OR) = 2.35, 95 % confidence interval [0.71, 10.59]. Although the point estimate of 2.35 suggests that providers with adequate knowledge were more than twice as likely to hold a positive attitude, the wide confidence interval crossing 1.0 and the non-significant *p*-value indicate that knowledge level alone did not reliably predict attitude. This lack of statistical significance is unsurprising given the very high baseline of positive attitudes (91.7 %)—a ceiling effect frequently observed when prior awareness campaigns have already elevated attitudes (Oshikoya & Senbanjo, 2008). Consequently, H2 is not supported: higher knowledge did not translate into a detectable increase in positive attitude toward ADR reporting.

H_{03}: There is no significant association between HCPs' knowledge of PV and their ADR reporting practices.

A binary logistic regression model was fitted to assess whether adequate knowledge of ADR reporting (≥11/14 correct) increases the likelihood of demonstrating adequate ADR-reporting practice (defined as a practice score >60% of the maximum). In this model, "adequate practice" served as the dependent variable (coded 1 = adequate; 0 = inadequate), and knowledge adequacy was the sole predictor. The analysis yielded a Wald *z* statistic of 1.70, corresponding to $p = .089$, with an odds ratio (OR) of 1.94 (95% CI [0.90, 4.19]). Thus, participants possessing adequate knowledge were approximately twice as likely to exhibit adequate reporting behaviors. However, this effect did not reach conventional levels of statistical significance ($\alpha = .05$), falling into the marginally significant range ($0.05 < p < 0.10$). The wide confidence interval and the relatively small proportion of "adequate" practitioners (18.3%) suggest that the study may be underpowered to detect a definitive effect. From a practical standpoint, these findings imply that while higher knowledge appears to trend toward better reporting practice, knowledge alone may not be sufficient to ensure consistent ADR reporting.

H_{04}: HCPs in oncology departments have favorable attitudes toward their role in ADR reporting.

HCPs in this study demonstrated overwhelmingly favorable attitudes toward ADR reporting; 91.7% scored in the "highly positive" range. The one-sample proportion test against the 75% benchmark was non-significant, $\chi^2(1, N = 180) = 25.79$, $p = 1.00$. Because the observed proportion comfortably exceeded the criterion, we failed to reject the null; the workforce already possesses the requisite positive mind-set. Therefore, poor reporting cannot be attributed to negative attitudes but rather to downstream barriers.

In practical terms, nearly nine out of ten oncology clinicians endorsed strong positive sentiments about their responsibility to identify and report ADRs.

H_{05}: There is no significant association between HCPs' attitudes toward ADR reporting and their reporting practices.

We tested whether a highly positive attitude toward ADR reporting predicts adequate reporting practice using binary logistic regression (Hosmer et al., 2013). In this model, "positive attitude" (mean ≥ 3.67) served as the predictor and "adequate practice" (> 52 % of the maximum practice score) was the binary outcome. The estimated odds ratio (OR) was 3.37 (95 % CI [0.64, 62.15]), indicating that providers with a highly positive attitude were, on average, 3.37 times as likely to report ADRs adequately compared to their less-positive counterparts. However, this effect did not reach statistical significance (Wald $z = 1.15$, $p = .249$). The wide confidence interval underscores substantial uncertainty in the point estimate—a direct consequence of the extremely low number of adequate-practice cases (only 33/180, or 18.3 %) among an overwhelmingly attitudinally positive sample (91.7 % of respondents). In essence, even though the OR suggests a potentially meaningful effect, the scarcity of adequate reporters within the high-attitude cohort inflated the standard error and rendered the test underpowered to detect significance (Peduzzi et al., 1996).

H_{06}: HCPs in oncology departments regularly report ADRs.

To determine whether a majority of oncology HCPs fail to report ADRs, we compared the observed proportion of "adequate practice" (i.e., completing ≥ 50 % of recommended reporting behaviors) against a neutral benchmark of 50 % using a one-sample proportion test. In our sample of 180 respondents, only 33 (18.3 %) achieved the

adequacy threshold, a figure starkly below the 50 % competence benchmark. The one-sample χ^2 test yielded $\chi^2(1, N = 180) = 70.94$, $p < .001$ (95 % CI [0.13, 0.25]). Consequently, the null hypothesis that at least half of providers demonstrate adequate ADR-reporting practice was emphatically rejected. These results confirm a pervasive under-reporting of ADRs among oncology practitioners

H_{07}: Training on PV and ADR reporting has no effect on ADR reporting frequency.

To evaluate whether formal PV training is associated with improved ADR-reporting behavior, we fitted a binary logistic regression model in which "adequate practice" (defined as completing at least 50 % of the recommended reporting tasks) served as the dependent variable and training receipt (yes/no) was the sole independent predictor. Of the 180 oncology HCPs surveyed, those who had received any structured ADR-reporting education—such as workshops, seminars, or on-the-job instruction—demonstrated markedly higher odds of meeting the minimal functional competence threshold. Specifically, trained individuals were nearly three times as likely to exhibit adequate practice compared to their untrained peers (OR = 2.89, 95 % CI [1.26, 6.50], Wald z = 2.56, p = .011). In concrete terms, this indicates that participation in at least one formal training session corresponds to a 189 % increase in the odds of performing the core ADR-reporting tasks. Finally, the statistically significant effect ($p < .05$) and reasonably narrow confidence interval reinforce a strong and likely causal relationship between training and practice.

Table 4.6: KAP adequacy level hypothesis testing

Hypothesis	Test	Null Hypothesis	χ^2(df = 1)	Adequate Estimate (n)	p-value
H1 (knowledge < 80 %)	1-sample proportion test (χ^2)	$\pi \geq 80$ % adequate knowledge	219.45	35.6 % (64)	<0.001
H4 (attitude < 75 %)	1-sample proportion test (χ^2)	$\pi \geq 75$ % favourable attitude	25.79	91.7 % (165)	1.000
H6 (practice < 50%)	1-sample proportion test (χ^2)	$\pi \geq 50$ % adequate practice	70.94	18.3% (33)	<0.001

Table 4.7: Associations Between KAP Dimensions:

Hypothesis	Test (Null Hypothesis)	Wald z	OR [95% CI]	p-value
H2 (knowledge → attitude)	Binary logistic regression (OR = 1)	1.28	2.35 [0.71–10.59]	0.200
H3 (knowledge → practice)	Binary logistic regression (OR = 1)	1.7	1.94 [0.9–4.19]	0.089
H5 (attitude → practice)	Binary logistic regression (OR = 1)	1.15	3.37 [0.64–62.15]	0.249
H7 (training → practice)	Binary logistic regression (OR = 1)	2.56	OR = 2.89 [1.26–6.5]	0.011

4.7.2 Barrier-Related Hypotheses (H_8–H_{12}): Impact on ADR-Reporting Practice

To investigate whether specific perceived obstacles diminish the likelihood of adequate ADR-reporting behaviour, we fitted five separate binary logistic regression models which are summarized in table 4.8. In each model, the dependent variable was practice adequacy (i.e., whether a provider met the ≥50 % practice threshold). The sole independent variable in each model was a dichotomous barrier indicator (yes = 1 if the respondent endorsed the barrier; no = 0 otherwise). Thus, each odds-ratio (OR) quantifies how the presence (versus absence) of that particular barrier affects the probability of reporting at least half of the recommended ADR-reporting tasks. We used a conventional two-sided alpha of .05, but we also comment on barriers whose p-values fell between .05 and .10 ("marginal").

H_{08}: Lack of knowledge about reporting rules does not affect ADR reporting practices.

Null Hypothesis: The odds of adequate HCP ADR-reporting practice are identical regardless of knowledge-rule awareness (OR = 1).

When respondents indicated that they did not know the formal rules for ADR reporting, their odds of performing adequately (i.e., completing at least half of the recommended ADR-reporting steps) were estimated to be 87 % lower than those who *did* know the rules (OR = 0.13, 95 % CI 0.03–0.37, $p < .001$) (Table 4.13). In other words, lack of familiarity with the reporting protocol emerged as a robust negative predictor: among providers without rule knowledge, only a small fraction (approximately one in ten) reported ADRs adequately, whereas rule-aware providers reported at far higher rates.

Because this effect was both highly significant and accompanied by a tight confidence interval, we have strong evidence that H_{08} is true; knowing the rules is a critical prerequisite for consistent ADR-reporting practice.

H_{09}: Time constraints are not associated with ADR reporting practice

Null Hypothesis: Reporting time constraints do not affect ADR-reporting practice (OR = 1).

Participants who endorsed "lack of time" as a barrier had roughly 62% lower odds of reporting adequately than those who did not cite time constraints (OR = 0.38). Although this effect did not quite reach conventional significance at $\alpha = .05$ ($p = .061$), it lies in the "marginally significant" zone (i.e., $.05 < p < .10$) (Table 4.13), suggesting a possible negative association that warrants attention. In practical terms, busy clinicians; especially oncologists and oncology nurses caring for high-acuity patients, may struggle to carve out time for paperwork. The marginal p-value may partially reflect limited statistical power (only 180 participants and only ~40% reporting time constraints), or it may indicate heterogeneous experiences; some providers who feel time pressured nonetheless manage to report, whereas others simply cannot prioritize it. Nevertheless, because the point estimate is substantial (OR = 0.38) and the upper bound of the CI (0.97) barely crosses 1, we interpret H_{09} as offering preliminary support: "lack of time" likely suppresses practice, but further research with a larger sample (or more precise time-cost quantification) would clarify the true magnitude of this effect.

H_{010}: Lack of feedback on ADR reports does not affect future reporting behaviour

Null Hypothesis: Receiving -or not receiving- feedback on past ADR reports has no bearing on current ADR-reporting practice (OR = 1).

Health care providers who cited "lack of feedback" as a barrier were estimated to be 60% more likely to practice adequate ADR reporting than those who did not - an effect in the opposite direction of our hypothesis - yet this association was not statistically significant ($p = .26$) (Table 4.13). In fact, the confidence interval spans 1.0 (0.69–3.57), indicating a high degree of uncertainty: some respondents lacking feedback may have intensified their reporting efforts (perhaps to seek feedback), whereas others cooled off. Overall, we conclude that H_{110} is not supported.

H_{011}: "Fear of legal consequences does not influence ADR reporting behaviour

Null Hypothesis: Fear of potential legal repercussions has no impact on ADR-reporting practice (OR = 1).

Counter to the hypothesis that "fear" would lower reporting, those who identified legal liability concerns as a barrier were actually over three times more likely to perform adequate ADR reporting (OR = 3.12). Because the association is statistically significant (p = .012) and the 95% CI (1.25–7.53) does not include 1, we reject H_{011} in its original form (Table 4.13).

H_{012}: Institutional ADR reporting systems do not influence reporting practice

Null Hypothesis: Having no clear in-hospital reporting framework does not affect ADR-reporting practice (OR = 1).

Participants who reported the absence of a designated ADR-reporting mechanism in their institution had significantly lower odds of adequate ADR reporting compared to those with such systems in place (OR = 0.24, 95% CI: 0.04–0.86, p = 0.06) (Table 4.13). Although this result was marginally non-significant at the conventional threshold (p < 0.05), the confidence interval narrowly excluded 1.0.

Among the five hypothesized barriers, "lack of knowledge of reporting rules" (H_8) was the strongest negative predictor of reporting behavior (OR = 0.13, p < .001). "Fear of legal responsibility" (H_{11}) was unexpectedly associated with increased reporting behavior (OR = 3.12, p = .012). The barriers "lack of time" (H_9) and "absence of an institutional system" (H_{12}) demonstrated marginal significance (p = 0.061 and p = 0.06, respectively), but both had substantial effect sizes (ORs < 0.40). Conversely, "lack of feedback on prior reports" (H_{10}) was not significantly associated with ADR reporting (p = 0.26).

Table 4.8: Barrier-Related Hypotheses (H_8–H_{12}) Testing and Results

Hypothesis	Test (Null Hypothesis)	Statistic (Wald z)	Estimate (OR) [95% CI]	p-value
H8 (no-rules → practice)	Binary logistic regression (OR = 1)	-3.3	0.13 [0.03–0.37]	<0.001
H9 (lack-time → practice)	Binary logistic regression (OR = 1)	-1.87	0.38 [0.12–0.97]	0.061

H10 (lack-feedback → practice)	Binary logistic regression (OR = 1)	1.13	1.6 [0.69–3.57]	0.260
H11 (fear-legal → practice)	Binary logistic regression (OR = 1)	2.5	3.12 [1.25–7.53]	0.012
H12 (no-system → practice)	Binary logistic regression (OR = 1)	-1.88	0.24 [0.04–0.86]	0.060

H_{013}: Workload is not associated with ADR reporting frequency

To assess whether heavier clinical workload reduces the likelihood of adequate ADR-reporting practice, we fitted a multivariate logistic regression with adequate practice (≥12/23 practice points) as the binary outcome and two predictors entered simultaneously as clarified in table 4.9:

- Standardized daily patient volume (z-score of number of cancer patients seen per day)
- Standardized weekly work hours (z-score of hours worked per week)

The null hypothesis for each predictor was OR = 1 (no effect of workload on reporting).

Neither standardized daily patient volume (OR = 0.82, 95 % CI [0.51–1.23], Wald z = –0.89, p = .371) nor standardized weekly work hours (OR = 1.24, 95 % CI [0.87–1.71], Wald z = 1.26, p = .206) was significantly associated with adequate practice, indicating that, when modeled together, variations in these workload measures did not predict whether clinicians completed at least half of the recommended PV tasks.

H13 is not supported in this sample. Future research might examine workload through richer metrics (e.g., patient acuity, administrative burden) or utilize longitudinal designs to better isolate the influence of workload on ADR-reporting behavior.

Table 4.9: Impact of Workload on ADR Reporting Practices

Hypothesis (Outcome = Practice)		Wald z	OR [95% CI]	P-value
H13	Patients seen daily	-0.89	0.82 [0.51–1.23]	0.371
	Working hours per week	1.26	1.24 [0.87–1.71]	0.206

Not: OR = odds ratio; CI = confidence interval. Each OR represents the change in odds of adequate ADR-reporting practice per 1 SD increase in the predictor.

H_{014}: Hospital policies and professional culture are not associated with ADR reporting.

To test whether an organizational safety-climate variable ("routine ADR discussion," P6) together with policy/culture factors influenced ADR-reporting behavior, we fitted a multivariate binary logistic regression with "adequate practice" (≥ 50% of practice items completed) as the outcome and three simultaneous predictors:

- Routine ADR discussions (P6): ordinal score (0 = none; 1 = rare/sometimes; 2 = informal team talk; 3 = recurring multidisciplinary meetings; 4 = formal lectures/workshops), the distribution of routine discussions percentages among HCPs appears in table 4.10.
- Fear of legal responsibility: dummy (0 = no; 1 = yes)
- ADR reporting harms professional image: dummy (0 = no; 1 = yes)

Table 4.10: Distribution of Routine Discussions (P6) (N = 180)

Routine Discussions Value	n	Percent
0: No discussion	127	70.6%
1: Rarely / sometimes	4	2.2%
2: Informal / tactical team talk	3	1.7%
3: Recurring multidisciplinary meetings	43	23.9%
4: Formal lectures / workshops	3	1.7%

It was revealed that each one-unit increase in routine ADR discussion frequency was associated with an 85% increase in the odds of adequate reporting (OR = 1.85, 95% CI [1.40, 2.48], $p < .001$). Additionally, clinicians reporting fear of legal responsibility exhibited a four-fold increase in odds (OR = 4.02, 95% CI [1.44, 11.30], $p < .001$), whereas concerns about harming one's professional image did not significantly predict practice (OR = 2.16, 95% CI [0.62, 7.05], $p = .210$).

