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Knowledge, Attitude, and Practice of Community Pharmacists towards Pharmacovigilance and Adverse Drug Reactions: A Study from Sudan

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Abstract

Purpose: *The concept of Pharmacovigilance (PhV) evolved to improve patient safety and the quality of provided healthcare. Community pharmacists are considered to be key players in the process of PhV and reporting adverse drug reactions (ADRs).The aim of this study is to assess the knowledge, attitude, and practice of community pharmacists in relation to pharmacovigilance and adverse drug reactions.*

Study Design: *A cross sectional study.*

Subjects and Methods: *An observational cross-sectional survey was carried out among community pharmacists in Sudan to evaluate their knowledge, attitude and practice (KAP) towards Pharmacovigilance. The study was carried out between March and May 2020, including 201 community pharmacists who were selected through simple random sampling. A self-administered questionnaire was used as a data collection tool. Statistical analysis was carried out using SPSS software version 24.*

Results: *A total of 201 community pharmacists were included in the survey. Females constituted 68.7% of the study participants. Two-thirds of the study population were between 23 and 30 years of age. The majority had a career experience between 1 and 5 years (52.2%). The mean knowledge score among males was 3.48 (± 1.51), and 3.75 (± 1.36) among females. The difference in the mean knowledge score between the two genders was not statistically significant (p-value 0.197). 73.1% showed a positive attitude towards Pharmacovigilance. The mean attitude score was higher among females (2.97 vs 2.90). However, the difference was not statistically significant (p-value 0.662).*

Conclusion: *Community pharmacists may have a prominent role in responding to the increase of ADR reporting if they have enough knowledge about Pharmacovigilance and how to report it. This survey showed that community pharmacists had a positive attitude about ADR but, unfortunately, many of them had insufficient knowledge.*

1. Introduction

The World Health Organisation (WHO) defines adverse drug reaction (ADR) as "A response which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function" (WHO,1972). Despite the intense phases of study that a drug goes through to ensure its safety before being registered, ADR continues to be inevitable. This can be attributed to the fact that the pre-marketing studies don't include all age groups, ethnicities and other unforeseen variables that may play a role in developing ADR (Gautier, 2003).

Following the famous disaster of the Thalidomide in the 1960s, ADRs had been

evolved to improve patient safety and the quality of provided healthcare. The WHO defines PhV as"the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem" (WHO, 2006). This led to the formation of the WHO Programme for International Drug Monitoring (PIDM) in 1968 (WHO, 2020).

In 2008, Sudan joined the WHO PIDM (Isah, 2012).However, reporting to the PVC remains to be weak. This can be attributed to the fact that there are no legal obligations to reporting. In Sudan, community pharmacists are considered to be easily accessible and affordable healthcare providers. Their role extends beyond dispensing medications. Hence, they have the opportunity to detect and report ADRs for un-hospitilized patients more than any other healthcare professional. Therefore, this study was carried out with the primary objective to evaluate the knowledge, attitude and practice (KAP) of community pharmacists in Khartoum, the capital city of Sudan, towards PhV and reporting of ADR.

2. Methodology and Procedures

Study Design

An observational cross-sectional survey was conducted among community pharmacists in Khartoum to assess their KAP on PhV.

Study Setting

The study was carried out in the city of Khartoum, the capital of Sudan.

Sample Size and Method

A total of 201 community pharmacists were enrolled in the survey that was conducted during the period between March and May 2020. They were selected through simple random sampling.

Data collection

The tool used for data collection was a self-administered questionnaire. No names or contact details were recorded on the questionnaire to maintain privacy and confidentiality. It was pilot-tested on 6 participants to ensure its validity. The questionnaire was divided into four sections: demographic data, knowledge, attitude and practice. The knowledge section consisted of seven questions, attitude section comprised four questions, and practice presented one question. To avoid missing information and to ensure the quality of the collected data, the questionnaire was revised after being filled by each study participant.

Data Processing and Analysis

Each correct answer on the knowledge part was given one point. Thus, the knowledge score ranged between 0 (with no correct answer) and 7 (for all correct answers). A cut-off point of < 5 indicated insufficient knowledge.

