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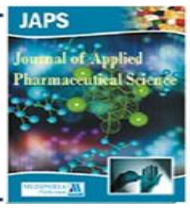

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Reporting of Adverse Drug Reactions: a study among Clinicians

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ABSTRACT

Spontaneous reporting of ADRs enhances detection of serious, unexpected and unusual ADRs. Healthcare professionals play an integral role in the success of safety surveillance of drugs. This study aimed to investigate knowledge, practice and factors affecting ADR reporting among clinicians. Cross sectional study was carried out among clinicians of a tertiary care centre irrespective of their gender, specialization and experience. A validated self-administered questionnaire was distributed among clinicians to assess the knowledge, practice and factors influencing ADR reporting. The 42 clinicians participated in the study comprised more than 50% males, had a mean age 36±8 years and represented a multi-ethnic population of varying clinical experience. With regard to ADR reporting, majority of the clinicians correctly identified which of the ADRs had to be reported and the individuals who can report ADRs. Very few clinicians had reported ADRs to the Pharmacovigilance Centre. The common factor discouraging reporting of ADR was not knowing how to report ADRs (71%). A majority of the clinicians were willing to undergo training on this aspect. The study revealed under-reporting of ADRs, and the willingness of clinicians to be trained in ADR reporting thus contributing to Pharmacovigilance program

Keywords: adverse drug reactions, clinicians, UAE.

INTRODUCTION

The World Health Organization defines adverse drug reactions (ADRs) as 'a reaction which is noxious and unintended and which occurs at doses normally used in humans for prevention, diagnosis or therapy of disease, or for the modification of physiological functions' (WHO, 2000). Adverse drug reactions (ADRs) are important public health problem and one of the leading causes of morbidity and mortality (Lazarou *et al.*, 1998). Indeed, it has been shown that approximately 5.3% of hospital admissions were associated with ADRs (Kongkaew *et al.*, 2008). ADRs are believed to be the one of the most common leading cause of death among hospitalized patients (Calis & Young, 2004). ADRs have a major impact on public health by imposing a considerable economic burden on the society and health care systems (Wu & Pantaleo, 2003).

Post-marketing surveillance of drugs is very important in analyzing and managing the risks associated with drugs once they are available for the use of the general population. Spontaneous reporting has contributed significantly to safety surveillance. The greater use of newer and more toxic drugs and the existing polypharmacy in the hospital set up warrant the review of the ADRs by these drugs. The contribution of health professionals towards reporting of ADRs is enormously significant. Spontaneous reporting of ADRs reporting by healthcare workers is one of the most important methods of ADR detection. Such a reporting system contributes to signal detection of unsuspected and unusual ADRs previously undetected during the initial evaluation of a drug (Wysowsky & Swartz, 2005; Lexchin, 2006). However, in spite of these benefits, under-reporting remains a major drawback of spontaneous reporting (Lexchin, 2006 ; Lopez-Gonzalez *et al.,* 2009). It is estimated that only 6–10% of all ADRs are reported (Smith *et al.,* 1996). This high rate of under-reporting can delay signal detection and consequently impact negatively on the public health. Accumulating evidences suggest that the attitudes of healthcare professionals toward their national ADR reporting procedure are a significant determinant of reporting rates and quality. Several studies carried out in African, European and Asian countries have documented that the knowledge of ADRs and reporting of ADRS are inadequate among health care professionals (Enwere & Fawole, 2008 ; Oshikoya & Awobusuyi, 2009; Herdeiro *et al.,* 2005; Rehan *et al* ., 2005; Li *et al.,* 2004). No studies have been reported with regard to the awareness of reporting of ADRs in United Arab Emirates.

Many factors are associated with the under-reporting of ADRs among health professionals. The factors influencing under-reporting may vary from one country to another. There have been no empirical studies from United Arab Emirates evaluating the awareness and attitude of ADR reporting among doctors. This study is therefore aimed at investigating the awareness and attitudes of doctors to ADR reporting in a multi-speciality teaching hospital, to evaluate their basic knowledge of ADR, and to identify the reasons for underreporting.

MATERIAL & METHODS

Study setting

This study was carried out at a tertiary care hospital in United Arab Emirates which is a teaching hospital providing medical, dental and super-speciality services.

Study design and Study population

A cross sectional study was carried out among all the doctors working at the hospital during the study period.

