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ADVERSE DRUG REACTION MONITORING AND REPORTING: KNOWLEDGE, ATTITUDE AND BELIEF OF PHYSICIANS & PHARMACISTS OF RAS AL KHAIMAH, UNITED ARAB EMIRATES (UAE)

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ABSTRACT: Adverse drug reactions (ADR) contribute significantly in health care cost through increased patient morbidity and mortality. Thus, there is an urgent need to create awareness among health care professionals towards ADR monitoring and reporting. The aim of our study is to assess the knowledge, attitude and belief of physicians and pharmacists towards ADR. This is a prospective cross-sectional survey based study. Questionnaire consists of 17 open ended and closed ended questions, was prepared and validated for its content and circulated to physicians and pharmacists from the selected hospitals and community pharmacies of Ras Al Khaimah, U.A.E. Majority of the physicians (n=50) were not aware of the ADR reporting system in UAE. Good number (n=19) of physicians did not know whom to report. The most common classes of medications associated with ADR were antibiotics. Great part of the physicians (n=45) have mentioned that only around 10% of their patients report their ADR. Only small number (n=15) of these physicians have reported the ADR to head of department or to drug manufacturer. Many physicians (n=31) were interested in getting trained on ADR reporting. We conclude that the awareness of ADR Reporting system in Ras Al Khaimah, U.A.E was limited. One of the main reasons for under reporting of ADR was did not know "whom" and "how to report". Hence, more ADR related awareness is needed to motivate the health care professionals to monitor, and report ADR for improving the health care quality.

INTRODUCTION: Globally, adverse drug reactions (ADR) are the most important problem representing one of the leading causes of mortality and morbidity in health care facilities [1]. Studies have demonstrated the occurrence of ADR in hospitalized patients [2, 3]. About 0.16% to 15.7% of hospital admissions occur due to ADR [4]. Studies conducted in developed countries have highlighted the need of reporting ADR to both local and international pharmacovigilance centers [5]. Some of these studies have also investigated the reasons for underreporting of ADR [5-7].

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It is well known that both physicians and pharmacists play an important role in monitoring and reporting of ADR [5-7]. It is also evident from previous literatures that in developed countries community pharmacists contribute significantly in

reporting of ADR6. Several studies conducted worldwide reveal that knowledge, attitude, belief and perceptions of healthcare professionals appear to be remarkably associated with reporting of ADR [5, 8].

Not much published data is available regarding the ADR monitoring and reporting activities in United Arab Emirates (U.A.E). The regulatory bodies in UAE such as Ministry of Health (MOH), Dubai Health Authority (DHA) and Health Authority of Abu Dhabi (HAAD) are making continuous efforts to create awareness among healthcare professionals to monitor and report ADR in U.A.E [9, 10]. A study conducted on detection and preventability of ADR at Al Qassimi Hospital, Sharjah, U.A.E has highlighted the importance of active monitoring in ADR reporting [11]. Based on our literature review, no published data was available regarding U.A.E pharmacists' involved ADR monitoring and reporting related studies.

Since ADR contribute for significant health care cost through increased patient morbidity and mortality [1, 3], there is an urgent need to create awareness among health care professionals towards ADR monitoring and reporting. Identifying the attitude and beliefs of health care professionals towards ADR monitoring and reporting might help in developing and improving the ADR reporting system. With this background this study was designed to assess the knowledge, attitude and belief of physicians and pharmacists towards ADR reporting.

MATERIALS AND METHODS:

Study Design: A prospective cross-sectional survey based study was conducted during October 2011 to February 2012. The required data was collected through surveying physicians and pharmacists of public and private hospitals, primary health care centers and selected community pharmacies of Ras Al Khaimah, U.A.E. A convenient sampling technique was used to determine the sample size. The study was approved by the Ethics and Research committee of Ras Al Khaimah Medical and Health Sciences University, Ras Al Khaimah, U.A.E.

A self-administered knowledge, attitude and belief (KAB) questionnaire was prepared based on the extensive literature review of ADR related research studies and guidelines. The questionnaire consists of 17 open ended and closed ended type of questions. The questionnaire was a two part questionnaire, the first part comprised of demographics of the survey participants, and the second part included KAB related questions, which was designed to collect information about the survey participants' knowledge of ADR reporting system, their attitude towards reporting, reasons for under-reporting and their interest in getting trained on reporting ADR.

