Saudi Pharmaceutical Journal xxx (2018) xxx–xxx

Contents lists available at ScienceDirect

Saudi Pharmaceutical Journal

journal homepage: www.sciencedirect.com

Original article

Assessment of knowledge, attitude and practice of adverse drug reaction reporting among healthcare professionals in secondary and tertiary hospitals in the capital of Pakistan

Zaka Un Nisa [a], Ayesha Zafar [b], Farooq Sher [c,*]

[a] Faculty of Medicine, Quaid-i-Azam University, Islamabad 45320, Pakistan
[b] Institute of Biochemistry and Biotechnology, University of the Punjab, Lahore 54590, Pakistan
[c] Department of Chemical and Environmental Engineering, University of Nottingham, University Park, Nottingham NG7 2RD, UK

ARTICLE INFO

Article history:
Received 14 October 2017
Accepted 5 February 2018
Available online xxxx

Keywords:
Adverse drugs reactions
Attitude
Knowledge
Pharmacovigilance
Practices and Spontaneous ADR reporting

ABSTRACT

Adverse Drug Reactions (ADRs) underreporting is a great challenge to pharmacovigilance. Healthcare professionals should consider ADR reporting as their professional obligation because the effective system of ADR reporting is important to improve patient care and safety. This study was designed to assess the knowledge, attitude, practice and factors associated with ADR reporting by healthcare professionals (physicians and pharmacists) in secondary and tertiary hospitals of Islamabad. A pretested questionnaire comprising of 27 questions (knowledge 12, attitude 4, practice 9 and factors influencing ADR reporting 2) was administered to 384 physicians and pharmacists in public and private hospitals. Respondents were evaluated for their knowledge, attitude and practice related to ADR reporting. Additionally, the factors which encourage and discourage respondents to report ADRs were also determined. The data was analysed by using SPSS statistical software. Among 384 respondents, 367 provided responses to questionnaire, giving a response rate of 95.5%. The mean age was 28.3 (SD = 6.7). Most of the respondents indicated poor ADR reporting knowledge (83.1%). The majority of respondents (78.2%) presented a positive attitude towards ADR reporting and only a few (12.3%) hospitals have good ADR reporting practice. The seriousness of ADR, unusualness of reaction, new drug involvement and confidence in the diagnosis of ADR are the factors which encourage respondents to report ADR whereas lack of knowledge regarding where and how to report ADR, lack of access to ADR reporting form, managing patient is more important than reporting ADR legal liability issues were the major factors which discourage respondents to report ADR. The study reveals poor knowledge and practice regarding ADR reporting. However, most of the respondents have shown a positive attitude towards ADR reporting. There is a serious need for educational training as well as sincere and sustained efforts should be made by Government and Hospital Authorities to ensure proper implementation of ADR reporting system in all of the hospitals.

1. Introduction

Adverse drug reaction (ADR) is defined by World Health Organisation (WHO) as 'Any reaction to a drug that is noxious, unintended and occurs at doses used for prophylaxis, diagnosis and therapy excluding failure to accomplish the intended response' (Ahmad et al., 2013). ADR is a major problem that occurs worldwide. Health professionals played a very vital role in reporting of ADR around the world which has led to the detection of serious and unusual ADR that were previously undetectable and many drugs like "rofecoxib" were withdrawn in the past, therefore, enhancing the safety of patients (Wysowski and Swartz, 2005). It has been noticed in the past that ADR reporting has provided early warning signs and therefore increases patient safety. Pharmacovigilance and report of adverse drug reaction were started after the thalidomide disaster in the mid-20th century (Canto, 2010). Thalidomide was the drug which was prescribed in many countries to alleviate morning sickness in pregnant women and this drug was teratogen and caused congenital disorder in newborns. After the disaster, National Pharmacovigilance Centres were established in a number of countries around the world.

* Corresponding author.
E-mail addresses: farooq.sher@nottingham.ac.uk, farooq.sher@gmail.com (F. Sher).
Peer review under responsibility of King Saud University.

Production and hosting by Elsevier

https://doi.org/10.1016/j.jsps.2018.02.014
1319-0164/

Please cite this article in press as: Nisa, Z.U., et al. Assessment of knowledge, attitude and practice of adverse drug reaction reporting among healthcare professionals in secondary and tertiary hospitals in the capital of Pakistan. Saudi Pharmaceutical Journal (2018), https://doi.org/10.1016/j.jsps.2018.02.014

Adverse drug reactions are the 4–6th leading cause of death. Patients who experienced adverse drug reaction are hospitalised 8–12 days longer than those who did not experience adverse drug events and their hospitalised cost is between $16,000–24,000 or more (Lazarou et al., 1998). Countries with lack of ADR reporting system are not able to protect their population from the harmful effect of medicines, therefore, an effective system of ADR reporting is very important to improve patient care and safety and in turn improving overall health. According to WHO best reporting rate include more than 200 reports/1000,000 people per year. However, reporting of ADR which is serious did not exceed 10% (Belton et al., 1995). Uppsala Monitoring Centre (UMC) is a collaborating centre for monitoring Global ADR database Vigibase. According to 2011 report WHO program has 105 countries as official members and 35 as associate members which include Pakistan as well (Kumar et al., Taneja and Ahuja, 2011, Shamim et al., 2016).

