

**GENERAL PUBLIC VIEWS, ATTITUDES AND
EXPERIENCES TOWARDS DRUG SAFETY AND
PHARMACOVIGILANCE RELATED ISSUES IN
DUBAI-UAE**

BY

DOAA KAMAL EDDIN ALKHALIDI

A thesis submitted in fulfillment of the requirement for the
degree of Doctor of Philosophy in Pharmaceutical Sciences
(Pharmacy Practice)

**Kulliyyah of Pharmacy
International Islamic University Malaysia**

JULY 2020

ABSTRACT

Ensuring drug safety among the public is the cornerstone of pharmacovigilance practice. Literature agreed that the engagement of medication consumers into pharmacovigilance practices is crucial. Currently, there is limited public contribution to the current system in the UAE. Therefore, this study has aimed to identify Dubai's public views, attitudes, and experiences regarding medication safety and ADR reporting procedures. The current study adopted a mixed-method approach, which was conducted through three different phases. The first phase was qualitative in which a semi-structured interview guide was used. Fourteen face-to-face in-depth interviews were carried out from September to October 2017 with individuals from the general public. The sample was selected purposively using the snowball sampling technique. The interviews were conducted at different locations in Dubai, and they have been recorded, transcribed verbatim, and thematically analysed for data analysis. The emergent themes and subthemes found gaps in the public's perspective of medication's safety, which may consequently impact their attitudes during the course of medication use. The second phase was quantitative. A cross-sectional study was conducted at different public areas in Dubai from February to May 2018. A self-administered questionnaire was developed, validated, and piloted. A convenient sample of 400 individuals from the general public was recruited manually. The collected questionnaires were anonymously analysed. The obtained results have shown that participants pose various views and attitudes toward medication safety, where the majority (67.3%) of the participants had defined adverse drug reactions as the side effects of medicines, whereas only 8% have included drug interaction as part of their answer. It was noticed that (71.5%) of the respondents had agreed that the side effects of the medicines were not limited to high doses of medicine only. More than (65%) showed positive views regarding the risk of duplicating therapies. Only (15.8%) of the participants documented their awareness of the current ADR reporting system in UAE. The chi-square test found a significant difference ($P < 0.01$) between males (41.1%) compared to females (26.8%) in the preference of the use of the telephone to report ADRs. Finally, the third phase analysed the pharmacovigilance unit database within 2013 - 2018. The extracted data showed 931 ADRs were reported, of which 69.7% were spontaneously reported and 47.2% were serious ADRs. Moreover, data has shown that the consumers' actual contribution was 20% of the total reported ADRs in UAE. Finally, current research has concluded that there are significant gaps in the public's views regarding medication safety, which consequently may impact patients' attitudes during the course of medication use. Efforts are to be strengthened to enhance the public's awareness of medication safety and ADR reporting in the UAE.

خلاصة البحث

يعد ضمان الأمان الدوائي حجر الزاوية في ممارسات اليقظة الدوائية وقد اتفقت المراجع على أن مشاركة مستهلكي الدواء في ممارسات اليقظة الدوائية أمر هام. تنحصر المشاركة العامة حاليًا في هذا النظام في الإمارات، ولهذا تهدف هذه الدراسة على التعرف على توجهات العامة وخبراتهم فيما يخص السلامة الدوائية وإجراءات الإبلاغ عن الآثار الجانبية في دبي. تبنت الدراسة الحالية نهجًا خليطًا، تمثلت خطواته في ثلاث مراحل. كانت المرحلة الأولى نوعية، تضمنت إجراء 14 مقابلة تفصيلية شخصية فيما بين سبتمبر وأكتوبر 2017، حيث اتبعت خطوات دليل موثوقية المقابلات، واختيرت العينة عمدًا بتقنية كرة الثلج لتحديد العينات. أجريت المقابلات في مواقع مختلفة من دبي، وسجلت، وفرغت، وحللت بياناتها نصًا وموضوعًا. وقد كشفت موضوعاتها الأساسية والفرعية عن فجوة في منظور العامة للأمان الدوائي، وهو ما يؤثر على توجهاتهم خلال استخدام الدواء. وكانت المرحلة الثانية كمية، حيث أجريت دراسة استقصاء مقطعي في عدة أماكن عامة مختلفة من دبي فيما بين فبراير إلى مايو 2018. صمم استبيان يجاب ذاتيًا، ودرست موثوقيته، وجرب، ثم وزع على عينة مكونة من 400 فرد للإجابة عليه. لم تُعرّف شخصيات مجيبي الاستبيان، وحللت البيانات المجموعة إحصائيًا. أظهرت نتائج الدراسة اختلاف وجهات نظر المشاركين وتوجهاتهم تجاه مأمونية الدواء، حيث وضع الغالبية (67.3%) أن تعريف الآثار الجانبية يشمل الآثار الجانبية للدواء فقط، في حين أشار (8%) منهم إلى التفاعلات الدوائية باعتبارها جزء من الإجابة. ولوحظ اتفاق (71.5%) من المشاركين على أن الآثار الجانبية للدواء لا تنحصر في الجرعات المرتفعة فقط، وأظهر (45.3%) اعتقادهم بأن الأدوية العشبية والمكملات الغذائية غير مضرّة. وفي المقابل أظهر (65%) توجهًا إيجابيًا بشأن مخاطر الازدواج الدوائي، في حين انحصرت معرفة المشاركين في الدراسة بنظام تسجيل الآثار الجانبية الحالي في الإمارات على نسبة (15.8%). أشار التحليل الإحصائي إلى وجود فرقًا ملحوظًا بين الذكور (41.1%) مقارنة بالإناث (26.8%) في تفضيل استخدام الهاتف للإبلاغ عن التفاعلات العكسية للدواء. وأخيرًا، قامت المرحلة الثالثة بتحليل قاعدة بيانات وحدة اليقظة الدوائية خلال 2013-2018. أظهرت البيانات المستخلصة 931 تقريرًا في هذا الخصوص. وكشفت الدراسة أنه قد تم الإبلاغ عن 69.7% من تلك التقارير بشكل تلقائي و 47.2% من التقارير المبلغ عنها كانت خطيرة. علاوة على ذلك، أظهرت البيانات أن مساهمة المستهلكين الفعلية كانت 20% من إجمالي التفاعلات المبلغ عنها في الإمارات العربية المتحدة. أخيرًا، خلص البحث الحالي إلى وجود فجوة كبيرة في وجهات النظر العامة فيما يتعلق بسلامة الأدوية، والتي قد تؤثر بالتالي على مواقف المرضى أثناء استخدام الدواء وأنه يجب تعزيز الجهود لزيادة الوعي العام بسلامة الأدوية ونظام الإبلاغ عن الآثار الجانبية والتفاعلات العكسية للدواء في دولة الإمارات العربية المتحدة.

