

Physician's Knowledge of Adverse Drug Reaction in Saudi Arabia

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ABSTRACT

Objectives: To state the physicians and dentists' knowledge and responsiveness of the adverse drug reaction (ADR) and reporting system in Saudi Arabia. **Methods:** It was a cross-sectional design of an authorized self-administered electronic survey about awareness and knowledge valuation of the ADR reporting system in Saudi Arabia. The electronic survey contained of demographic data and designated knowledge assessment of participants about the ADR reporting system. **Results:** The total number of participants was 151. Of those, 111 (73.5%) were physicians, while dentists were 39 (26.5%). Of those (93.38%) responders who perceived of the ADR reporting system and (54.3%) knew the diverse types of hypersensitivity reaction. Also, (45.33%) knew the official form of ADR reporting system, (43.71%) knew to reflect the ADR as sentinel events and (34.44%) knew about the legal provision in the medicine act that provides pharmacovigilance activities in Saudi Arabia. **Conclusion:** The physicians knowledge of ADR and reporting system was insufficient in the Kingdom of Saudi Arabia. Targeting education and training is a planned goal to recover physicians' ADR knowledge and all healthcare professionals and ADR's documentation system.

Key words: Physician, Knowledge, Reporting, Adverse drug reaction, Saudi Arabia.

INTRODUCTION

In 1957, thalidomide was presented as a treatment for morning sickness and nausea. It was supposed that safe and harmless and many pregnant women worldwide were employed for treating morning sickness and nausea related with pregnancy. As a result, it has instigated a catastrophe in the birth of more than 10,000 cases of extremities malformation.^[1-3] This disaster altered the system of pharmacovigilance; in 1968, the World Health Organization was institute programmed for International Drug Monitoring. Phase I, II and III clinical trials of the drug are inadequate to present all the drug's adverse effects; it applied to selected population and for choose time for the clinical trial, so after post-market of a drug many of adverse effects are present occasionally are serious, so that many drugs which are withdrawn from the market; as a result of it.^[1,3,4]

The World Health Organization (WHO) recognized ADR as "A response to a drug that is noxious and unintended, which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or the modifications of physiological function." The ADR measured the significant problems related with medications with different express severity, time of onset and duration. Also, the adverse drug reactions have negative effects on health and cost, leading to hospitalization, life-threatening consequences, damage, or impairment, or even death. Therefore, it is vital for healthcare professionals (physicians, pharmacists, nurses) to monitor, evaluate and report ADR. The reporting of ADR is the accountability of all healthcare professionals and even patients.^[2,5,6] The term Pharmacovigilance (PV) was well-defined as

"Process and science of monitoring the safety of medicines and taking action to reduce the risks and increase the benefits of medicines".^[1] The spontaneous reporting of ADR is the most crucial pharmacovigilance tool and measured helpful for classifying rare, infrequent, or delayed adverse drug reactions, therefore improving safety and the quality of life. It is a substantial problem toward pharmacovigilance. Many causes were leading to them, like lack of clinical expertise; therefore, it converts challenging to determine ADR, other reasons as lack of time and lack of knowledge to physicians.^[7] Pharmacovigilance is a new notion in Saudi Arabia. Many health care professionals have not obviously understood the pharmacovigilance and reporting process for ADR.^[5]

Knowledge of ADR Report

Knowledge is ultimate to reporting ADR. A lack of experience or lacking knowledge in healthcare professionals leads to deficient awareness about the importance of reporting ADR, how to work report and fill the form of ADR, also what ADR needs a report, all in finally lead to under-reporting and adverse effect on medication safety in the past ten years. Various information about the physician's knowledge of adverse drug reaction and reporting systems was taken. A systematic review study presented the poor physician knowledge of ADR and reporting system related issues. Besides, more than twenty-four studies were printed in 2015-2020 in ten countries between. The studies displayed 12-26% of physicians knew the pharmacovigilance center. In contrast, the physicians knowledge of the pharmacovigilance