Table 4.11 describes the likelihood-ratio comparison between an intercept-only model and the policy-culture model (routine discussions + fear of legal responsibility + professional-image concern) that adding the three predictors significantly improved

model fit, $\chi^2(3, N = 180) = 26.97$, $p < .001$. The model explained about 23 % of the variance in ADR-reporting practice (Nagelkerke $R^2 = .23$).

Table 4.11: Impact of Hospital Policies and Professional Culture on ADR Reporting Practices

Hypothesis (Outcome = Practice)		Test (Null Hypothesis)	Wald z	OR [95% CI]	P-value
H14	Routine discussions	Multivariate Logistic Regression (OR = 1 for each)	4.23	1.85 [1.40 – 2.48]	<0.001
	legal responsibility		2.68	4.02 [1.44 – 11.3]	<0.001
	negative professional image		1.25	2.16 [0.62 – 7.05]	0.210

4.8 Univariate Firth-Penalized Logistic Regression Predicting Adequate ADR-Knowledge

A series of univariate Firth-penalized logistic regressions assessed whether demographic and workload characteristics predicted adequate ADR-knowledge (Table 4.12). Three variables emerged as significant. First, occupational role showed a pronounced gradient: nurses were more than five times as likely as physicians to achieve the ≥ 80% knowledge cut-off, OR = 5.67, 95% CI [2.30, 16.56], $p < .001$. Second, holding a residency or specialist qualification was associated with markedly lower odds of adequate knowledge relative to diploma/bachelor holders, OR = 0.24, 95% CI [0.06, 0.70], $p = .018$. Third, Male clinicians were about 48 % less likely than their female counterparts to achieve the ≥ 80 % knowledge threshold, OR = 0.52, 95% CI [0.28, 0.96], $p = .039$.

All other demographic contrasts, including age, working hours, patient load, hospital, and length of professional or oncology experience—were non-significant (*ps* > .05). Notably, the near-significant trend for staff working 41–59 hours per week (OR = 1.89, $p = .071$)

Table 4.12: Predictors of Adequate ADR-Knowledge (≥ 80 % correct)

Predictor	Level (code)	OR [95%CI]	P-value
Sex (Female)	Male (1)	0.52 [0.28 - 0.96]	0.039*

Age band (20–29 y)	30–39 y (2)	0.70 [0.37 - 1.28]	0.258
	≥ 40 y† (3)	1.10 [0.63 - 1.91]	0.743
Weekly hours (≤ 40 hrs)	41–59 h (2)	1.89 [0.96 - 3.87]	0.071
	≥ 60 h (3)	0.57 [0.10 - 2.23]	0.456
Patients per day (≤ 10 petients)	11–19 (2)	1.48 [0.68 - 3.26]	0.327
	≥ 20 (3)	0.69 [0.31 - 1.52]	0.347
Qualification (Diploma/Bachelor)	Master (2)	1.01 [0.46 - 2.18]	0.977
	Residency/Specialist (3)	0.24 [0.06 - 0.70]	0.018*
Specialty (Physician)	Pharmacist (2)	2.55 [0.75 – 9.18]	0.530
	Nurse (3)	5.67 [2.30 - 16.56]	< .000*
Hospital (Al-Watani)	An-Najah (2)	1.98 [0.73 - 5.87]	0.192
	Istishari (3)	1.01 [0.29 - 3.60]	0.989
	Other (4)	0.45 [0.14 - 1.51]	0.185
Total experience (< 1 y)	1–3 y (2)	1.16 [0.29 - 5.42]	0.835
	3–5 y (3)	1.73 [0.43 - 8.25]	0.460
	5–10 y (4)	1.61 [0.44 - 7.16]	0.493
	> 10 y (5)	1.73 [0.49 - 7.47]	0.419
Oncology experience (< 1 y)	1–3 y (2)	1.20 [0.48 - 3.03]	0.695
	3–5 y (3)	0.92 [0.33 - 2.48]	0.862
	5–10 y (4)	2.05 [0.84 - 5.11]	0.118
	> 10 y (5)	1.84 [0.64 - 5.27]	0.254

Note: Each row represents a separate one-predictor Firth logistic model; odds ratios (ORs) > 1 indicate higher odds of meeting the ≥ 80 % knowledge threshold relative to the reference category. Boldface highlights statistically significant findings ($p < .05$). †The ≥ 40 y level combines the original 40–49 y and ≥ 50 y bands, as specified in the recoding step.

4.9 Univariate Firth-Penalized Logistic Regression Predicting a Highly Positive Attitude

Univariate Firth-penalized logistic regressions were estimated to explore whether demographic or workload characteristics predicted a highly positive attitude toward ADR reporting, operationalized as a mean attitude score of ≥ 3.67 on the five-point scale (Table 4.13). Across all twenty-seven contrasts tested, none achieved statistical significance at

the conventional α = .05. Some point estimates, however, reveal several patterns worth contextualizing.

In terms of workload indicators, respondents who saw 11–19 or ≥ 20 oncology patients per day were twice as likely as those seeing ≤ 10 patients to endorse a highly positive attitude (ORs = 2.14 and 2.05, respectively), but the confidence intervals were wide (0.61–8.18 and 0.61–7.12) and the p-values > .24. Likewise, staff working ≥ 60 h per week showed no reliable decrement in attitude (OR = 0.73, p = .750). For professional role and education: Neither specialty nor highest qualification distinguished providers' attitudinal stance. Compared with physicians, pharmacists showed similar odds (OR = 1.08), whereas nurses had lower odds (OR = 0.51); however, both estimates were nonsignificant. Holding a master's degree or a residency/specialist certificate granted no detectable advantage over a diploma/bachelor baseline. And total years in practice and oncology-specific tenure were unrelated to attitude adequacy. For instance, clinicians with > 10 years of oncology experience had odds comparable to the < 1-year group (OR = 0.65, p = .54).

The overall sample with 92% of respondents already met the "highly positive" threshold. When an outcome is common, logistic models have limited power to detect group differences, especially in strata with very small numbers of non-positive cases. Consequently, even moderately large odds-ratio estimates (e.g., 2.14 for moderate patient load) did not attain significance once penalization and exact likelihood were applied.

Table 4.13: Predictors of Highly Positive Attitude (mean ≥ 3.67)

Predictor	Level (code)	OR [95%CI]	P-value
Sex (Female)	Male (1)	0.69 [0.23 - 1.94]	0.490
Age band (20–29 y)	30–39 y (2)	0.87 [0.32 - 2.53]	0.778
	≥ 40 y (3)	0.93 [0.36 - 2.30]	0.882
Weekly hours (≤ 40 hrs)	41–59 h (2)	0.85 [0.24 - 2.57]	0.787
	≥ 60 h (3)	0.73 [0.12 - 7.73]	0.750
Patients per day (≤ 10 petients)	11–19 (2)	2.14 [0.61 - 8.18]	0.240
	≥ 20 (3)	2.05 [0.61 - 7.12]	0.242
Qualification (Diploma/Bachelor)	Master (2)	1.30 [0.36 - 6.95]	0.718
	Residency / Specialist (3)	0.97 [0.26 - 5.24]	0.966

Specialty (Physician)	Pharmacist (2)	1.08 [0.13 – 12.25]	0.945
	Nurse (3)	0.51 [0.10 - 1.82]	0.354
Hospital (Al-Watani)	An-Najah (2)	1.14 [0.20 - 4.49]	0.867
	Istishari (3)	7.29 [0.55 - 1029.22]	0.209
	Other (4)	1.54 [0.25 - 7.65]	0.606
Total experience (< 1 y)	1–3 y (2)	0.52 [0.00 - 7.00]	0.680
	3–5 y (3)	0.27 [0.00 - 3.11]	0.397
	5–10 y (4)	0.50 [0.00 - 5.65]	0.651
	> 10 y (5)	0.30 [0.00 - 2.72]	0.415
Oncology experience (< 1 y)	1–3 y (2)	2.44 [0.55 - 14.26]	0.262
	3–5 y (3)	1.90 [0.42 - 11.16]	0.423
	5–10 y (4)	2.38 [0.54 - 13.92]	0.276
	> 10 y (5)	0.65 [0.17 - 2.69]	0.540

Note: Each odds ratio (OR) derives from a separate one-predictor Firth logistic model; the reference category for every contrast is shown in parentheses. †The ≥ 40-year band combines the original 40–49 y and ≥ 50 y groups, as specified in the recoding step. No predictor reached statistical significance at the .05 level; therefore, no values are boldfaced.

4.10 Univariate Firth-Penalized Logistic Regression Predicting Adequate ADR-Reporting Practice

A series of one-predictor Firth-penalized logistic regressions examined whether demographics and workload predict adequate ADR-reporting practice (score ≥ 12/23). Results (Table 4.14) highlight four noteworthy associations.

- Workload intensity is the strongest driver: Providers working 41–59 hours per week were 7.2 times more likely than those working ≤ 40 hours to meet the practice threshold, OR = 7.22, 95% CI [2.25, 36.51], p = .004. A similar advantage was observed for ≥ 60-hour schedules (OR = 7.13, p = .028). Surprisingly, staff who worked longer hours reported ADRs more often.
- Early-mid-career clinicians lag behind: Participants aged 30–39 years had 68% lower odds of adequate reporting than the 20–29-year reference group (OR = 0.32, 95% CI [0.10 - 0.77], p = .023). No deficit emerged for the combined ≥ 40 years band.
- Nurses outperform physicians on practice: Relative to physicians, nurses were almost four times as likely to fulfil ≥ 50% of recommended behaviours (OR =

3.67, 95% CI [1.27, 14.22], p = .030). All other factors were not significant predictors (ps > .05).

Table 4.14: Predictors of Adequate Practice (score ≥ 12 / 23)

Predictor	Level (code)	OR [95%CI]	P-value
Sex (Female)	Male (1)	1.36 [0.65 - 2.93]	0.420
Age band (20–29 y)	30–39 y (2)	0.32 [0.10 - 0.77]	0.023
	≥ 40 y (3)	1.01 [0.43 - 2.24]	0.983
Weekly hours (≤ 40 hrs)	41–59 h (2)	7.22 [2.25 - 36.51]	0.004
	≥ 60 h (3)	7.13 [1.24 - 47.77]	0.028
Patients per day (≤ 10 patients)	11–19 (2)	1.15 [0.46 - 2.97]	0.769
	≥ 20 (3)	0.64 [0.24 - 1.70]	0.358
Qualification (Diploma/Bachelor)	Master (2)	1.03 [0.39 - 2.49]	0.949
	Residency/Specialist (3)	0.07 [0.00 - 0.54]	0.068
Specialty (Physician)	Pharmacist (2)	1.12 [0.17 - 6.21]	0.894
	Nurse (3)	3.67 [1.27 - 14.22]	0.030
Hospital (Al-Watani)	An-Najah (2)	14.04 [1.78 - 1813.37]	0.069
	Istishari (3)	15.81 [1.71 - 2106.29]	0.065
	Other (4)	3.62 [0.36 - 488.09]	0.396
Total experience (< 1 y)	1–3 y (2)	2.06 [0.48 - 12.01]	0.362
	3–5 y (3)	0.43 [0.06 - 3.12]	0.381
	5–10 y (4)	0.80 [0.18 - 4.76]	0.780
	> 10 y (5)	0.94 [0.23 - 5.36]	0.934
Oncology experience (< 1 y)	1–3 y (2)	2.14 [0.71 - 7.13]	0.188
	3–5 y (3)	0.53 [0.09 - 2.36]	0.423
	5–10 y (4)	1.94 [0.63 - 6.53]	0.259
	> 10 y (5)	3.02 [0.88 - 11.01]	0.082

Note: Odds ratios (ORs) > 1 indicate higher odds of achieving the ≥ 50 % practice threshold versus the reference category; ORs < 1 indicate lower odds. Bold type marks predictors significant at p < .05. †The ≥ 40-year band pools the original 40–49 y and ≥ 50 y groups (per recoding). Extremely large ORs with wide CIs for the two private hospitals reflect quasi-separation driven by very few "adequate-practice" cases.

4.11 Univariate Firth-Penalized Logistic Regression Predicting Adequate Overall KAP

Univariate penalized regressions were used to explore how demographic; professional and workload characteristics relate to an adequate overall KAP score (≥ 60% of the 87-point composite). Four contrasts reached or approached statistical significance (Table 4.15).

Moderate overtime is strongly associated with higher overall competence: Staff who worked 41–59 hours per week were three times more likely than those working ≤ 40 hours to attain the composite KAP threshold, OR = 3.08, 95% CI [1.35, 7.17], p = .008. While the ≥ 60-hour group did not attain the composite KAP threshold (OR = 0.59, p = .400),

- Early-mid career may be a vulnerable period: Providers aged 30–39 years showed 53% lower odds of adequate overall KAP relative to the 20–29-year reference group (OR = 0.47, p = .050).
- Pharmacists lag behind physicians: Pharmacists were about 66% less likely than physicians to achieve adequate overall KAP (OR = 0.34, 95% CI [0.11, 0.98], p = .049).
- Hospital effects are unstable yet suggestive: Working at Istishari Arab Hospital predicted markedly higher odds of adequate KAP (OR = 7.86, p = .033).

No significant associations were detected for gender, patient load, education level, total professional experience, or oncology-specific tenure.

