

# Factors Associated with the Public's Intention to Report Adverse Drug Reactions to Community Pharmacists in the Makkah Region of Saudi Arabia: An Application of the Theory of Planned Behavior

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**Objective:** This study aimed to evaluate the public's intention to report ADRs to community pharmacists in the Makkah region of Saudi Arabia and to identify the factors influencing this intention, using the TPB as the theoretical framework.

**Methods:** A cross-sectional study was conducted in the Makkah region of Saudi Arabia via a nonprobability sampling method. Data were gathered through an online self-report survey designed to assess the public's intention to report ADRs to community pharmacists. Multivariate logistic regression analysis was used to examine the influence of three constructs of the TPB on this intention.

**Results:** A total of 452 individuals participated in the study. Approximately 22% of them reported experiencing ADRs in the last six months, but only 21% were aware of the Saudi NPC. Approximately 62% of the participants expressed a strong intention to report ADRs to community pharmacists. The public exhibited a highly positive attitude toward reporting ADRs, alongside high subjective norms and perceived behavioral control. Among the TPB constructs, attitude had the most significant influence on the intention to report ADRs to community pharmacists, followed by subjective norms and perceived behavioral control.

**Conclusion:** This study revealed a strong public intention to report ADRs to community pharmacists in the Makkah region, driven primarily by positive attitudes, supportive subjective norms, and high perceived behavioral control. However, the findings highlight a critical gap in public awareness of the Saudi NPC, with only 21% of participants aware of its existence. These results underscore the importance of targeted initiatives to improve awareness of the Saudi NPC and to leverage positive attitudes and social norms to promote ADR reporting practices effectively.

**Keywords:** adverse drug reactions, pharmacovigilance, reporting, theory of planned behavior, public, Saudi Arabia

## Introduction

Adverse drug reactions (ADRs) continue to be major causes of morbidity and mortality.<sup>1,2</sup> Compared with other significant factors contributing to mortality, such as heart disease, cancer, and stroke, ADRs are among the fourth to sixth leading causes of death worldwide.<sup>3,4</sup> In England, the number of hospitalizations caused by ADRs increased from 1.2% in 2008 to 1.6% in 2015.<sup>5</sup> In Saudi Arabia, there are 8.5 per 100 admissions related to ADRs in one hospital.<sup>6</sup> Additionally, ADRs place a significant burden on the economy.<sup>7</sup> The cost of managing ADRs in the United States is predicted to reach 30.1 billion dollars.<sup>8</sup> In Europe, the cost of handling ADRs is thought to be €79 billion.<sup>9</sup> The World Health Organization (WHO) characterizes ADRs as any negative consequence that is unforeseen and not expected, resulting from the use of a medication as prescribed.<sup>10</sup>

Timely and precise reporting of ADRs plays a crucial role in overseeing the safety and effectiveness of pharmaceutical products. It empowers healthcare authorities to implement necessary measures, minimizing risks and promoting patient safety.<sup>11</sup> According to the WHO, pharmacovigilance involves various activities related to the detection, assessment, and avoidance of ADRs.<sup>12</sup> However, one of the greatest challenges facing pharmacovigilance programs is

inadequate reporting.<sup>13</sup> The global reporting rate for ADRs is estimated to be between 5% and 10%.<sup>8</sup> Thus, under-reporting is a real concern that we must consider.

Patient-reported ADRs serve as crucial sources of information for enhancing patient safety.<sup>14</sup> Consumer reports of ADRs can offer additional insights and fill gaps left by healthcare professionals' reports. Numerous studies comparing ADR reports from both patients and healthcare professionals have indicated that patient reports tend to be more detailed than those from healthcare providers.<sup>15,16</sup> Encouraging patients to participate in pharmacovigilance can increase spontaneous reporting and lead to the earlier identification of significant ADRs. As a result, patients have emerged as key contributors to pharmacovigilance efforts.