Sampling Procedure

A total of 110 doctors were working at the time of this study in this hospital. For this study a sample of 50 %(55 doctors) from the population were randomly recruited. The questionnaire was distributed among the 55 doctors. A total of 42 filled in questionnaire were returned and thus response rate was 76%.

Research tool

A self-administered questionnaire was used to assess the awareness of reporting of ADRs among clinicians. The questionnaire was structured to obtain the demographics of the doctors, information about their knowledge of ADR reporting, attitudes to reporting, factors that may influence reporting, and their training on ADR reporting. The questionnaire included both open-ended and close-ended questions. The questionnaire after its preparation was reviewed by subject experts in the field of Clinical Pharmacology as regards the face validity, content validity and the relevance and comprehensiveness. The questionnaire was validated through a pilot study of 5 randomly selected doctors.

Data collection

The approval from the ethics committee was obtained before starting the study. After obtaining the consent from the doctor the questionnaire was distributed to them. The doctors were given enough time to respond to the questions. The filled in questionnaire was collected back immediately.

Statistical analysis

Data analysis was performed using SPSS version 18. Descriptive statistics was used. Results are presented as mean ± standard deviation, numbers with percentages, graphic presentations. The association between variables was determined using chi-square test. p value <0.05 was considered significant.

Definitions

Adverse drug reaction

A reaction which is noxious and unintended and which occurs at doses normally used in humans for prevention, diagnosis or therapy of disease, or for the modification of physiological functions (WHO, 2000).

Pharmacovigilance

It is the science and activities relating to the detection, assessment, understanding and prevention of adverse drug effects or any other drug-related problem (WHO, 2000).

Serious ADR

An adverse drug reaction that requires hospitalization, prolongs hospitalization, is permanently disabling, or results in death of the patient (Lazarou *et al.,* 1998).

RESULTS

Demographic characteristics:

The filled in self administered questionnaire was returned by only 42 clinicians. Of the 42 clinicians, more than 50% of them were males and had a mean age of 36 ± 8 years with range of 26 years to 65 years. The clinicians who participated in the study represented a multi ethnic population of varying clinical experience with Egyptian and Indian Nationality predominating. A total of 22 (52.4%) were specialized clinicians while the other were general practioners. Of the 42 clinicians 41 had come across ADRs in their clinical practice which included serious ADRs as well. About

16.7% of the clinicians had noticed serious ADRs in their patients on a monthly basis. Drug induced rashes and diarrhoea were the most frequent ADRs the clinicians had come across. The commonly implicated drugs in the ADRs were antibiotics and analgesics. The serious ADRs observed by the doctors were Steven Johnson's syndrome and anaphylaxis.

Clinicians' knowledge of ADR reporting scheme and pharmacovigilance

With regard to the knowledge of ADRs that have to be reported, 97.6% stated serious ADR, 95% unusual ADR, and 88% mentioned both ADRs to new drugs and new ADRs to existing drugs. For the question on who can report ADRs, 97.6% opined clinicians, 81% stated nurses and pharmacist and 42.9% believed patients could report ADRs.

Only 19 (45.2%) of the clinicians were aware of the existence of a pharmacovigilance centre and only 6 of them had reported ADRs to the Pharmacovigilance Centre. Only 28 (66.7%) felt that ADR reporting was necessary. The characteristics of these clinicians are shown in Table 1.

Table 1: Characteristics of clinicians who felt ADR reporting is necessary.

Gender	**Male** 17 (60.7%)	**Female** 11 (39.3%)
Specialization	**Specialized** 14 (50%)	**Not specialized** 14 (50%)
Experience	**<10years** 19 (68.7%)	**>10years** 9 (32.1%)

Attitudes towards ADR reporting

With regard to the attitudes of the participants towards reporting of ADR, 13 (31%) respondents felt that ADR reporting is a professional obligation. 24 clinicians(57%) opined that ADR reporting should be made compulsory in the hospital setting while 13 (31%) of them stated that it should be a voluntary process

Factors encouraging and discouraging reporting of ADRs

The common factors encouraging and discouraging ADR reporting are shown in Figure 1a and 1b. The most common factor encouraging reporting of ADR was patient safety (96.4%) while not knowing how to report ADR (71%) was the most common discouraging factor to report ADR.