Table 4.15: Predictors of Adequate Overall KAP (≥ 60 % of maximum composite)

Predictor	Level (code)	OR [95%CI]	P-value
Sex (Female)	Male (1)	1.22 [0.57 - 2.63]	0.600
Age band (20–29 y)	30–39 y (2)	0.47 [0.22 - 1.00]	0.050
	≥ 40 y (3)	1.34 [0.71 - 2.53]	0.369
Weekly hours (≤ 40 hrs)	41–59 h (2)	3.08 [1.35 - 7.17]	0.008
	≥ 60 h (3)	0.59 [0.18 - 2.10]	0.400
Patients per day (≤ 10 patients)	11–19 (2)	1.30 [0.48 - 3.47]	0.596

	≥ 20 (3)	1.17 [0.45 - 2.93]	0.745
Qualification (Diploma/Bachelor)	Master (2)	1.10 [0.42 - 3.34]	0.859
	Residency / Specialist (3)	0.64 [0.24 - 1.84]	0.375
Specialty (Physician)	Pharmacist (2)	0.34 [0.11 - 0.98]	0.049
	Nurse (3)	1.89 [0.71 - 4.80]	0.186
Hospital (Al-Watani)	An-Najah (2)	2.55 [0.81 - 7.58]	0.096
	Istishari (3)	7.86 [1.44 - 81.42]	0.033
	Other (4)	1.56 [0.48 - 4.78]	0.441
Total experience (< 1 y)	1–3 y (2)	0.21 [0.00 - 2.14]	0.310
	3–5 y (3)	0.13 [0.00 - 1.23]	0.171
	5–10 y (4)	0.16 [0.00 - 1.41]	0.215
	> 10 y (5)	0.16 [0.00 - 1.39]	0.217
Oncology experience (< 1 y)	1–3 y (2)	1.03 [0.35 - 3.02]	0.957
	3–5 y (3)	0.90 [0.29 - 2.77]	0.847
	5–10 y (4)	1.68 [0.53 - 5.75]	0.383
	> 10 y (5)	1.10 [0.32 - 4.25]	0.884

Note: Each odds ratio (OR) arises from a separate one-predictor Firth logistic model; reference categories are shown in parentheses. Boldface indicates statistical significance ($p < .05$). †The ≥ 40 y level pools the original 40–49 y and ≥ 50 y bands (per recoding). Very large ORs with wide CIs for Istishari reflect quasi-separation because only a few respondents from that hospital fell below the KAP adequacy cut-off.

4.12 Summary

This chapter outlined the study's findings, starting with the construct reliability of the employed instrument, followed by a demonstration of the sample characteristics, a descriptive analysis of the KAP levels and obstacles to ADR reporting among HCPs, as well as their recommendations for enhancing reporting practices. Finally, the outcomes of the hypothesis testing were disclosed. The subsequent chapter will interpret and discuss these results.

Chapter Five: Discussion & Conclusion

5.1 Introduction

This chapter offers a comprehensive discussion of the study results, correlating them with current literature and illustrating their importance. It provides a comprehensive summary of the descriptive findings, including participant demographics, KAP level, reported barriers, and recommendations about ADR reporting. It also presents the main findings of our study, followed by actionable recommendations, practical implications, and a synthesis of the results. Finally, the chapter provides an examination of the study's strengths, limitations, conclusions and avenues for further research.

5.1.1 Summary of the Main Findings

This study explored the knowledge, attitudes, and practices (KAP) of healthcare providers toward adverse drug reaction (ADR) reporting in oncology departments across the West Bank. Out of 250 targeted participants, 180 responded, yielding a 72% response rate. The majority were nurses (62.8%), followed by physicians (22.8%) and pharmacists (14.4%).

The results revealed adequate knowledge in only 35.6% of participants, positive attitudes in 91.7%, and adequate ADR-reporting practices in merely 18.3%, reflecting a substantial gap between awareness and actual behavior. Despite strong attitudinal support for ADR reporting, underreporting remains widespread. Key barriers identified included insufficient training, lack of institutional reporting systems, fear of legal consequences, and time constraints.

Statistical analyses indicated that formal training in pharmacovigilance and ADR reporting significantly improved reporting practices, nearly tripling the odds of adequate reporting. Additionally, the presence of routine ADR discussions within institutions was positively associated with higher reporting rates, underscoring the role of organizational culture. Conversely, workload and time pressure were not significant predictors of reporting behavior.

Overall, the findings highlight a pronounced disconnect between healthcare providers' awareness and actual reporting behavior, emphasizing the urgent need for

structured education, institutional support, and integration of pharmacovigilance principles into oncology practice and curricula in Palestine.

5.2 A Reflection on the Highlights of the Demographic Data of the Study

The study achieved a response rate of 72% (n = 180), which surpasses the 67% benchmark identified in a systematic review and meta-analysis of survey response rate in health science research. (Wilson et al., 2024) Their demographic profile showed a varied and balanced representation across gender, age, professional roles, experience levels, and institutional settings, so improving the reliability and contextual relevance of the results. Closely reflecting the professional structure of the whole survey population (60.8% nurses, 26.4% physicians, and 12.8% pharmacists), nurses formed the majority of responders (62.8%), followed by doctors (22.8%) and pharmacists (14.4%). This alignment supports the generalizability of the results to the wider oncology workforce in the West Bank and reduces the extent of the nonresponse bias occurred (28% pf the study population).

With an average of 19.3 cancer patients daily and working long weekly hours, most participants were full-time workers handling a significant workload. These elements can help explain time-related obstacles in ADR reporting. (Tandon et al., 2015) The relatively young age of respondents (mean = 33.7 years) suggests a workforce open to system improvements and ongoing training, but also possibly in need of ongoing PV capacity building. Additionally, as for the academic qualifications and degrees of experience one-third (34.4%) of the sample have more than 10 years of general professional experience and a well-distributed range of oncology-specific experience capturing perspectives from both junior and senior practitioners.

Geographically, the sample reflected strong institutional representation of the eight hospitals included in the study. Notably, An-Najah National University Hospital, one of the largest oncology centres, accounted for 46.7% of the sample, followed by Istishari Arab Hospital (13.9%), Al-Watani Hospital (10.6%), and Beit Jala Governmental Hospital (8.9%). This proportional distribution captures the actual scene of oncology care in Palestine and fits the original research population. Additionally, the inclusion of both governmental and private institutions, and varying levels of clinical workload and work hours, guarantees a holistic understanding of ADR-related practices and challenges

across healthcare settings. This comprehensive demographic spread strengthens the study's conclusions and enhances its relevance for policy, training, and PV strategy development.

5.3 KAP of HCPs Toward ADR Reporting in Oncology Departments

5.3.1 Reflection on the KAP Highlights

Notably, while a large majority of participants (91.7%) expressed a positive attitude toward ADR reporting, only 35.6% demonstrated adequate knowledge, and an even smaller proportion (18.3%) reported adequate practices. This pattern is found in other studies where high attitude level is accompanied with low knowledge and practice levels. (Daghriri et al., 2024; Kassa Alemu & Biru, 2019; PAVELIU et al., 2013) This discrepancy indicates a significant KAP gap with serious consequences for PV initiatives in Palestine.

This study highlights a significant and widespread deficit in HCPs' knowledge of ADR reporting and understanding of PV. Only 35.6% (n=64) had adequate knowledge (≥ 11/14 correct. The test was highly significant, $p < .001$, 95 % CI [0.30, 0.42], confirming that the observed level of knowledge is not only insufficient but also statistically far from the expected standard. This finding reinforces earlier evidence of knowledge gaps in PV among HCPs (Almandil, 2016; Daghriri et al., 2024) and particularly in low- and middle-income countries. (Hailu & Mohammed, 2020; Kassa Alemu & Biru, 2019) On the other hand, the knowledge level in other studies was high and sufficient among HCPs in other developing countries, which is an indicator of the efforts and educational initiatives they are adopting to support PV and enhance ADR reporting. (Hussain et al., 2020a; Sabblah et al., 2014; Shah et al., 2021)

Given that sufficient knowledge is foundational to effective ADR reporting, and lack of knowledge and awareness is a known factor leading to underreporting (Tandon et al., 2015) these results highlight an urgent need for targeted educational interventions.

Because 91.7% of respondents already hold very positive opinions about their role in reporting ADRs (far exceeding our 75% benchmark), it is unreasonable to blame low ADR-reporting rates on a lack of interest or poor attitudes. Clinicians genuinely believe

reporting is important. Therefore, when actual ADR reporting remains low despite high enthusiasm, the logical conclusion is that other factors, such as cumbersome reporting forms, lack of institutional feedback, unclear procedures, or time pressures, are the real obstacles. (Kassa Alemu & Biru, 2019; Moyo et al., 2023; Tandon et al., 2015) In other words, the "problem" is not that doctors and nurses don't care; it is that the system makes it hard for them to act on their positive intentions.

At least half of the providers demonstrate that an adequate ADR-reporting practice was emphatically rejected. These results confirm a pervasive under-reporting of ADRs among oncology practitioners, echoing similar findings from both regional and global studies, which highlight that HCPs, particularly in oncology, frequently fall short in PV responsibilities. (Baldo et al., 2018; Khan & Karatas, 2022; Rabayah et al., 2019)

Such a low practice rate is particularly concerning in oncology care, where high-risk therapies demand vigilant PV. The observed gap likely reflects both individual-level constraints (e.g., insufficient training, lack of time) and system-level deficiencies (e.g., absence of streamlined reporting workflows, limited feedback loops). (Moyo et al., 2023; Tandon et al., 2015) Critically, the data reveal a significant and clinically meaningful gap in ADR reporting practices, this under-performance underscores the pressing need for multifaceted interventions such as integrated electronic reporting platforms, routine interdisciplinary training sessions, and stronger leadership endorsement to foster a sustainable culture of ADR surveillance and enhance patient safety. (Moyo et al., 2023; Routledge & Bracchi, 2023b)

The significant elevated attitude score indicates that the majority of participants acknowledge the significance of ADR reporting and are likely motivated to participate in this endeavor. Nonetheless, the inadequate knowledge and subpar practice scores indicate systematic deficiencies in training, resources, and institutional support. The mean knowledge score (9.3 out of 14) suggests that several respondents possess a fundamental comprehension of ADR ideas; nevertheless, this understanding may lack depth or practical applicability for precise and consistent reporting. The average practice score (8.3 out of 23) further substantiates that positive attitudes are not being converted into actions, maybe due to insufficient training, institutional obstacles, or a combination of both.

Upon analysis of the overall KAP score (mean = 59.4 out of 87), 82.2% of participants achieved the threshold for "adequate" performance across all three domains. This high percentage is affected by the high attitude level despite the low knowledge and practice levels, because attitude has high weight in the overall KAP level (50 points from 87). Therefore, even with high composite adequacy rate, there remains a clear need for interventions that target not only knowledge enhancement but also promote behavioral and systemic transformation.

5.3.2 Reflection on Predictors of Adequate ADR KAP

The univariate Firth-penalized logistic regression analyses identified several demographics, professional, and workload-related factors that significantly influenced HCPs' KAP toward ADR reporting in Palestinian oncology departments. These findings offer critical insights for tailoring interventions aimed at improving PV performance.

Occupational Role

Among all predictors, specialty appeared as the most significant factor. Nurses consistently outperformed physicians in both knowledge (OR = 5.67, $p < .001$) and practice (OR = 3.67, $p = .030$), validating their essential role in PV. Their regular patient interactions, ongoing monitoring duties, and learning willingness about medication safety likely enhance this expertise. This outcome indicates that nurses can serve as strategic allies in enhancing institutional ADR reporting systems and underscores the necessity to reevaluate and potentially recalibrate role-specific duties within PV processes.

Pharmacists, surprisingly, had considerably lower odds of having satisfactory overall KAP level in comparison to physicians (OR = 0.34, $p = .049$), contesting traditional beliefs regarding their core function in medication safety. (Lee et al., 2022) This could suggest the restricted clinical involvement, unclear roles, or insufficient institutional utilization. Future efforts should investigate particular obstacles and prospects to enhance pharmacists' participation in ADR monitoring.

Qualification Level and Specialization

Paradoxically, higher educational degree correlated with lower knowledge and practice. Specialists and residency program physicians were less likely to attain the knowledge criterion compared to individuals with a bachelor's or diploma-level education (OR = 0.24, p = .018). They may prioritize diagnostics or sophisticated therapies, with minimal emphasis on normal PV activities. This discovery highlights a deficiency in postgraduate training that necessitates rectification via compulsory PV modules and ongoing professional development. Comparable findings were reported by Gidey et al. (2020), who found that physicians demonstrated lower pharmacovigilance knowledge than pharmacists, suggesting that professional role and training orientation may influence awareness more than educational level alone. Moreover, factors such as age, workload, and years since graduation could also interact with educational level, contributing to differences in pharmacovigilance engagement. (Gidey et al., 2020)

Gender

Gender showed a significant association with knowledge, where male HCPs were 48% less likely than their female counterparts to achieve sufficient scores (OR = 0.52, p = .039). However, this may be confounded by occupational roles—nursing is predominantly female, while physicians are more often male. Caution is warranted in interpreting this result without multivariate adjustment.

Workload Intensity

Moderate overtime (41–59 hours/week) was associated with improved overall KAP (OR = 3.08, p = .008), as well as increased odds of sufficient ADR reporting (OR = 7.22, p = .004). These findings challenge the notion that increased workload hinders safety practices. Clinicians in higher-intensity settings may benefit from institutional protocols and exposure to a greater variety of drug-related issues this is true regarding the weekly working hours in the two private hospitals participated in the study “NNUH and IAH” which also have higher KAP level. However, the absence of benefit beyond 60 hours/week, which mainly presents with the residents more than other professions, suggests diminishing returns and the risk of burnout.

Age and Career Stage

A significant observation was the decreased probability of adequate ADR practice and KAP among HCPs aged 30–39 years relative to their younger counterparts (OR = 0.32, p = .023 for practice; OR = 0.47, p = .050 for KAP). This mid-career population frequently undertakes leadership positions and administrative responsibilities, which may diminish direct patient interaction and the time available for reporting. Customized support measures, including time-efficient digital reporting platforms and leadership involvement in PV, may facilitate the re-engagement of this group.

Hospital and Institutional Context

Hospital and Institutional Context was a significant KAP predictor. Staff at IAH demonstrated significantly higher odds of achieving sufficient KAP (OR = 7.86, p = .033), while both IAH and NNUH showed considerably higher odds of adequate ADR-reporting practice (OR = 15.81 and OR = 14.04, respectively). These findings it indicates that institutional policies, culture, or systems (e.g., electronic reporting, training focus) may substantially influence KAP levels. Organizational context must be taken into account while devising interventions. These findings highlight the need for system-wide policy harmonization and institutional accountability.

Training on PV and ADR reporting

Of the 180 oncology HCPs surveyed, those who had received any structured ADR-reporting education, such as workshops, seminars, or on-the-job instruction, demonstrated markedly higher odds of meeting the minimal functional competence threshold. Specifically, trained individuals were nearly three times as likely to exhibit adequate practice compared to their untrained peers (OR = 2.89, 95 % CI [1.26, 6.50], p = .011). In concrete terms, this indicates that participation in at least one formal training session corresponds to a 189 % increase in the odds of performing the core ADR-reporting tasks. These findings align closely with prior interventional research in high-risk specialties: for example, Li et al. (2020) showed that structured PV workshops more than doubled actual report submissions among oncology nurses over a six-month follow-up period, (Li et al., 2020) and in a systematic review by Pagotto et al. (2013) reported that educational interventions led to significant improvements in the total count, the frequency of reporting concerning ADR, and also facilitated an enhancement in the quality of reports by HCPs. (Pagotto et al., 2013) By addressing cognitive barriers (e.g.,

understanding which events qualify as reportable) and procedural hurdles (e.g., navigating the reporting form), robust training programs establish the foundational knowledge and skills necessary for routine ADR-reporting practice. (Baldo et al., 2018)

Finally, the statistically significant effect ($p < .05$) and reasonably narrow confidence interval reinforce a strong and likely causal relationship between training and practice, even though this analysis does not directly adjust for other demographic or workload factors. Taken together, these data underscore the critical role of hospital-based continuing-education departments: scaling up mandatory ADR-reporting modules, via periodic in-service sessions, hands-on simulation exercises, and accessible e-learning platforms, should be a strategic priority for oncology departments. Embedding such content into the standard professional development curriculum will leverage the demonstrable multiplier effect of training, thereby strengthen PV vigilance and ultimately improve patient safety outcomes. (Routledge & Bracchi, 2023b)

Other Predictors and Null Effects

Unexpectedly, factors including age, years of experience, patient volume, and educational level didn't provide a meaningful prediction to the knowledge or reporting habits. This indicates that experience alone does not guarantee PV proficiency without systematic reinforcement. Significantly, neither general nor oncology-specific years of experience predicted KAP adequacy, underscoring the need of formal training and feedback mechanisms.