APPROVAL PAGE

The thesis of Doaa Kamal Eddin Alkhalidi has been approved by the following:

Shazia Jamshed
Supervisor

Aznan Bin Md Aris
Chairman of Supervisory Committee

Ramadan Elkalmi
Co-Supervisor

Mirza Baig
Co-Supervisor

Azmi Hassali
Co-Supervisor

Che Suraya Mohd Zin
Internal Examiner

Mohd B. Makmor Bakry
External Examiner

Zainol Akbar Bin Zainal
External Examiner

Zulfaezal bin Che Azemin
Chairperson



DECLARATION

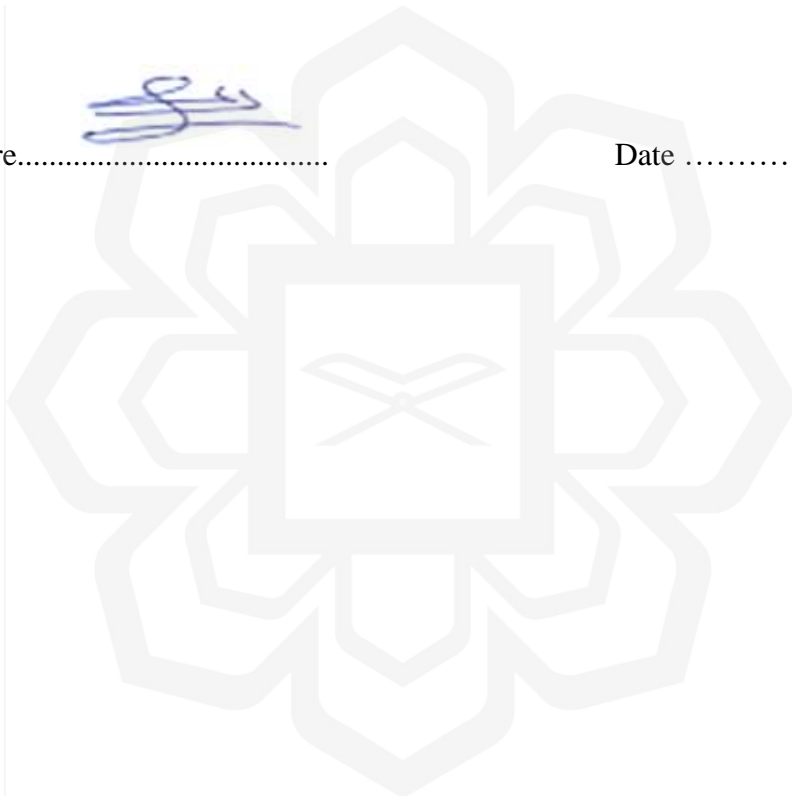
I hereby declare that this thesis is the result of my own investigations, except where otherwise stated. I also declare that it has not been previously or concurrently submitted as a whole for any other degrees at IIUM or other institutions.