In Saudi Arabia, the Saudi Food and Drug Authority (SFDA) established the National Pharmacovigilance Center (NPC) in 2009.<sup>17</sup> The NPC has established both paper and online methods to make ADR reporting more accessible and expects all healthcare practitioners, including doctors, pharmacists, and nurses, to do so. Additionally, patients can report ADRs directly to Saudi NPC. However, ADRs are still underreported in Saudi Arabia.<sup>17</sup> Saudi Arabia, with other Middle Eastern countries, accounts for only 0.6% of the world's safety reporting.<sup>18</sup> Sales et al reported that approximately 6% of the public was aware of the Saudi NPC in Riyadh, Saudi Arabia.<sup>19</sup> Furthermore, a study conducted by Kassem et al in the Qassim region of Saudi Arabia revealed that most patients were unaware of the existence of the ADR online reporting system in Saudi Arabia.<sup>20</sup> In the Eastern region of Saudi Arabia, approximately 8% of the general public has heard of the Saudi NPC.<sup>21</sup>

Patient-reported ADRs can significantly enhance understanding of the potential risks associated with medications, as these reports stem from direct experiences with drug effects. The unique perspectives and experiences patients provide offer valuable insights that complement and enrich the ADR descriptions documented by healthcare professionals. Community pharmacies are strategically located and readily accessible, providing a conducive and less formal setting that is well-suited to delivering services for patients managing their own care.<sup>22,23</sup> Pharmacists are widely recognized among healthcare professionals for their pivotal role in integrating pharmacovigilance principles into routine clinical practice and actively reporting ADRs, as these activities are fundamental to their professional responsibilities.<sup>24–26</sup> Multiple studies conducted in Saudi Arabia have demonstrated that community pharmacists possess a sufficient level of knowledge regarding pharmacovigilance.<sup>27,28</sup> A study conducted in Saudi Arabia reported that approximately 47% of community pharmacists encountered and documented at least one adverse drug reaction (ADR) per month.<sup>28</sup> Similarly, research conducted in Malaysia revealed that around 40% of community pharmacists reported ADRs within a six-month period.<sup>29</sup> Community pharmacists play a crucial role in the pharmacovigilance system, serving as an accessible and trusted point of contact for patients experiencing ADRs due to their frequent interactions with patients and their established position within the healthcare system. This study aimed to investigate the factors influencing the public's intention to report ADRs to community pharmacists. Although limited research has examined the impact of awareness and knowledge about the NPC on ADRs reporting among patients in Saudi Arabia, no known studies have utilized a theoretical framework to empirically explore the factors shaping public reporting behaviors. To address this gap, the present research applies the Theory of Planned Behavior (TPB) as a guiding framework to enhance understanding of the determinants of ADR reporting behavior, focusing on the Makkah region of Saudi Arabia.

The TPB, developed by Ajzen, is a widely used theoretical framework for understanding and predicting human behavior.<sup>30</sup> The TPB posits that an individual's intention to perform a behavior is influenced by three key components: attitude toward the behavior, subjective norms, and perceived behavioral control. Attitude refers to an individual's positive or negative evaluation of performing a behavior. Subjective norms are the perceived social pressures to perform or not perform the behavior. Perceived behavioral control refers to an individual's perception of their ability to perform a behavior.<sup>30</sup> By leveraging TPB, the study can comprehensively evaluate how these factors interact to influence public's intentions and actions regarding ADR reporting. Additionally, TPB provides a clear framework for identifying potential barriers to reporting behavior and for designing interventions aimed at improving ADR reporting practices by addressing the modifiable constructs. This approach not only enhances understanding of public behavior but also contributes to better pharmacovigilance and medication safety practices in the community pharmacy setting. In the context of ADR reporting, a study by Gavaza et al applied the TPB to understand pharmacists' intentions to report ADRs. They reported that attitudes toward ADR reporting and subjective norms were significant predictors of ADR reporting intentions.<sup>31</sup>

Another study revealed that positive attitudes toward ADR reporting and subjective norms were significant predictors of ADR reporting intentions among patients in Thailand.<sup>32</sup>

The primary aim of this research was to investigate the determinants influencing the public's intention to report ADRs to community pharmacists in the Makkah region of Saudi Arabia. Specifically, the study sought to evaluate the public's intention to report ADRs to community pharmacists and to analyze the impact of the TPB constructs on this intention.

## Methods

This research utilized a cross-sectional survey targeting individuals in the Makkah region of Saudi Arabia through a nonprobability sampling method. Data were gathered via a self-administered online survey hosted on Google Forms. In April 2024, the survey link was distributed to participants through Telegram and WhatsApp groups. To be eligible for the study, participants had to be at least 18 years old, able to provide informed consent, and reside in the western region of Saudi Arabia. The study aimed to include a minimum of 385 individuals from a population of 8,325,304, ensuring a 5% margin of error and a 95% confidence level for adequate analytical power.