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system and ADR displayed 27-64% only. Besides, 30% of physicians never perceived about ADR.^[8-31] The study was conducted in Saudi Arabia to assess the knowledge of ADR reporting or pharmacovigilance among healthcare professionals. The study contained of 135 participants (17 physicians). The results indicated that 54.07% of the participants only were acquainted with ADR reporting.^[13] Another study in Al-Madinah Al-Munawwarah city. The total number of participates was 384 participants (148 physicians among them). The findings exhibited that 39.6% of participants were not accustomed with the national pharmacovigilance system despite having a positive mindfulness of ADR reporting.^[9] In Riyadh at King Saud medical city, out of 399 participants (52 physicians of participants), only 14.8% of all participants knew the term ADR,^[15] while at King Khalid University Hospital out of 88.7%, 94 of physicians didn't know about the national pharmacovigilance system.^[10] In Al-Khobar at King Fahd Hospital studied with 331 participants (161 physicians among participants). The results revealed 62.5% of physicians was not accustomed with the pharmacovigilance term, 62.2% did not know the pharmacovigilance center and 89.9% had not looked any courses workshops.^[12] In Jeddah city, 337 hospital physicians participants, the results were specify to 75% of them knew correct definition of ADR, while only 16.6% had alertness about national pharmacovigilance center and 15.1% had not aware of any elements of ADR reporting.^[11] In multi-center study in Saudi Arabia, 336 participants, only 33% of healthcare professionals were aware of national pharmacovigilance center (24% of them physicians).^[16]

METHODS

It is a cross-sectional study of the physicians knowledge of ADR and reporting system in Saudi Arabia. It was a self-administered electronic investigation for physicians or dentists who functioned in Saudi Arabia with any specialisms and any geographical locations. All students or interns were not comprised in the study. The survey comprised of two parts. The first section contained of demographic data about the responders, while the second section entailed of various elements knowledge valuation of physicians about ADR and reporting system from earlier literatures.^[8-32] The 5-point Likert response scale system was employed with closed-ended questions. According to the previous literature, the sample calculation of a cross-sectional study with a confidence level of 95% with z score of 1.96, margin of error 5-6.5%, unlimited population size, population percentage 50% and drop-out

rate 10%. As a result, the sample size will equal to 251 to 432 with a power of study of 80%.^[33-35] The response rate required of calculated sample size at least 60-70% and above.^[35,36] The survey was disseminated through social media, comprising whatsapp and telegram, to various physicians and dentists. The reminder message and follow-up was taken every 1-2 weeks. The survey was legalized through the revision of expert reviewers and pilot testing. Besides, various tests of reliability like McDonald's ω , Cronbach alpha, Guttman's λ_2 and Guttman's λ_6 had been completed with the study. The survey analysis was done through the monkey survey system. SPSS, JASP and Microsoft excel sheet version 16 with description and frequency analysis, good of fitness analysis, correlation analysis and inferential analysis of factors affects physicians' knowledge of ADR and reporting system. The STROBE (Strengthening the reporting of observational studies in epidemiology statement: guidelines for reporting observational studies) directed the reporting of the current study.^[37,38]

RESULTS

The total number of responders was 151, with a response rate (60.15%). Of those 111

(73.5%) were physicians and 39 (26.5%) were dentists. Most responders from central 76 (50.68%) and north area 27 (18%), respectively with statistically significant among all regions ($p < 0.05$). The gender distribution was male 83 (54.97%) and female was 68 (46.03%) with non-statistically significant ($p > 0.05$). Most participants were in age (24-45) years 111 (73.5%) with statistically significant between all age levels ($p < 0.05$). Many responder' qualifications were residents 62 (41.33%) and consultants 42 (28%), while most of the participants held physicians or dental staff jobs 116 (77.33%) with statistically substantial among all types of qualifications and job positions ($p < 0.05$). Most of the responders had more than nine years' experience 60 (40%) and (1-3) years experiences 35 (23.33%) with statistically significant between all length's groups of experiences ($p < 0.05$). The most physicians' participants were medical 19 (12.67%) and surgical field was 17 (9.33%), while the dentists specialisms were restorative dentistry 9 (12.16%) from the total number of participants with statistically important among all specialisms ($p < 0.05$) (Table 1 and 2).