Doaa Kamal Eddin Alkhalidi

Signature.....



Date



INTERNATIONAL ISLAMIC UNIVERSITY MALAYSIA

**DECLARATION OF COPYRIGHT AND AFFIRMATION OF
FAIR USE OF UNPUBLISHED RESEARCH**

**GENERAL PUBLIC VIEWS, ATTITUDES AND EXPERIENCES
TOWARDS DRUG SAFETY AND PHARMACOVIGILANCE
RELATED ISSUES IN DUBAI-UAE**

I declare that the copyright holder of this thesis are jointly owned by the student and IIUM.

Copyright © 2020 Doaa Kamal Eddin Alkhalidi and International Islamic University Malaysia. All rights reserved.

No part of this unpublished research may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording or otherwise without prior written permission of the copyright holder except as provided below

1. Any material contained in or derived from this unpublished research may only be used by others in their writing with due acknowledgement.
2. IIUM or its library will have the right to make and transmit copies (print or electronic) for institutional and academic purpose.
3. The IIUM library will have the right to make, store in a retrieval system and supply copies of this unpublished research if requested by other universities and research libraries.

By signing this form, I acknowledged that I have read and understand the IIUM Intellectual Property Right and Commercialization policy.

Affirmed by Doaa Kamal Eddin AlKhalidi



.....

Signature

.....

Date

DEDICATION

I am dedicating this thesis to:

*My great parents who have raised me to be the person I am today and whose prayers
let me reach this point.*

*My wonderful mother and father in law for their great support in my postgraduate
studies.*

*My soulmate and partner of my life Yazid for his infinite help, favors, merits and
patience.*

*My beloved son Rakan who inspired me during this journey with his enthusiastic
words “mom, please don’t give up”.*

My lovely sweetie Lina who has granted me all types of supports.

My sweetheart Layan whose smiles and talks motivated me to extremities.

*My amazing supporters in life brothers and sisters: Anas, Mohammad, Amani, Abeer,
Budoor, Salma and Hind.*

My dear sisters in law for their kind help during my absence at home.

ACKNOWLEDGEMENTS

I thank ALMIGHTY ALLAH Subhanahu Wa-Ta'ala for blessing me to complete this work and creating the reasons towards facilitating all tasks.

I profoundly would like to express my grateful thanks to my supervisor Assistant Prof. Dr. Shazia Jamshed for her constant support, her continuous advice, immense knowledge and patience throughout my PhD journey. Her supervision and guidance helped me in all times of the research work. I have been extremely blessed to have a supervisor who cared extensively about my research work and responded my questions promptly.

My heartfelt thanks to my co-supervisors: Dr. Ramadan Elkalmi for the informative start and the first glance of the current research, Prof. Mirza R. Baig and Prof. Azmi Hassali for the insightful comments and contributions. Thanks to all my respected supervisors for their continued help and guidance.

My sincere gratitude also goes to Prof. Saeed A. Khan, Dean of Dubai Pharmacy College for the kind support and unlimited encouragement throughout my PhD study. Without his precious support, I would not be able to continue and complete it. His encouragement was the major inspiration to overcome all obstacles and to reach this stage.

I also offer my sincere thanks to His Excellency Dr. Amin Hussein Al Amiri, Assistant Undersecretary for Public Health Policy and Licensing Sector in the UAE's Ministry of Health and Prevention for his kind approval of sharing PV unit data. In addition, I would like to thank Dr. Katya Ailabouni, the pharmacovigilance officer for her coordination in sharing the required data.

I would like to thank Prof. Amina Mahdy (International School of Medicine, Medipol University), Prof. Mayyada Wazaify (University of Jordan), Dr. Juliana Roos (former associate professor in Dubai Pharmacy College) Dr. Eman Abu-Gharbieh (University of Sharjah), and Dr. Amira Said (Al Ain University of Science and Technology) for their valuable advices in developing the interview guide and validating the questionnaire.

Finally, I would like to thank Sr Nur Syuhaiha, Sr Nurul Shahida and Sr W. N. Shaheeda for their full help in the administrative tasks. Thanks to my colleagues: Rana Sammour, Samah Hamed, Adeel Aslam, Eman Diab and Sabaa Al Jasmi for their times that they dedicated me in discussions and suggestions to accomplish this work.

