

Adverse Drug Reactions Reporting: Knowledge and Perception among General Public in Eastern Province, Saudi Arabia

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ABSTRACT

Objectives: The current study aims to assess general public knowledge and perception toward Adverse Drug Reaction (ADR) reporting systems in Eastern province, Saudi Arabia. **Methods:** A cross-sectional survey based study was conducted from 1st September 2019 to 31st October 2019 among the community in Eastern province, Saudi Arabia. A validated self-administered questionnaire were distributed among easily approachable 1500 participants through social media in which 1038 respondents were completely filled the survey form. Chi square test were used for the calculation of variance among the group. *P*-value less than and equal to 0.05 is considered statistically significant. **Results:** The response rate of survey was 69.20%. The mean age of the survey respondents were 30.5± 8.37years. Among all the respondents 335(32.27%) respondents were male and 703(67.72%) respondents were female from community of Eastern province, Saudi Arabia. Only, 7.61% of the respondents were familiar with the Saudi National Pharmacovigilance Centre (NPC) (*p*<0.05). 87.57% general public of Eastern province, Saudi Arabia were aware about electronic Adverse drug reaction (ADR) reporting procedure (*p*<0.05). While 89.88% population think

that all marketed drugs are safe (*p*<0.05). **Conclusion:** General public of Eastern province, Saudi Arabia are not aware about ADRs reporting procedure and the currently implemented reporting system. Awareness about ADR reporting must be foster by healthcare workers and the other relevant stakeholder's bodies on issues related to ADRs detection.

Key words: ADR (Adverse Drug Reaction), Saudi National Pharmacovigilance Centre (Saudi NPC), Eastern province, Knowledge, Perception, Saudi Arabia.

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INTRODUCTION

In current years, laymen are progressively more worried about their health-care by actively participation in decision taking. Currently the prescribers needs to provide extra information regarding prescribed drugs. Consumers gutting information about medicine via various sources, generally through internet because of its easy accessibility and availability in many countries. In fact, it is very hard to trust on the information gotten from internet and, thus, authenticity of the internet information is debatable.¹ As a primary goals of pharmacovigilance (PV) was to identify, evaluate, recognize and suppress adverse effects (AE) to safeguard the common public and consumer self-reporting of adverse drug reactions (ADRs) was formerly an underexploited advantage.² Adverse drug reaction have a foremost effect on health of community by intruding significant economic load on society.³ Post marketing surveillance (PMS) of drugs is mandatory for new drugs and controlling the risks associated with drugs when they are manageable for the use of the common population.⁴ While many countries, For example the US, New Zealand and Canada, have allowable consumers to report ADRs directly subsequently in the beginning of their PV systems, there quiet remain to the numerous countries with lacking or non-existent approaches for direct consumer ADR reporting.⁵ In Saudi Arabia, NPC was launched in March 2009 with "boosting reasonable and safe use of medicine and the initial recognition of ADRs" included in its key objectives.⁶ Worldwide, PV teaching are the necessity of the hour for invariable observing of unwanted outcomes in hospital and community settings.⁷ The involvement of each stakeholder in the reporting of ADR is

of main accountability. Doctors, pharmacists, nurses, future practitioners as well as common people are everyone well knowledgeable for reporting ADRs, which in, shot boost to increased drug safety for the population.⁸⁻¹¹ In light of the suboptimal contribution of the common public in the efforts of the Saudi NPC, we obvious to meet with the Saudi community to acknowledge their consciousness and knowledge about PV and ADRs and wanted to acquire information that may gathered the reason behind their dormancy.⁵ ADRs reporting is a new provision accessible to the consumers by the Saudi NPC. We conducted public survey to evaluate the knowledge and perception of the Saudi community toward ADRs reporting and PV.

METHODS

Study plan

Study was performed amongst community of Eastern province, Saudi Arabia. Study was conducted by following descriptive cross sectional methods. Study was conducted after approval of study protocol by the Scientific Research Unit Mohammed Al-Mana College of Medical Sciences. Study period was 3 months (1st September 2019 to 30th November 2019).