Table 1: Demographic social information.

Nationality	Response Count	Response Percent	P-Value
Central area	76	50.67%	< 0.05
North area	27	18.00%	
South area	12	8.00%	
East area	16	10.67%	
West area	19	12.67%	
Answered question	150		
Skipped question	1		
Gender	Response Count	Response Percent	
Male	83	54.97%	> 0.05
Female	68	45.03%	
Answered question	151		
Skipped question	0		
Age	Response Count	Response Percent	
24-35	82	54.30%	< 0.05
36-45	29	19.21%	
46-55	16	10.60%	
> 55	24	15.89%	
Answered question	151		
Skipped question	0		

Table 2: Demographic, social information.

Physician Qualifications	Response Count	Response Percent	P-value
Intern	9	6.00%	< 0.05
Resident	62	41.33%	
General Practitioner	10	6.67%	
Specialist	27	18.00%	
Consultant	42	28.00%	
Answered question	150		
Skipped question	1		
Position Held	Response Count	Response Percent	
Director of medical unit	14	9.33%	< 0.05
Assistant director of the medical unit	5	3.33%	
Medical Director	14	9.33%	
Physician or Dentist staff	116	77.33%	
Program Coordinator	1	0.67%	
Answered question	150		
Skipped question	1		
Years of experiences in the medical career	Response Count	Response Percent	
< 1	21	14.00%	< 0.05
1 – 3	35	23.33%	
4 – 6	20	13.33%	
7 - 9	14	9.33%	
> 9	60	40.00%	
Answered question	150		
Skipped question	1		
Physician Specialties	Response Count	Response Percent	
Critical Care	6	4.00%	< 0.05
Emergency	6	4.00%	
Medical	19	12.67%	
Surgical	17	11.33%	
Pediatrics	14	9.33%	
Anesthesia	1	0.67%	
Psychiatry	2	1.33%	
Obstetrics and Gynecology	7	4.67%	
Dentistry	39	26.00%	
Family medicine	13	8.67%	
Non applicable	1	0.67%	
Other (please specify)	25	16.67%	

Knowledge of ADR Reporting

The second part of the survey was about the physicians' knowledge of the ADR report which 93.38% gotten about the concept of adverse drug reactions, 54.30% knew the different types of hypersensitivity reaction related to ADR. While less half of them quantified; 45.33% of the participants know the official standardized form of reporting adverse drug reactions in Saudi Arabia, 43.71% knew to deliberate the ADR as a sentinel event. Of those, 34.44% of responders knew the legal provision in the medicines act that delivers for pharmacovigilance activities in Saudi Arabia. While 33.77% of participants who heard about the concept of pharmacovigilance, 33.11% knew a strictness classification for ADR, 33.11% knew post-marketing surveillance, 32.45% knew how to get the ADR reporting form. One-third of physicians (28.67%) knew ADR viability assessment and 25.83% only appear a training session on pharmacovigilance. Also, 28.48% of physicians knew the time wanted to report a severe ADR. Moreover, 25.83% knew an ADR causality relationship assessment and 23.18% of participants only knew the National Pharmacovigilance Center. There was a statistically significant difference between answers within each aspect ($p < 0.05$) (Table 3). The reliability test of McDonald's ω (0.890), Cronbach alpha (0.879), Guttman's λ_2 (0.894) and Guttman's λ_6 (0.895).

Factors Affecting the Knowledge of ADR Reporting

Gender and Age

There are noteworthy differences in the knowledge of ADR among gender; the male more conversant than females in eight elements of knowledge ($p < 0.05$) (Table 4). There is no significant difference among all age groups in all features of ADR knowledge ($p > 0.05$) (Table 4).