Collectively, these findings highlight the significance of interventions that are customized to each profession, responsive to stages, and applicable at the system level. Nurses, as per to their demonstrable competencies, could be empowered and efficiently employed. strengthening the pharmacist's function in PV is crucial for optimizing patient safety. Training initiatives must be enhanced for physicians, males and mid-career clinicians, who are insufficiently supported by current educational frameworks.

Institutional policies can emphasize PV by incorporating reporting mechanisms into electronic health records, conducting regular training, and cultivating a culture that prioritizes safety reporting. (Moyo et al., 2023)Mitigating differences among institutions and roles is essential for establishing a sustainable and effective ADR reporting environment in Palestinian cancer care.

Future multivariable analyses and longitudinal research are necessary to confirm these tendencies and further elucidate the interaction of personal, professional, and institutional factors influencing PV behavior.

5.3.3 The relationships between ADR reporting knowledge, attitudes, and practice among HCPs

5.3.3.1 HCP knowledge and their attitudes toward ADR reporting

Although knowledge is commonly theorized to shape attitudes toward PV, the current study found no statistically significant relationship between adequate ADR knowledge and positive attitudes. While the odds ratio of 2.35 suggests a positive association, the result was not statistically significant ($p = 0.20$), with the confidence interval crossing 1.0, indicating insufficient evidence that knowledge predicts attitude. This lack of statistical significance is unsurprising given the very high baseline of positive attitudes (91.7 %), a ceiling effect frequently observed when prior awareness campaigns have already elevated attitudes (Daghriri et al., 2024; Oshikoya & Awobusuyi, 2009; PAVELIU et al., 2013). This outcome indicates that attitude formation may be affected by elements beyond mere knowledge, such as organizational norms and leadership support. Future treatments may be enhanced by addressing institutional and cultural issues to convert positive attitudes into consistent reporting behaviour.

5.3.3.2 HCP knowledge of PV and their ADR reporting practices

Participants possessing adequate knowledge were approximately twice as likely to exhibit adequate reporting behaviors. However, this effect did not reach conventional levels of statistical significance ($\alpha = .05$), falling into the marginally significant range ($0.05 < p < 0.10$). The wide confidence interval and the relatively small proportion of "adequate" practitioners (18.3%) suggest that the study may be underpowered to detect a definitive effect. From a practical standpoint, as aligned with other studies, these findings imply that while higher knowledge appears to trend toward better reporting practice, knowledge alone may not be sufficient to ensure consistent ADR reporting. (Hussain et al., 2020a; Shah et al., 2021)

Complementary strategies are needed to address this gap. Structural, technological, and cultural reinforcements are indispensable for translating theoretical understanding into routine PV practice. (Moyo et al., 2023; Oshikoya & Awobusuyi, 2009; Pagotto et al., 2013; Routledge & Bracchi, 2023b)

5.3.3.3 HCP attitudes toward ADR reporting and their reporting practices

This study highlights that clinicians with a markedly high attitude were, on average, 3.37 times more likely to report ADRs adequately compared to their other counterparts. Yet this association did not reach statistical significance ($p = .249$), likely due to the small number of adequate reporters (18.3%) within a predominantly high-attitude sample (91.7%). The resulting wide confidence interval reflects the study's limited power to detect meaningful differences, despite the suggestive odds ratio. (Peduzzi et al., 1996)

This discovery indicates that possessing a favorable attitude alone is insufficient to guarantee appropriate ADR reporting practices. Previous behavioral science models, such Ajzen's Theory of Planned Behavior, assert that attitudes must integrate with additional factors such as perceived behavioral control and normative influences to motivate action. (Bosnjak et al., 2020) Consistent with this viewpoint, our findings indicate that system-level facilitators (e.g., streamlined reporting processes, dependable feedback systems) and self-efficacy enhancement (e.g., structured training, explicit guidelines) are essential to convert positive intentions into regular, observable practices. (Routledge & Bracchi, 2023b) Without these complementary factors, favorable attitudes alone appear inadequate to overcome practical barriers that impede routine ADR reporting

5.4 Barriers to ADR reporting and Suggestions for improvement

The examination of perceived barriers to ADR reporting revealed both conceptual and operational challenges, consistent with findings from other low- and middle-income settings. (Moyo et al., 2023; Tandon et al., 2015) The most commonly reported barriers were unfamiliarity with reporting procedures (37.8%), challenges in assessing whether an occurrence constituted an ADR (37.8%), inadequate training (35.0%), and time

constraints (28.9%). The participants' identification of these impediments indicates significant self-awareness and a readiness for improvement, qualities that could be utilized in future interventions.

Infrequently cited obstacles, including apprehension regarding legal repercussions (15.6%) and anxiety about professional reputation (8.9%), indicate that psychological or reputational considerations may be less significant in this context compared to logistical and educational deficiencies. Notably, 11.1% of participants indicated the absence of barriers, potentially signifying either disengagement with the reporting system or ignorance of its deficiencies, both warranting more qualitative investigation.

Participants' suggestions for improvement aligned closely with the barriers they reported, around 22.8% of respondents endorsed regular training workshops and continuing education sessions, while 17.2% urged the establishment or upgrading of a formal reporting system. The modest proportion of participants proposing feedback systems (2.2%) or awareness campaigns (1.7%) may indicate either insufficient exposure to these activities or a diminished recognition of their significance, underscoring the need for additional study and awareness enhancement. These patterns underscore the immediate need for comprehensive educational and infrastructural reform.

Statistical analysis confirmed that several of these barriers had a significant or marginal impact on ADR reporting behavior. Among the five hypothesized barriers, "lack of knowledge of reporting rules" was the most powerful negative predictor of practice ($OR = 0.13$, $p < .001$), underscoring that knowing the rules is a critical prerequisite for consistent ADR reporting. This result is consistent with numerous studies, which have repeatedly identified "not knowing how" as a top-ranked HCP-related deterrent to submitting adverse-event reports. (Moyo et al., 2023)

Unexpectedly, instead of halting reporting, fear of legal responsibility seems to coincide with higher reporting rates ($OR = 3.12$, $p = .012$); that is, providers who worry about litigation may respond by erring on the side of caution and submitting reports more diligently. Here, fear of punitive repercussions paradoxically led to more frequent reporting rather than under-reporting, this opposes what can be found in other studies that fear is a barrier. (Moyo et al., 2023) Thus, interventions should not only aim to reassure providers with "safe harbor" policies, but also emphasize the legal protections that support responsible reporting.

Barriers such as “lack of time” and “absence of an institutional system” showed marginal statistical significance ($p = .061$ and $p = .060$, respectively), yet both had large effect sizes (ORs < 0.40), suggesting they may meaningfully inhibit practice but requiring further investigation. This finding may indicate that limited access to reporting tools (e.g., paper or digital forms) discourages HCPs from reporting ADRs as supported by a systematic review and meta-analysis (2016), which showed that hospitals with electronic reporting systems have doubled ADR submission rates. (Ribeiro-Vaz et al., 2016)Therefore, while the current evidence is suggestive rather than conclusive, it implies that institutional support mechanisms should be prioritized in future policy initiatives.

Conversely, the absence of feedback did not reliably discourage adequate ADR-reporting practice. This contrasts with some prior work in other specialties, (Kiguba et al., 2020) but may reflect oncology providers’ strong intrinsic motivation; when they believe an adverse event is serious, they report regardless of feedback loops.

Workload did not emerge as a statistically significant predictor in this context. Neither the number of cancer patients seen per day nor weekly working hours correlated with reporting behavior. Several contextual factors may explain this result; shared responsibilities among multidisciplinary teams. (Alkofide et al., 2024) The presence of institutional safety nets like EMR alerts and regular PV prompts that mitigate the effect of individual busyness. Additionally, the low number of “adequate reporters” (33 out of 180) may have limited the statistical power to detect smaller workload-related effects.

In a systematic review, Ariful Islam Anik noted that high patient-to-staff ratios negatively affect patient safety in some settings (Anik et al., 2025) whereas in others, well-defined workflows offset individual time constraints, mirroring our own findings. (Moyo et al., 2023) Moreover, we emphasize that “workload” is more than just a headcount or clocked hours. It also includes how sick the patients are, how many non-clinical tasks (paperwork, meetings) the provider must do, and whether there is adequate help from nurses, assistants, or pharmacists, therefore, our measure may not accurately represent the “true” workload in oncology practice. In other words, workload can still be a barrier—just not in a setting where these buffers exist.

Finally, hospital policies and professional culture, such as institutionally mandated ADR discussions, correlate strongly with higher odds of “adequate” ADR-reporting

practice (OR = 2.66). Oncology department leaders should therefore prioritize the creation and maintenance of interdisciplinary PV forums rather than relying solely on individual training or ad hoc directives. This finding aligns with safety-culture theory, which posits that regular, structured discussions about adverse events foster collective vigilance and normalize reporting. (Wang et al., 2014) In oncology specifically, routine "ADR rounds" or "PV huddles" encourage team members to share observations, reduce individual uncertainty, and reinforce a shared commitment to patient-safety best practices. (Alkofide et al., 2024) Although routine ADR discussion was measured through self-report, which may introduce social desirability bias; the strength of the association suggests real value in institutionalizing these forums.

For oncology leaders and administrators in the West Bank, these findings highlight the need to move beyond individual training and address system-level barriers. Initiatives such as designated ADR discussion times, integrated EMR prompts, and team-based PV reviews may significantly improve adherence to reporting practices. Future studies using audit data or longitudinal designs are needed to confirm causality and assess the long-term impact of such interventions.

5.5 Practical Implications and recommendations

Across all fourteen hypotheses, our data make it clear that knowledge deficits and system-level facilitators (training, clear reporting rules, routine ADR discussions) are far more decisive in shaping ADR-reporting behavior than attitudinal dispositions (which were already highly favorable) or raw workload (which, alone, did not significantly depress practice). In order to achieve a reliable, sustainable increase in ADR submission—especially vital in oncology, where high-risk chemotherapy regimens demand vigilant monitoring—hospitals must move beyond raising awareness and instead build robust practice-enabling infrastructure. By investing in ongoing education, streamlining reporting pathways, and embedding ADR vigilance into institutional culture, hospital leadership can translate positive intent into consistent, lifesaving action.

5.6 Study Recommendations

In light of the study results, the following recommendations have been formulated.

1. Expand and standardize training programs by:
    - Developing a mandatory, standardized PV curriculum—tailored to oncology—in collaboration with national PV centers. Modules should include hands-on form-completion workshops, ADR severity assessment simulations, and e-reporting system tutorials.
    - Offering refresher courses at least biannually. Provide brief "refresher bites" (e.g., 15-minute in-service sessions) during oncology team huddles or grand rounds.
    - Establishing clear reporting guidelines and protocols
        - Simplify ADR forms. Review existing ADR-reporting forms with frontline staff. Remove redundant fields and automate data-entry prompts wherever possible.
        - Distribute quick-reference guides. Create laminated pocket cards and digital cheat-sheets illustrating "step-by-step" reporting procedures—both paper-based and electronic.
        - Institutional policy memorandum. Hospital leadership should issue an official policy document—signed by department heads and quality directors—reiterating that ADR reporting is mandatory, protected from punitive consequences, and part of routine clinical responsibilities.
2. Institutionalise routine ADR discussions by:
    - Weekly/biweekly ADR rounds. Schedule dedicated ADR review sessions involving physicians, nurses, pharmacists, and the quality/safety team. Present actual ADR cases, discuss root causes, and highlight corrective actions.
    - Feedback loops. After each ADR submission, the quality department or PV officer should provide timely feedback (e.g., summary of causality assessment, recommended interventions). This addresses the "lack of feedback" barrier.

- Embed reminders in electronic health records (EHRs). Develop pop-up alerts that prompt clinicians to consider ADR reporting whenever certain high-risk medications are ordered or when adverse symptoms are charted.

3. Address specific systemic barriers through:

- Clarify legal protections. Develop and disseminate official guidance on legal safeguards for ADR reporters (e.g., nonpunitive clauses, confidentiality assurances). Partner with the Ministry of Health and legal counsel to reassure providers that good-faith reporting will not provoke legal repercussions.
- Alleviate time constraints. Experiment with "protected reporting slots": designate 5–10 minutes per shift where every provider must complete any pending ADR reports. Consider assigning "PV champions" in each unit—pharmacists or nurses responsible for tracking ADR cases and prompting physicians to file reports.
- Establish (or strengthen) an institutional ADR reporting system. If an electronic platform does not yet exist, implement a user-friendly, hospital-wide electronic ADR module (with single-sign-on via the EHR). If a paper system is still used, ensure that blank forms are always stocked in strategic areas: pharmacy, nursing stations, and physician lounges.

4. Consistently monitor and assess the impact by implementing:

- Key performance indicators (KPIs). Track monthly ADR-reporting rates (absolute counts and "reports per 100 beds") to gauge progress. Monitor changes in knowledge scores, attitude distributions, and practice frequencies every six months.
- Quality improvement (QI) cycles. Use Plan-Do-Study-Act (PDSA) cycles to pilot new interventions—such as an e-reporting prompt—then measure its effect on subsequent reporting. Iterate based on feedback.

5.7 Strengths and limitations of the study

5.7.1 Study Strengths

This study constitutes the first comprehensive examination in Palestine of the KAP, and factors affecting ADR reporting among oncology HCPs. Its strengths lie in both its originality and methodological rigor. In particular, the study offers a multidimensional perspective on ADR-reporting behavior by systematically assessing fourteen hypotheses across diverse domains. Furthermore, the inclusion of a broad and representative sample from multiple oncology sites throughout the West Bank enhances the generalizability of the findings. In addition, a response rate of 72% of the total target population strengthens the validity of the results, exceeding commonly accepted standards for healthcare surveys.

The questionnaire, adapted from previously validated instruments and tailored to the local context, ensured both relevance and content validity. Moreover, the study applied rigorous analytical techniques—including logistic regression and percentage testing—to examine relationships based on clearly defined KAP criteria. Notably, the finding that fear of legal liability correlates with increased reporting—rather than reduced reporting—offers a novel perspective that challenges established assumptions in the PV literature. Overall, this study delivers practical insights for health policy and clinical practice in a context where ADR reporting remains underdeveloped.

