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Pharmacists' Experiences on Adverse Drug Reactions in Saudi Arabia

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Abstract: Background and objectives: In Saudi Arabia, the evidence regarding pharmacists' experiences with adverse drug reactions (ADRs) in their daily practice is limited. It is crucial to comprehend their viewpoints to enhance patient safety and optimize pharmaceutical care. Therefore, we aimed to determine whether pharmacists could identify ADRs during their daily routines and to determine the actions they took once the ADRs were identified. **Methods:** This study was questionnaire-based and conducted between July 2024 and August 2024. Registered pharmacists employed at hospitals or community pharmacies in Saudi Arabia comprised the population. **Results:** The study involved 305 pharmacists, including 169 hospital/clinical pharmacists (HCPs, 55.4%) and 136 community pharmacists (CPs, 44.6%). A majority (n = 251, 82.3%) indicated direct patient encounters, while 67.2% (n = 205) reported observing suspected ADRs in the preceding 12 months. No significant difference in ADR types was seen between HCPs and CPs; however, cefuroxime (HCP = 17, CP = 1) and vancomycin (HCP = 23, CP = 2) exhibited a significant association with ADRs ($p < 0.001$). Most respondents filed ADR reports to the SFDA/NPC (HCP = 103, CP = 60) and hospital drug information centers (HCP = 89, CP = 64), with online forms being the favored mode (HCP = 122, CP = 96). Awareness of ADR reporting procedures was reported by 128 HCPs and 80 CPs. **Conclusion:** More than two-thirds of participants reported practicing ADR reporting, with greater adherence observed in hospital settings. Pharmacists predominantly depend on the Saudi Food and Drug Administration/National Pharmacovigilance Centre and hospital drug information centers for reporting, with a preference for online submission methods. Targeted educational interventions addressing the identified knowledge gaps could further improve ADR reporting practices

Keywords: adverse drug reactions (ADR); pharmacovigilance; pharmacists' experiences; Saudi Arabia; hospital pharmacists; community pharmacists; drug safety

1. Introduction

The World Health Organisation (WHO) defines adverse drug reaction (ADR) as "a response to a drug that is noxious and unintended, and that occurs at doses that are typically used in patients for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function" [1]. ADR is a significant public health concern that is linked to high morbidity and mortality rates, resulting in increased healthcare expenditure, unnecessary readmissions, and the prolongation of hospitalisation [2, 3]. Therefore, it is imperative to implement post-marketing surveillance to oversee ADRs associated with novel pharmaceuticals [3].

Reporting of ADRs that occur spontaneously is the primary method of monitoring newly marketed medications. Following the thalidomide incident, the WHO implemented the International Programme for Adverse Drug Reaction Monitoring to oversee global drug safety [4]. WHO, in collaboration with the European Medicines Agency and the United States Food and Drug

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Administration (FDA), has advanced the regulatory practice that safeguards the global community [4]. The Netherlands, United Kingdom, and Denmark were the first countries to implement spontaneous reporting systems in the 1960s [5]. Numerous nations subsequently adopted this approach. The Saudi Arabia's National Pharmacovigilance Centre is responsible for the submission of all suspected ADRs in Saudi Arabia [6]. These cases are subsequently submitted to the Uppsala Monitoring Centre in Sweden for inclusion in the WHO database [6]. Despite the existence of an ADR reporting system for decades, the issue of underreporting ADRs persists [6,7].

In comparison to other healthcare personnel, pharmacists are highly regarded for their primary responsibilities of reporting adverse drug reactions (ADRs) and implementing pharmacovigilance (PV) principles in their daily clinical practice [8,9]. Most pharmacists are knowledgeable of the existence of a reporting system; however, only a small number of pharmacists have reported [10]. Evidence indicates that pharmacists lack knowledge regarding the process of reporting an ADR or confidence in which ADR to report [5]. Detecting an ADR is a difficult task [5]. Healthcare personnel occasionally fail to recognise the occurrence of an ADR by misinterpreting patients' complaints or symptoms as minor and irrelevant, or as related to the progression of their medical conditions. This may account for the fact that a significant number of ADRs are never identified [11]. These underscore the necessity of pharmacists receiving a comprehensive education in pharmacovigilance and spontaneous ADR reporting systems [9].