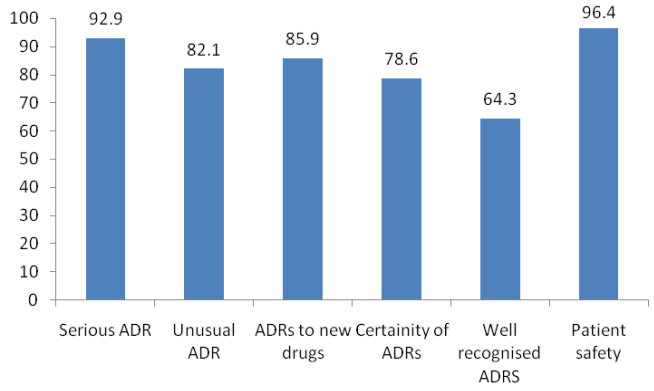

Fig. 1a: Factors encouraging reporting of ADRs.

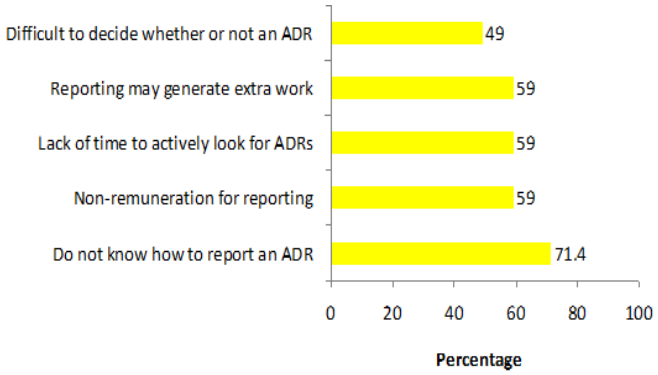

Fig. 1b: Factors discouraging reporting of ADRs. .

Measures to improve ADR reporting

The common measures suggested by clinicians to improve ADR reporting were training in reporting of ADRs, availability of ADR reporting information sheets at the OPDs and training other health care professionals to report ADRs (Figure.2).

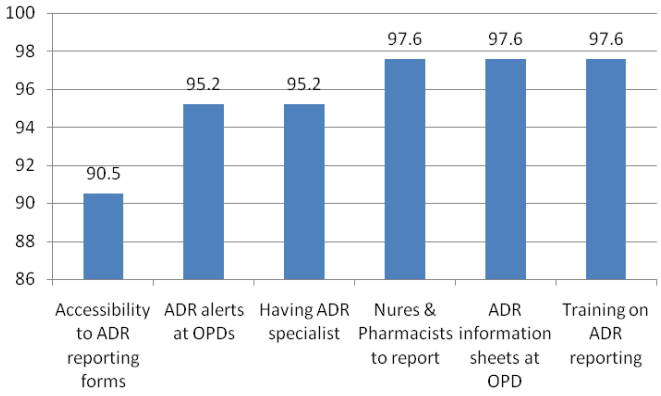

Fig. 2: Measures to improve reporting of ADRs.

Education and training on ADRs

Only three respondents had received training on how to report ADR and all three had received training from India. Majority (97.6%) of the clinicians were willing to be trained in reporting of ADRs.

DISCUSSION

The investigation into the awareness, attitude, knowledge and practice of ADR reporting revealed that all respondents had knowledge of the perceived risks of ADRs and were keen to report ADRS. The primary intention for initiating Pharmacovigilance program by the WHO is to ensure safe and ration use of medications after their approved for use among the general population (WHO, 2002). Spontaneous reporting of ADRs is the widely practiced method of detection of ADRs and withdrawal of drugs that can result in serious and life threatening among patients (Shankar *et al.*, 2006). However, the underreporting of ADRs by health care professionals is the major hindrance in the pharmacovigilance program. The present study showed the prevalence of under-reporting of ADRs which was similar to studies across the world [Europe (Herdeiro *et al.*, 2005), Africa

(Enwere & Fawole, 2008 ; Oshikoya & Awobusuyi, 2009) , Asia (Rehan *et al.,* 2002 ; Li *et al.,* 2004)] . There is a need for greater awareness and interventions such as educational programs among clinicians to encourage the reporting of ADRs. Initiates can be taken to teach pharmacovigilance in the undergraduate curriculum and train medical students to report ADRs as groundwork so as to inculcate this habit in them and apply this knowledge their future clinical practice (Pirmohamed *et al.,* 2004; Amit & Rataboli, 2008).

