

Pharmacist's Awareness and Knowledge of Reporting Adverse Drug Reactions in Saudi Arabia

Fatimah Fouad Al Doughan^{1*}, Yousef Ahmed Alomi² , Mais Hasan Iflaifel³

¹Pharmacy Practice Department, College of Clinical Pharmacy, King Faisal University, Alahsaa, SAUDI ARABIA.

²The Former General Manager of General Administration of Pharmaceutical Care and Former Head, National Clinical Pharmacy and Pharmacy Practice and Pharmacy R and D Administration, Ministry of Health, Riyadh, SAUDI ARABIA.

³Pharmacy Practice Department, College of Clinical Pharmacy, King Faisal University, Alahsaa, SAUDI ARABIA.

Abstract

Objectives: Pharmacovigilance is considered a useful tool in detecting, assessing, understanding and preventing Adverse drug reactions (ADRs) to ensure the safety of medications and protect consumers from ADRs. Consequently, the progression and expansion of pharmacovigilance is urgent for safe and effective clinical practice; therefore, in this study, we aimed to compare the awareness and knowledge of the community and hospital pharmacists toward reporting ADRs in different regions of Saudi Arabia.

Methods: This cross-sectional study was conducted from January 2016 to March 2016 in Saudi Arabia. A validated and structured questionnaire was distributed by hand or via Internet to 263 hospital and community pharmacists. The questionnaire collected pharmacists' demographic information and pharmacists' understanding and knowledge of the pharmacovigilance system and reporting of ADRs.

Results: A total of 263 pharmacists responded to the questionnaire with 208 (79.09%) pharmacists from hospital pharmacy sites and 55 (20.91%) pharmacists from community pharmacy responding to the questionnaire. There is a significant difference in the pharmacovigilance concept ($p < 0.05$) between the hospital and community pharmacists. Most community pharmacists were unfamiliar with the existence of a pharmacovigilance center in Saudi Arabia. Furthermore, community pharmacists were unaware of where they could get an ADR reporting form, but hospital pharmacists were aware of this ($p < 0.05$).

Conclusion: The results of this study demonstrated that pharmacists who work at hospitals among different regions in Saudi Arabia had a higher awareness of the pharmacovigilance system than that of community pharmacists who worked at the community pharmacy.

Key words: Pharmacovigilance, Adverse drug reactions, Pharmacists, Knowledge, Awareness, Saudi Arabia.

Received: 05-09-2018;

Accepted: 13-11-2018

*Correspondence to:

Dr. Fatima Fouad Al Doughan
College of Clinical Pharmacy,
King Faisal University, Alahsaa,
SAUDI ARABIA.

Email: faldoughan369@gmail.com

DOI: 10.5530/ijpcs.2019.8.11

Copyright: © the author(s), publisher and licensee International Journal of Pharmacology and Clinical Sciences. This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial License, which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

This is an open access article distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License

Access this
article online



www.ijpcs.net

INTRODUCTION

In recent years, the roles of a pharmacist has significantly progressed in shifting from product-oriented to patient-oriented services. Nowadays, drug safety is considered one of the primary roles of a pharmacist.^[1]

which is more critical as the number of new drugs has continued to increase in the market. According to the US FDA, a total of 5,412 INDs have been registered in 2015, many of them containing active moieties reached 95% in 2015 that have not yet been approved.^[2] Many clinical trials do not test the new drugs with respect to their safety and long-term adverse effects,