TABLE OF CONTENTS

Abstract	ii
Abstract in Arabic	iii
Approval Page	iv
Declaration	vi
Dedication	viii
Acknowledgements	ix
Table of Contents	x
List of Tables	xvi
List of Figures	xviii
Operational Definitions	xix
List of Abbreviations	xx

CHAPTER ONE: INTRODUCTION

1.1 Background of Study	1
1.1.1 Medication Safety and Pharmacovigilance	1
1.1.2 Importance of Pv	2
1.1.3 Global Challenges of Medication Safety And Pv	2
1.1.4 Seriousness of Unsafe Medication Practice	3
1.1.5 The Public (Medications Consumers) as A Partner	3
1.2 Health Care in United Arab Emirates (Dubai)	4
1.2.1 A Brief about the Country	4
1.2.2 Healthcare Regulatory Authorities in the Uae	5
1.3 Pv System in Uae	5
1.3.1 Adr Reporting in Uae	7
1.4 Statement of the Problem	8
1.5 Research Objectives	9
1.6 Research Questions	9
1.7 Research Hypotheses	9
1.8 Rationale of the Study	10

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction	11
2.2 Drug Safety among the Public	13
2.2.1 Assessment/Evaluation of Medication Safety among the Public	14
2.2.2 Patient Involvement	18
2.2.3 Drug Safety Topics of Concern	21
2.2.3.1 Relevant Definitions	21
2.2.3.2 Causes of Undesirable Effects of the Medications	22
2.2.3.3 Therapy Duplication and Drug Interactions	22
2.2.3.4 General Medication Safety Issues	23
2.2.3.5 The National Adr Reporting System	23

2.2.3.6	Attitudes and Experiences of Adr among the Public	24
2.2.4	Promoting the Role of Medication Consumers in Drug Safety and Pv System	24
2.2.4.1	Summary of Reviewed Studies from Different Regions	27
2.2.4.1.1	Studies from Developed Countries	27
2.2.4.1.2	Studies from Developing Countries	28
2.2.5	Highlights from Developed and Developing Countries	41
2.2.5.1	Patients' Awareness, Knowledge and Barriers towards Adrs Reporting	41
2.2.5.2	Patients Knowledge or Awareness towards Adr Reporting in Developed Countries	41
2.2.5.3	Patients Knowledge or Awareness towards Adr Reporting from Developing Countries	42
2.2.5.4	Who is to Report Adr and to Whom and The Location of Adr Reporting Centre.....	42
2.2.5.5	Awareness on Reporting Procedure and Reporting Form	43
2.2.5.6	Awareness about the Importance of Adrs Reporting	44
2.2.5.7	Severity of Adrs and Reporting	45
2.2.6	Worldwide Shortage of Patients and Public Adr Reporting	46
2.2.7	Conclusion	47

CHAPTER THREE: METHODOLOGY..... 49

3.1	Introduction	49
3.2	Research Methodology	49
3.3	First Phase: Qualitative Method	50
3.3.1	Sampling Design	52
3.3.1.1	Sampling Process / Technique	52
3.3.1.2	Study Population	53
3.3.1.2.1	Inclusion Criteria.....	53
3.3.1.2.2	Sample Size	54
3.3.2	Data Collection	54
3.3.2.1	Preparation for Interviews	54
3.3.2.2	Interviews.....	55
3.3.2.3	Development of the Interview Guide (Ig).....	56
3.3.2.4	Validation of the Interview Guide	57
3.3.2.5	Interviewing he Participants Aand Data Collection	57
3.3.2.6	Data Analysis	58
3.3.2.6.1	Transcribing and Checking	58
3.3.2.6.2	Coding	58
3.3.2.6.3	Theming	59
3.3.2.7	Data Validity and Reliability	59
3.4	Second Phase: Quantitative Method.....	60
3.4.1	Survey Research	61
3.4.1.1	Questionnaire	62
3.4.1.1.1	Selection of the Questionnaire Type	62
3.4.1.1.2	Development of the Questionnaire.....	63
3.4.1.1.3	Questionnaire Translation Process	64

3.4.1.1.4	Piloting of the Questionnaire.....	65
3.4.1.2	Validity and Reliability.....	66
3.4.1.2.1	Types of Validity in the Current Study	66
3.4.1.2.1.1	Content Validity.....	66
3.4.1.2.1.2	Face Validity.....	67
3.4.1.2.2	Reliability	68
3.4.1.3	Sampling Design in the Current Quantitative Research	68
3.4.1.3.1	Sample Size	68
3.4.1.3.2	Sampling Technique.....	69
3.4.1.3.3	Inclusion and Exclusion Criteria	70
3.4.1.4	Data Collection	71
3.4.1.4.1	Data Collection Site	71
3.4.1.4.2	Data Collection Procedure.....	71
3.4.1.5	Data Analysis	72
3.5	Third Phase: Data Collection from Pharmacovigilance Unit in Dubai.....	73
3.5.1	Study Setting	73
3.5.2	Study Design	74
3.5.3	Data Analysis.....	76
3.6	Ethical Considerations	76
CHAPTER FOUR: QUALITATIVE PHASE.....		78
4.1	Introduction.....	78
4.1.1	Objectives of the Study	79
4.1.1.1	General.....	79
4.1.1.2	Specific	79
4.2	Methodology	79
4.2.1	Sampling and Recruitment	80
4.2.2	Data Collection and Analysis	80
4.3	Results.....	81
4.3.1	Demographic Data.....	81
4.3.2	First Theme: Views about Medication Safety	83
4.3.2.1	Sub-Theme 1: Perceptions about Medication Safety- Related Terms	83
4.3.2.2	Sub-Theme 2: Thoughts Towards Safe Use of Medications	84
4.3.2.3	Sub-Theme 3: Drug-Safety-Related Issues in the Uae Community.....	85
4.3.3	Second Theme: Attitudes towards Drug-Safety-Related Issues.....	87
4.3.3.1	Sub-Theme 1: Reading Patients' Information Leaflets.....	87
4.3.3.2	Sub-Theme 2: A Public Approach towards Drugs Interactions	88
4.3.3.3	Sub-Theme 3: Inappropriate Self-Medication Practice	89
4.3.3.4	Sub-Theme 4: Drug's Cost–Safety Relationship	91
4.3.4	Third Theme: Experiences towards Newly Discovered Risks of Marketed Medicines	91
4.3.4.1	Sub-Theme 1: A Mixture of Justifications and Arguments Regarding the Newly Realised Undesirable Effects of an Existing Medicine.....	91