Position and Experiences

There is no substantial difference between physician positions (director of medical units, assistant director of the medical department, medical director and physician staff) and knowledge of adverse drug reaction ($p > 0.05$). There is no any statistically significant differences between years of experience and knowledge feature of ADR ($p > 0.05$) excluding the presence of pharmacovigilance activities and pharmacovigilance center in Saudi Arabia. One to three years of experience gained more knowledge than (>9) years experiences ($p < 0.05$).

Table 2: Con't

Answered question	150		
Skipped question	1		
Dentist Specialties	Response Count	Response Percent	
Dental Public Health	4	5.41%	< 0.05
Endodontics	2	2.70%	
Oral and Maxillofacial Surgery	3	4.05%	
Oral Medicine and Pathology	1	1.35%	
Oral and Maxillofacial Radiology	0	0.00%	
Orthodontics and Dentofacial Orthopedics	1	1.35%	
Pediatric Dentistry	4	5.41%	
Periodontics	0	0.00%	
Prosthodontics	2	2.70%	
Restorative dentistry	9	12.16%	
Special needs dentistry	0	0.00%	
Family dentistry	2	2.70%	
General dentist	4	5.41%	
Non-applicable	39	52.70%	
Other (please specify)	3	4.05%	
Answered question	74		
Skipped question	77		

Qualifications and Specialty

There is no statistically significant difference between physician qualifications (resident, specialist and consultant) and the majority of elementary knowledge of adverse drug reaction except the knowledge of the presence of pharmacovigilance activities with medicine act, presence of pharmacovigilance center in Saudi Arabia. The resident had more knowledge than consultant ($p < 0.05$), the whole consultant had more knowledge of ADRs standards in Saudi Arabia ($p < 0.05$). There is no noteworthy difference among all type of physician specialisms (critical care, emergency, medical, surgical, pediatric, anesthesia, psychiatric, family medicine, obstetrics and gynecology and dentistry) in all elements of ADR knowledge ($p > 0.05$).

There is not any statically significant relationship between factors (location, gender, age, qualifications, positions, years of experiences, physicians specialties and dentists specialisms) and all knowledge elements except between age and qualifications of medium correlation spearman rho (0.67) or Kendall tau (0.598) ($p < 0.001$) or age and number of years experiences with high relationship spearman rho (0.77) or Kendal tau (0.657) ($p < 0.001$).

Table 3: Physicians knowledge of ADR.

Items	Yes		No		Uncertain		I do not know		Total	Weighted Average	P-value
1- Have you ever heard about the concept of pharmacovigilance?	33.77%	51	52.32%	79	11.92%	18	1.99%	3	151	3.18	< 0.05
2- Have you ever heard about the concept of adverse drug reactions?	93.38%	141	3.97%	6	0.66%	1	1.99%	3	151	3.89	< 0.05
3- Have you ever had a course/ attended a workshop about pharmacovigilance or ADR?	25.83%	39	70.20%	106	2.65%	4	1.32%	2	151	3.21	< 0.05
4- In Saudi Arabia, are there legal provisions in the medicines act that provide for pharmacovigilance activities?	34.44%	52	5.30%	8	16.56%	25	43.71%	66	151	2.3	< 0.05
5- In Saudi Arabia, is there a pharmacovigilance center?	23.18%	35	3.31%	5	23.18%	35	50.33%	76	151	1.99	< 0.05
6- In Saudi Arabia, is there an official standardized form for reporting adverse drug reactions?	45.33%	68	6.67%	10	19.33%	29	28.67%	43	150	2.69	< 0.05
7- Do you know from where you can get the ADR reporting form?	32.45%	49	27.15%	41	11.92%	18	28.48%	43	151	2.64	< 0.05