The ADR reporting behaviours of pharmacists and other healthcare professionals have been the primary focus of previous studies in Saudi Arabia [12-14]. Nevertheless, there is a significant gap in the evidence that pertains to the experiences of pharmacists with ADRs in their daily clinical practice. Therefore, we aimed to determine whether pharmacists could identify ADRs during their daily routines and to determine the actions they took once the ADRs were identified. The findings of this research can serve as a benchmark for stakeholders to implement a strategy that enhances pharmacists' knowledge, attitude, and practices in the identification and reporting of ADRs.

2. Methods

2.1. Study Design and Setting

This study was questionnaire-based and conducted between July 2024 and August 2024. Registered pharmacists employed at hospitals or community pharmacies in Saudi Arabia comprised the population. Data collection was conducted utilizing Google Forms.

2.2. Study Tool

The survey was adopted from a previous study with slight revisions to improve relevance and comprehensiveness [5]. A pilot sample of 10 pharmacists was used to establish the face and content validity of the questionnaire's draft. Based on piloting feedback, we evaluated the questionnaire to make sure it was easy to read and complete. The goal is to complete it in ten minutes. The questionnaire comprises four sections and a total of 21 items. The demographic information of the respondents was collected in Section A. A screening question is included in Section B to determine whether the respondents have had direct patient contact within the past six months. The analysis excluded individuals who lack direct contact. Respondents' experiences with ADR were assessed in Section C: 1) whether they have observed an ADR within the past six months, 2) How frequently they have observed an ADR in the past six months, 3) What types of ADRS were observed? The respondents were provided with a list of prevalent ADRs based on reports received by the National Pharmacovigilance Centre and literature. They were permitted to select more than one response. An open-ended option is also included for the respondents to complete if the ADR was not listed. 4) Respondents provided with a list of prevalent drugs that were associated with the observed ADRs, based on the National Pharmacovigilance Centre and literature. They were permitted to select more than one response. An open-ended option was also provided for the respondents to complete if the medicine was not listed. 5) Responses to the observed ADR (a list of actions was generated in

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accordance with the literature), and respondents were permitted to select multiple responses. If the action was not specified, the respondents were also provided with an open-ended option to complete. Respondents' attitudes and awareness regarding the reporting of ADRs were assessed in Section D. This included their comprehension of the available system's objectives, the types of ADRs that should be reported, and the factors that promote and discourage ADR reporting.

2.3. Recruitment

An email invitation to participate in the online survey was distributed to the pharmacists working in Saudi Arabia. The researchers disseminated the survey link to individuals in their personal network, including friends and coworkers through social media platforms such as Facebook, LinkedIn Twitter, and WhatsApp. These participants were requested to distribute this survey to colleagues through social media platforms. A reminder email was sent after one week.

2.4. Ethical Considerations

This research was initiated after the ethics approval. The completion of the survey was considered as implied consent.

2.5. Sample Size and Data Analysis

A recent study reported that the total number of pharmacists in Saudi Arabia is 30, 840 [15]. A sample size of 380 was estimated using the Raosoft calculator, taking into consideration the population size, a 95% confidence level, and a 5% margin of error. All data was subjected to descriptive statistics. To guarantee that the data was entered accurately and comprehensively, the frequencies of variables were calculated and verified for values that exceeded the permissible range. The pharmacist groups' experiences with ADRs were compared using the Pearson chi-square test. All statistical analyses were conducted using IBM SPSS Statistics version 27. The level of significance was considered at $p < 0.05$.

2.6. Data Analysis

A sample size of 380 was estimated using the Raosoft calculator, taking into consideration the population size, a 95% confidence level, and a 5% margin of error. All data was subjected to descriptive statistics. To guarantee that the data was entered accurately and comprehensively, the frequencies of variables were calculated and verified for values that exceeded the permissible range. The pharmacist groups' experiences with ADRs were compared using the Pearson chi-square test. All statistical analyses were conducted using IBM SPSS Statistics version 27. The level of significance was considered at $p < 0.05$.