5.7.2 Study Limitations

Despite its contributions, this study has several limitations that should be acknowledged. First, it was geographically restricted to the West Bank, excluding oncology centers in East Jerusalem and Gaza due to travel barriers. Consequently, the findings may not be fully generalizable to all oncology HCPs in Palestine. Additionally, given the fragmented nature of healthcare delivery across different regions, some adverse ADRs may have been recorded in institutions not covered by the study. Second, the cross-sectional design limits the ability to infer causal relationships between ADR reporting behaviors and explanatory variables. Furthermore, as data were collected via self-administered questionnaires, the results may be subject to recall bias and social

desirability bias, potentially affecting the accuracy of reported KAP. Although the response rate was relatively high (72%), the possibility of non-response bias remains, as those who chose not to participate may differ systematically from respondents. Another limitation involves the operational definition of "adequate practice," which was based on an arbitrary threshold of ≥50% of the maximum score. While this cutoff was methodologically justified, it may not reflect a universal or clinically validated standard for ADR reporting. Finally, the binary classification of knowledge and attitude levels may have oversimplified inherently continuous constructs, potentially masking nuanced variations in HCP behavior.

5.8 Conclusion

This study undertook a comprehensive analysis of ADR reporting behavior among oncology HCPs in the West Bank by systematically testing fourteen hypotheses across multiple domains—including knowledge, attitudes, practices, perceived barriers, workload, and institutional factors. The objective was to identify not only what facilitates ADR reporting but also what impedes it within a high-risk clinical context. In doing so, the study offers a multidimensional understanding of how individual- and system-level determinants interact to shape PV behavior in oncology settings. The findings contribute new insights to the literature by quantifying the relative impact of various predictors and highlighting areas where interventions may be most effective.

The results reveal that knowledge gaps are substantial: only 35.6% of respondents met the ≥80% competency threshold, indicating widespread deficits in PV understanding. However, knowledge alone was not a statistically significant predictor of either attitude or practice. Although providers with adequate knowledge were more likely to express favorable attitudes and engage in ADR reporting, these associations did not reach statistical significance—likely due to ceiling effects in attitudinal responses and low overall rates of adequate practice. Indeed, over 91% of participants already exhibited positive attitudes toward ADR reporting, limiting the ability to detect incremental effects of knowledge on attitudes or practice.

Practice behaviors lagged notably behind attitudes, with only 18.3% of participants meeting the defined adequacy threshold. While both knowledge and positive attitudes

were associated with increased odds of reporting, neither emerged as independent predictors in multivariate analyses. In contrast, specific system-level factors demonstrated stronger associations. Formal training in PV significantly increased the likelihood of adequate practice, nearly tripling reporting odds. Similarly, providers who worked in institutions where ADRs were routinely discussed were more than twice as likely to report, underscoring the importance of organizational culture and peer dialogue.

Barriers such as lack of knowledge about reporting procedures and absence of institutional systems for ADR documentation were found to significantly reduce reporting. Interestingly, fear of legal liability—often assumed to discourage reporting—was associated with higher reporting rates, suggesting that heightened awareness of legal consequences may motivate more cautious and documented practice. Lack of time and feedback were also explored; while time constraints showed a marginal effect, lack of feedback did not significantly influence behavior, possibly because providers already had low expectations for institutional follow-up.

Workload factors, including number of patients seen per day and weekly working hours, did not significantly predict reporting practices. These finding challenges common assumptions that clinical busyness alone is a primary barrier and highlights the need to focus on more modifiable organizational and educational factors.

Taken together, these findings suggest that improving ADR reporting requires more than increasing knowledge or promoting positive attitudes—both of which were already relatively high. Rather, the greatest gains are likely to come from dismantling institutional barriers, offering targeted PV training, and fostering environments where ADRs are routinely and openly discussed. In other words, knowledge is necessary but insufficient; attitudinal readiness is present but underutilized; and practice remains limited but responsive to system-level interventions. Addressing these dynamics through policy, education, and infrastructure has the potential to substantially strengthen PV practice in Palestinian oncology settings.

5.9 Future Research

Future studies should consider utilizing larger, multisite samples to enhance statistical power and detect more nuanced associations, particularly regarding marginal

effects such as workload and institutional system barriers. Expanding the sample size across diverse oncology settings may also improve generalizability and uncover context-specific patterns in ADR reporting. Studies to evaluate KAP among non-oncology departments for comparison. In addition, mixed-methods approaches—such as qualitative interviews and focus groups—could provide deeper insight into unexpected findings. For example, the paradoxical positive correlation between fear of legal responsibility and increased reporting behavior warrants further exploration to understand the underlying motivations. Similarly, the lack of association between feedback mechanisms and reporting may reflect already diminished expectations among providers, an area best explored through qualitative inquiry. Finally, a longitudinal design could be employed to track changes in knowledge, attitudes, and practices over time. Transforming this cross-sectional snapshot into a prospective cohort study would allow researchers to assess how targeted interventions—such as policy changes or training programs—impact ADR reporting behavior over a sustained period.

References

Alkofide, H., Almalag, H. M., Alromaih, M., Alotaibi, L., Altuwaijri, N., Al Aloola, N., Alsabhan, J. F., Bawazeer, G. A., Al Juffali, L., Alfaraj, R., Alkhudair, N., Aljadeed, R., Aljadeed, R., & Alnaim, L. S. (2024). Pharmacovigilance Practices by Healthcare Providers in Oncology: A Cross-Sectional Study. *Pharmaceuticals 2024, Vol. 17, Page 683*, *17*(6), 683. https://doi.org/10.3390/PH17060683

Almandil, N. B. (2016). Healthcare professionals' awareness and knowledge of adverse drug reactions and pharmacovigilance. *Saudi Medical Journal*, *37*(12), 1350–1355. https://doi.org/10.15537/SMJ.2016.12.17059,

Alsaleh, F. M., Alzaid, S. W., Abahussain, E. A., Bayoud, T., & Lemay, J. (2017). Knowledge, attitude and practices of pharmacovigilance and adverse drug reaction reporting among pharmacists working in secondary and tertiary governmental hospitals in Kuwait. *Saudi Pharmaceutical Journal*, *25*(6), 830–837. https://doi.org/10.1016/J.JSPS.2016.12.004

Alshammari, T. M., Mendi, N., Alenzi, K. A., & Alsowaida, Y. (2019). Pharmacovigilance Systems in Arab Countries: Overview of 22 Arab Countries. *Drug Safety*, *42*(7), 849–868. https://doi.org/10.1007/s40264-019-00807-4

Anik, A. I., Islam, T., & Uddin, B. (2025). Relationship Between Nurse Workload and Patient Safety in Critical Care. *Asia Pacific Journal of Nursing Research*, *6*(1), 1–9. https://doi.org/10.70818/APJNR.2025.V06I01.019

Bakhsh, T. M. A., Baloshi, A. H. Al, Bakhsh, H. M. A., Al-Dosaari, D. S., & Qureshi, N. A. (2016). Adverse Drug Reactions and Pharmacovigilance: A Narrative Mini-review of Relevant Literature. *Journal of Advances in Medical and Pharmaceutical Sciences*, *11*(1), 1–18. https://doi.org/10.9734/JAMPS/2016/30653

Baldo, P., Fornasier, G., Ciolfi, L., Sartor, I., & Francescon, S. (2018). Pharmacovigilance in oncology. *International Journal of Clinical Pharmacy*, *40*(4), 832. https://doi.org/10.1007/S11096-018-0706-9

Barr, A., & Alsulami, F. T. (2025). Hospital Pharmacists' Attitudes and Intentions Toward Adverse Drug Reaction Reporting in Saudi Arabia: Insights from the Theory of Planned Behavior. *Healthcare 2025, Vol. 13, Page 1111*, *13*(10), 1111. https://doi.org/10.3390/HEALTHCARE13101111

Baruch, Y., & Holtom, B. C. (2008). Survey response rate levels and trends in organizational research. *Human Relations*, *61*(8), 1139–1160. https://doi.org/10.1177/0018726708094863

Beninger, P. (2018). Pharmacovigilance: An Overview. *Clinical Therapeutics*, *40*(12), 1991–2004. https://doi.org/10.1016/j.clinthera.2018.07.012

Bosnjak, M., Ajzen, I., & Schmidt, P. (2020). The theory of planned behavior: Selected recent advances and applications. *Europe's Journal of Psychology*, *16*(3), 352–356. https://doi.org/10.5964/EJOP.V16I3.3107

Daghriri, S. H., Alnaami, H. A., Almusallam, A. H., Yahya, M., Assiri, A., Swelleh, W. E., Alasmari, M. A., Awadh, N., Alanazi, H., Alharbi, O. Z., Muhaddel, A., Alwani, S., & Alotaibi, A. M. (2024). Knowledge, Attitude, and Practice of Healthcare Professionals at Selected Public Hospitals Regarding Adverse Drug Reaction Reporting and Related Factors. *Journal of International Crisis and Risk Communication Research* , *10*, 1624–1632. https://doi.org/10.63278/JICRCR.VI.2294

Ekman, E., Petersson, G., Tågerud, S., & Bäckström, M. (2012). Awareness among nurses about reporting of adverse drug reactions in Sweden. *Drug, Healthcare and Patient Safety*, *4*(1), 61. https://doi.org/10.2147/DHPS.S31103

Etikan, I., Musa, S. A., & Alkassim, R. S. (2015). Comparison of Convenience Sampling and Purposive Sampling. *American Journal of Theoretical and Applied Statistics 2016, Volume 5, Page 1*, *5*(1), 1–4. https://doi.org/10.11648/J.AJTAS.20160501.11

Fornasier, G., Francescon, S., Leone, R., & Baldo, P. (2018). An historical overview over Pharmacovigilance. *International Journal of Clinical Pharmacy*, *40*(4), 744–747. https://doi.org/10.1007/S11096-018-0657-1/FIGURES/2

Fornasier, G., Taborelli, M., Francescon, S., Polesel, J., Aliberti, M., De Paoli, P., & Baldo, P. (2018). Targeted therapies and adverse drug reactions in oncology: the role of clinical pharmacist in pharmacovigilance. *International Journal of Clinical Pharmacy*, *40*(4), 795–802. https://doi.org/10.1007/S11096-018-0653-5/TABLES/3

Gidey, K., Seifu, M., Hailu, B. Y., Asgedom, S. W., & Niriayo, Y. L. (2020). Healthcare professionals knowledge, attitude and practice of adverse drug reactions reporting in Ethiopia: a cross-sectional study. *BMJ Open*, *10*(2), e034553. https://doi.org/10.1136/BMJOPEN-2019-034553

Hailu, A. D., & Mohammed, S. A. (2020). Adverse Drug Reaction Reporting in Ethiopia: Systematic Review. *BioMed Research International, 2020*. https://doi.org/10.1155/2020/8569314,

Hussain, R., Hassali, M. A., Ur Rehman, A., Muneswarao, J., & Hashmi, F. (2020a). Physicians' understanding and practices of pharmacovigilance: Qualitative experience from a lower middle-income country. *International Journal of Environmental Research and Public Health*, *17*(7). https://doi.org/10.3390/IJERPH17072209,

Hussain, R., Hassali, M. A., Ur Rehman, A., Muneswarao, J., & Hashmi, F. (2020b). Physicians' Understanding and Practices of Pharmacovigilance: Qualitative Experience from a Lower Middle-Income Country. *International Journal of Environmental Research and Public Health*, *17*(7). https://doi.org/10.3390/IJERPH17072209

Jha, N., Rathore, D. S., Shankar, P. R., Gyawali, S., Alshakka, M., & Bhandary, S. (2014). An educational intervention's effect on healthcare professionals' attitudes towards pharmacovigilance. *The Australasian Medical Journal*, *7*(12), 478. https://doi.org/10.4066/AMJ.2014.2235

Kassa Alemu, B., & Biru, T. T. (2019). Health care professionals' knowledge, attitude, and practice towards adverse drug reaction reporting and associated factors at selected public hospitals in northeast Ethiopia: A cross-sectional study. *BioMed Research International*, *2019*. https://doi.org/10.1155/2019/8690546,

Khan, Z., & Karatas, Y. (2022). Adverse drug reaction reporting for more than a decade: The need for pharmacovigilance policy implementation in Turkey. *Journal of Taibah University Medical Sciences*, *17*(2), 340. https://doi.org/10.1016/J.JTUMED.2021.12.009

Khdour, M., Yaghmour, N., Hallak, H., Dweib, M., Al-Shahed, Q., Khdour, M. ;, Yaghmour, N. ;, Hallak, H. ;, Dweib, M. ;, Al-Shahed, Q. ;, & Jarab, A. (2016). Pharmacovigilance and Adverse Drug Reactions Reporting Process in West-Bank, Palestine. *Palestinian Medical and Pharmaceutical Journal*, *1*(2), 1. https://doi.org/10.59049/2790-0231.1031

Kiguba, R., Ndagije, H. B., Nambasa, V., Manirakiza, L., Kirabira, E., Serwanga, A., Olsson, S., Speybroeck, N., & Mukonzo, J. (2020). Pharmacovigilance of suspected or confirmed therapeutic ineffectiveness of artemisinin-based combination therapy: extent, associated factors, challenges and solutions to reporting. *Malaria Journal*, *19*(1), 1–10. https://doi.org/10.1186/S12936-020-03463-7/TABLES/5

Kommu, S., Carter, C., & Whitfield, P. (2024). Adverse Drug Reactions. *StatPearls*. https://www.ncbi.nlm.nih.gov/books/NBK599521/

Laatikainen, O., Sneck, S., & Turpeinen, M. (2022). Medication-related adverse events in health care—what have we learned? A narrative overview of the current knowledge. *European Journal of Clinical Pharmacology*, *78*(2), 159–170. https://doi.org/10.1007/S00228-021-03213-X,

Lavan, A. H., O'Mahony, D., Buckley, M., O'Mahony, D., & Gallagher, P. (2019a). Adverse Drug Reactions in an Oncological Population: Prevalence, Predictability, and Preventability. *The Oncologist*, *24*(9), e968–e977. https://doi.org/10.1634/THEONCOLOGIST.2018-0476,

Lavan, A. H., O'Mahony, D., Buckley, M., O'Mahony, D., & Gallagher, P. (2019b). Adverse Drug Reactions in an Oncological Population: Prevalence, Predictability, and Preventability. *The Oncologist*, *24*(9), e968–e977. https://doi.org/10.1634/THEONCOLOGIST.2018-0476

Lee, L. M., Carias, D. C., Gosser, R., Hannah, A., Stephens, S., Templeman, W. A., & Hawkins, B. (2022). ASHP Guidelines on Adverse Drug Reaction Monitoring and Reporting. *American Journal of Health-System Pharmacy*, *79*(1), e83–e89. https://doi.org/10.1093/AJHP/ZXAB324

Li, R., Zaidi, S. T. R., Chen, T., & Castelino, R. (2020). Effectiveness of interventions to improve adverse drug reaction reporting by healthcare professionals over the last decade: A systematic review. *Pharmacoepidemiology and Drug Safety*, *29*(1), 1–8. https://doi.org/10.1002/PDS.4906

Ministry of Health. (2023). *NATIONAL CANCER CONTROL PROGRAMME STATE OF PALESTINE 2024-2034*.

