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

BY

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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.

خلاصةالبحث

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 نصاً وموضوعاً. 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 ذاتياً، ودرست موثوقيته، وجرب، ثم وزع على عينة مكونة من 400 فرد للإجابة عليه. لم تُعَرَّف شخصيات مجيبي الاستبيان، وحللت البيانات المجمعة إحصائيًا.أظهرت نتائج الدراسة اختلاف وجهات نظر المشاركين وتوجهاتهم تجاه مأمونية الدواء، حيث وضح 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 مضرة. 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 ملحوظابين 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 931تقريرا في هذا الخصوص. وكشفت الدراسة أنه قد تم الإبلاغ عن 69.7٪ من تلك التقارير بشكل تلقائي و 47.2٪ من التقارير المبلغ عنها كانتخطيرة .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

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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.

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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.

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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