3. Results

A total of 305 professionals were recruited for this study. Most of the study participants, 169, were employed as hospital or clinical pharmacists, while 136 others were community pharmacists. Only 4.9% of respondents gained more than 30 years of professional experience. Twenty-nine percent of respondents had sixteen to thirty years of experience, thirty-three percent had six to fifteen years, and 36.4% had less than five years. When pharmacists were asked about their direct interactions with patients. A substantial plurality of the respondents (82.3%) reported that they had direct contact with the patients, while only 15.7% reported that they had no such contact. Within the previous year, two-thirds of the respondents reported that they had observed ADR suspects. Additionally, respondents were requested to provide information regarding the daily, weekly, and monthly case flow. Pharmacists highlighted that 41% visited fewer than one case per month, 20.3% visited monthly, 15.1% visited weekly, and 20.3% visited daily.

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Table 1. Demographic data of pharmacists.

Demographic variables	**Frequency (N)**	**Percentage (%)**
Profession		
Hospital/clinical pharmacist	169	55.4
Community pharmacist	136	44.6
Professional Experience		
< 5 years	111	36.4
6-15 years	102	33.4
16-30 years	76	24.9
More than 30 years	15	4.9
Missing	1	.3
Direct contact with patients		
Yes	251	82.3
No	48	15.7
Missing	6	2.0
Observed a suspect ADR last 12 months		
Yes	215	70.5
No	87	28.5

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Missing	3	1.0
Observed a suspect ADR last 6 months		
At least 1 case per day	62	20.3
At least 1 case per week	46	15.1
At least 1 case per month	62	20.3
Less than 1 case per month	125	41.0
Missing	10	3.3

The comparison between hospital/clinical and community pharmacists was illustrated in Table 2. Initially, the comparison was made based on the observed ADRs, which indicated that no significant difference existed between the two groups. The table below shows that dermatitis, hyperkalaemia, and hyperglycaemia were present in HCP (n=93, 16, and 15) and CP (n=55, 4, and 5). Additionally, Table 2 contains a comprehensive inventory of all observed ADRs. In the same vein, Table 2 displays medications that induce adverse drug reactions. Cefuroxime and Vancomycin were the only two medicines listed that were significant, with a p-value of less than.001. Cefuroxime was administered to 17 HCP patients and 1 CP patient, while Vancomycin was administered to 23 HCP patients and 2 CP patients. Apart from this, all were non-significant and were included in Table 2.

Table 2. Comparison of responses between hospital/clinical and community pharmacists on observed ADRs and drug-caused ADRs .

	Overall	**HCP (n=169)**	**CP (n=136)**	**P-value**
Observed ADRs				
Cough	87	47	40	.758
Dry cough	116	70	46	.251
Dizziness	78	38	40	.269
Itchiness	128	75	53	.341

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Rash	148	93	55	.011
Anaphylaxis reaction	38	24	14	.304
Headache	90	54	36	.297
Hyperkalaemia	20	16	4	.022
Hyperglycaemia	19	15	4	.033
Bleeding	32	21	11	.219
Oedema	62	32	30	.500
Diarrhea	40	25	15	.333
Nausea	57	32	25	.902
Vomiting	42	27	15	.213
Renal failure	14	9	5	.494
Jaundice	11	8	3	.239
Acute hepatitis	11	9	2	.073
Steven Johnson Syndrome	12	8	4	.423
Erythema	16	9	7	.945
Heartburn	32	20	12	.394
Gastritis	34	17	17	.501

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Constipation	27	16	11	.673
Palpitation	75	50	25	.024
Flatulence	15	7	8	.485
Myalgia	30	17	13	.884
Thrombocytopenia	22	16	6	.090
Other	17	7	10	.223
Drugs Caused ADR				
Perindopril	96	56	40	.486
Aspirin	95	56	39	.403
Diclofenac	71	37	34	.523
Amlodipine	95	53	42	.929
Atorvastatin	87	54	33	.139
Metformin	69	44	25	.112
Allopurinol	15	10	5	.368
Co-trimoxazole	18	10	8	.990
Heparin	34	22	12	.247
Lovastatin	8	5	3	.683