Ministry of Heath. (2024). *Health Annual Report, Palestine 2023*. www.moh.ps

Montané, E., & Santesmases, J. (2020). Adverse drug reactions. *Medicina Clinica*, *154*(5), 178–184. https://doi.org/10.1016/j.medcli.2019.08.007

Moyo, E., Moyo, P., Mangoya, D., Imran, M., & Dzinamarira, T. (2023). Adverse drug reaction reporting by healthcare providers in sub-Saharan Africa: A scoping review of the challenges faced and the strategies to address the challenges. *International Journal of Africa Nursing Sciences*, *19*, 100639. https://doi.org/10.1016/J.IJANS.2023.100639

Oshikoya, K. A., & Awobusuyi, J. O. (2009). Perceptions of doctors to adverse drug reaction reporting in a teaching hospital in Lagos, Nigeria. *BMC Clinical Pharmacology*, *9*, 14. https://doi.org/10.1186/1472-6904-9-14

Pagotto, C., Varallo, F., & Mastroianni, P. (2013). Impact of educational interventions on adverse drug events reporting. *International Journal of Technology Assessment in Health Care*, *29*(4), 410–417. https://doi.org/10.1017/S0266462313000457

Palestinian Ministry of Health. (n.d.). *نموذج إبلاغ عن أعراض جانبية عكسية لمستحضر صيدلاني [Adverse drug reaction reporting form]*. Retrieved May 30, 2025, from https://pharmacy.moh.ps/index/Form/Language/ar

Palestinian Ministry of Health. (2017). *Pharmacovigilance and adverse drug reaction reporting system*. https://pharmacy.moh.ps/index/ArticleView/ArticleId/599/Language/ar

PAVELIU, M. S., BENGEA-LUCULESCU, S., TOMA, M., & PAVELIU, S. F. (2013). Perception on Adverse Drug Reaction Reporting by Physicians Working in Southern Romania. *Mædica*, *8*(1), 17. https://pmc.ncbi.nlm.nih.gov/articles/PMC3749755/

Peduzzi, P., Concato, J., Kemper, E., Holford, T. R., & Feinstem, A. R. (1996). A simulation study of the number of events per variable in logistic regression analysis. *Journal of Clinical Epidemiology*, *49*(12), 1373–1379. https://doi.org/10.1016/S0895-4356(96)00236-3

Phougat, P., Beniwal, M., Kapoor, G., Aggarwal, N., Kumari, A., Sharma, R., Chopra, H., Sharma, R., & Kamal, M. A. (2024). Role and Responsibilities of Various Stakeholders in Pharmacovigilance (PV). *Current Drug Safety*, *19*(1), 19–32. https://doi.org/10.2174/0115748863277574240125045459/CITE/REFWORKS

Rabayah, A. A. Al, Hanoun, E. M., & Rumman, R. H. Al. (2019). Assessing knowledge, attitude, and practices of health-care providers toward

pharmacovigilance and adverse drug reaction reporting at a comprehensive cancer center in Jordan. *Perspectives in Clinical Research*, *10*(3), 115. https://doi.org/10.4103/PICR.PICR_4_18

Rehan, H. S., Sah, R. K., & Chopra, D. (2012). Comparison of knowledge, attitude and practices of resident doctors and nurses on adverse drug reaction monitoring and reporting in a tertiary care hospital. *Indian Journal of Pharmacology*, *44*(6), 699–703. https://doi.org/10.4103/0253-7613.103253,

Ribeiro-Vaz, I., Silva, A.-M., Santos, C. C., & Cruz-Correia, R. (2016). *How to promote adverse drug reaction reports using information systems-a systematic review and meta-analysis*. https://doi.org/10.1186/s12911-016-0265-8

Routledge, P. A., & Bracchi, R. (2023a). Improving the spontaneous reporting of suspected adverse drug reactions: An overview of systematic reviews. *British Journal of Clinical Pharmacology*, *89*(8), 2377–2385. https://doi.org/10.1111/BCP.15791

Routledge, P. A., & Bracchi, R. (2023b). Improving the spontaneous reporting of suspected adverse drug reactions: An overview of systematic reviews. *British Journal of Clinical Pharmacology*, *89*(8), 2377–2385. https://doi.org/10.1111/BCP.15791

Sabblah, G. T., Akweongo, P., Darko, D., Dodoo, A. N. O., & Sulley, A. M. (2014). Adverse drug reaction reporting by doctors in a developing country: a case study from Ghana. *Ghana Medical Journal*, *48*(4), 189–193. https://doi.org/10.4314/GMJ.V48I4.4,

Saini, V. K., Sewal, R. K., Ahmad, Y., & Medhi, B. (2015). Prospective observational study of adverse drug reactions of anticancer drugs used in cancer treatment in a tertiary care hospital. *Indian Journal of Pharmaceutical Sciences, 77*(6), 687–693. https://doi.org/10.4103/0250-474X.174990,

Salazar, L. F., Crosby, R. A., & Diclemente, R. J. (2015). *Research methods in health promotion* (second). Wiley.

Salehi, T., Seyedfatemi, N., Mirzaee, M. S., Maleki, M., & Mardani, A. (2021). Nurses' Knowledge, Attitudes, and Practice in Relation to Pharmacovigilance and Adverse Drug Reaction Reporting: A Systematic Review. *BioMed Research International*, *2021*. https://doi.org/10.1155/2021/6630404,

Schatz, S. N., & Weber, R. (2015). *Adverse Drug Reactions*. www.nccmerp.org/about-medication-errors.

Shah, R., Parajuli, S. B., & Pokhrel, S. (2021). Knowledge of adverse drug reactions reporting among doctors and nurses in a tertiary care hospital: A descriptive cross-sectional study. *Journal of the Nepal Medical Association*, *59*(233), 22–25. https://doi.org/10.31729/JNMA.5386,

Shanableh, S., Zainal, H., Alomar, M., & Palaian, S. (2023). A national survey of knowledge, attitude, practice, and barriers towards pharmacovigilance and adverse drug reaction reporting among hospital pharmacy practitioners in the United Arab

Emirates. *Journal of Pharmaceutical Policy and Practice*, *16*(1), 1–19. https://doi.org/10.1186/S40545-023-00593-6/TABLES/13

Sharma, M. V. (2024). Knowledge, Attitude, and Practice Survey in Health Care – How Does it Matter? *Journal of Advanced Lung Health*, *4*(1), 2–3. https://doi.org/10.4103/JALH.JALH_52_23

Tandon, V. R., Mahajan, V., Khajuria, V., & Gillani, Z. (2015). Under-reporting of adverse drug reactions: A challenge for pharmacovigilance in India. *Indian Journal of Pharmacology*, *47*(1), 65–71. https://doi.org/10.4103/0253-7613.150344,

Tuccori, M., Montagnani, S., Capogrosso-Sansone, A., Mantarro, S., Antonioli, L., Fornai, M., & Blandizzi, C. (2015). Adverse reactions to oncologic drugs: spontaneous reporting and signal detection. *Expert Review of Clinical Pharmacology*, *8*(1), 61–75. https://doi.org/10.1586/17512433.2015.974555

Uppsala Monitoring Centre. (n.d.). *Uppsala Monitoring Centre | UMC*. Retrieved May 31, 2025, from https://who-umc.org/

Uppsala Monitoring Centre. (2025). *Member countries | UMC*. https://who-umc.org/about-the-who-programme-for-international-drug-monitoring/member-countries/

Wang, X., Liu, K., You, L. ming, Xiang, J. gen, Hu, H. gang, Zhang, L. feng, Zheng, J., & Zhu, X. wen. (2014). The relationship between patient safety culture and adverse events: A questionnaire survey. *International Journal of Nursing Studies*, *51*(8), 1114–1122. https://doi.org/10.1016/j.ijnurstu.2013.12.007

WHO Uppsala Monitoring Centre. (2025). *About the WHO PIDM | UMC*. https://who-umc.org/about-the-who-programme-for-international-drug-monitoring/about-the-who-pidm/

Wilbur, K. (2013). Pharmacovigilance in Qatar: A survey of pharmacists. *Eastern Mediterranean Health Journal*, *19*(11), 930–935. https://doi.org/10.26719/2013.19.11.930

Wilson, A. B., Brooks, W. S., Edwards, D. N., Deaver, J., Surd, J. A., Pirlo, O. J., Byrd, W. A., Meyer, E. R., Beresheim, A., Cuskey, S. L., Tsintolas, J. G., Norrell, E. S., Fisher, H. C., Skaggs, C. W., Mysak, D., Levin, S. R., Escutia Rosas, C. E., Cale, A. S., Karim, M. N., … Lufler, R. S. (2024). Survey response rates in health sciences education research: A 10-year meta-analysis. *Anatomical Sciences Education*, *17*(1), 11–23. https://doi.org/10.1002/ASE.2345,

Worakunphanich, W., Youngkong, S., Suwankesawong, W., Anderson, C., & Thavorncharoensap, M. (2022). Comparison of Patient Adverse Drug Reaction Reporting Systems in Nine Selected Countries. *International Journal of Environmental Research and Public Health*, *19*(8). https://doi.org/10.3390/IJERPH19084447,

World Health Organization. (2002). *Safety of Medicines*.

World Health Organization. (2015). *WHO PHARMACOVIGILANCE INDICATORS: A PRACTICAL MANUAL FOR THE ASSESSMENT OF PHARMACOVIGILANCE SYSTEMS*.

Appendices

Appendix 1: Study Questionnaire

Study Questionnaire

Study title: Healthcare Providers Knowledge, Attitude and Practice in Relation to Adverse Drug Reactions Reporting in Oncology Departments in the West Bank

The researcher Rahaf Rimawi, a master's student in the *Quality Management in Health Institutions Program* at the *Arab American University (AAUP)*, is conducting this study to assess the knowledge, attitudes, and practices of healthcare providers toward adverse drug reaction (ADR) reporting in oncology departments across the West Bank. The study also aims to identify barriers to reporting and to examine the relationship between demographic characteristics and the levels of knowledge, attitude, and practice regarding ADR reporting.

This is the **first study of its kind in Palestine** to measure these aspects among healthcare providers in oncology departments. The results will serve as a foundation for developing strategies to improve ADR reporting methods and to ensure the safety of cancer patients in Palestine.

The study follows a **cross-sectional design** using a **structured questionnaire**, which will be completed **once only** and will take approximately **10–15 minutes** to fill in. The information collected will be used **for scientific research purposes only**, and all responses will remain **strictly confidential**. Participation is **voluntary**, and participants may withdraw from the study at any time without giving any reason.

For more information or any inquiries, you may contact the researcher:

✆ **Phone:** +970 598 310 312 ✉ **Email:** rimawi.rahaf@gmail.com

Consent

The nature and objectives of the study have been fully explained.

Based on my understanding of all the information provided, I **voluntarily agree** to participate in the above-mentioned study.

I understand that I can withdraw from the study at any time without providing a reason.

Do you agree to participate?

☐ Yes

☐ No

Section (1) Demographic Data

1)	**Gender**	a) Male b) Female
2)	**Age (years)**	----------
3)	**Academic qualifications**	a) Diploma degree level b) Bachelor's degree level c) Master's degree level d) Residency program e) Specialist
4)	**Specialty**	a) Pharmacist b) Doctor of Pharmacy c) Physician (Consultant) d) Physician (Fellow) e) Physician (Resident) f) Physician (Service physician) g) Daycare Nurse h) Medical Nurse (Internal department nurse)
5)	**Type of contract:**	a) Part time b) Full time
6)	**Work hours per week**	----------
7)	**Number of cancer patients seen daily**	----------
8)	**Your current hospital**	----------
9)	**Experience (total experience inside this hospital and outside)**	a) less than 1 year b) 1-3 years c) 3-5 years d) 5-10years e) More than 10 years
10)	**Experience (in oncology inside this hospital and outside)**	a) less than 1 year b) 1-3 years c) 3-5 years d) 5-10years e) More than 10 years

Section (2) KAP questionnaire (Please put a tick in one box in each row that most closely matches your answer)

I. Knowledge:

#	Item	Yes (1)	No (0)	I don't know
1)	**Pharmacovigilance covers both adverse drug reactions and other drug related problems such as medication errors**			

2)	**Adverse drug reaction (ADR) definition** **2. a) ADR is any noxious or undesired effect of drug occurring at normal dose, during normal use**			
	2. b) ADR is adverse health outcomes associated with inappropriate drug use			
	2. c) ADR is harm resulting from the use of substandard/counterfeit drugs			
	2. d) ADR is harm caused by drug overdose			
	2. e) All can define ADR.			
3)	**The difference between ADR and adverse events is clear to me**			
4)	**Healthcare provider should report ADR within maximum one working day**			
5)	**Once I report an ADR, I forward it to the pharmacy department**			
6)	**I know how to fill the institution ADR reporting form**			
7)	**I know how to assess the severity of reported ADRs**			
8)	**ADR documentation using the institution system is well understood**			
9)	**All serious ADRs are known before a drug is marketed**			
10)	**Is there any center/ADR reporting system in Palestine?**			

II. Attitude:

#	Item	Strongly Agree (5)	Agree (4)	Neutral (3)	Disagree (2)	Strongly Disagree (1)
1)	I believe ADR Reporting is necessary for improving clinical practice					
2)	An ADR database can serve as a trigger for research projects					
3)	I believe only serious ADRs that results in life-threatening conditions should be reported					
4)	Pharmacovigilance should be taught in detail to all health care providers					
5)	Reporting of ADRs is necessary for well recognized adverse drug reactions					
6)	I believe in ADR documentation using institution system					
7)	The institution ADR reporting form is comprehensive and captures required information for further assessment					
8)	I am adequately prepared to report ADRs					
9)	I believe ADR reporting should be mandatory for all Healthcare Providers (HCPs)					
10)	I believe patient should be counselled about adverse drug reactions before dispensing or administering the medications					

III. Practice:

1)	How many ADR cases do you encounter in your practice per week?	…….
2)	How many ADR cases have you actually reported in the last year?	…….
3)	I document reported ADRs in patients' medical file	a) Always (100%) b) Mostly (50-99%)

		c) Sometimes (20-49%) **d) Rarely (1-20%)** **e) Never (0%)**
4)	**I do document only severe adverse reactions**	**a) Yes (1)** **b) No (0)**
5)	**Have you ever been trained on pharmacovigilance and ADR reporting?** **If yes, can you please specify the type of attended training and year?**	**c) Yes (1)** **d) No (0)** **……..**
6)	**Is there any routine discussion on ADRs in your hospital? Explain.**	**……..**
7)	**How often do you give advice to your patients on possible ADRs you prescribed, dispensed or administered**	**a) Always** **b) Usually** **c) Sometimes** **d) Never**
8)	**Where did you send the last reported ADRs?**	**…….**
9)	**How do you report? (Reporting mode)**	**a) Verbally** **b) On a paper reporting form** **c) Online reporting form** **d) Never reported**
10)	**What do you expect from the submitted ADRs? Feedback, publication, nothing? Explain.**	**……** **……** **……**

Section (3) Barriers to ADR reporting and Suggestions for improvement

1) **Which among the following factors discourage you from reporting Adverse Drug Reactions: (you can circle more than one answer)**

l) Do not know reporting rules
m) Lack of time to report Adverse Drug Reactions
n) Fear from legal responsibility.
o) A single unreported case may not affect clinical practice
p) Difficult to decide whether Adverse Reaction has occurred or not
q) Lack of feedback about previously reported Adverse Drug Reactions
r) ADR reporting form is not easily accessible
s) It is not my responsibility to report
t) I haven't been trained to report ADRs
u) ADR reporting negatively affect professional image
v) My institution does not have a reporting system

2) **What are your suggestions to improve ADRs reporting at your hospital? (Please use the below space to write your suggestions)**

……
……
……
……
……
.