regardless of their efficacy. Moreover, some groups in the community, depending on the type of studies, such as pregnant women and children, are prohibited from participating in such trials due to ethical concerns; therefore, the safety of the new drugs is not well known in this sensitive population. The clinical trial environment itself is different when comparing it to the real world with the presence of polypharmacy, drug interaction in specific populations, gene mutations and so on. Here comes the importance of post-marketing surveillance in tracking these new drugs after they have released to the market to monitor their unwanted adverse events. (ADR) is defined according to WHO^[3] as “any response to a drug whose effect is noxious and unintended and occurs at doses usually used in humans for prevention, diagnosis or therapy for disease or the modification of physiological function, whereas side effects are generally related to the therapeutic activities of a drug that may be beneficial as well as harmful”.^[4] Many studies have reported that ADRs are one of the primary reasons for the increased morbidity and mortality among patients.^[5,6] Establishing a pharmacovigilance system and reporting ADRs might help to overcome the problem of benefits versus risks.^[7] Pharmacovigilance is defined as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems”.^[8] Thus, it plays a significant role in preventing ADRs. In pharmacovigilance, safety means a collection of reports of adverse effects related to the drug.^[1] All healthcare providers and patients (anyone who deals with medications) are responsible for the reporting of ADRs.^[7,9] A pharmacist is also crucial in reporting and preventing ADRs.^[10] In 2009, Saudi Arabia initiated a pharmacovigilance system, which along with the drug safety centers made electronic and paper ADR forms available.^[7] According to the statistics conducted by the Saudi FDA, (75,486) (98%) reports have been received that are related to ADRs; and 1% of the reports were for medication errors and 0.5% of the reports were for product quality, 75% of the ADRs reports were serious ADRs and 25% of them were not serious ADRs. Pharmaceutical companies did most of the reporting (95%), but 4% of the reports were generated from various hospitals.^[11] The question is whether the pharmacists are aware of this system and their opportunity to make a difference in saving patient's life in the future. Different studies have been conducted in Riyadh,^[12] Al-Ahssa^[13] and Makkah^[14] to assess the awareness of the pharmacists regarding ADR reporting system among the community and hospital pharmacies

in Saudi Arabia. The results were disappointing; most of the community and hospital pharmacists were not familiar with ADR reporting system or the pharmacovigilance system. Consequently, their response in reporting ADRs is substantially inferior to what is required. The success and effectiveness of the pharmacovigilance system depend significantly on reporting ADRs from all healthcare providers and the patients as they deal with medications.^[9]

To the best of our knowledge, no study has compared community and hospital pharmacists' awareness of the pharmacovigilance system in Saudi Arabia. Therefore, in this study, we aimed to assess the knowledge and awareness of ADR reporting system and the pharmacovigilance system between the hospital and community pharmacists in Eastern, Western, Central and other regions of Saudi Arabia.

METHODS

This cross-sectional study was conducted from January 2016 to March 2016 in Al-Sharqiyah, Riyadh, Jeddah and another regions in Saudi Arabia. A total of 263 pharmacists (both hospital and community pharmacists) enrolled in this study and with the approval of health research center in the eastern region, the questionnaire was distributed among hospital pharmacists (both public and private) and community pharmacists (chain and independent pharmacies). Pharmacists completed the validated structured questionnaire and the questionnaires were delivered by hand or via Internet depending on the accessibility. Informed consent was obtained from all participants and were informed that their information was private and confidential and that the results would be presented anonymously. A questionnaire was prepared and adapted from.^[15] The questionnaire collected pharmacists' demographic information and there were nine questions to assess the pharmacists' understanding and knowledge regarding the pharmacovigilance system and ADR reporting and there were questions regarding pharmacists recommendations and suggestions. We used SPSS version 21 for the statistical analysis. P value was calculated by the chi-squared test for categorical variables. Mean and standard deviation (SD) were used to describe continuous variables, whereas percentage was used to describe qualitative variables.

RESULTS

In this study, there were a total of 263 responders; of

them, 208 (79.09%) responded from hospital pharmacy sites and 55 (20.91%) responded from community pharmacy. Most community pharmacies were from Al-Sharqyah (43 (78.18%)), whereas the highest percentage of hospital pharmacies were from Al-Riyadh (78 (37.68%)) and from Al-Sharqyah (73 (35.27%)). The number of responders was statistically significant between most of the cities ($p < 0.05$). Most of the responders were males (173 (65.78%)) with statistically significant responders from hospital pharmacies and with significantly more female responders; male responders from community pharmacy were higher than that of female responders ($p < 0.05$). Most of the pharmacists participated in this study were in the age group of 24–35 years without any statistically significant differences between hospital or community pharmacies ($p > 0.05$). BSc in pharmacy was the highest level of education between groups (88.89% community pharmacist and 52.88% hospital pharmacists) without any statistically significant differences among all

educational levels ($p < 0.05$) except for Ph.D. degree; the number of pharmacists in hospital pharmacists were more than those in community pharmacy ($p < 0.05$). However, nine years of experience were more common in community pharmacists' group ($p > 0.05$), whereas pharmacists in hospital pharmacies had 1–3 years of experience ($p < 0.05$) (Table 1).