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Cloxacillin	16	7	9	.335
Ticlopidine	4	3	1	.428
Rifampicin	9	8	1	.040
Phenytoin	10	6	4	.767
Amoxicillin	30	18	12	.594
Carbamazepine	78	51	27	.040
Nifedipine	68	44	24	.080
Erythromycin	17	9	8	.833
Captopril	52	31	21	.503
Paracetamol	22	10	12	.329
Atenolol	13	9	4	.306
Cefuroxime	18	17	1	<.001
Ceftriaxone	15	7	8	.485
Mefenamic acid	7	4	3	.926
Chlorothiazide	18	9	9	.634
Penicillin	25	15	10	.630
Vancomycin	25	23	2	<.001

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Alendronate	13	10	3	.111
Prednisolone	11	9	2	.073
Isotretinoin	18	11	7	.616
Morphine	7	5	2	.388
Dexamethasone	13	10	3	.111
Infliximab	7	5	2	.388
Adalimumab	13	8	5	.650
Fingolimod	4	3	1	.428
Other	42	20	22	.341

Table 3 illustrated that specific actions were implemented in response to ADR reporting. The initial step taken by HCP (n=98) and CP (n=66) was to complete the form and submit the report to the Saudi Food and Drug Administration/National Pharmacovigilance Centre (SFDA/NPC). The second action that HCP (n=89) and CP (n=64) staff took was to complete the ADR form and submit the report to the hospital drug information center. Third, pharmacists notified the hospital drug information center at both the HCP (n= 68) and CP (n= 55) levels. The subsequent step was to notify the in-charge physician (inform the associated pharmaceutical company) and the CP (n= 43) and HCP (n= 48). Similarly, pharmacists conducted additional assessments to verify the condition. The subsequent action was to document a note in the patient's record and recommend that the patients inform their physician. Another course of action could involve discontinuing the medication or substituting it with a different medication that elicited the reaction. Patients were advised that their medication may be reacting, and to mitigate the reaction, they were advised to take an alternative medication. It was also observed that no action was taken to manage the condition, as per the findings.

Table 3. Comparison of responses between hospital/clinical and community pharmacists on action taken and reporting system.

	Overall	**HCP (n=169)**	**CP (n=136)**	**P-value**
Action Taken				

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Fill ADR report form and send it to the Saudi Food and Drug Administration/National Pharmacovigilance Centre	164	98	66	.100
Fill ADR report form and send it to the hospital drug information center	153	89	64	.331
Inform the pharmacist in the hospital drug information center	123	68	55	.971
Inform the physician in charge e. Inform the associated pharmaceutical company	91	48	43	.542
Do further evaluation (e.g. patient medication history)	60	34	26	.827
Make note in the patient's chart/record	72	41	31	.764
Suggest to the patient that they inform their doctor	78	45	33	.638
Suggest to the patient to try a different medicine	49	22	27	.106
Suggest to the patient to stop the medicine	59	28	31	.171

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Suggest to the patient a medicine to relieve the reaction(s)	46	24	22	.632
Explain to the patient that it may be a reaction to their medicine	91	49	42	.720
No action	18	14	4	.049
Other	13	6	7	.493
Reported a suspected ADR to the Saudi Food and Drug Administration/National Pharmacovigilance Centre?				
Yes	163	103	60	.005
No	135	61	74	
Missing	7	5	2	
Form for reporting suspected ADRs to the Saudi Food and Drug Administration/National Pharmacovigilance Centre				
Yes	208	128	80	.007
No	94	40	54	
Missing	3	1	2	

Table 3 indicates that the Saudi Food and Drug Authority/National Pharmacovigilance Centre received reports of suspected adverse drug reactions from Healthcare Professionals (n=103) and Consumers (n=60). HCP (n=61) and CP (n=74) did not simultaneously indicate a probable ADR. Additionally, when HCP and CP were questioned regarding their awareness of reporting suspected adverse drug reactions (ADR) to the Saudi Food and Drug Authority/National Pharmacovigilance

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Centre (SFDA/NPC), 128 and 80 respectively confirmed their knowledge, while the remaining respondents are listed in the table.

