

# Community Pharmacist's Knowledge, Practice and Barrier towards Reporting of Adverse Drug Reactions in Dammam, Saudi Arabia: A Cross-Sectional Survey Based Study

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## ABSTRACT

**Objectives:** The current study aims to assess community pharmacist's knowledge, practice and barriers towards ADR reporting systems in the Dammam, Saudi Arabia. **Methods:** A cross-sectional study was conducted from 1<sup>st</sup> August 2019 to 31<sup>st</sup> October 2019 among the Community pharmacies in the Dammam, Saudi Arabia. 101 easily approachable community pharmacists participated in study. **Results:** The survey was sent to the 150 community pharmacists (CP), while only 101 surveys were received completely filled, the response rate of survey was 67.33%. The mean age of the survey respondents were 35.2±6.66 years. Among all the respondents 73(72.27%) were male and 28(27.73%) were female. Mean years of experience was 7.5±3.37. Overall, 90 (89.1%) respondents familiar with the term Pharmacovigilance ( $p<0.05$ ). 40 (39.60%) community pharmacists agreed upon that they have sufficient knowledge and training on how to report ADRs ( $p<0.05$ ). 67(66.34%) respondents never reported new ADR (not mentioned in drug leaflet) for any drug ( $p=0.001$ ). 55(54.45%) respondents prevent different kind of serious ADRs during their practice ( $p=0.370$ ).

**Conclusion:** Community pharmacist working in Dammam were found to be unsatisfactory knowledge and practice on ADR reporting. The study also identified factors contribute in under reporting of ADR by community pharmacist. Drug regulatory agency and pharmacovigilance centres should take necessary steps to increase the awareness on ADR reporting among community pharmacist.

**Key words:** ADR (Adverse Drug Reaction), Community pharmacist, Dammam, Knowledge, Saudi Arabia.

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## INTRODUCTION

Pharmacist job responsibility have been transmitted from traditional aspect of preparation and dispensing of medicines to more vital role that includes many aspects of pharmaceutical care, like stopping medication errors and ADRs, that may make satisfactory quality of life (QOL) and enlightening economic outcomes.<sup>1-3</sup> Community pharmacists may play a key role in both pharmacovigilance related activities and ADRs reporting.<sup>4</sup> Pharmacists are to be expected may identify more ADRs in comparison to other healthcare workers (HCWs), either in the community or hospital setting.<sup>5</sup> Adverse drug reactions (ADRs) are usual reasons of mortality and morbidity in community as well as in hospital settings. In the current scenario 5% - 20% of hospital admissions are due to ADRs.<sup>6,7</sup>

Hence, post marketing surveillance (PMS) is obligatory for monitoring the risk and benefits of marketed pharmaceutical products.<sup>8</sup> As a program to promote and monitor Adverse drug reaction (ADR) reporting, the Saudi Food and Drug Authority (SFDA) has reestablished a National Pharmacovigilance Center (NPC) that has made online reporting forms and papers forms available to encourage ADR reporting by healthcare workers and public.<sup>9</sup>

One study has been conducted in the Kingdom of Saudi Arabia (KSA) study reveals that lesser knowledge of the ADR reporting system and a poor reporting rate (13.2%). Obstacles towards ADR reporting recognized by this study comprised, most commonly, a lack of awareness about where and how to report ADRs and unavailability of ADR reporting forms.<sup>10</sup>

Evaluation of knowledge, practice and experiences of community pharmacists towards spontaneous reporting of ADRs is highly significant. When pharmacists have adequate knowledge towards ADR reporting process, they can take part in improvement of other healthcare professional's knowledge regarding ADR reporting.<sup>11</sup>

In the Saudi Arabia several study have been conducted regarding estimation of community pharmacist's knowledge, attitude and practices for ADR reporting are inadequate and most of study were conducted before the establishment of the National Pharmacovigilance Centre.<sup>10</sup> That's why, the objective of our research was to evaluate Community pharmacist's knowledge, perspectives and barrier in the reporting of adverse drug reactions in Dammam, Saudi Arabia after establishment of National Pharmacovigilance Centre.

