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# SPONTANEOUS REPORTING OF ADVERSE DRUG REACTIONS IN UAE: OBSTACLES AND MOTIVATION AMONG COMMUNITY PHARMACISTS

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**Keywords:**

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**ABSTRACT:** Spontaneous reporting of adverse drug reactions (ADRs) is a broadly experienced technique of practicing pharmacovigilance (PV) activity. However, the progression of pharmacovigilance programs is limited by under-reporting of ADRs, as it is considered one of the major problems associated with PV programs development. This is the first study of its kind in the United Arab Emirates (UAE) that examines what inhibits and what motivates the community pharmacists (CPs) to report ADRs. Face to face questionnaire was used for data collection. Random sampling method was used to approach the potential respondents. Descriptive analysis was conducted using SPSS 20. Many barriers had been revealed that prohibit pharmacists participation in PV program; unavailability of reporting forms (81.8%), unknown address to contact (79.8%), the belief that all serious ADRs are detected before registration (70%), pharmacists unfamiliarity of how to report (69.1%) were the commonly shared reasons for under-reporting by CPs. Also, the majority (82.1%) of the respondents agreed that encouraging patients to report ADRs to the pharmacists is an important factor necessary for reporting ADRs. Also, 75.8% advised that ADRs reporting concept should be included in the university curriculum as it will enhance the reporting process. In Conclusion, the UAE PV center and the Ministry of Health (MOH) can play a major role in enhancing pharmacists' participation in ADRs reporting program and implementing an active collaborative role to overcome the obstacles revealed by the study.

**INTRODUCTION:** Establishing PV center program is one of the best strategies for monitoring ADRs, which in turn helps encouraging health care professionals to report suspected ADRs they may encounter in their clinical practice [1-6]. Spontaneous ADRs reporting is considered a major source of medicine safety data [7-11].

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It also plays an active role in ensuring the safe use of medicines and in minimizing the occurrence and severity of ADRs [3, 8-14]. With such systems, reporters submit ADRs reports voluntarily, and then the information entered into a database for assessment and signal generating [15]. However, there is a low level of reporting in which less than 10% of serious reactions are identified [16]. Poor understanding of the health care professionals towards the importance of reporting ADRs might be one of the reasons for under-reporting [1, 17, 18]. Also, the lack of knowledge about any ADRs reporting system was reported by most pharmacists in Hong Kong [19].

In Malaysia, the major reason for under-reporting was the lack of awareness about the purpose and function of national ADRs reporting [20]. While in China, the major reason for under-reporting is that the health care professionals have low basic knowledge about voluntary reporting of ADRs [1]. In 2008, the Health Authority in Abu Dhabi (HAAD) established a PV program for receiving all adverse reactions and medication errors reports and for monitoring the safety of all medicines in the UAE [21]. Participation of all health care professionals in reporting ADRs is the cornerstone for a successful PV program.

The pharmacist is often the last member of the health care team to see the patient before the medicine is taken. The pharmacist can even educate the patient about signs and symptoms that should be reported immediately. A major problem faced is the unavailability of published data regarding the role of the pharmacist toward PV activity.

Determination of ADRs reporting obstacles and encouraging factors among CPs will provide useful baseline data that help in assessing and improving the current PV system. Also, it will provide solutions, mechanisms, and a plan for decision makers to improve the ADRs reporting among UAE CPs.

**Study Objectives:** To determine the barriers faced by UAE CPs in reporting ADRs and the factors that may encourage the pharmacists to enhance the reporting process.

## MATERIALS AND METHODS:

**RESULT:** A descriptive cross-sectional that study report ADRs was run from February 2013 to June 2013. The study sampling was licensed CPs working in Ajman and Sharjah community pharmacies that are willing to participate.

The sample size of the study was calculated on steps by referring to similar studies conducted in Malaysia and Saudi Arabia [22-24]. Objectives of sample size were to ensure the achievement of maximum response and reliable statistical sample size. Rao soft online sample size calculator was used in calculating the minimum sample size required (218) [25]. The final chosen sample size was 300 to overcome nonresponse and to avoid decreased sample size than the minimum.

Two recruited pharmacists were requested to administer the questionnaire in a face to face interview; they were trained in an accumulative session to ensure understanding and uniform questionnaire administration. One licensed community Pharmacist invited to participate in the study from each Pharmacy.

The interviewer intervened only to clarify a question if required. Participants were informed that participation is voluntary. Informed consent from participants was obtained before conducting the study. Feedback given by the participants of the pilot study was considered, and corrections were made accordingly. Questions adjustments were made to the questionnaire to improve its validity. Data analysis was conducted using SPSS version 20. The study objectives were analyzed by descriptive analysis.