The pharmacists' perspective on the procurement of forms for ADR reporting is illustrated in Table 4. HCP (n=123) and CP (n=78) reported that they obtained forms from the SFDA website. The hospital's drug information center (HCP = 103, CP = 80), national and local health departments (HCP = 36, CP = 30), drug information texts (HCP = 24, CP = 16), and miscellaneous sources (HCP = 13, CP = 15) were additional sources for acquiring forms. When HCPs and CPs were asked regarding their preferred method for submitting suspected adverse drug reactions (ADRs) to the Saudi Food and Drug Authority/National Pharmacovigilance Centre (SFDA/NPC), HCPs (n = 122) and CPs (n = 96) favoured submission via an online form, followed by the Saudi Vigilance mobile application (HCP = 83, CP = 56), mobile phone (HCP = 33, CP = 24), and email (HCP = 41, CP = 27). In addition, they reported that they used the hospital's drug information center exclusively (HCP = 48, CP = 43), faxed forms (HCP = 17, CP = 19), mailed ADR reports (HCP = 39, CP = 31), and completed forms (HCP = 17). The results suggest that the preferred mode of form submission was online.

Table 4. Comparison of responses between hospital/clinical and community pharmacists on form availability and preferences to submit a report about suspected ADR.

	Overall	**HCP (n=169)**	**CP (n=136)**	**P-value**
Availability of form for ADR reporting				
From the Saudi Food and Drug Administration online webpage	201	123	78	.005
From the hospital's drug information center	183	103	80	.707
From national or local health department	66	36	30	.873
From the drug information book	40	24	16	.531
Other	28	13	15	.316
Preference to submit a report about a suspected ADR to the Saudi Food and Drug Administration/National Pharmacovigilance Centre				
Filling in an online form	218	122	96	.758

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Submit an ADR form through the Saudi Vigilance mobile application	139	83	56	.167
Reporting by phone	57	33	24	.676
Reporting by email at NPC.Drug@sfda.gov.sa	68	41	27	.358
Filling out a form and faxing it	36	17	19	.293
Mailing/posting an ADR report	70	39	31	.953
Reporting to the hospital's drug information center only	91	48	43	.542

Table 5 illustrates the methods by which HCP and CP staff were motivated to report suspected ADRs to the SFDA/NPC. Initially, the HCP (n=132) and CP (n=85) staff were motivated to report based on the severity of the clinical reaction. Secondly, the pharmaceutical company's explicit request (HCP= 78 & CP= 58), a reaction that was not widely known (HCP= 78 & CP= 62), a specific typology of the reaction (HCP= 32 & CP= 36), the involvement of a newly licensed drug (HCP= 47 & CP= 38), and an obvious causal relationship with the drug administration (HCP= 33 & CP= 29) also contributed. The results indicated that the severity of reactions was the only variable that exhibited significant findings at a significance level of $p<.005$. Furthermore, the following factors were identified as deterrents to reporting suspected adverse drug reactions (ADRs). Uncertainty regarding reporting (HCP= 81 & CP= 53), uncertainty regarding the causal relationship with the drug administration (HCP= 52 & CP= 47), and low severity levels (HCP= 99 & CP= 65) were the most prominent factors. Factors such as a lack of information (HCP= 57 & CP= 42) and knowledge of reporting rules, regulations, and procedures (HCP= 44 & CP= 20), difficulty in obtaining forms (HCP= 36 & CP= 32), and the complexity of the form (HCP= 33 & CP= 22) were also included in the list. A few additional items were also referenced in the table below. The results indicated that none of the factors yielded substantial outcomes.

Table 5. Comparison of responses between hospital/clinical and community pharmacists factors encourage and discourage the reporting of ADRs.