The questionnaire was validated for its content before it was finalized 12. It was then distributed to the participants by the study investigators upon visiting the different study sites. Survey questionnaires were distributed by the study investigators and were collected after a period of 1 – 2 days after distribution, based on respondent's convenience and availability.

Data Analysis: The collected data was entered into Microsoft Excel worksheet (Microsoft office 2007) for analysis and then transferred to Statistical Package for Social Sciences (SPSS) software program version 18 for further statistical analysis. Data was presented in the form of frequency and percentages.

RESULTS AND DISCUSSION:

Demographics of the survey respondents: A total of 75 physicians and 50 community pharmacists of Ras Al Khaimah, U.A.E. have completed the KAB questionnaire. Ours was the first survey-based study conducted in Ras AL Khaimah, U.A.E which assesses the knowledge, attitude and belief of hospital physicians and community pharmacists towards ADR reporting. However, similar types of studies have been conducted in other parts of the world, which indicates a diverse range in knowledge, attitude and belief of health care professionals towards ADR monitoring and reporting [13-18].

Responses to KAB Questionnaire Items:

Belief regarding safety of medications: A total of 39 (78%) community pharmacists and 61(81.3%) physicians believed that all the available medications were not safe.

Frequency of noticing ADR: Responses regarding how often the participants noticed ADR in their patients, a good number of the pharmacists 25 (50%) and physicians 43 (57.3%) mentioned it as "rarely" noticed.

Identification of ADR: A total of 27 (54%) pharmacists and 31 (41.3%) physicians mentioned that around 11 - 20% of their patients have reported ADR to them. Most of the pharmacists 34 (68%) mentioned that they confirmed occurrence of an ADR mainly by patient interview, whereas physicians 59 (78.7%) confirmed occurrence of ADR based on their clinical experience (**Table 1**).

The physicians who participated in the survey confirmed the occurrence of an ADR based on their clinical experience, which was similar to the findings of Kazeem *et al*., [19], whereas the pharmacists have mostly confirmed ADR by patient interview. Responses regarding how often the participants have noticed ADR in their patients, majority of the respondents mentioned it as "rarely" noticed. While good number of studies have reported higher rate of ADR observation by physicians and pharmacists. This difference in the observation could be due to the difference in the sample size of the referred studies and secondly, majority of these studies have been conducted in the countries or sites where there is an established ADR reporting system exists [20-25].

ADR reporting: Only 14 (28%) pharmacists and 10 (13.3%) physicians were aware of the ADR reporting system in U.A.E. Only 9 (18%) pharmacists and 16 (21.3%) physicians mentioned that they have reported ADR to different set-ups. Out of these, 3 (6%) pharmacists and 11 (14.7%) physicians have reported ADR "twice". A total of 5 (10%) pharmacists have reported the ADR primarily to the physician, while 5 (6.7%) physicians have reported the ADR to the drug manufacturer.

In the present study, majority of the pharmacists and physicians were not aware of the ADR reporting system in UAE, hence only a small number of them have reported ADR. A similar response is given by participants in earlier studies [26]. Findings of the present study is similar to that of other studies, which have reported limited awareness of health care professionals about the local or national ADR reporting system in their countries [27, 28]. This indicates the importance of creating awareness regarding the local reporting system among health care professionals. In our study most of the pharmacists who have reported ADR was to the physician, whereas physicians have reported the ADR mainly to the drug manufacturer.

Reasons for under reporting: The reasons for not reporting or under reporting of ADR, given by most of the pharmacists 23 (46%) and physicians 36 (48%) was that they didn't know whom to report ADR and 17 (34%) pharmacists and 21 (28%) physicians mentioned that the ADR noticed are very commonly observed and well documented in the literature hence they didn't feel the importance of reporting (**Figure 1**).

The main reason for under-reporting of ADR quoted was "not aware of the method by which reporting can be done successfully". Other reasons include that the ADR were very common to be reported and the unavailability of the ADR reporting forms. This was in comparison with a study done by Tabali M *et al* [29]. Some other responses given by the participants are lack of financial incentives and lack of awareness of the importance of ADR reporting or the worry about legal consequences of ADR reporting. This is highlighted in a study conducted by Vallano A et al [30]. While other studies indicate reasons such as unaware of ADR reporting process and identification of ADR does not influence the treatment [31, 32].