## Data Collection

The research survey included a set of validated instruments. These instruments included a sociodemographic instrument, an instrument for measuring individuals' intentions toward ADRs to community pharmacists, an instrument for assessing individuals' awareness of the Saudi NPC and the electronic ADR reporting procedure in Saudi Arabia, and three constructs of the TPB instrument (attitude, subjective norms, and perceived behavioral control). These instruments were based on relevant literature and reviewed by two expert academic pharmacists, who provided feedback that was used to make necessary adjustments. The survey underwent face and content validity checks through a pilot test with ten participants whose responses were excluded from the final analysis. The survey items were designed to be simple and were provided in both English and Arabic to prevent misunderstandings. Additionally, the reliability of the three TPB constructs was evaluated via Cronbach's alpha test.

### The Intention of Participants to Report ADRs to Community Pharmacists

This instrument is assessed via four items, such as "If I experience abnormal symptoms from my medications, I will report them to the community pharmacist" and "I plan to report to the community pharmacist if my family members experience abnormal symptoms from taking medications". These items were adapted from the literature.<sup>32</sup> The participants' responses were recorded on a 5-point Likert scale. The overall mean score of the intention instrument ranged from 1 to 5, with higher scores indicating a greater intention to report ADRs to community pharmacists. This mean score was then used as a cutoff to classify participants into two groups: those with high intention, assigned a score of one, and those with low intention, assigned a score of zero. The intention to report ADRs to community pharmacist instruments demonstrated strong internal consistency, as indicated by a Cronbach's alpha of 0.89.

### The TPB Constructs

The TPB instrument encompassed three main constructs, including attitudes toward reporting ADRs to community pharmacists, subjective norms regarding reporting ADRs to community pharmacists, and perceived behavioral control over reporting ADRs to community pharmacists. These constructs were adapted from the literature.<sup>32</sup> The attitude toward reporting ADRs was evaluated via six items, such as "reporting abnormal symptoms or health issues caused by my medications to a community pharmacist is beneficial" and "by reporting these issues to a community pharmacist, I can use my medications more safely". Subjective norms were assessed through five items, including statements such as "my physician encourages me to report abnormal symptoms or health problems from my medications to a community pharmacist" and "community pharmacists encourage me to report such issues". Perceived behavioral control was measured with four items, such as "I can report abnormal symptoms and health problems from my medications to a community pharmacist" and "I have access to community pharmacists to report these issues". Participants responded via a 5-point Likert scale, and an average score between 1 and 5 was calculated for each TPB construct. A higher score indicated a stronger positive attitude, higher subjective norms, and greater perceived behavioral control regarding

reporting ADRs to the community pharmacist. The internal consistency of the TPB construct scales, as determined by Cronbach’s alpha, demonstrated reliability, with values between 0.90 and 0.93.

## Data Analysis

The study utilized a descriptive method to characterize and summarize the dataset. Additionally, a multivariate logistic regression analysis was used to determine the impact of independent variables (including sociodemographic characteristics and TPB constructs) on the dependent variable (intention to report ADRs to community pharmacists). All analyses were conducted via the IBM® Statistical Package for the Social Sciences (SPSS), version 29.0.

## Results

### Demographic Characteristics

A total of 452 participants were enrolled in this study because they met the inclusion criteria. The average age was 35.49 years. Approximately 75% of the participants were female, and approximately 56% were married. Additionally, approximately 70% had a bachelor’s degree. Approximately 47%, 39%, and 14% of the participants were employed, looking for a job, and retired, respectively. Approximately 39% had a monthly income of less than 2999 Saudi Riyals, 18% had a monthly income between 3000 and 6999 Saudi Riyals, 17% had a monthly income between 7000 and 10,999 Saudi Riyals, 10% had a monthly income between 11,000 and 14,999 Saudi Riyals, and 16% had a monthly income of 15,000 Saudi Riyals or more (Table 1).

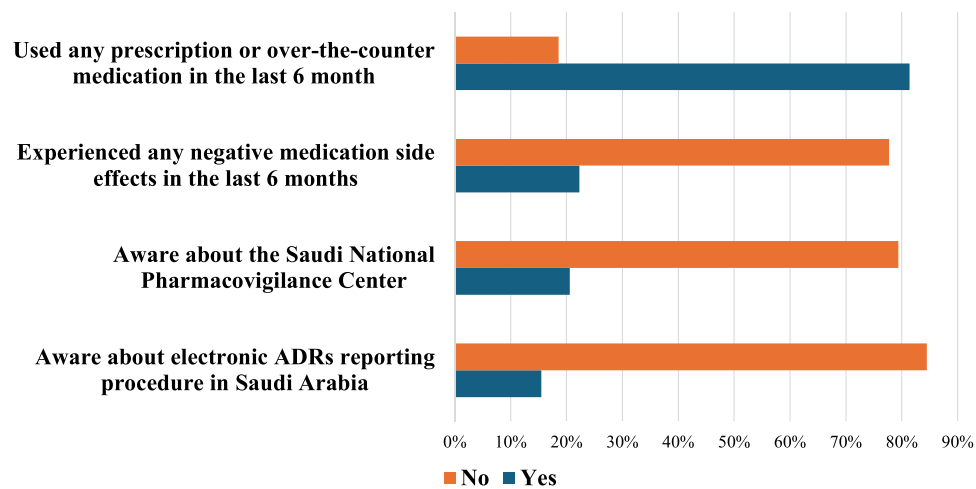
### Medication Usage, ADR Experiences, and Awareness of Saudi NPC