	Overall	**HCP (n=169)**	**CP (n=136)**	**P-value**

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Encourage reporting a suspected ADR to the Saudi Food and Drug Administration/National Pharmacovigilance Centre.				
The high degree of severity of a clinical reaction	217	132	85	.003
The explicit request of a pharmaceutical company	136	78	58	.540
The reaction is not widely known	140	78	62	.922
The specific typology of the reaction (unusual/unexpected)	68	32	36	.116
The involvement of newly licensed drug	85	47	38	.980
The obvious causal relationship with the administration of the drug	62	33	29	.698
Factors discourage you from reporting a suspected ADR to the Saudi Food and Drug Administration/National Pharmacovigilance Centre.				
The low degree of severity of a clinical reaction	164	99	65	.060
Uncertainty regarding the type of reactions to be reported	134	81	53	.117

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The uncertainty of a causal relationship with the administration of the drug	99	52	47	.482
A lack of information from the affected patient	99	57	42	.598
The reaction is widely known	78	48	30	.207
A lack of knowledge regarding the regulations and procedure for reporting	64	44	20	.016
The difficulty in obtaining a form for reporting	68	36	32	.642
The complexity of the form to be completed	55	33	22	.449
The fear of medical-legal consequences	47	30	17	.207
Reporting does not seem worthwhile	48	22	26	.146
A lack of time to report reactions due to heavy responsibilities	87	54	33	.139
A lack of support from your organization/ head of department/ colleagues etc	72	43	29	.400

The ADRs that the HCP and CP staff require to be reported are shown in Table 6. The study identified several common concerns, including suspected reactions (HCP= 103 & CP= 75), certain reactions (HCP= 98 & CP= 69), severe reactions (HCP= 88 & CP= 67), mild reactions (HCP= 55 & CP= 34), long-term used drug reactions (HCP= 45 & CP= 26), reactions to new drugs (HCP= 62 & CP= 41), known reactions (HCP= 28 & CP= 20), and unexpected and unusual reactions (HCP= 67 & CP= 44).

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Additionally, the interaction between drugs was reported (HCP= 42 & CP= 32), as well as teratogenicity phenomena (HCP= 54 & CP= 34), reactions to vaccination (HCP= 64 & CP= 36), and the lack of efficacy of a drug because of the development of a newly resistant strain (HCP= 61 & CP= 31). Respondents expressed their intention to measure the incidence (HCP= 129 & CP= 86), indication for drug prescription (HCP= 102 & CP= 76), factors predisposing patients (HCP= 93 & CP= 65), uncommon ADRs (HCP= 74 & CP= 57), previously unknown ADRs (HCP= 40 & CP= 41), safe drugs (HCP= 65 & CP= 49), and keeping records of ADRs (HCP= 76 & CP= 52). The findings indicated that the most effective method of identifying spontaneous putative adverse drug reactions (ADRs) was to monitor the frequency of reporting.

Table 6. Comparison of responses between hospital/clinical and community pharmacists highlighting the importance and aims of spontaneous monitoring the reporting of ADRs.

	Overall	**HCP (n=169)**	**CP (n=136)**	**P-value**
ADRs should be reported to the Saudi Food and Drug Administration/National Pharmacovigilance Centre.				
Suspected reactions (For which the intake of one or more drugs is only one of several possible explanations)	178	103	75	.307
Certain [sure, ascertained] reactions (For which the causal relationship with the intake of one or more drugs is obvious)	167	98	69	.206
Severe reactions	155	88	67	.626
Mild reactions	89	55	34	.150
Reactions to drugs that have been in use for a long time	71	45	26	.123
Reactions to new drugs	103	62	41	.230

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Known reactions (Listed on the package leaflet or already described in the literature)	48	28	20	.657
Unexpected/ unusual reactions	111	67	44	.188
Interactions between drugs	74	42	32	.789
Teratogenicity phenomena	88	54	34	.183
Reactions to vaccination	100	64	36	.035
Lack of efficacy of a drug due to the development of a newly resistant strain	92	61	31	.012
Aims of monitoring the spontaneous reporting of suspected ADRs to the Saudi Food and Drug Administration/National Pharmacovigilance Centre				
To measure the incidence of ADRs	215	129	86	.013
To identify the indication for which the drugs are prescribed	178	102	76	.431
To identify factors predisposing patients to ADRs	158	93	65	.209
To identify uncommon ADRs (allergic, idiosyncratic, etc.)	131	74	57	.742
To identify previously unknown ADRs	81	40	41	.203

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To identify safe drugs	114	65	49	.663
To maintain a database of ADRs	128	76	52	.236

4. Discussion

The current study aimed to explore the experiences of pharmacists working in both community and hospital settings with ADR reporting, as well as the barriers and facilitators influencing the reporting process in the Kingdom of Saudi Arabia. Over the course of a year, 70.5% of participants observed suspected ADRs, and of those, 53.4% reported the ADRs to the SFDA. Participants rated the high severity of the drug reaction as the most important factor encouraging them to report the ADR, followed by situations where the reaction is not widely known and an explicit request from a pharmaceutical company, in that order.