4.3.4.2	Sub-Theme 2: Willingness of Knowing about the New Side Effects	92
4.3.4.3	Sub-Theme 3: Discontinuation of the Medication with A Newly Discovered Risk.....	92
4.3.5	Fourth Theme: Main Source of Drug-Safety-Related Information	93
4.3.5.1	Sub-Theme: Physicians and Pharmacists Are the Best Sources despite Some Obstacles	93
4.4	Discussion	93
4.4.1	Participants' Perceptions towards Definitions of Some Related Terms	94
4.4.2	Views and Attitudes towards Drug Interactions.....	95
4.4.3	Drug Safety Related Issues in Uae Community	95
4.4.4	Inappropriate Self-Medication Practice.....	96
4.4.5	Misbelief of Drug's Cost-Safety Relationship	98
4.4.6	Post Marketing Developed Adrs.....	98
4.4.7	Sources of Drug Safety Related Information	99
4.5	Conclusion	100
CHAPTER FIVE: QUANTITATIVE PHASE		101
5.1	Introduction	101
5.1.1	Objectives of the Study.....	102
5.1.1.1	General	102
5.1.1.2	Specific	102
5.2	Methodology	102
5.2.1	Study Instrument (Questionnaire)	103
5.2.2	Sampling Design.....	103
5.2.3	Data Collection and Analysis	104
5.3	Results.....	105
5.3.1	Demographic Data.....	105
5.3.2	Public Views and Knowledge of Medication Safety.....	107
5.3.2.1	Respondents' Views regarding the Most Age Category of Risk to Develop Adrs.....	114
5.3.2.2	Sources of Knowledge towards Drug Safety Related Information.....	114
5.3.2.3	Overall views of Respondents towards Drug Safety.....	115
5.3.2.4	Associations between Demographic Data and overall views of Drug Safety	116
5.3.3	Public Views Regarding Adrs Reporting	118
5.3.3.1	Overall Public Views of Adrs Reporting	121
5.3.3.2	Associations between Demographic Data and Overall Views of Adrs Reporting.....	122
5.3.4	Public Attitudes & Experiences towards Drug Safety Issues.....	124
5.3.4.1	Overall Respondents Attitudes & Experiences towards Drug Safety Issues.....	125
5.3.4.2	Associations Between Demographic Data and Overall Attitudes towards Drug Safety Issues	126
5.3.5	Attitudes & Experiences towards Adr Reporting	128

5.4 Discussion	130
5.4.1 Public Views and Knowledge Regarding Medication Safety and Adr Reporting	131
5.4.2 Public Views Regarding Adrs Reporting	140
5.4.3 Public Attitudes and Relevantly Experiences towards Ensuring Medication Safety	143
5.4.4 Attitudes and Experiences of Adrs among Participants	145
5.5 Conclusion	147

CHAPTER SIX: PHARMACOVIGILANCE DATABASE ANALYSIS

PHASE	149
6.1 Introduction	149
6.1.1 Objectives of the Study.....	149
6.1.1.1 General	149
6.1.1.2 Specific.....	150
6.2 Methodology	150
6.2.1 Study Setting.....	150
6.2.1.1 Features and Accessibility of Adr Reporting System in Uae	151
6.2.2 Study Design, Data Collection and Data Analysis	152
6.3 Results.....	153
6.3.1 Reported Adrs in 2013.....	153
6.3.2 Reported Adrs in 2014.....	154
6.3.3 Reported Adrs in 2015.....	154
6.3.4 Reported Adrs in 2016.....	155
6.3.5 Reported Adrs in 2017.....	156
6.3.6 Reported Adrs in 2018.....	156
6.3.7 Overview of Adr Reports by Consumer Exclusively	157
6.3.8 Distribution of Adrs According to Soc Category and Type of Reporters.....	160
6.3.8.1 Adrs by Soc in 2013	160
6.3.8.2 Adrs by Soc in 2014	161
6.3.8.3 Adrs by Soc in 2015	162
6.3.6.4 Adrs by Soc in 2016	164
6.3.8.4 Adrs by Soc in 2017	165
6.3.8.5 Adrs by Soc in 2018	167
6.4 Discussion	170
6.5 Conclusion	173