## MATERIALS AND METHODS

### Survey design and setting

Study was performed amongst community pharmacist of Dammam, Saudi Arabia. Study was conducted by following descriptive cross sectional methods. Study was conducted for a period of 3 months from 1<sup>st</sup> August 2019 to 31<sup>st</sup> October 2019.

### Study tool

A self-administered, 42-items questionnaire was used to record respondent's views about ADR reporting and their barriers to their

reporting. The study questionnaire was adopted from previously published literature.<sup>10,12,13</sup> The questionnaire was basically composed of three parts. First part comprised of ten items, mainly information related to the demographics and pharmacy and pharmacy practice associated information (Table 1). The 2<sup>nd</sup> part of questionnaire comprised of thirteen questions of likert scale to measure community pharmacist's perception towards ADR reporting. The third part of the questionnaire consisted eight questions of close-ended question designed to estimate community pharmacist's practice regarding ADRs. The third part of the questionnaire consisted ten questions of likert scale to measure community pharmacist's barriers on ADR reporting. The link of survey (Google Forms) has been distributed through social media to the community pharmacist located in Dammam region, Saudi Arabia. After sending the link of survey prior to close the survey three reminders were also given to participate in survey.

### Study sample and data collection

A total of 135 questionnaires link were distributed among community pharmacist of Dammam region through social media, of which only 101 participants 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/18. 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 22 (SPSS V.22) (Institute Inc: Cary, NC, USA). Demographic characteristics were applied to calculate the numbers (frequencies) and percentages; mean  $\pm$  standard deviation). Associated factors within group were calculated using the chi-square ( $\chi^2$ ) test. A  $p$ -value  $\leq 0.05$  was considered statistically significant.

## RESULTS

The survey was sent to the 150 community pharmacists, while only 101 surveys were received completely filled, there response rate of survey was 67.33%. The mean age of the survey respondents were 35.2 $\pm$ 6.66 years. Among all the respondents 73(72.27%) respondents were male and 28(27.73%) respondents were female community pharmacist. Of all the community pharmacist answered questionnaire, 23(22.77%) were Diploma, 55 (54.45%) were Bachelor, 19(18.81%) were Master and 4(3.96%) were PhD. Mean years of experience was 7.5 $\pm$ 3.37. The average number of prescription dispensed per day by the community pharmacist were 39.89 $\pm$ 15.86 per day. While average time spent with patient were 7.5 $\pm$ 3.37 per minutes. Detailed information about the demographics are shown in Table 1.

### Community pharmacist's knowledge about the ADR reporting system in Saudi Arabia

Knowledge regarding ADRs and their reporting was evaluated using the five items shown in Table 2. Overall, 90 (89.1%) of the respondents familiar with the term Pharmacovigilance ( $p < 0.05$ ). 40 (39.60%) community pharmacists agreed upon that they have sufficient knowledge and training on how to report ADRs ( $p < 0.05$ ), 10(9.9%) strongly agree, 9(8.91%) disagree, 5(4.95%) strongly disagree and 37(36.63%) given their neutral response. 89(88.11%) respondents knows about availability of official and standard form for ADR reporting in Saudi Arabia ( $p < 0.05$ ) while 12(11.89%) have no idea. 47(46.53%) respondents are strongly agree on, reporting Adverse Drug Reactions (ADRs) is important for