Among the 305 pharmacists surveyed in the current study, 70.5% had observed a suspected ADR in the past 12 months, and 53.8% reported the suspected ADR to the SFDA. When a suspected ADR was observed, the most reported actions included filling out the ADR reporting form and submitting it to the SFDA, completing the form and sending it to the hospital drug information center, and informing the pharmacist at the hospital drug information center. Additional measures are detailed in the results section. The most frequently reported ADRs were rash, itchiness, and dry cough. This figure is higher compared to reports from previous studies on community pharmacists in Saudi Arabia, where the proportion of participants who reported to the SFDA ranged from 13.5% to 47.7% [16,17,18].

The observed increase in ADR reports compared to previous studies may be attributed to differences in the study settings. An analysis of the reported figures shows that hospital pharmacists had higher ADR reporting rates compared to community pharmacists, although this difference was not statistically significant. The dominance of hospital pharmacists in pharmacovigilance activities has also been documented in a study conducted in Spain, where hospital pharmacists reported suspected ADRs far more frequently than their community pharmacist counterparts[19]. Earlier studies primarily focused on community pharmacies, where both clients and pharmacists are typically less engaged in ADR reporting. In contrast, hospital pharmacies handle more severe ADR cases, which account for a significant proportion of hospital admissions[20]. Moreover, previous research has highlighted a lack of awareness among community pharmacists about the ADR reporting system in the country[21].

However, the current report aligns with a study from the UAE among hospital pharmacists, where 53.2% of participants reported suspected ADRs to the authority responsible[22]. Overall, both the current study and previous research highlight that under-reporting of ADRs by pharmacists remains common in Saudi Arabia, emphasizing the need for continued efforts to enhance ADR reporting activities by all stakeholders.

The current study also found that pharmacists' interest in reporting increased when the suspected ADR is severe, the reaction is unknown, there is an explicit request from a pharmaceutical company, etc. Conversely, participants were less motivated to report when the suspected ADR is less severe, there is uncertainty about the type of reaction, or the causal relationship with the medication is unclear, etc. Similar findings were reported in the literature reviewed[23,24,25,26]. Pharmacists are more likely to report severe reactions due to the associated health risks, ethical and legal responsibilities. Additionally, the awareness of consequences gained during their academic career, along with continuous training on severe ADRs, serves as further motivation for pharmacists to report.

The current study explored participants' viewpoints on which types of ADRs should be reported. Suspected reactions, confirmed reactions, and severe reactions were the most identified categories, along with other types. The current findings align with WHO recommendations, which

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advocate reporting all clinically relevant suspected reactions. This includes suspected reactions to new drugs, increased frequency of known reactions, and unusual suspected ADRs associated with well-established medications[27]. Participants' responses regarding the aims of ADR reporting emphasized identifying factors that expose patients to ADRs, detecting uncommon ADRs, and maintaining an ADR database as the most cited objectives. This aligns with guideline recommendations, which generally emphasize that ADR reporting helps assess drug safety in real-world conditions[28].

Study Limitations

Sampling bias was a concern due to the use of social media for survey distribution, as it may have excluded individuals outside the social network. This approach also made it more difficult to reach a diverse range of participants within the target population, limiting the generalizability of the findings.

5. Conclusions

More than two-thirds of participants reported practicing ADR reporting, with greater adherence observed in hospital settings. Pharmacists predominantly depend on the SFDA/NPC and hospital drug information centers for reporting, with a preference for online submission methods. Targeted educational interventions addressing the identified knowledge gaps could further improve ADR reporting practices

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