The majority of the clinicians knew which ADRs needed to be reported, as was also observed by Oshikoya *et al.,* 2009. All serious, unexpected and new ADRs must be reported, thus contributing to post-marketing surveillance. It is a well documented fact that ADR results in financial burden on the patient as well as increase the hospital costs. The incidence of serious ADRs from reports from UK and US varies from 6.5% - 6.7% and majority of these ADRs were preventable in nature (Wiffen *et al.,* 2002; Blenkinsopp *et al.,* 2007). The majority of the clinicians knew that all health professionals could report ADR. This finding was similar to that reported by Oshikoya *et al.,* 2009. Healthcare systems primarily depend on the spontaneous reporting of suspected ADRs by health care professionals to identify new reactions, to record their frequency of occurrence, to provide this information to prescribers to prevent future ADRs (Bello & Umar, 2011). Patient reporting has been incorporated into the pharmacovigilance systems in several countries, including the USA, Canada, Australia, New Zealand, Sweden and the Netherlands (Bello & Umar, 2011). Less than 50% clinicians were aware that patients can also report ADRs. In a review published on the reporting of ADRs by patients indicated that patient reporting of suspected ADRs has more potential benefits than drawbacks. ADRs that were not previously reported by health professionals were picked up by direct patient ADR reports. It was also noted that the quality of patient reports were comparable to that of health professional reports (Blenkinsopp *et al*., 2007). Among the clinicians who felt ADR reporting wais necessary, the majority were male clinicians with less than 10 years of experience, as reported by Bello & Umar *et al.,* 2011 and Bartels *et al.,* 2008. The reason for this finding could be that the younger clinicians are more aware of the existence of pharmacovigilance centers.

Less than 50% of the clinicians were aware of the existence of pharmacovigilance centers, which could be the probable reason for the practice of under-reporting observed in this study. The common reason for not reporting ADRs were; lack of awareness on reporting, extra work and the lack of time. These findings were in line with Amit & Rataboli,2008; Belton *et al.,* 1995; Green *et al.,* 2001 and Ramesh et al., 2009. There is a need for increasing sensitization and pharmacovigilance education program among clinicians and other health care professionals. In addition to education programmes, one of the other ways to encourage ADR reporting among doctors is to provide them with an easy and quick method of reporting. Easy availability of ADRs reporting forms and ADR Drop Boxes can be put up the Out Patient Departments and wards of the hospital (Pirmohamed *et al.,* 2004). The ADR reporting form can be designed in such a manner that it would be very easy to report an ADR by any health care professional (Amit & Rataboli, 2008). One of the positive observations noted in the study was that majority of the clinicians were willing to undergo training in reporting ADRs. Previous studies have documented that ADR reporting improves with educational programs (Pirmohamed *et al.,* 2004; Scott *et al.,* 1990; Figueiras *et al.,* 2006). This finding indicates the doctors are willing to improve their knowledge of ADR reporting and increase their participation in Pharmacovigilance program. The other methods recommended by the respondents such as availability of ADR reporting information sheets at the OPDs and training other health care professionals to report ADRs very important and should be instituted in the hospital to enhance ADR reporting.

More than 50% participants felt ADR reporting should be made compulsory and about 31% voluntary reporting. This finding is in concordance to Oshikoya *et al.,* 2009 report. About 30% of clinicians felt ADR reporting is a professional obligation. Oshikoya *et al.,* 2009 reported more than 60% of the clinicians in their study stated ADR reporting as a professional obligation. Clinicians are responsible for patient safety and ADR reporting eventually contributes to the aspect of medical ethics.

Limitations of the study include; results are of only a single hospital and those inherent to questionnaire-based studies such as subjective response and recall bias. The study findings can be generalized if further extended to other hospitals in the country

CONCLUSION

In conclusion, the study results revealed the existence of underreporting of ADRs, but also the willingness of clinicians to be trained in ADR reporting and contributing to the pharmacovigilance programme. It is desirable to initiate workshops and training programs on ADR reporting to overcome the underreporting, and ADR reporting should be considered as an integral part of the clinical activities by the health care providers.

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