Study instrument

A self-administered, validated 20-items questionnaire was used to record respondent's knowledge of ADRs and perception to their reporting. The

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questionnaire was mainly composed of three parts. First part consisted of four items, mainly information related to the demographics. The second part questionnaire consist ten questions to measure general public knowledge to ADR reporting. The third part of the questionnaire consist five questions designed to measure general public perception towards ADRs reporting.

Study sample size and data collection

The sample size was estimated by Raosoft® online sample computation with the margin of error 5% and confidence level of (CI) 95% so, the suggested sample size was calculated to be 385. A total of convenient 1500 questionnaire survey link were distributed among general public of Eastern province, Saudi Arabia through social media and e-mail, of which 1038 completely answered the questionnaire.

Ethical approval

Study protocol has been approved from Scientific Research Unit Mohammed Al-Mana College for Medical Sciences with reference number: SR/RP/21. Moreover, online consent was also requested from the study participants who wished to participate in the study.

Data analysis

Data analysis was performed using the Statistical Package for Social Science Version 23 (SPSS V.23) (Institute Inc: Cary, NC, USA). Demographic characteristics were applied to calculate the numbers (frequencies) and percentages; mean±standard deviation). Associated factors within group were calculated using the chi-square (χ^2) test. A p -value ≤ 0.05 was considered statistically significant.

RESULTS

The survey was sent to the 1500 general people in community of Eastern province, Saudi Arabia, while only 1038 surveys were received completely filled from respondents, the response rate of survey was 69.20%. The mean age of the survey respondents were 30.5 ± 8.37 years. Among all the respondents 335 (32.27%) were male and 703 (67.72%) were female. Of all the respondents answered questionnaire, 54 (5.20%) were Elementary School, 278 (26.78%) were High School, 208 (20.03%) were Diploma, 465 (44.79%) were Bachelor and 33 (3.17%) were Master. Mean years of experience was 7.5 ± 3.37 . Out of 1038, 215 (20.71%) respondents are working in healthcare, 352 (33.91%) respondents are working in non-health care while 471 (45.37%) respondents are unemployed. Detailed information about the demographics are shown in Table 1.

General public knowledge about the ADR reporting system in Eastern province, Saudi Arabia

The respondents were requested whether they had ever heard of the "Saudi National Pharmacovigilance Center (NPC)". Only 79 (7.61%) of participants were aware with Saudi NPC. 706 (68.01%, $p < 0.05$) participants knows about meaning of "adverse drug reaction (ADR)". 933 (89.88%, $p < 0.05$) respondents agree that all marketed drugs are safe while 862 (83.04%, $p < 0.05$) participants agree that ADR is somewhat serious. Only 129 (12.42%, $p < 0.05$) respondents knows about electronic ADR reporting procedure in Saudi Arabia. 1005 (96.82%, $p < 0.05$) respondents seeking from healthcare provider for the necessary information about the medication that has been prescribed. 476 (45.85%, $p < 0.05$) respondents experienced any side-effects due to the medications that have been taken by them. 406 (39.11%, $p < 0.05$) participants getting information about side-effects of medications from Pharmacist. Most of respondents 416 (40.07%, $p < 0.05$) think that adverse drug reaction (ADR) reporting is physician's responsibility while second highest respondents 293 (28.22%, $p < 0.05$) think that Pharmacovigilance Center's responsibility

then Pharmacist's 246 (23.69%) then nurse 83 (7%). 738 (71.09 %), respondents don't know that consumer can also report adverse drug reaction (ADR). Detailed information about the Knowledge on ADR reporting among community of Eastern province, Saudi Arabia is shown in Table 2.