CHAPTER SEVEN: CONCLUSION

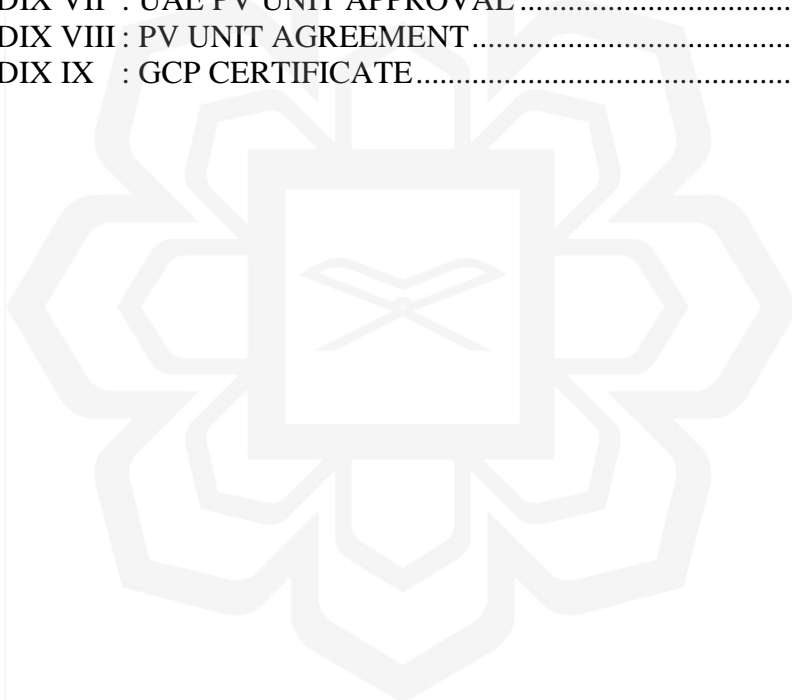
7.1 Introduction	174
7.2 Recommendations	175
7.2.1 Recommendations to Ensure Medications Safety among the Public	176
7.2.2 Recommendations to Enhance Adr Reporting among the Public	177
7.3 Future Studies	178
7.4 Study Limitations and Constrains	178

7.5 Strength Points and Research Implications.....	179
--	-----

REFERENCES.....	180
------------------------	------------

APPENDICES	197
-------------------------	------------

APPENDIX I : INFORMED CONSENT OF QUALITATIVE STUDY	197
APPENDIX II : INTERVIEW GUIDE OF QUALITATIVE STUDY	201
APPENDIX III : INFORMED CONSENT OF QUANTITATIVE STUDY	204
APPENDIX IV : QUESTIONNAIRE OF QUANTITATIVE STUDY (ENGLISH VERSION)	208
APPENDIX V : QUESTIONNAIRE OF QUANTITATIVE STUDY (ARABIC VERSION)	214
APPENDIX VI : MOHAP ETHICAL APPROVAL	220
APPENDIX VII : UAE PV UNIT APPROVAL	222
APPENDIX VIII : PV UNIT AGREEMENT	223
APPENDIX IX : GCP CERTIFICATE	227



LIST OF TABLES

Table 2.1	Studies from developed countries	29
Table 2.2	Studies from developing countries	37
Table 4.1	Demographic data of participants	82
Table 5.1	Demographic details of respondents	106
Table 5.2	Defining of adverse drug reactions by participants	108
Table 5.3	Conditions were considered as an ADR by participants	109
Table 5.4	First part: respondents' views towards the safe use of medications (true/false questions)	111
Table 5.5	Second part: respondents' views towards the safe use of medications	113
Table 5.6	Respondents' view towards the categories that are at high risk of developing ADR	114
Table 5.7	Preferred source of knowledge regarding drug safety related information among the participants	115
Table 5.8	The mean of total score of respondents' views towards drug safety	115
Table 5.9	Overall views towards drug safety among respondents	116
Table 5.10	Demographic data versus overall scores of respondents' views regarding drug safety	117
Table 5.11	Public views regarding ADRs reporting	121
Table 5.12	Collective views of participants regarding ADRs reporting	122
Table 5.13	Demographic data and associations with the overall scores of respondents' views regarding ADR reporting	123
Table 5.14	Respondents attitudes & experiences towards drug safety issues	124
Table 5.15	Overall attitudes towards drug safety issues	126
Table 5.16	Demographic data versus overall attitudes towards drug safety issues	126
Table 5.17	Respondents actions when undesirable effect takes place	128