**Table 1: Respondent's demographic characteristics of (n=101) community pharmacists.**

Parameter	Number (n=101)	(%)
Age in Years [Mean $\pm$ SD = 35.2 $\pm$ 6.66]		
20-30	23	22.77
31-40	59	58.41
41-50	18	17.83
50 and above	1	0.99
Gender		
Male	73	72.27
Female	28	27.73
Graduation year from pharmacy college		
< 5 Years	28	27.73
5-10 years	37	36.63
>10 years	36	35.64
Highest level of pharmacy qualification		
Diploma	23	22.77
Bachelor	55	54.45
Master	19	18.81
PhD	4	3.96
Experience years Age in Years[Mean $\pm$ SD = 7.5 $\pm$ 3.37]		
5 years or less	23	22.77
6-9 years	39	38.61
10 years or more	39	38.61
Number of prescription dispensed per day[Mean $\pm$ SD = 39.89 $\pm$ 15.86]		
< 30	31	30.69
31-50	37	36.63
>50	33	32.67
Time spent with patient[Mean $\pm$ SD = 7.5 $\pm$ 3.37]		
< 5 Min	47	46.53
6-10 min	46	45.54
>10 min	8	7.92
Hours worked per week		
< 20 hr	10	9.90
21-40 hr	39	38.61
>40 hr	52	51.48

patient care ( $p < 0.05$ ) while 27(26.73%) are agree, 4(3.96%) strongly disagree, 2(1.98%) disagree and 21(20.79%) respondents given their neutral response. Among all study participants 38(37.62%) were agreed upon, reporting of ADRs should be mandatory for community pharmacists ( $p < 0.05$ ) while 25(24.75%) strongly agree, 8(7.92%) strongly disagree, 3(2.97%) disagree and 27(26.73%) are neutral.

**Table 2: Responses to the knowledge related questions.**

Questions	Frequency (%)	P-Value ( $\chi^2$ test)
Are you familiar with the term Pharmacovigilance?		
Yes	90 (89.1)	<0.05
No	11(10.89)	
I currently have sufficient knowledge and training on how to report ADRs		
Agree	40(39.60)	<0.05
Disagree	9(8.91)	
Neutral	37(36.63)	
Strongly agree	10(9.90)	
Strongly disagree	5(4.95)	
An official and standard form is available for ADR reporting in Saudi Arabia.		
Yes	89(88.11)	<0.05
No	12(11.89)	
Reporting Adverse drug Reactions (ADRs) is important for patient care		
Agree	27(26.73)	<0.05
Disagree	2(1.98)	
Neutral	21(20.79)	
Strongly agree	47(46.53)	
Strongly disagree	4(3.96)	
Reporting of ADRs should be mandatory for community pharmacists		
Agree	38(37.62)	<0.05
Disagree	3(2.97)	
Neutral	27(26.73)	
Strongly agree	25(24.75)	
Strongly disagree	8(7.92)	

\*Significant *p*-value (<0.05)

### Community pharmacists' practice about the ADR reporting in Saudi Arabia

The details of community pharmacist practice regarding ADR reporting has been listed in Table 3. 53(52.47%) of the respondents notice any ADRs by the use of medicine within the last 12 months ( $p=0.618$ ). 44(43.56 %)of the respondents sent a suspected ADR report to Saudi Food and Drug Authority (SFDA) or manufacturer during their practice ( $p=0.195$ ). Only 37(36.63%) of the respondents ever reported any ADRs related to OTC or herbal products in the last 12 months ( $p=0.007$ ). 67(66.34%) of the respondents never reported new ADR (not mentioned in drug leaflet) for any drug ( $p=0.001$ ). 55(54.45%) of the respondents prevent any serious ADRs during their practice ( $p=0.370$ ). In addition 61(60.39%) of the respondents read an article related to ADRs in the last 12 months ( $p=0.036$ ). 62(61.38%) of the respondents involved in counselling of the patient regarding ADRs in the last 12 months ( $p=0.022$ ). Overall 77(76.23%) of the respondents are involved in counselling of the patient regarding food/drug interaction in the last 12 months ( $p=0.00$ ). Overall 66(65.35%) of the respondents don't have private patient counselling room in their pharmacy ( $p=0.002$ ). 70(69.30%) of the