General public perception towards ADR reporting in Saudi Arabia

437 (42.10 %, $p > 0.05$) participants suggested that provide a 7/24 phone number to receive consumers calls to report any ADR reporting system can motivate the consumers to report about ADR. Among all the participants 436 (42.03%, $p > 0.05$) participants agreed that awareness campaign can educate our community about the importance of ADR reporting. 509 (49.03%, $p < 0.05$) respondents also suggested that lack of knowledge of Saudi NPC is the main reason of patients do not report ADRs. Among all the respondents 336 (32.36%, $p < 0.05$) respondents agreed upon that physician is the main resources to search about an ADR. 687 (66.18%, $p < 0.05$) respondents suggested that main advantages the community can acquire from the ADR reporting system is increase in the awareness of ADR among the community while 138 (13.29%) respondents agreed that increase the medication safety. Detailed information about the general public perception on ADR reporting among community of Eastern province, Saudi Arabia is shown in Table 3.

DISCUSSION

This study comprises the knowledge and opinion to ADR reporting and its system amongst the community of Eastern province, Saudi Arabia. A survey based has been conducted, self-administered questionnaire was used and this is considered to be one of the best ways to reach the common population. The findings of current research shows that, the public is liable to obtain information regarding ADRs and understand the welfares of ADRs reporting, their accepting of their vital role in reporting ADRs is deficient. However, their knowledge of the probable magnitude of harm that may happen from ADRs is inadequate. Many of the participants were unaware about Saudi NPC however only 7.61%

Table 1: Socio-demographic characteristics of study participants (n=1038).

Characteristics	Frequency (%)
Age in Years[Mean ± SD = 30.5 ± 8.37]	
15-25	339 (32.65)
26-35	373 (35.93)
36-45	305 (29.38)
46 and above	21 (2.02)
Gender	
Male	335(32.27)
Female	703(67.72)
Educational level	
Elementary School	54 (5.20)
High School	278 (26.78)
Diploma	208 (20.03)
Bachelor	465 (44.79)
Master	33 (3.17)
Occupation	
Healthcare related	215 (20.71)
Non-Healthcare related	352 (33.91)
Unemployed	471 (45.37)

Table 2: Knowledge towards adverse drug reactions (ADRs) among general public.

Statement	Frequency	P- Value (χ^2 test)
Have you heard about the Saudi National Pharmacovigilance Center?		
Yes	79(7.61)	<0.05
No	959(92.38)	
Do you know about electronic ADR reporting procedure in Saudi Arabia?		
Yes	129(12.42)	<0.05
No	909(87.57)	
Is all marketed drugs are safe?		
Yes	933 (89.88)	<0.05
No	84 (8.09)	
I don't know	21 (2.02)	
Do you know what side effects "adverse drug reaction (ADR)" means?		
Yes	706 (68.01)	<0.05
No	332 (31.02)	
Do you think that an ADR is harmful?		
Very harmful	862(83.04)	<0.05
Somewhat serious	138(13.29)	
Not harmful	38(3.66)	
I do not know		
Is it necessary for the healthcare provider to provide the information about the medication that has been prescribed?		
Yes	1005(96.82)	<0.05
No	33(3.17)	
Did you experienced any side-effects due to the medications that have been taken by you?		
Yes	476(45.85)	<0.05
No	562(45.14)	
From where you are getting information about side- effects of medications that you are taking?		
Doctor	261 (15.89)	<0.05
Pharmacist	406 (39.11)	
Nurse	26 (2.50)	
Others	345 (33.23)	
I don't know		
Who can report an adverse drug reaction (ADR)?		
Physician	416(40.07)	<0.05
Pharmacist	246(23.69)	
Nurses	83(7.00)	
Pharmacovigilance Center	293(28.22)	
Consumer can also report adverse drug reaction (ADR)?		
Yes	97 (9.34)	<0.05
No	203 (19.55)	
I don't know	738(71.09)	

Table 3: Public perception toward ADR reporting.