The same scoring format was applied to the attitude part. Hence, the attitude score ranged between 0 and 4. A cut-off point of < 3 reflected a poor attitude, while a score of ≥ 3 a positive attitude. Statistical analysis of the collected data was carried out using SPSS software version 24. The mean and standard deviation (SD) were used as measures of central tendency and dispersion, respectively, to analyse the numerical variables.

T-test and ANOVA were used to compare the mean in knowledge and attitude scores between the different demographic variables. A p-value of<0.05 was set as a measure of statistical significance.

Statement of Ethics

A community pharmacist who was selected as a potential subject for the research was given a participant-information sheet that clearly stated the study title and the purpose of carrying it out. The selection process was also explained. Participation in the study was completely voluntary. Filling the questionnaire and handing it back was considered as consent for participating in the research.

3. Results and Discussion

Main Characteristics of the Sample

A total of 201 community pharmacists were included in the survey with a response rate of 88.2%. Females constituted 68.7% of the study participants, while 31.3% were males. Two-thirds of the study population were between 23 and 30 years of age. 29.4% were between 31 and 40 years and 3.5% between 41 and 50 years. The majority had a career experience between 1 and 5 years (52.2%). 27.4% had an experience between 6 to 10 years, 11.9% had less than a year and 8.5% above 10 years. The main characteristics of the sample are summarized in table 1.

Knowledge

57.7% of the surveyed sample had sufficient knowledge of PhV. This was reflected by a knowledge score ≥ 5. 26.4% were aware of the exact concept of PhV endorsed by the WHO and 70.1% understood what is meant by an ADR. The majority of the respondents appreciated the difference between an ADR and a medication error (84.1%), and 30.3% knew that ADRs are identified at the fourth phase of clinical trials. 47.3% were aware of the presence of a PV programme in Sudan, and 49.3% knew that the National Medicines and Poisons Board (NMPB) is the regulatory body responsible for monitoring ADRs in the country. The results of the knowledge section are presented in table 2.

The mean knowledge score among males was 3.48 (± 1.51), and 3.75 (± 1.36) among females. The difference in the mean knowledge score between the two genders was not statistically significant (p-value 0.197). The same applied to the difference in the mean knowledge score between the different age groups (p-value 0.075). However, the difference in the mean knowledge score in relation to the years of career experience was statistically

significant with a p-value of 0.048.The difference in the mean knowledge score among the different variables is presented in table 3.

Attitude

63.2% of the studied community pharmacists think that all ADRs should be reported and 62.7% stated that they had encountered ADRs during their professional practice. The majority (92.5%) agreed that ADR reporting and monitoring system would benefit the patient, and 76.6% think that ADR reporting is a professional obligation. The results of the attitude section are shown in table 4.

73.1% showed a positive attitude towards PhV. The mean attitude score was higher among females (2.97 vs 2.90). However, the difference was not statistically significant (p-value 0.662). The age group with the highest attitude score was31 – 40 years with a mean score of 3.24. The difference in mean attitude score among the different age groups had a p-value of 0.064. In regards to the years of experience, the difference also didn't show statistical significance. The difference in attitude score among the different variables is summarized in table 5.

Practice

Community pharmacists demonstrated a weak practice towards PhV, with only 10.4% reporting ADR to the NMPB during their professional practice. 80.1% stated that they were unclear about the reporting process. This can be attributed to lacking training, as 19.9% of the interviewed participants have received training on reporting ADRs.

Discussion

PhV centres effectiveness depends on the reporting of suspected ADRs. Despite the great steps that have been made in PhV, underreporting remains to be a vital issue. One of the reasons is the lack of knowledge which is considered to be the starting point to deal with the problem of underreporting of ADRs.