**Table 3: Community pharmacist practice regarding ADRs reporting in Saudi Arabia.**

Questions	Yes (%)	No (%)	P-Value ( $\chi^2$ test)
Have you notice any ADRs within the last 12 months?	53(52.47)	48(47.52)	0.618
Have you ever sent a suspected ADR report to SFDA or manufacturer?	44(43.56)	57(56.43)	0.195
Have you ever reported any ADRs related to OTC or herbal products in the last 12 months?	37(36.63)	64(63.37)	0.007
Have you ever reported a new ADR (not mentioned in drug leaflet) for any drug?	34(33.66)	67(66.34)	<b>0.001*</b>
Have you ever prevent any serious ADRs?	55(54.45)	46(45.55)	0.370
Have you read an article related to ADRs in the last 12 months?	61(60.39)	40(39.60)	<b>0.036*</b>
Have you ever counselled patient regarding ADRs in the last 12 months?	62(61.38)	39(38.62)	<b>0.022*</b>
Have you ever counselled patient regarding food /drug interaction in the last 12 months?	77(76.23)	24(23.76)	<b>0.00*</b>
Do you have private patient in counselling room in your pharmacy?	35(34.65)	66(65.35)	<b>0.002*</b>
Do you have pharmacy technician in your pharmacy?	70(69.30)	31(30.69)	<b>0.001*</b>
Do you have automation facility in your pharmacy?	51(50.49)	50(49.50)	0.920

\* Significant *p*-value (<0.05)

respondents have pharmacy technician in their pharmacy ( $p=0.001$ ) while nearly half, 51 (50.49%) of the respondents agreed that they automation facility in their pharmacy ( $p=0.920$ ).

### Community Pharmacist barriers toward reporting of ADRs

The second last section of the study focused on exploring the barriers toward ADR reporting in Eastern province, Saudi Arabia. Community pharmacists have a professional obligation to report ADRs was the first barrier towards ADR reporting ( $p<0.05$ ). Other barriers were the lack of time to report ADRs as part of their professional practice ( $p=0.003$ ). Other factors are shown in Table 4.

### Factors encouraging toward reporting of ADRs

The last part of the questionnaires in the current study was about the facilitators that might motivate/encourage frequency to report an ADR. 41(40.59%) respondents suggested that community pharmacist would be stimulated to report more ADRs if general education is provided on the importance of pharmacovigilance. Rest of facilitators are shown in Figure 1.

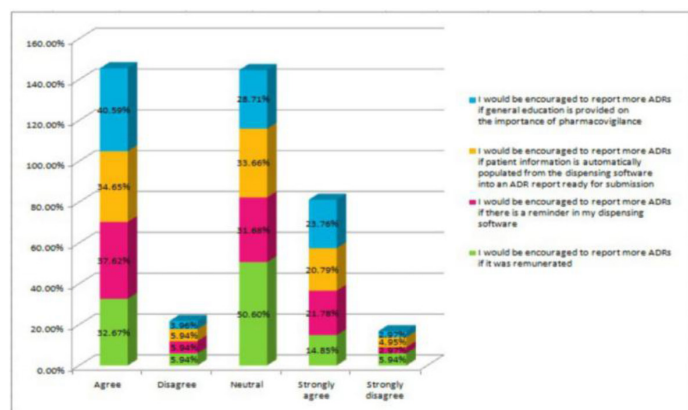
## DISCUSSION

We did this survey based study to investigate knowledge, practice, barrier and recommendation towards ADR reporting and its system amongst the community pharmacist of Dammam region, Saudi Arabia. Our study results displays that community pharmacists have insufficient knowledge