Statement	Frequency	P- Value (χ^2 test)
How to motivate the consumers to report any ADR?		
Increase the awareness about ADR reporting system	385(37.09)	<0.05
Increase the awareness about the importance of ADR report	48(4.62)	
Make it mandatory for patients	46(4.43)	
Make the reporting processes easier	122(11.75)	
Provide a 7/24 phone number to receive patients calls to report any ADR	437(42.10)	
How can we educate our community about the importance of ADR reporting?		
Awareness campaign	436(42.03)	<0.05
Pharmacist should explain to the patient the importance of reporting any ADR	319(30.73)	
Publish any reports that received from patients in newspapers	101(9.73)	<0.05
Write slogans or few words on the medication's package to show the importance of ADR reporting ADR	179(17.24)	
Other	3(0.002)	
Why patients do not report ADRs?		
Don't know if it is from the medication or not	470(45.27)	
Does not know about Pharmacovigilance centre	509(49.03)	<0.05
Others	59(5.68)	
Which of the following resources do you use to search about an ADR?		
Asking the pharmacist who dispensed the medication	231(22.25)	<0.05
Asking your physician who prescribed the medication to you	336(32.36)	
From books or magazines	9(0.086)	
From Internet	188(18.11)	
From the leaflet that comes with the medication	274(26.39)	
What advantages the community can get from the ADR reporting system?		
A solution for the low reporting issue	31(2.98)	<0.05
Improve our quality life	59(5.68)	
Increase the awareness of ADR among the community	687(66.18)	
Increase the medication safety	138(13.29)	
Strengthening and protecting the human rights	110(10.59)	
Others	13(1.25)	

study participants heard about NPC which also reveals same result of other study which was conducted in Riyadh, Saudi Arabia.⁵ Even though these accomplishments and the efforts of the Saudi NPC in stimulating the ADRs reporting system, consumer knowledge on ADRs reporting still is depressingly low. Participants, low volume toward reporting of ADRs could be influenced by the relative inattentiveness placed on reporting ADRs by treating physician themselves.

While respondents showed that they proactively demand information to their medications from their Healthcare providers (HCPs) and consider them as a source of reference about ADRs, most physicians and pharmacists do not enthusiastically inspire their patients and consumers to submit ADR reports.

Although the most of healthcare providers recognize the significance of ADRs reporting, their knowledge of the reporting system in Saudi Arabia and their factual reporting of ADRs are suboptimal. Though, 59.1% were unaware of the availability of the Saudi NPC.¹² One study was conducted in Dammam, Saudi Arabia reveals that only 54.07% healthcare providers were familiar with the ADR reporting process.¹³ Our research suggest that healthcare providers should come forward by example in PV activities and ADR reporting, particularly as the majority of patients thinks that the healthcare care provider should report ADRs.

In a mentioned study, healthcare workers have recognized numerous challenges to PV practice in Saudi Arabia.

Reason behind why consumers do not report ADRs diligently varied amongst those who thought that patients do not know whether the reaction is from the drug or not, those who are unknown of the Saudi NPC, those who think that patients don't know to the importance of ADR reporting and those think that patients probably don't have knowledge about how to report ADRs. This supports the faith of healthcare professionals that drug education is crucial to the accomplishment of direct-patient ADR.⁸

CONCLUSION

Our study suggests that community of Eastern province, Saudi Arabia are not attentive to the ADRs reporting procedure and the presently implemented reporting system. The findings also suggests that increase in the awareness about ADR reporting system by healthcare providers and the other relevant stakeholder's bodies on concerns related to ADRs, recognition and reporting could be foster by the contribution of consumers in ADRs reporting procedure.

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CONFLICT OF INTEREST

All author(s) declared there is no conflict of interest.

ABBREVIATIONS

ADR: Adverse Drug Reaction; **Saudi NPC:** Saudi National Pharmacovigilance Centre; **PV:** Pharmacovigilance; **AE:** Adverse Effects; **PMS:** Post marketing surveillance; **HCPs:** Healthcare providers.

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