Over 80% of the participants had used prescriptions or over-The-counter medication (OTC) in the last 6 months. Additionally, approximately 22% of the participants experienced ADRs during the same period. However, only approximately 21% of the participants were aware of the Saudi National Pharmacovigilance Center (NPC).

**Table 1** Demographic Characteristics of Respondents (n = 452)

Demographic Characteristics	Frequency	Percentage
Age	Mean: 35.49 years old	SD: 11.88
Gender		
Female	339	75%
Male	113	25%
Marital status		
Not married	201	44.5%
Married	251	55.5%
Education level		
High School or less	65	14.4%
Diploma degree	37	8.2%
Bachelor’s degree	316	69.9%
Higher education degree	34	7.5%
Employment status		
Employee	212	46.9%
Looking for job	175	38.7%
Retired	65	14.4%
Income level		
Less than 2999 SAR	176	38.9%
3000–6999 SAR	82	18.1%
7000–10,999 SAR	77	17%
11,000–14,999 SAR	45	10%
15,000 SAR or More	72	15.9%

**Abbreviation:** SAR, Saudi Riyal.



**Figure 1** Participant medication usage, ADRs experiences, and awareness of the Saudi National Pharmacovigilance center and electronic ADRs reporting procedure.

Furthermore, only approximately 16% of the participants were aware of the electronic ADR reporting procedure in Saudi Arabia (Figure 1).

## Intention to Report ADRs to Community Pharmacists

Over 70% of the participants agreed or strongly agreed that if they experienced abnormal symptoms from medicines, they would report them to their community pharmacist, and they would intend to report any abnormal symptoms experienced by their family members. Additionally, approximately 65% agreed or strongly agreed that if their friends experienced abnormal symptoms from medicines, they would help them report these symptoms to the community pharmacist. Approximately 53% agreed or strongly agreed that, regardless of whether their abnormal symptoms from medicines are severe or have resolved, they would attempt to report them to the community pharmacist (Table 2).

The overall intention score for reporting ADRs to community pharmacists was 3.92 out of 5. Consequently, 61.5% of the participants ( $n = 278$ ) had a high intention to report ADRs to the community pharmacist, whereas 38.5% ( $n = 174$ ) had a low intention to report ADRs to the community pharmacist.

## Attitudes Toward Reporting ADRs to Community Pharmacists

Over 70% of the participants agreed or strongly agreed that reporting abnormal symptoms or health problems caused by their medicines to a community pharmacist is beneficial. By reporting these issues, they believe that they can safely use medicines, avoid harm, understand the cause of symptoms, obtain more information about medicines, and improve the medicine leaflet (Table 3). The overall mean score of the attitude scale was 4.24 out of 5, indicating that participants had a positive attitude toward reporting ADRs to the community pharmacist.

**Table 2** Intention to Report ADRs to Community Pharmacists

Items	Disagree or Strongly Disagree	Not sure	Agree or Strongly Agree
Intention			
1. If I have abnormal symptoms from my medicines, I will report them to community pharmacist.	13.5%	15.70%	70.8%
2. I intend to report to community pharmacist if my family has abnormal symptoms from taking medicines	16.0%	11.70%	72.4%
3. If my friends have abnormal symptoms from taking medicines, I will help them to report community pharmacist.	16.8%	17.90%	65.3%
4. No matter whether my abnormal symptoms from my medicines are not severe or resolved, I try to report to community pharmacist.	23.2%	24.10%	52.7%