The hospital pharmacists were aware of the concept of pharmacovigilance system, which was statistically and significantly more 156 (75%) than that of community pharmacists (30 (54.55%)) ($p < 0.05$). About 27 (49.04%) responders among the community pharmacists did not know the meaning of pharmacovigilance and only 20 (36.36%) responders knew about it, whereas 59 (30.89%) responders among hospital pharmacists defined the meaning of pharmacovigilance correctly and 82 (42.93%) responders did not; this result was without any statistically significant differences between groups ($p < 0.05$). About the definition of

Table 1: Demographic data for study sample (N = 263).

Parameter	Hospital Pharmacy	Community Pharmacy	Total	P value
Location, N (%)				
Al-Riyadh	78 (37.68)	8 (14.55)	86 (32.82)	< 0.05
Al-Sharqyah	73 (35.27)	43 (78.18)	116 (44.27)	< 0.05
Jeddah	33 (15.94)	2 (3.64)	35 (13.36)	< 0.05
Other	23 (11.11)	2 (3.64)	25 (9.54)	> 0.05
Total	207 (79.01)	55 (20.99)	262 (100)	
Gender				
[Female; N (%)]	89 (42.79)	1 (1.82)	90 (34.22)	< 0.05
[Male; N (%)]	119(57.21)	54 (98.18)	173 (65.78)	< 0.05
Total	208 (79.09)	55 (20.91)	263 (100)	
Age [years]				
24–35	153 (73.91)	43 (78.18)	196 (74.81)	> 0.05
36–45	50 (24.15)	11 (20.00)	61 (23.28)	> 0.05
46–55	4 (1.93)	1 (1.82)	5 (1.91)	> 0.05
> 55	0 (0.00)	0 (0.00)	0 (0.00)	> 0.05
Total	207 (79.01)	55 (20.99)	262 (100)	
Educational level; N (%)				
BSc in pharmacy	110 (52.88)	48 (88.89)	158 (60.31)	< 0.05
PharmD	52 (25.00)	3 (5.56)	55 (20.99)	< 0.05
Masters	40 (19.23)	3 (5.56)	43 (16.41)	< 0.05
PhD	6 (2.88)	0 (0.00)	6 (2.29)	> 0.05
Total	208 (79.39)	54 (20.61)	262 (100)	
Years of practice [years]				
< 1	2 (0.97)	1 (1.82)	3 (1.15)	> 0.05
1 – 3	75 (36.23)	9 (16.36)	84 (32.06)	< 0.05
4 – 6	41 (19.81)	17 (30.91)	58 (22.14)	> 0.05
7 - 9	30 (14.49)	8 (14.55)	38 (14.50)	> 0.05
> 9	59 (28.50)	20 (36.36)	79 (30.15)	> 0.05
Total	207 (79.01)	55 (20.99)	262 (100)	

ADR, 24 (44.44%) and 107 (57.22%) respondents from community and hospital pharmacies, respectively, defined it correctly without any statistically significant differences ($p>0.05$). Most of the community and hospital pharmacists did not attend a course or a workshop about pharmacovigilance prior to the conduct of this study (94.44%, 78.74%) with statistically significant differences ($p<0.05$). In addition, 31 (56.36%) community pharmacists and 99 (47.60%) hospital pharmacists, were not familiar with the existence of legal provisions in the Medicines Act that provide for pharmacovigilance activities. There was a significant difference between hospital pharmacists and community pharmacists' awareness of the existence of a pharmacovigilance center in Saudi Arabia and the presence of an official, standardized form for reporting ADRs ($p <0.05$ and <0.05 , respectively). About 43 (78.18%) community pharmacists did not know from where to get the ADR reporting form, whereas 141 (63.50%) hospital pharmacists did know about it without any significant differences between them.