Common class of medication(s) causing ADR: Pharmacists and physicians had a different point of view towards the most common class of medications causing ADR. In accordance to 45 (90%) pharmacists, "anti-diabetics" were the most common class of medication involved in causing ADR followed by "antibiotics" as quoted by 39 (78%) participants. Antibiotics ranked the first category of medications to cause an ADR as specified by 18 (24%) physicians, followed by non-steroidal anti-Inflammatory drugs (NSAIDs) as mentioned by 14 (18.7%) physicians (Table 1). Amongst the most common class of medications causing ADR, anti-diabetics and antibiotics were the common ones as per the pharmacists' and physicians' opinion respectively.

Similar responses were identified by A Oshikoya *et al* [19]. However, NSAIDs were the most common class of medications causing ADR in other studies [33-35].

TABLE 1: KAB OF PHARMACISTS & PHYSICIANS REGARDING ADR REPORTING & MONITORING

KAB Questionnaire items	Pharmacists (n=50) N (%)	Physicians (n=75) N (%)
How do you confirm occurrence of an adverse drug reaction in a patient?		
▪ By patient interview	34 (68.0%)	55 (73.3%)
▪ By review of literature	02 (4.0%)	25 (33.3%)
▪ By clinical experience	21 (42.0%)	59 (78.7%)
▪ Discuss with my colleagues	08 (16.0%)	11 (14.7%)
▪ From pharmacist or physician	10 (20.0%)	08(10.7%)
▪ Others	18 (16%)	01(1.3%)
According to you which type of ADR should be reported?		
▪ Only serious and life threatening	38 (76.0%)	54 (72%)
▪ Rare and when it causes disability to patient	22 (44.0%)	39 (52%)
▪ Even mild and those causes less damage to patient	20 (40.0%)	28 (37.3%)
▪ Those causing inconvenience to patients	10 (20.0%)	11 (14.7%)
▪ Don't know	03 (6.0 %)	05(6.7%)
▪ Others	01 (2.0 %)	07(9.3%)
In your opinion, Who should report ADR?		
▪ Physician	40 (80%)	62 (82.7%)
▪ Nurse	17(34%)	38 (50.7%)
▪ Pharmacist	34 (68%)	30 (40%)
▪ Patient	23(46%)	31 (41.3%)
What are the most common classes of medications associated with ADR that you have noticed during your practice?		
▪ Anti-diabetics	45 (90%)	05 (6.7%)
▪ Antibiotics	39 (78%)	18 (24%)
▪ NSAIDs	16 (32%)	14 (18.7%)
▪ Cardiovascular medications	11 (22%)	13 (17.3%)

Who should report ADR? Multiple responses were given by both physicians and pharmacists regarding who should report ADR. Majority of the pharmacists 40 (80%) and physicians 62 (82.7%) believed that ADR should be reported primarily by "physicians". Subsequently 34 (68%) pharmacists mentioned it as it should be reported by "pharmacists". Whereas 62 (82.7%) physicians thought "pharmacists" should have the priority to report ADR followed by "nurses" as mentioned by 38 (50.7%) physicians. **Table 2** represents the responses of physicians and pharmacists on who should report ADR. In reference to who should report ADR, most of the participants believe that physicians followed by pharmacists are mainly responsible for ADR reporting. Approximately more than half of the participants did not anticipate the role of patients and nurses in reporting ADR, which is similar to the results of a study done in Desai C *et al* [36].

When to report ADR? A total of 38 (76%) pharmacists and 54 (72%) physicians chose to report ADR only when they are "serious and life threatening" followed by 22 (44%) pharmacists and 39 (52%) physicians believed that rare ADR that may cause disability to the patient should also be reported (Table 1).

Most of the survey participants' state that ADR should be reported only when they are "serious and life threatening" or "rare and when it has caused disability to patient". Whereas a study conducted by Khalili H *et al.*, encouraged reporting adverse effects of newly marketed drugs in addition to reporting serious ADR 25. International guidelines on monitoring and reporting of ADR suggests to report all suspected ADR for newly marketed drugs and fatal, serious, life threatening or disabling ADR for all established drugs, vaccines, high risk drugs and those which occurs in high risk patients [37-39].