A study in Kuwait among pharmacists working in governmental hospitals showed that 61.5% were knowledgeable about PhV and 72.6% about ADRs (Alsaleh et al., 2017). Another cross-sectional surveyrevealed that 66.7% and 78.0% of pharmacists in the city of Basra, Iraq were aware about PhV and ADRs respectively. When compared to the results obtained in this study, we find that there is a noticeable difference when it comes to understanding the concept of PhV. 26.4% of the enrolled study participants were aware of the WHO definition of PhV. However, there was not much difference in understanding the definition of ADRs with 70.1% being aware of it.

The results of this study in regards to knowledge about PhV and ADRs are close to other studies in the same regional setting. A cross-sectional study conducted in two of the largest cities in Jordan, Amman and Zarga, showed that 19.2% of community pharmacists were aware about the definition of PhV and 67.7% about ADRs (Ali et al., 2018). In Yemen, 23.8% and 57.1% of community pharmacists in the capital city Sana'a knew what is meant by PhV and ADRs respectively (Al-Worafi et al., 2017).

49.3% of the community pharmacists participating in this survey were aware that the NMPB is the regulatory authority responsible for receiving ADRs reports. Suyagh et al. stated that 55.1% of the pharmacists in Jordan knew that the Food and Drug Administration in Jordan is the relevant authority for reporting ADRs (Ali et al., 2018). This reflects an area of professional weakness that needs to be addressed.

76.6% of the study participants view ADR reporting as a professional obligation. This is close to the figure reported by Al-Worafi et al. in Yemen (76.2%) (Al-Worafi et al., 2017) and lower than the one mentioned by Sharrad in Iraq (84.1%) (Sharrad, 2017). In their study, Alsaleh et al. reported that 26.8% of the surveyed participants previously reported an ADR. The main reason for underreporting was not knowing/familiar with the reporting process. Other reasons included poor communication between healthcare professionals and patients, poor time management by healthcare professionals and lack of awareness. This figure is higher than the one reported in this study (10.4%). It is also higher than the numbers reported in Iraq (6.1%) and Jordan (19.5%) (Sharrad, 2017; Ali et al., 2018). The absence of a legal obligation in Sudan to reporting ADRs can be a contributing factor to the reported figure in this survey (10.4%).

Community pharmacists enrolled in this survey highlighted a number of barriers to reporting ADRs in Sudan. These included unclearness of the reporting process, lack of time due to the work load and considering the reaction to be too well known. Some of these obstacles have been highlighted in other studies as well in different states. Khan points out that the unavailability of a professional environment to discuss ADRs is the first barrier in the reporting process in the eastern region in Saudi Arabia. Other obstacles included unavailability of ADR reporting forms and poor understanding of the reporting mechanism (Khan, 2013).

Suyagh et al. highlighted certain factors in Jordan that discourage ADRs reporting. These can be summarized in the following points: insufficient information from the patient, unavailability of the ADR reporting form, unawareness of the existence of a national PhV system, ADRs being too trivial to report and unclearness of the reporting process (Ali et al., 2018). Again, we see that particular barriers seem to be shared in common between different countries.

4. Conclusion and Suggestion

Community pharmacists have the opportunity to interact with patients, especially patients with chronic diseases. This can be attributed to the ease of access to them compared to other HCP who are usually based in hospitals or healthcare centres. Thus, it can be considered that community pharmacists may have a prominent role in responding to increase ADR reporting if they have enough knowledge about PV and how to report it. This survey showed that community pharmacists had a positive attitude about ADR but, unfortunately, many of them had insufficient knowledge.

The concept of PV needs to be integrated and emphasized in the undergraduate syllabus. Professional training programmes on ADRs reporting needs to be promoted. In addition, creative methods on the reporting process need to be adapted to cope with the era of mass media and telecommunications.

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Conflict of Interest

The authors have no conflicts of interest to declare.

Author Contributions

Rana Mohammed Tahir drafted the introduction, designed the questionnaire and wrote the discussion and conclusion. Mustafa Hussein designed the study, carried out the statistical analysis and drafted the results. Both authors read and approved the final manuscript.