Moreover, community and hospital pharmacists were not aware of the period which should report serious ADRs (85.45% and 70.19%, respectively) without any significant differences between them (Table 2).

Pharmacists' suggestions and recommendations of reporting of ADRs among healthcare providers

Most of the pharmacists were requested to conduct workshops and training sessions for the healthcare providers at their work site to raise awareness regarding the pharmacovigilance and reporting process. They also recommended the pharmacovigilance course and reporting process to be taught to pharmacy students. Some pharmacists recommended connecting it with the annual employee evaluation. Other pharmacists recommended joining all hospitals and medical centers with SFDA (pharmacovigilance center). Some pharmacists showed interest in receiving moral incentives such as "receiving feedback from SFDA to the reporters on the reported ADR or a monthly report

Table 2: Assessment of pharmacists' understanding of pharmacovigilance concepts and policies.

No.	Factors	Type of working site	Yes (%)	No (%)	I do not know (%)	No. of respondents	P value
1	Have you ever heard about the concept of pharmacovigilance? Yes	CP	30 (54.55)	25 (45.45)	-	55 (20.91)	< 0.05
		HP	156 (75)	52 (25)	-	208 (79.09)	< 0.05
		Total	186 (70.72)	77 (29.28)	-	263 (100)	
2	What is the definition of Pharmacovigilance? Correct Answer	CP	20 (36.36)	8 (14.55)	27 (49.09)	55(22.36)	< 0.05
		HP	59 (30.89)	50 (26.18)	82 (42.93)	191(77.64)	< 0.05
		Total	79 (32.11)	58 (23.58)	109 (44.31)	246 (100)	
3	What is the definition of adverse drug reaction? Correct Answer	CP	24(44.44)	23(42.59)	7 (12.96)	54 (22.41)	< 0.05
		HP	107 (57.22)	51(27.27)	29 (15.51)	187(77.59)	< 0.05
		Total	131 (54.36)	74 (30.71)	36 (14.94)	241 (100)	
4	Have you ever had a course/ attended a workshop about pharmacovigilance? Yes	CP	3 (5.56)	51 (94.44)	-	54 (20.69)	< 0.05
		HP	44 (21.26)	163 (78.74)	-	207 (79.31)	< 0.05
		Total	47 (18.01)	214 (81.99)	-	261(100)	
5	In Saudi Arabia, are there legal provisions in the Medicines Act that provide for pharmacovigilance Activities? Yes	CP	19 (34.55)	5 (9.09)	31 (56.36)	55 (20.91)	> 0.05
		HP	102 (49.04)	7 (3.37)	99 (47.60)	208 (79.09)	> 0.05
		Total	121 (46.01)	12 (4.56)	130 (49.43)	263 (100)	
6	In Saudi Arabia, is there a pharmacovigilance center?	CP	12 (21.82)*	2 (3.64)	41 (74.55)*	55 (20.91)	*< 0.05
		HP	124 (59.62)*	7 (3.37)	77 (37.02)*	208 (79.09)	*< 0.05
		Total	136 (51.71)	9 (3.42)	118 (44.87)	263 (100)	
7	In Saudi Arabia, is there an official, standardized form for reporting adverse drug reactions? Yes	CP	16 (29.09)*	2 (3.64)	37 (67.27)*	55 (20.91)	*< 0.05
		HP	151 (72.60)*	6 (2.88)	51 (24.52)*	208 (79.09)	*< 0.05
		Total	167 (63.50)	8 (3.04)	88 (33.46)	263 (100)	
8	Do you know from where can you get the ADR reporting form?	CP	12 (21.82)	43 (78.18)	-	55 (20.99)	< 0.05
		HP	141 (68.12)	66 (31.88)	-	207 (79.01)	< 0.05
		Total	153 (58.40)	109 (41.60)	-	262 (100)	
9	Do you know what is the period within which you should report a serious ADR experienced by a patient?	CP	8 (14.55)	47 (85.45)	-	55 (20.91)	< 0.05
		HP	62 (29.81)	146 (70.19)	-	208 (79.09)	< 0.05
		Total	70 (26.62)	193 (73.38)	-	263 (100)	

from SFDA specifying any trends would be nice to see in the future.” Some community pharmacists requested for Internet access and a printed protocol on how to report ADR in the pharmacy.