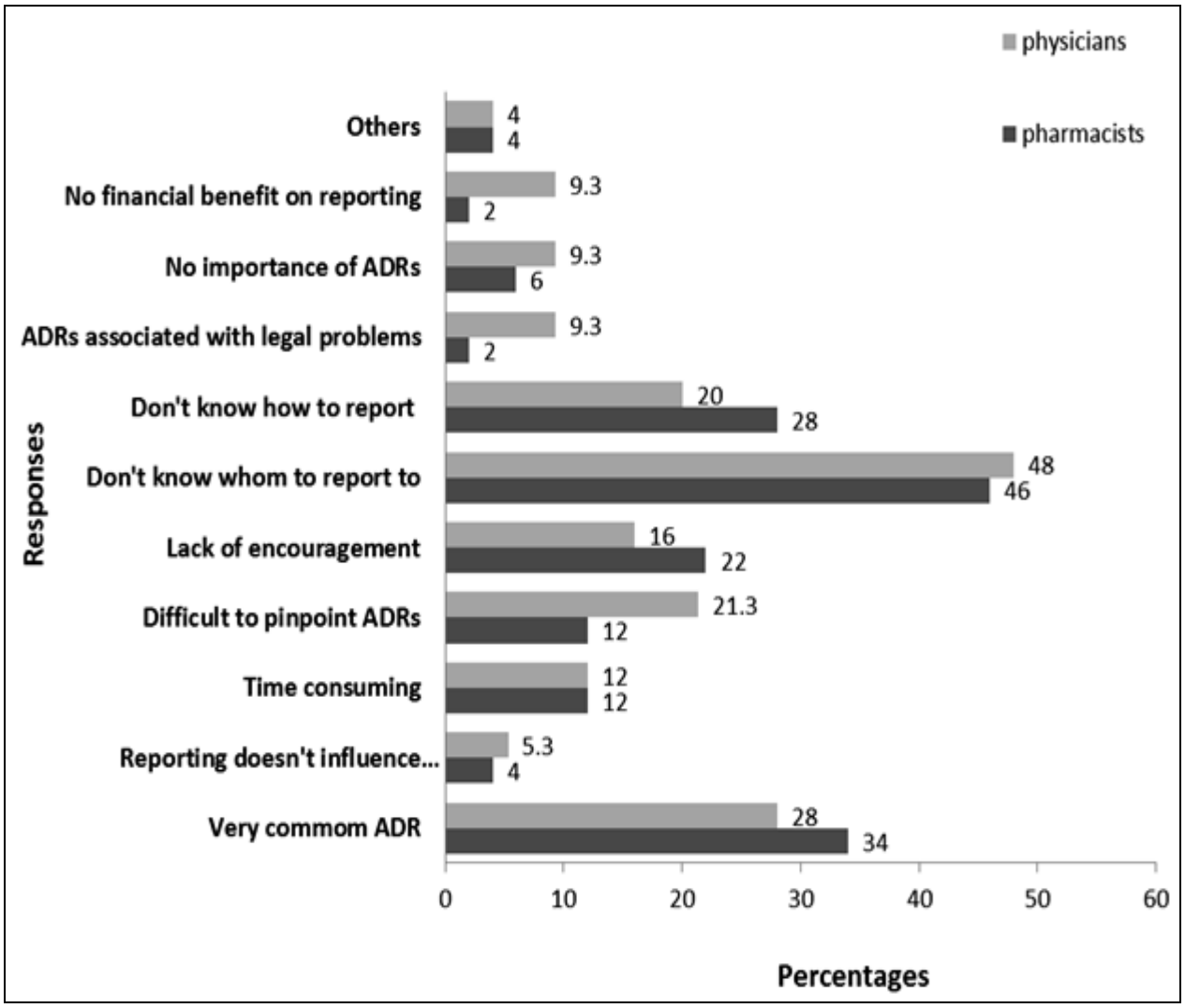

FIGURE1: REASONS FOR UNDER REPORTING OF ADR

However, recommendations from health Canada suggest reporting all ADR regardless of its type and severity [40].