**TABLE 1: DEMOGRAPHIC DATA OF THE RESPONDENTS**

| Variables | Subgroup | Male 111- 49.8% | | Female 112- 50.2% | | Total 223 | |
|---|---|---|---|---|---|---|---|
| | | N | % | N | % | N | % |
| -Age | 22-30 | 29 | 26.1 | 54 | 48.2 | 83 | 37.2 |
| | 31-40 | 36 | 32.4 | 44 | 39.3 | 80 | 35.9 |
| | 41-50 | 32 | 28.8 | 11 | 9.8 | 43 | 19.3 |
| | 51 or over | 14 | 12.6 | 3 | 2.7 | 17 | 7.6 |
| -Nationality | Southeastern | 60 | 54.1 | 28 | 25.0 | 88 | 39.5 |
| | Asia | 27 | 24.3 | 76 | 67.9 | 103 | 46.2 |
| | Arab | 24 | 21.6 | 8 | 7.1 | 32 | 14.3 |
| -Year of graduation from college of pharmacy | <5 years | 21 | 18.9 | 40 | 35.7 | 61 | 27.4 |
| | 5-10 years | 30 | 27.0 | 36 | 32.1 | 66 | 29.6 |
| | >10 years | 60 | 54.1 | 36 | 32.1 | 96 | 43.0 |
| -Postgraduate certificate | -Yes | 13 | 11.7 | 11 | 9.8 | 24 | 10.8 |
| | No | 98 | 88.3 | 101 | 90.2 | 199 | 89.2 |

Out of 223 participants, 215 had not reported even a single ADR. The most common reasons for that, the reporting forms were not available (81.8%). Eighty percent of the pharmacists were unaware of the address to contact. Seventy percent of the participants believed that all serious ADRs are detected before registration. Sixty-nine percent didn't know how to report **Table 2**.

**TABLE 2: BARRIERS OF REPORTING ADRs**

| Barriers | N | % |
|---|---|---|
| 1. Reporting forms are not available. | 181 | 81.8 |
| 2. I don't know the address where these reports should be sent. | 178 | 79.8 |
| 3. The reporting form is too complicated to fill in. | 133 | 59.6 |
| 4. Reporting ADRs is time-consuming. | 103 | 46.2 |
| 5. All serious ADRs are detected before registration. | 156 | 70.0 |
| 6. I want to publish the case by myself. | 91 | 40.8 |
| 7. I am not convinced about the confidential handling of the reports. | 144 | 64.6 |
| 8. I fear it may harm the confidence of my patients. | 91 | 40.8 |
| 9. I find it difficult to admit that the patient has been harmed. | 120 | 53.8 |
| 10. I fear legal liability for reported ADR. | 89 | 39.9 |
| 11. I am not motivated to report. | 89 | 39.9 |
| 12. I have insufficient clinical knowledge regarding ADR. | 96 | 43.0 |
| 13. I don't know how to report an ADR. | 154 | 69.1 |
| 14. I am not convinced that ADR is caused by the drug. | 104 | 46.6 |
| 15. I think it is the doctor's responsibility. | 86 | 38.6 |
| 16. I think reporting ADRs useless. | 58 | 26.0 |
| 17. Reporting ADRs puts my career at risk. | 52 | 23.3 |
| 18. One report made no difference to ADR reporting process | 74 | 33.2 |

The majority (82.1%) of the respondents had agreed that encouraging patients to report ADRs to the pharmacist is an important factor necessary for reporting ADRs. Also, 75.8% had selected more attention to ADRs reporting in university curriculum will enhance the reporting process **Table 3**.

**TABLE 3: IMPORTANT FACTORS NECESSARY TO REPORT ADRs**

| Factors | N | % |
|---|---|---|
| 1. There was an obligation to do so. | 136 | 60.0 |
| 2. There are incentives. | 134 | 60.1 |
| 3. I see my colleagues doing so. | 130 | 58.3 |
| 4. My attention is drawn to it by a publication, for instance, the drug bulletin. | 143 | 64.1 |
| 5. I receive feedbacks from relevant authorities. | 155 | 69.5 |
| 6. The reporting process becomes simpler than what it is now. | 155 | 69.5 |
| 7. I can report through the internet. | 142 | 63.7 |
| 8. More attention to ADR reporting in the university curriculum. | 169 | 75.8 |
| 9. Encouraging patients to report ADRs to the pharmacist. | 183 | 82.1 |
| 10. There were regular updates and CME on ADR monitoring and reporting. | 165 | 74.0 |
| 11. Availability of telephone-based reporting service. | 149 | 66.8 |

**DISCUSSIONS:** This study acknowledged the most influential barriers hindering CPs in UAE from reporting ADRs. Some of the obstacles are logistics, such as unknown ADRs reporting program address (79.8%), lack of reporting forms (81.8%), the complexity of reporting forms (59.6%), and pharmacists' unfamiliarity of how to report (69.1%). Other difficulties are linked to pharmacists' understanding of the concept and their recognition to report spontaneous ADRs reporting program. These difficulties include CPs uncertainty of causality connection (46.6%), the belief that all serious ADRs are already known (70%), the perception that one ADR report has no effect (33.2%), ADRs reporting is time consuming (46.2%), clinical ignorance (43%), the CPs impression that its physicians' duty (38.6%), concern about legal accountability (39.9%), reporting may jeopardize CPs career (23.3%), lack of motivation to report (39.9%) and the impression that reporting is useless (26%). All of these barriers can be resolved by legitimate organization

and publicity of the ADRs program. Other barriers require prosperous training and UAE guidelines of ADRs reporting. Related outcomes were noted about CPs in a study conducted in Sweden [26]. Unavailability of ADRs reporting forms in community pharmacies considerably influenced the practice of ADRs reporting as the study revealed. It's the major reason for under-reporting in UAE (81.8%), as only 18.2% of pharmacists claimed to have ADRs reporting forms. This study finding reflects that community pharmacies are not sufficiently prepared with the required tools to support and enable CPs to participate actively in their working place in PV process.