**Table 4: Barriers toward reporting of ADRs.**

Questionnaire	Agree (%)	Disagree (%)	Neutral (%)	Strongly agree (%)	Strongly disagree (%)	P-Value ( $\chi^2$ test)
I don't have the time to report ADRs as part of my professional practice	28(27.72)	19(18.81)	32(31.68)	6(5.94)	16(15.84)	0.003
I fear that there may be legal repercussions if I report an ADR to the SFDA	23(22.72)	14(13.86)	46(45.54)	4(3.96)	14(13.86)	<0.05
I have a professional obligation to report ADRs	36(35.64)	15(14.85)	35(34.65)	12(11.88)	3(2.97)	<0.05
There are no results or actions taken based on ADRs that I report	21(20.79)	17(16.83)	47(46.53)	3(2.97)	13(12.87)	<0.05
Reporting forms are not available	23(22.72)	20(19.80)	34(33.66)	4(3.96)	20(19.80)	0.001
Reporting forms are too complicated	22(21.78)	14(13.86)	46(45.54)	2(1.98)	17(16.83)	<0.05
Reporting is time consuming	25(24.75)	14(13.86)	43(42.57)	5(4.95)	14(13.86)	<0.05
I fear legal liability of the reported ADR	18(17.82)	13(12.87)	48(47.52)	6(5.94)	16(15.84)	<0.05
I am not motivated to report	18(17.82)	24(23.76)	34(33.66)	3(2.97)	22(21.78)	<0.05
I am not confident whether it is an ADR	20(19.80)	22(21.78)	40(39.60)	2(1.98)	17(16.83)	<0.05
Insufficient knowledge of pharmacotherapy in detecting ADR	20(19.80)	21(20.79)	40(39.60)	7(6.93)	13(12.87)	<0.05
Unavailability of professional environment to discuss ADR	26(25.74)	13(12.87)	43(42.57)	8(7.92)	11(10.89)	<0.05

\* Significant p-value (<0.05)



**Figure 1:** Responses to the recommendation towards reporting of ADRs.

regarding ADR reporting, few community pharmacists have reported ADRs and the majority are aware of the process of ADR reporting. The findings of current study are nearer to previous studies conducted in the Riyadh, Saudi Arabia.<sup>10</sup> Only 50.0% community pharmacists have sufficient knowledge and training on how to report ADR in Saudi Arabia. The main reason for this might be the lack of encourage and facilities on ADR reporting in community pharmacy services. Moreover, community pharmacy in Saudi Arabia is knowingly business directed.

Thus, the concept of facilities and reporting of ADRs might be observed as a second priority by pharmacy tycoons. However, globally, community pharmacists in Australia, Nigeria and the UAE were not aware of the ADR reporting programs in their countries.<sup>14-16</sup> In addition to awareness among community pharmacists, the role of regulatory authorities is also questionable due to the lack of implementation of regulations in community pharmacy practice.<sup>10</sup> The survey included community pharmacist's from one city in Saudi Arabia which limits its generalization. In the current study, some pharmacists indicated that they have enough facility in their pharmacy, this may be moderately time spent on to the underreporting of ADRs. Also, community pharmacist's heavy workload might have limited the response rate. Although there is a reporting system in Saudi Arabia that deals with ADRs in both paper and electronic

format, all ADR must send to SFDA or manufacturer the majority of community pharmacists are unaware of where to send ADR. The entire respondents in survey agreed that ADR reporting is important for patient care in community pharmacies. Operative ADR reporting systems in community pharmacies are a necessary element in any healthcare setup. Addition of PV topics in the curriculum of pharmacy education and training of pharmacy students in community pharmacy as internship may increase the wakefulness of upcoming pharmacists regarding ADR monitoring, detection and reporting.<sup>17</sup> Moreover, pharmacy proprietors could allow the excess of internet and software facility in community pharmacies for online ADR reporting to drug regulatory authority.

## CONCLUSION

Community pharmacist working in Dammam, Saudi Arabia were noticed having unsatisfactory knowledge and practice on ADR reporting. The study also identified factors contribute in under reporting of ADR by community pharmacist. Drug regulatory agency and pharmacovigilance centres should take obligatory steps to straightway and design interventional programs in order to accelerate the cognition and consciousness of community pharmacist's towards the reporting procedure of the ADR. A multiple shareholders approach can also foster ADR reporting as well as helps in development of huge awareness among community pharmacist.

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## CONFLICT OF INTEREST

The authors declare no conflict of interests.

## ABBREVIATIONS

**ADR:** Adverse Drug Reaction; **CP:** Community pharmacists; **QOL:** Quality of Life; **HCWs:** Healthcare Workers; **PMS:** Post Marketing Surveillance; **SFDA:** Saudi Food and Drug Authority; **NPC:** National Pharmacovigilance Centre; **KSA:** Kingdom of Saudi Arabia.

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