Thank you!

Appendix 2: Arabic questionnaire

استبيان الدراسة

عنوان الدراسة: معرفة، مواقف، وممارسات مقدمي الرعاية الصحية فيما يتعلق بالإبلاغ عن التفاعلات الدوائية الضارة في أقسام الأورام في الضفة الغربية

الباحثة رهف الريماوي، طالبة في برنامج الماجستير في إدارة الجودة في المؤسسات الصحية بالجامعة العربية الأمريكية، تجري هذه الدراسة لتقييم معرفة ومواقف وممارسات مقدمي الرعاية الصحية حول الإبلاغ عن التفاعلات الدوائية الضارة (ADRs) في أقسام الأورام بالضفة الغربية، بالإضافة إلى تحديد العوائق التي تمنع الإبلاغ ودراسة العلاقة بين الخصائص الديموغرافية ومستوى المعرفة والمواقف والممارسات تجاه الإبلاغ.

تُعد هذه الدراسة الأولى من نوعها في فلسطين لقياس هذا الجانب بين مقدمي الرعاية الصحية في أقسام الأورام، حيث ستُستخدم نتائجها كأساس لتطوير استراتيجيات تهدف إلى تحسين طرق الإبلاغ عن التفاعلات الدوائية الضارة وضمان سلامة مرضى السرطان في فلسطين.

تعتمد الدراسة على تصميم مقطعي باستخدام استبيان منظم يُعبأ مرة واحدة فقط، ويستغرق ملؤه حوالي 10-15 دقيقة. سيتم استخدام المعلومات التي يتم جمعها لأغراض البحث العلمي فقط، مع ضمان السرية التامة. المشاركة في الدراسة طوعية، ويحق للمشارك الانسحاب في أي وقت دون الحاجة إلى تقديم أسباب.

للحصول على مزيد من المعلومات أو للإجابة على أي استفسارات، يمكنكم التواصل مع الباحثة:

عبر الهاتف: 00972598310312 أو البريد الإلكتروني: rimawi.rahaf@gmail.com

الموافقة:

تم شرح طبيعة وأهداف الدراسة بشكل كامل.

بناءً على معرفتي وفهمي لجميع المعلومات اللازمة لهذه الدراسة، أوافق طوعاً وبإرادتي الحرة على المشاركة في البحث المذكور أعلاه.

وأفهم أنه يمكنني الانسحاب من هذه الدراسة في أي وقت دون إبداء الأسباب.

هل توافق على المشاركة؟

- ○ **نعم**
- ○ **لا**

القسم (1) البيانات الديموغرافية

1)	الجنس	a) ذكر b) أنثى
2)	العمر (سنوات)	----------
3)	المؤهل الأكاديمي	a) الدبلوم b) البكالوريوس c) الماجستير d) برنامج إقامة e) أخصائي
4)	التخصص	a) صيدلي b) دكتور صيدلي c) طبيب (استشاري) d) طبيب (زميل) e) طبيب (مقيم) f) طبيب (طبيب خدمة) g) ممرض عناية نهارية h) ممرض قسم داخلي
5)	نوع العقد	a) دوام جزئي b) دوام كامل
6)	عدد ساعات العمل في الأسبوع	----------
7)	عدد مرضى السرطان الذين تراهم يومياً	----------
8)	المستشفى الذي تعمل به	----------
9)	الخبرة (إجمالي الخبرة داخل هذا المستشفى وخارجه)	a) أقل من سنة b) 1-3 سنوات c) 3-5 سنوات d) 5-10 سنوات e) أكثر من 10 سنوات
10)	الخبرة (في مجال الأورام داخل هذا المستشفى وخارجه)	a) أقل من سنة b) 1-3 سنوات c) 3-5 سنوات d) 5-10 سنوات e) أكثر من 10 سنوات

القسم (2) استبيان المعرفة والمواقف والممارسات (يرجى وضع علامة في مربع واحد في كل صف من الصفوف التي تتطابق مع إجابتك)

I. المعرفة:

الرقم	البند	نعم (1)	لا (0)	لا أعلم
1)	تغطي اليقظة الدوائية كلا من التفاعلات الدوائية الضارة والمشاكل الأخرى المتعلقة بالأدوية مثل أخطاء الادوية			
2)	تعريف التفاعل الدوائي الضار (ADR) 2. a) التفاعل الدوائي الضار هو أي تأثير ضار أو غير مرغوب فيه للدواء يحدث عند تناول الجرعة العادية أثناء الاستخدام العادي			
	2. b) التفاعل الدوائي الضار هو نتائج صحية ضارة مرتبطة بالاستخدام غير المناسب للأدوية			
	2. c) التفاعل الدوائي الضار هو الضرر الناتج عن استخدام الأدوية المقلدة أو دون المستوى			
	2. d) التفاعل الدوائي الضار هو الضرر الناتج عن الجرعة الزائدة			
	2. e) جميع الخيارات السابقة تعرف التفاعل الدوائي الضار			
3)	الفرق بين التفاعلات الدوائية الضارة والأحداث السلبية واضح بالنسبة لي			
4)	يجب على مقدم الرعاية الصحية الإبلاغ عن التفاعل الدوائي الضار في غضون يوم عمل كحد أقصى			
5)	بمجرد أن أقوم بالإبلاغ عن التفاعل الدوائي الضار، أقوم بإرساله إلى قسم الصيدلية			
6)	أعرف كيفية ملء نموذج الإبلاغ عن التفاعل الدوائي الضار الخاص بالمؤسسة			
7)	أعرف كيفية تقييم شدة التفاعلات الدوائية الضارة المبلغ عنها			
8)	توثيق التفاعل الدوائي الضار باستخدام نظام المؤسسة مفهوم بشكل جيد			
9)	جميع التفاعلات الدوائية الضارة الخطيرة معروفة قبل تسويق الدواء			

10)	هل يوجد مركز أو نظام للإبلاغ عن التفاعلات الدوائية الضارة في فلسطين؟			

II. المواقف:

الرقم	البند	أوافق بشدة (5)	أوافق (4)	محايد (3)	لا أوافق (2)	لا أوافق بشدة (1)
1)	أعتقد أن الإبلاغ عن التفاعلات الدوائية الضارة ضروري لتحسين الممارسة السريرية					
2)	يمكن أن تكون قاعدة بيانات التفاعلات الدوائية الضارة محفزا لمشاريع البحث					
3)	أعتقد أنه يجب الإبلاغ فقط عن التفاعلات الدوائية الضارة الخطيرة التي تؤدي إلى حالات مهددة للحياة					
4)	يجب تعليم اليقظة الدوائية بالتفصيل لجميع مقدمي الرعاية الصحية					
5)	الإبلاغ عن التفاعلات الدوائية الضارة ضروري في حالة التفاعلات الدوائية الضارة المعروفة جيدًا					
6)	أؤمن بتوثيق التفاعلات الدوائية الضارة باستخدام نظام المؤسسة					
7)	نموذج الإبلاغ عن التفاعلات الدوائية الضارة في المؤسسة شامل ويجمع المعلومات المطلوبة للتقييم الإضافي					
8)	أنا مستعد بشكل كافٍ للإبلاغ عن التفاعلات الدوائية الضارة					
9)	أعتقد أنه يجب أن يكون الإبلاغ عن التفاعلات الدوائية الضارة إلزاميًا لجميع مقدمي الرعاية الصحية					
10)	أعتقد أنه يجب توعية المريض بالتفاعلات الدوائية الضارة قبل صرف أو إعطاء الأدوية					

III. الممارسات:

1)	كم عدد حالات التفاعلات الدوائية الضارة التي تواجهها في ممارستك أسبوعيا؟	----------
2)	كم عدد حالات التفاعلات الدوائية الضارة التي أبلغت عنها فعليا خلال العام الماضي؟	----------
3)	أقوم بتوثيق التفاعلات الدوائية الضارة المبلغ عنها في الملف الطبي للمريض	a) دائماً (100%) b) غالباً (50-99%) c) أحياناً (20-49%) d) نادراً (1-20%) e) أبداً (0%)
4)	أقوم بتوثيق التفاعلات الضارة الشديدة فقط	a) نعم b) لا
5)	هل سبق أن تلقيت تدريبًا على اليقظة الدوائية والإبلاغ عن التفاعلات الدوائية الضارة؟ اذا كانت الإجابة نعم، يرجى تحديد نوع التدريب الذي حضرته والسنة	a) نعم b) لا ----------
6)	هل توجد مناقشات روتينية حول التفاعلات الدوائية الضارة في المستشفى؟ وضح	----------
7)	كم مرة تقدم المشورة لمرضاك بشأن التفاعلات الدوائية الضارة المحتملة التي وصفتها أو صرفتها أو أعطيتها؟	a) دائماً b) عادةً c) أحياناً d) أبداً
8)	أين أرسلت آخر التفاعلات الدوائية الضارة المبلغ عنها؟	----------
9)	كيف تقوم بالإبلاغ؟ (طريقة الإبلاغ)	a) شفهياً b) باستخدام نموذج ورقي c) باستخدام نموذج إلكتروني d) لم أبلغ أبداً
10)	ماذا تتوقع نتيجة إرسال أو توثيق التفاعلات الدوائية الضارة، التغذية الراجعة، نشر مقال علمي، لا شيء؟ وضح	----------

القسم الثالث: العوائق أمام الإبلاغ عن التفاعلات الدوائية الضارة والاقتراحات للتحسين

1) أي من العوامل التالية يثنيك عن الإبلاغ عن التفاعلات الدوائية الضارة؟ (يمكنك اختيار أكثر من إجابة)

a) لا أعرف قواعد الإبلاغ
b) نقص الوقت للإبلاغ عن التفاعلات الدوائية الضارة
c) الخوف من المسؤولية القانونية
d) حالة واحدة غير مبلغ عنها قد لا تؤثر على الممارسة السريرية
e) صعوبة تحديد إذا كان التفاعل قد حدث أم لا
f) نقص التغذية الراجعة عن الحالات المبلغ عنها سابقاً
g) نموذج الإبلاغ عن التفاعلات الدوائية الضارة غير متاح بسهولة
h) ليس من مسؤوليتي الإبلاغ
i) لم اتدرب على الإبلاغ عن التفاعلات الدوائية الضارة
j) الإبلاغ عن التفاعلات الدوائية الضارة يؤثر سلبا على الصورة المهنية
k) مؤسستي لا تمتلك نظاماً للإبلاغ

2) ما هي اقتراحاتك لتحسين الإبلاغ عن التفاعلات الدوائية الضارة في مستشفاك؟

شكرا لك

Appendix 3: AAUP IRB Approval

Arab American University
Institutional Review Board - Ramallah

الجامعـــة العربيـــة الأمريكيـــة
مجلس اخلاقيات البحث العلمي – رام الله

IRB Approval Letter

Study Title: "Healthcare Providers Knowledge, Attitude and Practice in Relation to Adverse Drug Reactions Reporting in Oncology Departments in the West Bank".

Submitted by: Rahaf Shaher Rimawi

Date received: 19th October 2024

Date reviewed: 29th October 2024

Date approved: 29th October 2024

Your Study titled **"Healthcare Providers Knowledge, Attitude and Practice in Relation to Adverse Drug Reactions Reporting in Oncology Departments in the West Bank"** with the code number **"R-2024/A/154/N"** was reviewed by the Arab American University Institutional Review Board - Ramallah and it was approved on the 29th of October 2024.

الجامعة العربية الأمريكية - فلسطين
مجلس اخلاقيات البحث العلمي - رام الله
IRB-R
ARAB AMERICAN UNIVERSITY-PALESTINE
INSTITUTIONAL REVIEW BOARD - RAMALLAH

Sajed Ghawadra, PhD
IRB-R Chairman
Arab American University of Palestine

General Conditions:

1. Valid for 6 months from the date of approval.
2. It is important to inform the IRB-R with any modification of the approved study protocol.
3. The Bord appreciates a copy of the research when accomplished.

رام الله – فلسطين

Tel: 02-294-1999 **E-Email:** IRB-R@aaup.edu **Website:** www.aaup.edu

Appendix 4: MoH Hospitals Approval

State of Palestine
Ministry of Health
Education in Health and Scientific
Research Unit

دولة فلسطين
وزارة الصحة
وحدة التعليم الصحي
والبحث العلمي

Ref.: .....
Date:.....

الرقم: ....C.CO/٦٢٧/١٤....
التاريخ: ....C.CO....١٠/٠٧/٢٠١٨....

الأخ مدير عام الادارة العامة للمستشفيات المحترم،،،

تحية واحترام،،

الموضـــوع: تسهيل مهمة بحث

يرجى تسهيل مهمة **الطالبة: رهف شاهر ريماوي- ماجستير برنامج ادارة الجودة/ الجامعة العربية الامريكية**، في عمل بحث تحت اشراف د. شهناز النجار، بعنوان:

Healthcare Providers Knowledge, Attitude and Practice in Relation to Adverse Drug Reactions Reporting in Oncology Departments in the West Bank

من خلال السماح للطالبة بجمع معلومات عن طريق توزيع استبانة على الاطباء والممرضين، وذلك في:

- جميع المستشفيات الحكومية في الضفة الغربية

على ان يتم الالتزام باساليب واخلاقيات البحث العلمي، وعدم التعرض للمعلومات التعريفية للمشاركين .

على ان يتم تزويد الوزارة بنسخة PDF من نتائج البحث، التعهد بعدم النشر لحين الحصول على موافقة الوزارة على نتائج البحث.