DISCUSSION

In this study, our primary objective was to assess the awareness of both hospital and community pharmacists in different regions of Saudi Arabia with respect to pharmacovigilance and reporting of ADRs. According to our results and previous reports, lack of knowledge regarding the pharmacovigilance and reporting of ADRs was the most crucial factor for the underreporting of ADRs, which many countries have experienced, indicating that it is a common problem.^[16-19] Hospital pharmacists have a significantly higher awareness regarding pharmacovigilance system and ADR reporting than that of community pharmacists. Their increased awareness might be explained by the nature of their work, which exposes them to situations requiring reporting. This shows the efforts of the drug regulatory body toward enhancement of awareness among hospital pharmacists.^[12] Because hospital pharmacists are more aware of pharmacovigilance practice, their reports on such matters were 20 times more than those reported by community pharmacists.^[20] Furthermore, some previous studies have reported a poor awareness regarding pharmacovigilance and ADR reporting among community pharmacists.^[12-14,21]

In this study, community pharmacists displayed poor awareness regarding reporting of ADRs as they were not aware of an ADR form, much less from where they would get one. To improve the state of underreporting especially by community pharmacists, low awareness should be considered as a starting point. As reported in previous studies, pharmacists' knowledge plays a significant role in enhancing ADR reporting; it is an attitude and considered as a modifiable variable that can be improved by educational programs that have the power to influence ADR reporting.^[20] It is noteworthy that pharmacists who participated in this study showed a keen interest to learn and improve their roles as suggested by them to conduct workshops and training sessions on the same. Other pharmacists suggested that pharmacovigilance course and reporting process should be included in their academic curriculum. Furthermore, a collaborative effort between pharmacists themselves and the SFDA, MOH and universities is highly warranted in order to raise awareness among pharmacists in Saudi Arabia

especially pharmacists who work in community pharmacies as they need more attention and care regarding pharmacovigilance and reporting of ADRs.

Study limitations

There were some limitations in this study. First, part of the questionnaire was in an electronic format, which could have contributed to some bias. Second, some paper questionnaires were not collected at the same time because pharmacists were busy. Finally, they might were not willing to reveal their practice deficiencies.

CONCLUSION

Hospital pharmacists are more aware of the pharmacovigilance system than community pharmacists are. Educational programs are required to increase pharmacists' awareness about the pharmacovigilance system.

ACKNOWLEDGEMENT

We wish to thank health research center in eastern region for distributing the questionnaire among hospitals.

CONFLICT OF INTEREST

None.

ABBREVIATIONS

ADRs: Adverse Drug Reactions; **FDA:** Food and Drug Administration; **SFDA:** Saudi Food and Drug Authority; **MOH:** Ministry of Health; **INDs:** investigational new drugs; **NMEs:** New molecular entities; **BSc:** Bachelor of Science; **SPSS:** Statistical Package for the Social Sciences.

ORCID ID

Yousef Ahmed Alomi  <https://orcid.org/0000-0003-1381-628X>

REFERENCES

1. Janarthanan VV, Ramakrishnan G, Krishnamurthy S, Sahar AI. Pharmacist as Pharmacovigilance Practitioner. *Indian J Pharm Pract.* 2015;8(1):2-6.
2. Jenkins JK. CDER New Drug Review: 2015 Update. 2015.