Complying with the finding of Hasford et al. 2002, the current study revealed that 70% of CPs understood that ADRs are already detected and known before registration, so they were unwilling to report known ADRs.UAE CPs need to be well educated about drug pre-registration protocols and the limitations of clinical trials which highlight the continuous need for PV activity. Although, the PV HAAD center requirement encourages pharmacists to report all ADRs even without causality assessment, the vast majority of CPs had shared thought that only ADRs with proven causality could be sent. These findings comply with other study findings [28]. These observations reflect the common anxieties among the reporters as it is not mandatory to confirm the relationship between the drug and the ADRs. When an ADR is suspected, even those not known to be related to the drug should be reported. These finding highlight the need to focus on education through continuous medical education (CME), workshops, and conferences for CPs.

Several countries, including Australia, Canada, Sweden, New Zealand, Netherlands, and the USA included patient reporting in PV system [29]. Eighty-two percent of the CPs were aware of the patients' role in reporting ADRs to pharmacists as a motivating factor for reporting. This finding highlights the importance of establishing good communication with patients to increase patients' confidence in pharmacists, increasing ADRs reporting.

Many reports have connected pharmacists ADRs knowledge to practicing in spontaneous ADRs reporting [23, 30]. The results of the present study had indicated that having regular updates and CME on ADRs monitoring and reporting will increase pharmacists' participation in ADRs reporting activity (74%). Previous studies reported that an educational program is effective in successfully increasing the CPs knowledge score about PV and in improving their attitude towards the ADRs reporting process [23, 24, 28, 31]. An educational program can include presentations, workshops, and small group discussions. Also, providing information about PV for healthcare workers by mail, newsletters, reminders, advertisement, and continuous education to increase CPs knowledge about ADRs.

PV can be included in the pharmacy college curriculum to introduce students to this concept early in their career as 75.8% of the respondents consider more attention to ADRs reporting in university curriculum will enhance the reporting process.

In addition to educational programs, another approach recommended by the respondents that could enhance reporting is providing an easy and quick method for reporting (69.5%). Easy availability of ADRs reporting forms and ADRs Drop Boxes were also suggested in a previous study [31]. The ADRs reporting form can be designed more simply to ensure easy and wide reporting practice by any health care professional [32].

Sixty-four percent of the pharmacists agreed that online reporting would improve pharmacists' reporting activity. Parallel to previous studies supported that online ADRs reporting is a good approach to simple and wide participation of CPs in PV activity [22, 27]. These findings should encourage PV HAAD center and other relevant authorities to publicize this facility between CPs to maximize the response rate. All ADRs reporting programs concepts should be located on the internet, and pharmacists should be knowledgeable and stimulated to use them.

Another ADRs reporting facilitator is the publication of ADRs bulletins (64.1%) as it will play a vital role in expanding pharmacists' knowledge about the program regularly. Similar findings were revealed from another study [22].

Furthermore, 69.5% of enrolled participants believed that PV HAAD center feedback to sender would motivate pharmacists for more participation. Several studies supported such finding [22, 28]. About 60.1% of the pharmacists believed that receiving a reward for reports submitted will improve reporting; these findings comply with the findings of Van Grootheest *et al*., 2002. It is interesting to find out that financial reward to pharmacists will increase their participation in reporting ADRs. While, in fact, reporting is supposed to be an inherited and natural pharmacist professional activity. However, these findings contradict with the findings of Bawazir, 2006 and Vessal *et al.*, 2009, where the vast majority of the pharmacists considered compensation is a source of problems rather than a solution for under-reporting.

**CONCLUSION:** The results have emphasized the critical need for immediate interventions to motivate participation in ADRs reporting and to rectify the barriers identified by the study. It's the responsibility of PV HAAD center and the MOH to plan serious approaches to promote ADRs reporting program.

**LIMITATIONS:** The major limitation of this study is that the findings were restricted to only community pharmacists working in two cities in UAE, Sharjah, and Ajman. The outcomes would have been more significant if the study was conducted in all UAE cities.

**RECOMMENDATIONS:** PV HAAD center should build up the existing PV system by establishing an active rather than passive monitoring system of PV in the UAE. The new system should provide feedback to healthcare personnel for reported ADRs to inspire and provoke them to report more. Making ADRs reporting forms a regulatory requirement for the establishment, and running a community pharmacy will ensure reporting improvement.

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