Table 5.18 Respondents reasons of not informing about undesirable effect when takes place	129
Table 6.1 Details of ADR reports in 2013	154
Table 6.2 Details of ADR reports in 2014	154
Table 6.3 Details of ADR reports in 2015	155
Table 6.4 Details of ADR reports in 2016	155
Table 6.5 Details of ADR reports in 2017	156
Table 6.6 Details of ADR reports in 2018	157
Table 6.7 Overall Distribution of ADR Reports within 2013-2018	157
Table 6.8 ADRs by SOC in 2013	161
Table 6.9 ADRs by SOC in 2014	162
Table 6.10 ADRs by SOC in 2015	163
Table 6.11 ADRs by SOC in 2016	164
Table 6.12 ADRs by SOC in 2017	166
Table 6.13 ADRs by SOC in 2018	167
Table 6.14 Overall ADRs by SOC within 2013-2018	168

LIST OF FIGURES

Figure 1.1	Pharmacovigilance System in UAE	7
Figure 3.1	Qualitative phase flow chart	52
Figure 3.2	Flow chart of quantitative phase	61
Figure 3.3	Flow chart of data collection from PV unit	73
Figure 4.1	Emergent themes and sub-themes	83
Figure 6.1	Trend analysis of ADRs within 2013-2018 by reporters	158
Figure 6.2	Trend analysis of ADRs within 2013-2018 by spontaneous reports	158
Figure 6.3	Trend analysis of ADRs within 2013-2018 by solicited reports	159
Figure 6.4	Trend analysis of ADRs within 2013-2018 by serious ADRs reports	159
Figure 6.5	Trend analysis of ADRs within 2013-2018 by non-serious ADRs reports	160
Figure 6.6	Highest frequencies of reported ADRs by SOC within 2013-2018	170

OPERATIONAL DEFINITIONS

The followings are definitions as per Uppsala Monitoring Centre and World Health Organisation glossaries.

Term	Definition
Adverse drug reaction:	A harmful effect suspected to be caused by a drug. This term has been used quite loosely to include all kinds of adverse events, many of which are not 'reactions' in the strict sense at all, and have not been subject to any assessment of causality. The term is properly reserved for late-stage analysis when the association between a medicine and an adverse effect has moved beyond 'immeasurability' or 'uncertainty'.
Adverse effect:	A negative or harmful patient outcome that seems to be associated with treatment.
Side effect:	Any unintended outcome that seems to be associated with treatment. This term has come to be used exclusively in the sense of 'adverse effect'.
Serious ADR:	An ADR that results in death; requires hospitalisation or extension of hospital stay; results in persistent or significant disability or incapacity; is life-threatening.
Adverse drug event:	Any negative or harmful occurrence that takes place during treatment, which may or may not be associated with a medicine.
Consumer:	A person may or may not be an actual consumer of health care or medicines at a given time, but all members of the general public are potential patients or consumers.
General public/ the public:	People collectively as members of the community.
Patient:	Person waiting or under medical or health care treatment. This concept includes anyone taking medicines, also those who are self-medicating.

LIST OF ABBREVIATIONS

ADR	Adverse Drug Reaction
CIOMS	Council for International Organisations of Medical Sciences
DHA	Dubai Health Authority
FDA	Food And Drug Administration
GCP	Good Clinical Practice
HAAD	Health Authority Abu Dhabi
HCP	Health Care Professional
IG	Interview Guide
MOHAP	Ministry Of Health And Prevention
OTC	Over The Counter
PIL	Patient Informed Leaflet
PV	Pharmacovigilance
REC	Research Ethical Committee
RWD	Real World Data
SOC	System Organ Class
SPSS	Statistical Package for Social Sciences
SSIG	Semi Structured Interview Guide
UAE	United Arab Emirates
WHO	World Health Organisation
YCS	Yellow Card Scheme

CHAPTER ONE

INTRODUCTION

1.1 BACKGROUND OF STUDY

1.1.1 Medication Safety and Pharmacovigilance

Drug safety, which is also known by the concept of medication safety, is not new. However, it remains one of the most critical recent topics in daily medical practice (Alshammari, 2016; Cohen, 2000). Successful medication safety practice is highly necessary, but it cannot be achieved unless medication errors, adverse drug events and adverse drug reactions are reduced among medications consumers such as hospitalised patients, outpatients and general public (Lainer et al., 2013). As per the World Health Organisation (WHO), an adverse drug reaction (ADR) is defined as, “a noxious and unintended response to a drug that occurs at doses normally administered for the prophylaxis, diagnosis or therapy of disease in a human, or for modification of physiological function” (WHO, 1972). ADRs range from minor common side effects to potentially life threatening (Shakib et al., 2019). Therefore ADRs are sometimes referred to in the literature as the drug’s side effects (O’Donovan et al., 2019). Accordingly, the terms ‘ADRs’ and ‘side effects’ are used interchangeably in the patient’s information leaflets and in other contexts (O’Donovan et al., 2019). Medications side effects are among the leading causes of complications and or death, showing a considerable impact on morbidity and mortality rates worldwide (Avery et al., 2011; Mann & Andrews, 2007; O’Donovan et al., 2019). Consequently, drug safety has evolved the model of pharmacovigilance (PV), which is defined by WHO as, “the science and activities relating to the detection, assessment, understanding and