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Table 1: Baseline characteristics of the sample population

Characteristics	Frequency, n (%)
Gender	
Female	138 (68.7%)
Male	63 (31.3%)
Age	
23 – 30 years	134 (66.7%)
31 – 40 years	59 (29.4%)
41 – 50 years	7 (3.5%)
51 years and above	1 (0.5%)
Career Experience	
< 1 year	24 (11.9%)
1 – 5 years	105 (52.2%)
6 – 10 years	55 (27.4%)
11 years and above	17 (8.5%)

Table 2: Knowledge Section

Question	Frequency, n (%)
What is pharmacovigilance?	
• The science detecting the type and incidence of adverse drug reaction (ADR) after drug is marketed	104 (51.7%)
• The science that monitors ADR's occurrence in hospitals	8 (4.0%)
• The process of improving drug safety	15 (7.5%)
• The detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem	53 (26.4%)
• I don't know	21 (10.4%)
What is an adverse drug reaction?	
• A response which is noxious and unintended, and which occurs at NORMALLY used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function	141 (70.1%)
• **A response which is noxious and unintended, and which occurs at** HIGHERdoses in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function	15 (7.5%)
• An error (of commission or omission) at any step along the pathway that begins when a clinician prescribes a medication and ends when the patient actually receives the medication	16 (8.0%)
• I don't know	29 (14.4%)
Is there a difference between an adverse drug reaction and medication error?	
• Yes	169 (84.1%)

• No	3 (1.5%)
• I don't know	29 (14.4%)
During which phase of clinical trials can ADR be identified?	
• Phase 1	20 (10.0%)
• Phase 2	29 (14.4%)
• Phase 3	21 (10.4%)
• Phase 4	61 (30.3%)
• I don't know	70 (34.8%)
Had any medicine been banned due to an ADR?	
• Yes	153 (76.1%)
• No	5 (2.5%)
• I don't know	43 (21.4%)
Is there a pharmacovigilance programme in Sudan?	
• Yes	95 (47.3%)
• No	22 (10.9%)
• I don't know	84 (41.8%)
Which regulatory body is responsible for monitoring ADR in Sudan?	
• Ministry of Health	27 (13.4%)
• Sudan Medical Council	11 (5.5%)
• Drug Information Centre	64 (31.8%)
• National Medicines and Poisons Board	99 (49.3%)

Table 3: Knowledge difference between the demographic variables

Characteristic	**Knowledge Score, mean (SD)**	**p-value**
Gender		
Male	3.48 (1.51)	0.197
Female	3.75 (1.36)	
Age		
23 – 30	3.50 (1.38)	0.075
31 – 40	4.07 (1.47)	
41 – 50	3.43 (0.97)	
51 and above	4.00 (0)	
Experience		
< 1	3.50 (1.02)	0.048
1 – 5	3.46 (1.53)	
6 – 10	3.96 (1.31)	
11 and above	4.24 (1.14)	

Table 4: Attitude Section

Question	**Frequency, n (%)**
Should all ADRs be reported?	
• Yes	127 (63.2%)

• No	48 (23.9%)
• I don't know	26 (12.9%)
Have you ever experienced ADR during your professional practice?	
• Yes	126 (62.7%)
• No	57 (28.4%)
• Maybe	18 (9.0%)
Do you think ADR reporting and monitoring system would benefit the patient?	
• Yes	186 (92.5%)
• No	4 (2.0%)
• Maybe	11 (5.5%)
Do you think ADR reporting is a professional obligation?	
• Yes	154 (76.6%)
• No	15 (7.5%)
• I don't know	32 (15.9%)

Table 5: Attitude difference between the demographic variables

Characteristic	**Attitude Score, mean (SD)**	**p-value**
Gender		
Male	2.90 (1.11)	0.662
Female	2.97 (0.93)	
Age		
23 – 30	2.82 (1.01)	0.064
31 – 40	3.24 (0.93)	
41 – 50	3.00 (0.81)	
51 and above	3.00 (0.00)	
Experience		
< 1	2.79 (1.10)	0.312
1 – 5	2.87 (0.97)	
6 – 10	3.13 (1.05)	
11 and above	3.12 (0.69)	

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