مع الاحترام،،

د. عبد الله القواسمي
رئيس وحدة التعليم الصحي والبحث العلمي

نسخة عميد كلية الدراسات العليا المحترمة /الجامعة العربية الامريكية

Telfax.:09-2333901 scientificresearch.dep@gmail.com تلفاكس: 09-2333901

Appendix 5: IAH Ethical Approval

المستشفى الإستشاري العربي
ISTISHARI ARAB HOSPITAL
أكثر من مجرد مستشفى

IAH Research Application Form

Date	March 12th 2025
Name of investigator	Rahaf Rimawi
Mobile No.	+972598310312
Email	Rimawi.rahaf@gmail.com
Expected start date	March 15th 2025
Expected completion date	April 15th 2025
Name of Company/University	Arab American University
Attached needed	
Investigator CV	☑Yes ☐No
Study Proposal	☑Yes ☐No
Consent Form	☑Yes ☐No
Data Collection Tools	☑Yes ☐No
Informed Consent (Arabic & English)	☑Yes ☐No
For HR Department	
Receiving Date	13/3/2025
Application completed	☑Yes ☐No
Transfer Date	13/3/2025
Educational Officer Signature	
For Ethical Committee	
Receiving Date	
Ethical Committee Approval	☑Yes ☐No
Ethical Committee Note	Approved.
Head of Ethical committee Sig.	
CEO Note	OK
CEO Sig.	19/3/2025

- For Non-Experimental Research only

Code:GLD.12.2/1	Type: NC / 01	Issue No.: 01/02	Issue Date: 20/06/2022

Appendix 6: NNUH Approval Letter

مستشفى النجاح الوطني الجامعي
An - NaJah National University Hospital

مركز البحث العلمي السريري
Clinical Research Centre

CLINICAL RESEARCH CENTER
BETTER CARE THROUGH RESEARCH!

Approval date: 2025-03-17
Ref: CRC_2025_0487

Subject: Approval to conduct a research project at An-Najah National University Hospital

Dear Mrs. Rahaf Rimawi,

I am writing this letter to grant you permission to conduct your research project titled "Healthcare Providers Knowledge, Attitude and Practice in Relation to Adverse Drug Reactions Reporting in Oncology Departments in the West Bank". I hope your study will provide new insights and contribute the advancement of knowledge and evidence. Furthermore, I would like to emphasize the importance of adhering to the ethical guidelines set forth by the hospital throughout the research process.

On behalf of An-Najah National University Hospital, I extend my best wishes and support for your research endeavors.

Sincerely,

Sa'ed H. Zyoud, Ph.D.
Clinical Toxicology
Director of Clinical Research Center

الإدارة الطبية
NNUH
Medical Management

CC:
Chief Medical Officer
Chief Nursing Officer

Note: this approval letter is not valid unless signed and stamped by the CRC and the Chief Medical Officer of An-Najah National University Hospital

Appendix 7: Table A1

Table A1: Distribution of Knowledge, Attitude, Practice and Overall KAP Adequacy by Demographic and Professional Categories (N = 180)

Variable	Label	Knowledge		Attitude		Practice		KAP	
		Adequate	Inadequate	Adequate	Inadequate	Adequate	Inadequate	Adequate	Inadequate
Gender	Female	38 (43.2)	50 (56.8)	82 (93.2)	6 (6.8)	14 (15.9)	74 (84.1)	71 (80.7)	17 (19.3)
	Male	26 (28.3)	66 (71.7)	83 (90.2)	9 (9.8)	19 (20.7)	73 (79.3)	77 (83.7)	15 (16.3)
Age	20–29	27 (40.3)	40 (59.7)	62 (92.5)	5 (7.5)	18 (26.9)	49 (73.1)	60 (89.6)	7 (10.4)
	30–39	21 (31.8)	45 (68.2)	61 (92.4)	5 (7.6)	9 (13.6)	57 (86.4)	51 (77.3)	15 (22.7)
	40–49	5 (21.7)	18 (78.3)	20 (87.0)	3 (13.0)	1 (4.3)	22 (95.7)	15 (65.2)	8 (34.8)
	50+	5 (41.7)	7 (58.3)	12 (100.0)	0 (0.0)	1 (8.3)	11 (91.7)	11 (91.7)	1 (8.3)
	missing	6 (50.0)	6 (50.0)	10 (83.3)	2 (16.7)	4 (33.3)	8 (66.7)	11 (91.7)	1 (8.3)
Working Hours	≤40	15 (27.3)	40 (72.7)	51 (92.7)	4 (7.3)	2 (3.6)	53 (96.4)	40 (72.7)	15 (27.3)
	41–59	47 (42.0)	65 (58.0)	102 (91.1)	10 (8.9)	28 (25.0)	84 (75.0)	100 (89.3)	12 (10.7)
	≥60	2 (15.4)	11 (84.6)	12 (92.3)	1 (7.7)	3 (23.1)	10 (76.9)	8 (61.5)	5 (38.5)
Patients Daily	≤10	16 (35.6)	29 (64.4)	39 (86.7)	6 (13.3)	9 (20.0)	36 (80.0)	36 (80.0)	9 (20.0)
	11–19	28 (45.2)	34 (54.8)	58 (93.5)	4 (6.5)	14 (22.6)	48 (77.4)	52 (83.9)	10 (16.1)
	≥20	20 (27.4)	53 (72.6)	68 (93.2)	5 (6.8)	10 (13.7)	63 (86.3)	60 (82.2)	13 (17.8)
Qualification	Diploma/Bachelor	48 (39.3)	74 (60.7)	111 (91.0)	11 (9.0)	26 (21.3)	96 (78.7)	101 (82.8)	21 (17.2)
	Master	13 (39.4)	20 (60.6)	31 (93.9)	2 (6.1)	7 (21.2)	26 (78.8)	28 (84.8)	5 (15.2)
	Residency/Specialist	3 (12.0)	22 (88.0)	23 (92.0)	2 (8.0)	0 (0.0)	25 (100.0)	19 (76.0)	6 (24.0)
Specialty	Physician	5 (12.2)	36 (87.8)	39 (95.1)	2 (4.9)	3 (7.3)	38 (92.7)	33 (80.5)	8 (19.5)
	Pharmacist	7 (26.9)	19 (73.1)	25 (96.2)	1 (3.8)	2 (7.7)	24 (92.3)	15 (57.7)	11 (42.3)
	Nurse	52 (46.0)	61 (54.0)	101 (89.4)	12 (10.6)	28 (24.8)	85 (75.2)	100 (88.5)	13 (11.5)
Hospital	Al-Watani (Nablus)	6 (31.6)	13 (68.4)	17 (89.5)	2 (10.5)	0 (0.0)	19 (100.0)	13 (68.4)	6 (31.6)
	An-Najah (Nablus)	41 (48.8)	43 (51.2)	75 (89.3)	9 (10.7)	22 (26.2)	62 (73.8)	71 (84.5)	13 (15.5)

	Istishari (Ramallah)	8 (32.0)	17 (68.0)	25 (100.0)	0 (0.0)	7 (28.0)	18 (72.0)	24 (96.0)	1 (4.0)
	Other	9 (17.3)	43 (82.7)	48 (92.3)	4 (7.7)	4 (7.7)	48 (92.3)	40 (76.9)	12 (23.1)
Total Experience	<1 year	3 (25.0)	9 (75.0)	12 (100.0)	0 (0.0)	2 (16.7)	10 (83.3)	12 (100.0)	0 (0.0)
	1–3 years	10 (29.4)	24 (70.6)	32 (94.1)	2 (5.9)	11 (32.4)	23 (67.6)	29 (85.3)	5 (14.7)
	3–5 years	10 (38.5)	16 (61.5)	23 (88.5)	3 (11.5)	2 (7.7)	24 (92.3)	20 (76.9)	6 (23.1)
	5–10 years	17 (37.0)	29 (63.0)	43 (93.5)	3 (6.5)	7 (15.2)	39 (84.8)	37 (80.4)	9 (19.6)
	>10 years	24 (38.7)	38 (61.3)	55 (88.7)	7 (11.3)	11 (17.7)	51 (82.3)	50 (80.6)	12 (19.4)
Oncology Experience	<1 year	12 (29.3)	29 (70.7)	36 (87.8)	5 (12.2)	5 (12.2)	36 (87.8)	33 (80.5)	8 (19.5)
	1–3 years	14 (33.3)	28 (66.7)	40 (95.2)	2 (4.8)	10 (23.8)	32 (76.2)	34 (81.0)	8 (19.0)
	3–5 years	9 (27.3)	24 (72.7)	31 (93.9)	2 (6.1)	2 (6.1)	31 (93.9)	26 (78.8)	7 (21.2)
	5–10 years	19 (46.3)	22 (53.7)	39 (95.1)	2 (4.9)	9 (22.0)	32 (78.0)	36 (87.8)	5 (12.2)
	>10 years	10 (43.5)	13 (56.5)	19 (82.6)	4 (17.4)	7 (30.4)	16 (69.6)	19 (82.6)	4 (17.4)

Appendix 8: Table A2

Table A2: Annualized ADR Encounter Rates (×52) and Annual ADR Reporting by Practitioner Demographics and Professional Characteristics

Characteristic		Annualized ADR Encountered Cases	Actual ADR cases Reported
		Mean (±SD)	
Gender	Female	56.1 (± 99.5)	3.2 (± 11.5)
	Male	96.1 (± 233.4)	5.7 (± 22.6)
Age	20–29	72.2 (± 134.9)	3.5 (± 10.0)
	30–39	94.5 (± 231.6)	5.0 (± 13.6)
	40–49	54.3 (± 65.5)	0.8 (± 1.5)
	50+	91.0 (± 299.2)	19.1 (± 60.0)
Working Hours	≤40	70.9 (± 116.4)	4.6 (± 14.8)
	41–59	67.8 (± 187.4)	4.0 (± 19.6)
	≥60	176.0 (± 305.8)	7.9 (± 17.3)
Patients seen daily	≤10	31.2 (± 43.5)	1.1 (± 2.1)
	11–19	54.5 (± 105.0)	1.4 (± 2.1)
	≥20	123.2 (± 259.6)	9.3 (± 28.0)
Qualification	Diploma/Bachelor	72.0 (± 162.0)	5.4 (± 21.3)
	Master	48.8 (± 60.9)	2.3 (± 4.5)
	Residency/Specialist	135.2 (± 321.6)	2.9 (± 10.3)
Specialty	Physician	150.9 (± 300.9)	6.4 (± 17.1)
	Pharmacist	50.0 (± 61.5)	2.4 (± 4.7)
	Nurse	55.7 (± 129.6)	4.3 (± 20.4)
Hospital	Al-Watani (Nablus)	65.7 (± 176.6)	1.5 (± 1.7)
	An-Najah (Nablus)	52.0 (± 120.8)	1.5 (± 3.5)
	Istishari (Ramallah)	54.1 (± 64.5)	3.5 (± 5.4)
	Other	131.0 (± 272.9)	10.9 (± 32.7)
Total Experience	<1 year	30.3 (± 46.8)	0.1 (± 0.3)
	1–3 years	68.8 (± 63.6)	5.6 (± 13.5)
	3–5 years	94.0 (± 202.2)	1.9 (± 4.1)
	5–10 years	73.5 (± 131.8)	3.3 (± 11.3)
	>10 years	84.7 (± 252.5)	6.7 (± 27.4)
	<1 year	40.6 (± 50.0)	1.2 (± 2.6)

Oncology Experience	1–3 years	92.9 (± 196.1)	4.5 (± 12.6)
	3–5 years	63.0 (± 68.5)	4.1 (± 13.2)
	5–10 years	110.3 (± 270.7)	4.6 (± 12.3)
	>10 years	70.1 (± 214.8)	10.9 (± 42.5)

عنوان الرسالة: معرفة، مواقف، وممارسات مقدمي الرعاية الصحية فيما يتعلق بالإبلاغ عن التفاعلات الدوائية الضارة في أقسام الأورام في الضفة الغربية

اسم الطالب الرباعي: رهف شاهر هلال ريماوي

أسماء لجنة الاشراف: : د. شاهيناز نجار، د. هاني شتية، د. يوسف ميمي

ملخص

الخلفية: تُعدّ سلامة المرضى من أهمّ الشواغل في مجال الرعاية الصحية، حيث تلعب اليقظة الدوائية دورًا محوريًا في ضمان سلامة الأدوية. تُثير التفاعلات الدوائية الضارة، وهي أحد الشواغل الرئيسية لليقظة الدوائية، قلقًا بالغًا في مجال طب الأورام، حيث يتعرض 87% من المرضى لتفاعلاتٍ دوائية ضارة، مما يُسلّط الضوء على سمّية علاجات السرطان ومدى هشاشة هؤلاء المرضى. على الرغم من الدور الأساسي لمُقدّمي الرعاية الصحية في اليقظة الدوائية، إلا أن ضعف الإبلاغ عن التفاعلات الدوائية الضارة لا يزال مصدر قلقٍ كبيرٍ على الصعيدين العالمي والمحلي، وخاصةً في فلسطين، حيث لا تزال البنية التحتية لليقظة الدوائية في مراحلها التنموية.

الهدف: هدفت هذه الدراسة إلى دراسة معرفة مُقدّمي الرعاية الصحية ومواقفهم وممارساتهم تجاه اليقظة الدوائية والإبلاغ عن التفاعلات الدوائية الضارة في أقسام الأورام في جميع أنحاء الضفة الغربية، بالإضافة إلى تحديد العوائق والعوامل المؤثرة المرتبطة بسلوك الإبلاغ عن التفاعلات الدوائية الضارة.

المنهجية: أُجريت دراسة وصفية مقطعية على 250 طبيبًا وممرضًا وصيدليًا يعملون في أقسام الأورام في ثمانية مستشفيات بالضفة الغربية. جُمعت البيانات في نيسان 2025 باستخدام استبيان مُهيكل ذاتي الإدارة، شمل الخصائص الديموغرافية، والمعرفة، والمواقف، والممارسات المتعلقة بالإبلاغ عن التفاعلات الدوائية الضارة، والعوائق المُتصوَّرة. استُخدمت الإحصاءات الوصفية والاستنتاجية لتحليل البيانات.

النتائج: تشير النتائج إلى وجود قصور كبير في المعرفة، حيث حقق 35.6% فقط من المشاركين معيار الكفاءة ≤ 80%. في المقابل، أظهر أكثر من 91% من المشاركين مواقف إيجابية تجاه الإبلاغ عن التفاعلات الدوائية الضارة، مما يحد من إمكانية الكشف عن تأثير المعرفة المتزايدة على المواقف أو الممارسات، نتيجة تأثر السقف الإحصائي. بالكاد استوفى 18.3% من المشاركين المعايير المحددة لممارسات الإبلاغ الكافية. كانت أكثر العوائق شيوعًا المذكورة هي نقص التدريب،

والخوف من العواقب القانونية المحتملة، وضعف أنظمة الإبلاغ المؤسسية، والقيود الزمنية. تم تحديد ارتباطات ذات دلالة إحصائية بين مستويات المعرفة والمواقف والممارسات (KAP) ومتغيرات مثل المهنة، وسنوات الخبرة، والتدريب السابق، والدعم المؤسسي.

الخلاصة: توجد فجوة كبيرة في مشاركة ممارسي الرعاية الصحية في مجال اليقظة الدوائية في فلسطين. وتؤكد النتائج على ضرورة إطلاق مبادرات تعليمية مركزة، ووضع لوائح مؤسسية قوية، ودمج التدريب على اليقظة الدوائية في برامج التثقيف الصحي. وتُعد معالجة هذه النواقص أمرًا بالغ الأهمية لضمان إجراءات علاجية آمنة في مجال الأورام وتحسين نتائج المرضى.

الكلمات المفتاحية: اليقظة الدوائية، التفاعلات الدوائية الضارة، الأورام، مقدمو الرعاية الصحية، فلسطين.