3. World Health Organization. The Importance of Pharmacovigilance - Safety Monitoring of medicinal products. WHO. 2002;1-52. Available from: <http://apps.who.int/medicinedocs/pdf/s4893e/s4893e.pdf>
4. Rohilla A, Yadav S. Adverse drug reactions: An Overview. *Int J Pharmacol Res.* 2013;3(1):10-2.
5. Patel H, Bell D, Molokhia M, Srishanmuganathan J, Patel M, Car J, *et al.* Trends in hospital admissions for adverse drug reactions in England: Analysis of national hospital episode statistics 1998-2005. *BMC Clin Pharmacol.* 2007;7(1):9.
6. Pirmohamed M, James S, Meakin S, Green C. Adverse drug reactions as cause of admission to hospital. *BMJ Br Med J.* 2004;329(7463):460.
7. Alshammari TM, Alshakka M, Aljadhey H. Pharmacovigilance system in Saudi Arabia. *Saudi Pharm J.* 2017;25(3):299-305.
8. World Health Organization. Reporting and Learning System for Medication Errors: The Role of Pharmacovigilance Centres. WHO Press. 2014;96. Available from: http://apps.who.int/iris/bitstream/handle/10665/137036/9789241507943_eng.pdf?sequence=1
9. Sales I, Aljadhey H, Albogami Y, Mahmoud MA. Public awareness and perception toward Adverse Drug Reactions reporting in Riyadh, Saudi Arabia. *Saudi Pharm J.* 2017;25(6):868-72.
10. Kaboli PJ, Hoth AB, McClimon BJ, Schnipper JL. Clinical Pharmacists and Inpatient Medical Care. *Arch Intern Med.* 2006;166(9):955-64
11. Saudi Food and Drug Authority - Drug Sector [Internet]. [cited 2019 Jan 22]. Available from: <https://www.sfda.gov.sa/en/drug/Pages/default.aspx>.
12. Mahmoud MA, Alswaida Y, Alshammari T, Khan TM, Alrasheedy A, Hassali MA, *et al.* Community pharmacists' knowledge, behaviors and experiences about adverse drug reaction reporting in Saudi Arabia. *Saudi Pharm J.* 2014;22(5):411-8.
13. Khan TM, Azhar S. A study investigating the community pharmacist knowledge about the appropriate use of inhaler, Eastern Region AlAhsa, Saudi Arabia. *Saudi Pharm J.* 2013;21(2):153-7.
14. Al-Hazmi NN, IL N. A Study of Community Pharmacists?. Awareness and Contributions to Adverse Drug Reactions (ADRs) Reporting Systems in the Makkah, Kingdom of Saudi Arabia (KSA). *J Clin Trials.* 2013;3(1):1-5.
15. Suyagh M, Farah D, Abu FR. Pharmacist's knowledge, practice and attitudes toward pharmacovigilance and adverse drug reactions reporting process. *Saudi Pharm J.* 2015;23(2):147-53.
16. Generali JA, Danish MA, Rosenbaum SE. Knowledge of and attitudes about adverse drug reaction reporting among Rhode Island pharmacists. *Ann Pharmacother.* 1995;29(4):365-9.
17. Granas AG, Buajordet M, Stenberg-Nilsen H, Harg P, Horn AM. Pharmacists' attitudes towards the reporting of suspected adverse drug reactions in Norway. *Pharmacoepidemiol Drug Saf.* 2007;16(4):429-34.
18. Green CF, Mottram DR, Rowe PH, Pirmohamed M. Attitudes and knowledge of hospital pharmacists to adverse drug reaction reporting. *Br J Clin Pharmacol.* 2001;51(1):81-6.
19. Toklu HZ, Uysal MK. The knowledge and attitude of the Turkish community pharmacists toward pharmacovigilance in the Kadikoy district of Istanbul. *Pharm World Sci.* 2008;30(5):556-62.
20. Herdeiro MT, Figueiras A, Polnia J, Gestal-Otero JJ. Influence of Pharmacists Attitudes on Adverse Drug Reaction Reporting. *Drug Saf.* 2006;29(4):331-40.
21. Nimisha HMS, Muhammed LTB. The Current Perspective of Community Pharmacists towards Pharmacovigilance. *J Pharmacovigil.* 2015;3(5).

Cite this article as: Doughan FFA. Pharmacist's Awareness and Knowledge of Reporting Adverse Drug Reactions in Saudi Arabia. *Int J Pharmacol. Clin. Sci.* 2019;8(1):60-5.