**Table 3** Attitude Toward Reporting ADRs to Community Pharmacists

Items	Disagree or Strongly Disagree	Not Sure	Agree or Strongly Agree
Attitude			
1. There is a benefit to report abnormal symptoms or health problems from taking my medicines to community pharmacist.	10.2%	12.2%	77.6%
2. By reporting abnormal symptoms or health problems from medicines to community pharmacist, I can safely use medicines.	14.6%	14.6%	70.8%
3. By reporting abnormal symptoms or health problems from medicines to community pharmacist, I can avoid harm from using medicines.	10.8%	14.6%	74.6%
4. By reporting abnormal symptoms or health problems from medicines to community pharmacist, I can know the cause of abnormal symptoms or health problems.	9.1%	13.3%	77.7%
5. By reporting abnormal symptoms or health problems from medicines to community pharmacist, I can get more information about medicines.	9.1%	9.7%	81.2%
6. By reporting abnormal symptoms or health problems from medicines to community pharmacist, it is a benefit to improve leaflet of medicines.	9.8%	11.9%	78.3%

### Subjective Norms About Reporting ADRs to Community Pharmacists

Approximately 60% of the participants agreed or strongly agreed that community pharmacists encourage them to report abnormal symptoms or health problems related to their medications. Similarly, 60% of the participants agreed or strongly agreed that their families or relatives also encouraged them to report ADRs to the community pharmacist. Additionally, approximately 56% agreed or strongly agreed that their physicians encourage them to report abnormal symptoms or health problems to the community pharmacist. Furthermore, 58% agreed or strongly agreed that their friends encouraged them to report abnormal symptoms or health problems to the community pharmacist. Finally, 58% agreed or strongly agreed that people whose opinions they trust encourage them to report abnormal symptoms or health problems to the community pharmacist (Table 4). The overall mean score of the subjective norms construct was 3.72 out of 5, indicating that participants perceived more positive subjective norms about reporting ADRs to the community pharmacist.

### Perceived Behavioral Control to Report ADRs to Community Pharmacists

Approximately 75% of the participants agreed or strongly agreed that they could report abnormal symptoms and health problems from medicines to a community pharmacist. Additionally, more than 66% of the participants agreed or strongly agreed that they have complete control to report abnormal symptoms or health problems from their medicines to

**Table 4** Subjective Norms About Reporting ADRs to Community Pharmacists

Items	Disagree or Strongly Disagree	Not Sure	Agree or Strongly Agree
Subjective norms			
1. Physician encourages me to report abnormal symptoms or health problems from my medicines to community pharmacist.	22.6%	20.8%	56.6%
2. Community pharmacists encourage me to report abnormal symptoms or health problems from my medicines to community pharmacist.	21.4%	18.4%	60.2%
3. My family or relative encourages me to report abnormal symptoms or health problems from my medicines to community pharmacist.	17.6%	22.3%	60.0%
4. My friends encourage me to report abnormal symptoms or health problems from my medicines to community pharmacist.	19.9%	21.9%	58.2%
5. People whose opinions I trust report abnormal symptoms or health problems resulting from taking their medications to the community pharmacist.	17.2%	24.1%	58.6%



a community pharmacist, that they can access community pharmacists to report abnormal symptoms or health problems from their medicines, and that they can report abnormal symptoms and health problems from medicines to community pharmacists, even though it is difficult to explain their abnormal symptoms (Table 5). The overall mean score of the perceived behavioral control construct was 4.03 out of 5, indicating that participants perceived more behavioral control when reporting ADRs to the community pharmacist.

## Predictors of the Intention to Report ADRs to Community Pharmacists

A multivariate logistic regression analysis was conducted to identify the effects of independent variables, including age, gender, marital status, education level, employment status, income level, attitudes, subjective norms, and perceived behavioral control, on the intention to report ADRs to community pharmacists. The model was significant ( $\chi^2 = 257.12$ ,  $p$  value  $< 0.001$ ) and explained approximately 59% of the variation in the intention to report ADRs to community pharmacists (Nagelkerke  $R^2 = 0.589$ ). Age, attitude, subjective norms, and perceived behavioral control were significantly associated with the intention to report ADRs to community pharmacists. Older participants were less likely to have a high intention to report ADRs to community pharmacists ( $OR = 0.955$ ,  $p$  value = 0.024). Among the TPB constructs, attitude had the greatest effect on the intention to report ADRs to community pharmacists, followed by subjective norms and perceived behavioral control. Participants with a highly positive attitude were more likely to have a high intention to report ADRs to community pharmacists ( $OR = 3.625$ ,  $p$  value  $< 0.001$ ). Additionally, participants with high subjective norms were also more likely to have a high intention to report ADRs to community pharmacists ( $OR = 2.116$ ,  $p$  value  $< 0.001$ ). Finally, participants with high perceived behavioral control were more likely to have a high likelihood of reporting ADRs to community pharmacists ( $OR = 1.631$ ,  $p$  value = 0.013) (Table 6).