With the passage of time use of drugs is also increased which in turn leads to more adverse drug reaction occurrence. The financial burden on patients also reduces by ADR reporting because ADR causes additional treatment (Ramachandudu, 2015). Reporting of ADR can result in detection of serious and unusual ADR which was remained undetected during a clinical trial. Rational use of medicines not only decreases morbidity and mortality but also increases the quality of life (Gustafsson et al., 2011), so in order to improve rational use of medicines the safety efficacy and quality of medicine should be ensured, on the other hand irrational use of medicines can be life threatening because it could be the reason for serious adverse drug reaction (Mahmood et al., 2011). An efficient system of ADR reporting is very important for pharmacovigilance program (McBride, 1961, Ramesh et al., 2003, Khan et al., 2006). In developed countries like Europe, USA and Canada it is stated that every single ADR is important to report. Some developing countries such as India, Malaysia and some African countries are also making efforts to develop proper ADR reporting system.

Pakistan is a country which extends from mountains of the Himalayas to the Arabian sea bordering with China, India, Iran and Afghanistan. It is located along the ancient trade route between Asia and Europe (Azhar et al., 2009). Private sector serves **7**0% of the population whereas 10,000 public health facilities are present which range from basic health unit to tertiary care health facilities (Ghaffar et al., 2000). National Health Policy (NHP) exists in Pakistan (Su et al., 2010) but pharmacovigilance is not included in the National drug policy of Pakistan. There is no proper system or institution for monitoring of ADR. Laws also exist regarding ADR monitoring but the National Pharmacovigilance Centre that is linked to Medicines Regulatory Authority (MRA) does not exist (WHO, 2010). For ADR reporting official form is used which is available at the website of Ministry of Health, Pakistan.

National ADR database does not exist in Pakistan. In previous years, no ADR was reported to WHO database. Monitoring of ADR is not conducted in public health programs (Raza and Jamal, 2015). Pharmacovigilance system in Pakistan is still in its initial stages of development, this is due to the lack of knowledge, ignorance or lack of training as very few studies have been conducted on ADR system in the past (Shakeel et al., 2014). Therefore, the present study is undertaken to determine the current status of ADR reporting system in the capital of Pakistan, to investigate knowledge and attitude of physicians and pharmacists towards ADR reporting in secondary and tertiary hospitals.

2. Methodology

2.1. Study design and sampling strategy

This cross-sectional study was conducted in Islamabad the capital city of Pakistan. The study was commenced from January to June 2017 for the period of six months. A survey involving three hundred and eighty-four physicians and pharmacists from six public and thirteen private hospitals was carried out. These numbers were selected by non-probability convenience sampling technique. The sample size was calculated by using the proportional formula of OpenEpi by assuming the population size of 100,000 and anticipated frequency of 50%. Sample size came out to be 384 at confidence interval 95%. A validated structured questionnaire was delivered to each participant by hand and was asked to fill it.

2.2. Questionnaire

Information regarding knowledge attitude and practice of ADR reporting in different countries around the world was collected. Different structured questionnaires which were used for various knowledge, attitude, practice (KAP) studies around the world were also examined and initial draft of the questionnaire was designed as multiple choice questions (Desai et al., 2011, Kamtane and Jayawardhani, 2012, Upadhyaya et al., 2012, Gupta et al., 2015). The questionnaire was developed in English as most of the participants were fluent in the English language. The validity of the questionnaire was assessed by pretesting the questionnaire with 40 healthcare professionals working in 4 different hospitals. The cronbach alpha was calculated which was 0.72 and after that, no modifications were carried out. After pilot-scale testing, the questionnaire was distributed to final respondents of the study. The questionnaire consisted of four sections. The first section included demographic information such as age, gender, hospital category and speciality whether a person is a physician or pharmacist. The second section was having twelve questions that were used to measure the knowledge of pharmacists and physicians related to ADR reporting. The third section was comprised of four questions with the help of which participants' attitude towards ADR reporting was assessed. The fourth section included nine questions with the help of which practice of ADR reporting by pharmacists and physicians in hospitals were determined. Finally, the fifth section was limited to two questions with the help of which factors encouraging and discouraging to physicians and pharmacists to report ADR were determined.

2.3. Ethical approval

Ethical approval was taken from ethics committee present at Quaid-i-Azam University in Islamabad, Pakistan. Written informed consent was also taken from every respondent who was willing to participate in the study. Written ethical approval was taken from some private hospitals where the ethical committee was present and functional. The physicians and pharmacists were briefed about the rationale of the study and participants were assured of the privacy and confidentiality.

2.4. Data collection and statistical analysis

Survey of various hospitals was carried out the physicians and pharmacists were contacted directly in their department and questionnaires were distributed to them. Participants were explained about the purpose of the study. Any clarification needed in the understanding questionnaire was provided. Informed consent was also attached with the distributed questionnaire. Those physicians and pharmacist who were agreed to participate in the study were requested to fill the questionnaire in 30 min. The questionnaires were left to those participants who were busy at that time and were collected after 2–3 days. Some questionnaires were distributed via hospital directors, such as Shifa International Hospital. Some questionnaires were distributed via Email or social networking sites like Facebook. The collected data was analysed using

Please cite this article in press as: Nisa, Z.U., et al. Assessment of knowledge, attitude and practice of adverse drug reaction reporting among healthcare professionals in secondary and tertiary hospitals in the capital of Pakistan. Saudi Pharmaceutical Journal (2018), https://doi.org/10.1016/j.jsps.2018.02.014