8- Do you know the period within which you should report a serious ADR experienced by a patient?	28.48%	43	26.49%	40	14.57%	22	30.46%	46	151	2.53	< 0.05
9- Do you know the post-marketing surveillance?	33.11%	50	27.81%	42	13.25%	20	25.83%	39	151	2.68	< 0.05
10- Do you know the causality relationship assessment for ADR?	25.83%	39	31.79%	48	17.88%	27	24.50%	37	151	2.59	> 0.05
11- Do you know a voidability assessment for ADR?	28.67%	43	33.33%	50	13.33%	20	24.67%	37	150	2.66	< 0.05
12- Do you know the severity classification for ADR?	33.11%	50	31.79%	48	14.57%	22	20.53%	31	151	2.77	< 0.05
13- Do you know the different types of hypersensitivity reactions related to ADR?	54.30%	82	20.53%	31	12.58%	19	12.58%	19	151	3.17	< 0.05
14- Do you know to consider the ADR as a sentinel event?	43.71%	66	24.50%	37	15.89%	24	15.89%	24	151	2.96	< 0.05
Answered										151	
Skipped										0	

Table 4: Factor gender affecting the Knowledge of ADR reporting.

		factors	Yes		No		Uncertain		I do not know		Total		Weighted Average	p-value
1	Have you ever had a course attended a about pharmacovigilance or ADR?	Male	32.53%*	27	62.65%*	52	3.61%	3	1.20%	1	54.97%	83	3.27	<0.05
		Female	17.65%*	12	79.41%*	54	1.47%	1	1.47%	1	45.03%	68	3.13	<0.05
2	In Saudi Arabia, is there an official standardized form to report ADR?	Male	53.66%*	44	6.10%	5	19.51%	16	20.73%*	17	54.30%	82	2.93	<0.05
		Female	35.29%*	24	7.35%	5	19.12%	13	38.24%*	26	45.03%	68	2.4	<0.05
3	Do you know from where you can get the ADR reporting form?	Male	42.17%*	35	24.10%	20	15.66%	13	18.07%*	15	54.97%	83	2.9	<0.05
		Female	20.59%*	14	30.88%	21	7.35%	5	41.18%*	28	45.03%	68	2.31	<0.05
4	Do you know the time needed within which you should report a severe ADR experienced by a patient?	Male	36.14%*	30	25.30%	21	13.25%	11	25.30%	21	54.97%	83	2.72	<0.05
		Female	19.12%*	13	27.94%	19	16.18%	11	36.76%	25	45.03%	68	2.29	<0.05
5	Do you know the post-marketing surveillance?	Male	42.17%*	35	22.89%	19	20.48%*	17	14.46%*	12	54.97%	83	2.93	<0.05
		Female	22.06%*	15	33.82%	23	4.41%*	3	39.71%*	27	45.03%	68	2.38	<0.05
6	Do you know the severity classification for ADR?	Male	40.96%*	34	28.92%	24	16.87%	14	13.25%*	11	54.97%	83	2.98	<0.05
		Female	23.53%*	16	35.29%	24	11.76%	8	29.41%*	20	45.03%	68	2.53	<0.05
7	Do you know the different types of hypersensitivity reactions related to ADR?	Male	62.65%*	52	19.28%	16	10.84%	9	7.23%*	6	54.97%	83	3.37	<0.05
		Female	44.12%*	30	22.06%	15	14.71%	10	19.12%*	13	45.03%	68	2.91	<0.05
8	Do you know to consider the ADR as a sentinel event?	Male	45.78%	38	31.33%*	26	13.25%	11	9.64%*	8	54.97%	83	3.13	<0.05
		Female	41.18%	28	16.18%*	11	19.12%	13	23.53%*	16	45.03%	68	2.75	<0.05