**Table 5** Perceived Behavioral Control to Report ADRs to Community Pharmacists

Items	Disagree or strongly disagree	Not sure	Agree or strongly agree
Perceived behavioral control			
1. I can report abnormal symptoms and health problems from medicines to community pharmacist.	10.2%	14.8%	75.0%
2. I have complete control to report abnormal symptoms or health problems from my medicines to community pharmacist.	12.8%	19.5%	67.7%
3. I can access community pharmacists to report abnormal symptoms or health problems from my medicines.	14.1%	19.7%	66.2%
4. I can report abnormal symptoms and health problems from medicines to community pharmacists, although it is difficult to explain my abnormal symptoms.	13.8%	19.9%	66.3%

**Table 6** Multivariate Logistic Regression Model of the Intention to Report ADRs to Community Pharmacists

Variables	Coefficient	SE	Wald	OR	Lower 95% CI	Upper 95% CI	p-value
Age	-0.046	0.020	5.101	0.955	0.918	0.994	0.024*
Gender				Reference			
Female							
Male	-0.211	0.337	0.392	0.810	0.418	1.569	0.531
Marital status				Reference			
Not married							
Married	0.626	0.366	2.932	1.870	0.913	3.830	0.087
Education level				Reference			
High school or less							

(Continued)

**Table 6** (Continued).

Variables	Coefficient	SE	Wald	OR	Lower 95% CI	Upper 95% CI	p-value
Diploma degree	-0.052	0.610	0.007	0.949	0.287	3.137	0.932
Bachelor's degree	0.030	0.438	0.005	1.030	0.437	2.431	0.946
Higher education degree	0.182	0.702	0.067	1.199	0.303	4.747	0.796
Employment status							
Employee				Reference			
Looking for job	0.508	0.464	1.199	1.663	0.669	4.131	0.274
Retired	0.472	0.531	0.788	1.603	0.566	4.539	0.375
Income level							
Less than 2999 SAR				Reference			
3000-6999 SAR	0.249	0.485	0.263	1.283	0.496	3.319	0.608
7000-10,999 SAR	0.063	0.521	0.014	1.064	0.384	2.954	0.904
11,000-14,999 SAR	0.303	0.628	0.233	1.354	0.395	4.638	0.630
15,000 SAR or more	0.974	0.632	2.374	2.648	0.767	9.138	0.123
Attitude	1.288	0.231	31.048	3.625	2.304	5.702	< 0.001*
Subjective norms	0.750	0.148	25.518	2.116	1.582	2.830	< 0.001*
Perceived behavioral control	0.489	0.198	6.105	1.631	1.106	2.404	0.013*

**Note:** \*Significant associated with intention to report ADRs to community pharmacist.

**Abbreviation:** SAR, Saudi Riyal.

## Discussion

The present study aimed to assess the factors affecting the public's intention to report ADRs to community pharmacists in the western region of Saudi Arabia. While over 80% of the participants used OTC or prescription medications, only 20% of the study participants were aware of the Saudi NPC. This finding is greater than that of another study conducted in Riyadh in 2017, where approximately 9% of participants were aware of the Saudi NPC.<sup>19</sup> This suggests a growing awareness over the past few years, potentially due to increased efforts in public health education and outreach. However, despite this improvement, overall awareness remains relatively low, highlighting the need for continued efforts to educate the public on the importance of reporting adverse drug reactions and other pharmacovigilance activities to ensure medication safety and efficacy.

Furthermore, approximately 22% of the study participants experienced ADRs in the past six months, which aligns with the findings of a broader study across 13 regions of Saudi Arabia, which reported that approximately 28% of participants experienced ADRs.<sup>33</sup> The relatively high prevalence of ADRs underscores the importance of enhancing pharmacovigilance activities to ensure patient safety. Additionally, these findings highlight the need for continuous education and training of healthcare professionals to recognize and manage ADRs effectively. It is also crucial to encourage patients to report any adverse reactions promptly to healthcare providers. This proactive approach can help in the early detection and mitigation of ADRs, ultimately improving patient outcomes. Strengthening the infrastructure for ADR reporting and fostering a culture of safety within healthcare settings are imperative steps toward minimizing the impact of ADRs.