prevention of adverse effects or any other drug-related problem” (WHO, 2014). Drug related-problems could be due to unnecessary drug therapy, wrong drug, too low or high doses, ADR, inappropriate adherence or a need for additional drug therapy (Westberg et al., 2018). Thus drug safety and PV have become complementary to each other and have remained a dynamic, clinical and scientific discipline (Jeetu & Anusha, 2010).

1.1.2 Importance of PV

Nowadays, PV is considered to be the latest approach to drug safety, and it is currently showing an increase in importance (Faillie et al., 2016).

Clinical safety assessment of a drug is currently a pre-request for medical authorisation and marketing, where assessments are based on the results of pre-marketing clinical trials. However, these trials are normally conducted on certain patients or population, which means that these trials highlight only the most common ADRs. The safety related issues of the investigated drugs in clinical trials are limited by the exclusion criteria of the clinical studies, the short duration of the clinical trial, and sometimes, the concomitant administration of other medications. In response, the clinical trial population cannot be representative of the routine patients in the real medical care. Safety profiles of the drug can only be evaluated after using the medicine for longer periods of time in large populations (Wise et al., 2009).

1.1.3 Global Challenges of Medication Safety and PV

At the latest WHO Global Patient Safety Challenge in 2017, it was reported that there were four fundamental problems facing medication safety. The first problem is related to the patients and public who are made to be passive consumers of medicines and are

not educated to play actively in the medication safety process. The second problem is the lack of clear information about medicines on the label or the package. Third problem is due to inappropriate prescription and administration of medicines through health care professionals (HCP). The fourth problem is because of complex and dysfunctional systems and practices of medications which can be safer when they are organised and well understood (Donaldson et al., 2017).

Jeetu and Anusha (2010) have stated that the key challenges facing PV are Pharmaceutical globalisation, as well as web-based sales and information, in addition to the broader safety concerns, and the contradiction between the public health versus pharmaceutical industry economic growth, where several organisations are monitoring the market established products, attitudes and perceptions according to the risk and benefit balance.

1.1.4 Seriousness of Unsafe Medication Practice

Unsafe medication practice (such as inadequate therapy monitoring) may cause preventable ADRs and medication errors among patients and medications consumers. It is estimated that medication errors cost globally around US\$ 42 billion annually (Donaldson et al., 2017). Consequently, both HCP and the medication consumer have a significant role in ensuring the safe use of medications (Greenwald et al., 2010).

1.1.5 The Public (Medications Consumers) As A Partner

It is acknowledged worldwide that the patients who consume medications should be encouraged to take an active role in their own health care (Davis et al., 2007). In this regard, the participation of medications consumers is likely to reduce unexpected incidents such as ADRs which may lead to harm (Koutantji et al., 2005). Moreover,

public awareness and appropriate understanding of the process of monitoring medication safety, based on ADR reporting and the PV system are integral to an effective patient care process (Jeetu & Anusha, 2010). Accordingly, inadequate or insufficient medication knowledge among the public will lead to negative attitudes, which will adversely affect the patients' health (Najjar et al., 2015; Romero-Sanchez et al., 2016).

1.2 HEALTH CARE IN UNITED ARAB EMIRATES (DUBAI)

1.2.1 A Brief about the Country

The United Arab Emirates (UAE) is a constitutional federation of seven emirates that has been founded by His Highness, the late Sheikh Zayed bin Sultan Al Nahyan, the first president of the UAE. The UAE capital city is Abu Dhabi, and other emirates are Dubai, Sharjah, Ajman, Umm Al Quwain, Ras Al Khaimah and Fujairah. The second largest emirate is Dubai. The official language spoken in the UAE is Arabic, and the official religion is Islam. The population is made up of 10% locals (Emirati) and the remaining are expatriates (non-Emirati) (UAE Fact Sheet, 2019). Expatriates are considered as the bulk of the UAE's population. They are well settled in the country and have rights and responsibilities as per law.

Health care criteria and standards are generally considered to be high in the UAE, where the government is keen on increasing the spending to develop community health standards during strong economic years. The UAE government has stated that the total expenditures on health care from 1996 to 2003 were 1,601,384,360.05 United Arab Dirhams (Dhs), which is equivalent to [US\$436 million]. In 2004, the total Emirati expenditure on health care was estimated to be 2.9 percent of the gross domestic product (GDP), and per capital expenditure for health