Training on ADR Monitoring and Reporting: The last part of our survey questionnaire included the interest of survey participants in getting trained in the area of ADR monitoring and reporting.

Training: A total number of 46 (92%) pharmacists and 64 (85.3%) physicians mentioned that they have not been trained to report ADR, but a good number of 43 (86%) pharmacists and 56 (74.7%) physicians were interested in getting trained. It is significant to emphasize that 41 (82%) pharmacists and 59 (78.7%) physicians preferred having a local pharmacovigilance center. In our study, most of the participants mentioned that they have not been trained on monitoring and reporting ADR and they pointed out that getting trained would inspire them to report an ADR. This was in support of a study highlighting the importance of training to motivate ADR monitoring and reporting activities [26].

Reporting: Regarding whether ADR reporting would be beneficial to the patients, "Yes" response was given by 48 (96%) pharmacists and 68 (90.7%) physicians. While reporting ADR, 32 (64%) pharmacists and 52 (69.3%) physicians preferred to keep patient details confidential.

A significant number of pharmacists 36 (72%) and physicians 51 (68%) anticipated the role of information technology in order to facilitate ADR reporting. A vast number of pharmacists 48 (96%) and physicians 54 (72%) mentioned that they don't have ADR reporting forms in their department (Table 2).

TABLE 2: KAB REGARDING ADR TRAINING & REPORTING

KAB questionnaire items	YES		NO		Not sure	
	Pharmacists (n=50) N (%)	Physicians (n=75) N (%)	Pharmacists (n=50) N (%)	Physicians (n=75) N (%)	Pharmacists (n=50) N (%)	Physicians (n=75) N (%)
Are you trained to report ADR?	4 (8.0%)	6 (8.0%)	46 (92%)	64 (85.3%)	-	-
Are you interested in getting trained to report ADR?	43 (86.0 %)	56 (74.7 %)	6 (12.0 %)	13 (17.3 %)	-	-
Should the patient details be kept confidential while reporting?	32 (64.0 %)	52 (69.3 %)	10(20.0%)	11 (14.7 %)	8(16.0%)	7 (9.3 %)
Do you anticipate the role of information technology (mobile phone & e-mail reminders) in further facilitating & strengthening of ADR reporting system in U.A.E?	36 (72%)	51 (68%)	4 (8%)	7 (9.3%)	8 (16%)	10 (13.3%)
Are ADR reporting forms available in your department / work place?	2 (4.0%)	10 (13.3%)	48(96.0%)	54(72.0%)	-	-
Would ADR reporting be beneficial to patients?	48 (96.0 %)	68 (90.7 %)	0 (0.0 %)	1 (1.3 %)	2 (4.0 %)	1 (1.3 %)
Do you prefer having a local ADR/Pharmacovigilance center?	41 (82.0%)	59 (78.7%)	4 (8.0%)	3 (4.0%)	5(10.0%)	8 (10.7%)

Vast majority of the participants prefer having local pharmacovigilance centers and they also anticipate the role of information technology like the use of frequent reminder massages and e-mails to facilitate the reporting activities in UAE.

The main limitations of our study were that our study was limited sample size and was circulated only to hospital physicians and community pharmacists. Since, it was a survey-based study; the results were only based on the responses given by the survey participants and were not supported by any evidence. Personal opinions given by the respondents were considered.

Not all the surveys were included for analysis due to the incomplete/missing data.

CONCLUSION: We conclude that the awareness of ADR Reporting system in Ras Al Khaimah, U.A.E was limited. One of the main reasons for under reporting of ADR was that the respondents did not know "how to report" and "whom to report".

Hence, more ADR related awareness and training programs are required to continuously motivate the health care professionals to monitor, document and report ADR. Appointing clinical pharmacists in every hospital would be beneficial to enhance the ADR monitoring and reporting. We feel sending frequent reminders to health care professionals to report ADR through e-mails or short message service (SMS) to mobile phones could be beneficial in creating awareness & for further strengthening of pharmacovigilance activities.

Establishing a local pharmacovigilance center that would facilitate the reporting activities and would be more beneficial to help improve the ADR monitoring & reporting in UAE.

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Conflict of interest: Nil

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