Approximately two-thirds of the study participants had a high intention to report ADRs to the community pharmacist, which is consistent with another study conducted in Thailand, where approximately 65% of the participants were willing to report ADRs to the community pharmacist.<sup>32</sup> Additionally, Sales et al reported that approximately 71% of the public preferred to notify pharmacists about ADRs in Riyadh city, Saudi Arabia.<sup>19</sup> The high level of intention to report ADRs to community pharmacists underscores the trust and reliance that the public places on pharmacists for medication safety.<sup>34</sup> This trend suggests a growing recognition of the importance of pharmacists in the healthcare system and the need for continuous encouragement and facilitation of ADR reporting to increase patient safety and care quality. However, while the intention to report is high, actual reporting rates in many regions remain low, indicating potential barriers among



patients, such as lack of awareness about the reporting process, fear of repercussions, or misunderstanding about what constitutes ADRs.<sup>35</sup>

Study participants perceived a highly positive attitude toward reporting ADRs to the community pharmacist, which aligns with findings from a similar study conducted in Thailand.<sup>32</sup> Both studies highlight the trust and confidence the public places in community pharmacists. This positive attitude can be attributed to several factors, including the approachability of community pharmacists, their accessibility compared with other healthcare providers, and their expertise in medication management. Despite this positive attitude, several challenges remain in ensuring effective ADR reporting. These include a lack of standardized reporting procedures, limited awareness among patients about what constitutes an ADR, and concerns about the consequences of reporting.<sup>35</sup> Addressing these challenges requires a multifaceted approach involving policy changes, training programs for pharmacists and other healthcare providers, and public awareness campaigns.

More than half of the study participants agreed and strongly agreed that community pharmacists and physicians encourage them to report ADRs. However, Sales et al reported that approximately 30% of the public in Riyadh city, Saudi Arabia, indicated that physicians and pharmacists ask them to report ADRs if they experience any.<sup>19</sup> These differences may be attributed to several factors, such as differing levels of awareness and education about ADR reporting among healthcare professionals and the public's general knowledge and attitudes toward ADR reporting. Furthermore, there is a year gap between the two studies, with the study conducted in Riyadh having been completed seven years ago compared with the present study. Overall, these findings highlight the importance of continuous education and awareness campaigns for both healthcare professionals and the public to ensure effective ADR reporting and patient safety. This can be achieved through targeted training programs, awareness campaigns, and the integration of ADR reporting into routine healthcare practices.

Age was negatively associated with the intention of individuals to report ADRs to the community pharmacist. This aligns with another study that reported that younger people were more likely to report ADRs than older people were.<sup>36</sup> This could be attributed to several factors, including that younger individuals tend to be more proactive about their health and may be more familiar with online health resources.<sup>37</sup> They might also have greater health literacy and be more aware of the importance of pharmacovigilance.<sup>38</sup> In contrast, older individuals might have less confidence in using technology or might not recognize the importance of reporting ADRs. Therefore, targeted interventions to educate and encourage older adults to report ADRs could be beneficial for improving pharmacovigilance and overall medication safety.

In addition, attitude was the strongest factor influencing the intention to report ADRs to community pharmacists. Individuals with a positive attitude were more likely to report ADRs, which aligns with findings from other studies conducted in various countries.<sup>32,39,40</sup> This could be explained by the fact that a positive attitude toward reporting ADRs reflects an individual's belief in the value, relevance, and benefits of engaging in this behavior. Furthermore, a positive attitude likely enhances motivation and reduces psychological barriers, encouraging individuals to act on their intention to report ADRs. Therefore, enhancing patient education and simplifying the ADR reporting process are critical steps in promoting a positive attitude toward ADR reporting. These efforts can ultimately lead to better medication safety, improved patient outcomes, and higher-quality healthcare delivery.

Subjective norms were also positively associated with the intention to report ADRs to community pharmacists, which is similar to the findings of other studies.<sup>19,20,32,41</sup> Patients who received recommendations about reporting ADRs from pharmacists, physicians, and family were more likely to do so. This finding highlights the crucial role of healthcare professionals and family support in promoting pharmacovigilance practices among patients. Additionally, educational interventions and awareness campaigns involving both healthcare providers and patients' social circles could further increase ADR reporting rates.

Perceived behavioral control was the least predictor associated with the intention to report ADRs to the community pharmacist, which is consistent with the findings of another study.<sup>32</sup> Individuals who believed that they had complete control over reporting ADRs to the community pharmacist and could easily access the pharmacist were more likely to report ADRs. This finding suggests that while perceived behavioral control plays a role in reporting behavior, other factors, such as attitudes toward reporting ADRs and subjective norms, might be more significant predictors. Efforts to improve ADR reporting could benefit from focusing on enhancing positive attitudes toward reporting and strengthening

support systems and expectations surrounding ADR reporting among healthcare providers and patients. Additionally, ensuring that patients feel confident and empowered to report ADRs by improving accessibility to community pharmacists and simplifying the reporting process may also contribute to higher reporting rates.