DISCUSSION

Drug-related problems had a noteworthy apprehension clinically and economically in Saudi Arabia and the rest of the world.^[39-43] Drug-related problems contained of various issues, comprising medication errors, adverse drug reactions, drugs without indication, indications without medications, non-compliance and poisoning.^[44] The pharmaceutical care concept was executed before 20 years to prevent drug-related problems worldwide.^[45] One of the major programs applied in Saudi Arabia was medication safety programs to evade drug-related problems.^[46] The program updated and implemented various concepts and adverse drug reaction (ADR) was among them.^[47] The ADR policy procedures and tracking system of collecting ADR data were recognized and implemented.^[47] However, the documentation of ADR was reconnoitered by multiple studies done in Saudi Arabia and other countries.^[11,21,22,25,27] As a result, the research was finished to announce the other opinions of physicians' knowledge of ADR as part of unseen reasons for underreporting. The current study presented most of the responder's physicians were new and residents and physicians' staff which using electronic survey format more conversant than old physicians which contained of the former study.^[3,11,18,29] Most of the responder's physicians had insufficient knowledge of the ADR concept or the ADR reporting system, which in range one quarter to one third knew ADR essentials. As a result, the underreported of ADR was excepted. Most responder's physicians was not acquainted with the basic concept of pharmacovigilance and they did not appear educations or training about ADR, which look like previous studies⁹⁾.^[8,9,12,13,17,18,20-22,27-29,31,48,49] Also, the physician's responders was not familiar with the legal issue of the ADR reporting system or ADR valuation, which was an essential part of the ADR reporting form resembled of previous studies.^[50] Besides, the physicians perceived about the ADR concept, which had deficient knowledge of the concept of ADR definition. The responder's physicians had good knowledge of ADR classification in the practice which imitate education of hypersensitivity reaction but unsuitable knowledge of how to document or viability assessment.

The age levels was touching knowledge physicians of ADR because there were not any education or training program about ADR for all age levels and which contained with former studies which differ from another study excepting higher knowledge than younger physicians.^[3,21,28,48,51] In comparison, the male had noteworthy knowledge than the female without defensible reasons. The position or

number of years' experience did not move the physicians knowledge of ADR except those who had skilled more than nine years because they had expanded knowledge by experience and healthcare colleagues, which look like other studies.^[48] The study presented the physician's qualifications or subject did not affect the related knowledge of ADR. All physicians had the same system of ADR situations with any enduring education or training at their healthcare organizations in the Kingdom of Saudi Arabia, like the earlier study.^[48] However, the residents had more knowledge than consultants with efficient ADR issues like pharmacovigilance center or ADR standards in Saudi Arabia. Based on physicians' poor knowledge, the reporting of ADR will be unsuitable and even not reporting properly. Special education and training about ADR are highly optional for all new and old physicians frequently based on the years. If the education and training could not be showed, the ADR reporting system should be under pharmacy services from bagging until ended.

Limitations

Despite the practicality of evidence from the current study, a separate study examined the current physician's knowledge of the ADR program with an authenticated survey. However, the study checked various limitations, comprising the number of sample size was insufficient to signify the number of physicians in the Kingdom of Saudi Arabia. Also, most responders were young, which unexploited sufficient samples from other older physicians with high qualifications. The study combined physicians and dentists with a lacking number of dentists. Another examination with a high sample-sized with equal qualifications with one type of physicians or dentist is defensible.

CONCLUSION

The study reveals the physician's knowledge of the ADR concept and reporting system. The outcomes followed most of the earlier studies of the survey. The questionnaire was legalized by the various methods with additional pilot and biostatistics analysis of reliability tests. The study indicated insufficient physicians and dentists' knowledge of the ADR program, which was measured with most preceding studies available in Saudi Arabia or the rest of the world. The physicians and dentists was exceedingly demand periodic education and training about ADR during medical and dentistry school. Also, the sharing responsibilities ADR reporting system with pharmacists to take an active role in maintaining and updating the system is highly optional to implement in Saudi Arabia.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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Consent for Publications

This research is not applicable

Ethical Approval

This research is exempted from research and ethical committee or an institutional review board (IRB) approval.

<https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html>

ABBREVIATIONS

MOH: Ministry of Health; KSA: Kingdom of Saudi Arabia; ADR: Adverse Drug Reactions; PV: Pharmacovigilance; WHO: World Health Organization; SPSS: Statistical Package of Social Science; JASP: Jeffery's Amazing Statistics.

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