## Limitations and Strengths

This study has several limitations that should be acknowledged. First, it measures the intention to respond without assessing actual reporting behavior. While intention is theoretically linked to behavior, it may not always translate into action. Second, the study relied on self-reported data, which are susceptible to recall bias. The participants may have inaccurately recalled past experiences or provided incorrect information about ADRs. Additionally, social desirability bias could have influenced the responses, as the participants might have answered questions about attitudes, subjective norms, and perceived behavioral control in a manner that they perceived as socially acceptable. Third, the study sample was limited to the Makkah region of Saudi Arabia, potentially restricting the generalizability of the findings to other regions or populations. Fourth, use of a non-probability sampling method in this study limits the ability to generalize the findings to the entire population. Furthermore, the use of Google Forms for questionnaire distribution limited participation to individuals with internet access.

Despite these limitations, this study has several strengths. This study provides valuable insights into the factors influencing the intention to report ADRs within the Makkah region, which could inform targeted interventions to improve reporting rates. The use of a theoretical framework to assess intentions adds rigor to the analysis, and the study's focus on a specific region allows for a detailed understanding of the local factors influencing ADR reporting. Moreover, the anonymous and voluntary nature of the survey helps reduce potential biases, such as social desirability bias, by encouraging honest responses.

## Implications of the Study

The findings of this study highlight the critical role community pharmacists can play as accessible healthcare professionals within the pharmacovigilance system. Specifically, the results indicate that the public's intention to report ADRs to community pharmacists exceeds their awareness of direct reporting mechanisms, suggesting a significant opportunity to expand the pharmacovigilance framework by integrating pharmacists more systematically into ADR reporting workflows. By equipping pharmacists with appropriate tools, targeted training, and public awareness initiatives, they can serve as vital intermediaries in the ADR reporting process, ultimately enhancing reporting rates and strengthening the overall pharmacovigilance system.

To capitalize on these findings, policies and programs should be developed to formalize the role of community pharmacists in ADR reporting. This could include specialized training in ADR recognition, reporting procedures, and effective patient engagement. Additionally, public awareness campaigns can bridge the gap between intention and action by educating individuals on the role of pharmacists in ADR reporting.

The study also emphasizes the need to convert intention into actionable behavior through simple and practical strategies. These include designing public awareness campaigns that highlight the ease and importance of reporting ADRs to pharmacists via social media, community outreach, and educational materials distributed in pharmacies. Visual prompts such as posters, brochures, or digital kiosks in pharmacy settings could further encourage individuals to report ADRs during their visits. Moreover, proactive pharmacist-led discussions with patients about potential ADRs during consultations can help normalize reporting practices and alleviate public hesitation.

These recommendations align with the TPB, addressing the components of attitudes (emphasizing the value of ADR reporting), subjective norms (normalizing reporting behaviors through interaction with pharmacists), and perceived behavioral control (streamlining and simplifying the reporting process). By implementing these strategies, the study provides a roadmap for enhancing public engagement in ADR reporting and leveraging community pharmacists' pivotal role in pharmacovigilance.

## Conclusion

This study highlights limited public awareness of the Saudi NPC in the Makkah region, with only one-fifth of participants aware of its existence. Despite this, 62% of respondents expressed a strong intention to report ADRs to community pharmacists. Key factors associated with this intention include age, attitude, subjective norms, and perceived behavioral control, with attitudes exerting the most significant influence. These findings suggest that interventions aimed at fostering positive public attitudes toward ADR reporting could significantly enhance reporting rates. Future research should leverage the TPB framework to design

targeted strategies that promote ADR reporting, thereby improving pharmacovigilance practices and public health outcomes in the region.

## Abbreviations

ADRs, adverse drug reactions; WHO, World Health Organization; SFDA, Saudi Food and Drug Authority; NPC, National Pharmacovigilance Center; TPB, Theory of planned behavior; OTC, Over-The-counter medication.

## Data Sharing Statement

This article contains all of the study's data.

## Ethics Approval and Consent to Participate

The survey was carried out on a voluntary and anonymous basis, with participants providing implied informed consent prior to participation. The study adhered to the principles of the Declaration of Helsinki and was approved by the Taif University Ethics Committee under protocol number TU IRB 45–327.

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## Disclosure

The author declares no conflicts of interest.

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