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## **Health Awareness of Adverse Drug Reactions Among Patients in Saudi Arabia**

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### **Abstract**

The goal of the current study was to evaluate Saudi Arabian patients' knowledge about adverse drug responses as it relates to their health. The study employed a qualitative methodology. The qualitative method focuses on correctly describing and presenting the phenomenon both qualitatively and numerically. It involves treating the phenomenon as it



actually is. The results showed that although the majority of healthcare professionals were aware of ADRs, they were unable to give a precise definition of the term "pharmacovigilance". Healthcare workers were more familiar with ADR reporting, but hospitals rarely employ it. In their systems of follow-up paperwork, the majority of hospitals did not include ADR reporting. Most local pharmacists weren't aware that Saudi Arabia has a pharmacovigilance facility. Furthermore, community pharmacists are unaware of where to get an ADR reporting form, unlike hospital pharmacists. The Saudi Arabian national pharmacovigilance facilities were unknown to pharmacists and medical professionals. Based on the conclusions reached by the study, the study came out with some recommendations, hospitals and other healthcare facilities could start campaigns to encourage medication safety, pharmacovigilance, and ADR reporting. workshops and hands-on training should be provided for managing ADRs and assessing medication side effects. Medication safety officers should oversee all activities relating to drug safety in all hospitals. The long-term goal should be to use technology to involve patients in ADR reporting.

**Keywords:** *Adverse drug reactions (ADRs); Pharmacovigilance; Awareness; Hospitals; Healthcare professionals (HCPs); Saudi Food and Drug Authority (SFDA).*

## 1. Introduction

One of the biggest problems and leading causes of mortality and morbidity are adverse drug reactions (ADRs), which are a serious issue (Lazarou et al., 1998). According to WHO (2002a), an adverse drug reaction (ADR) is any reaction to a drug that is unpleasant and undesired and takes place at levels typically used in humans for disease prevention, diagnosis, treatment, or alteration of physiological function. ADRs constitute a major global clinical problem, causing substantial mortality and morbidity (Bouvy et al., 2015). ADRs are produced for a variety of reasons, including those relating to patients, medications, healthcare providers (HCPs), and society (Alomar, 2014).

In-hospital ADR rates are 5.6% in the United States (US), 4.8% in Germany, and 3.2% in the United Kingdom, according to a study of data from developed countries (UK) (Stausberg, 2014). Hospitalization is the result of the most serious ADRs, and hospital stays might result in more ADRs. Therefore, hospitals and HCPs can significantly contribute to reducing ADR-related morbidity and mortality (Bouvy et al., 2015).

In order to prevent any unintended ADRs, HCPs can play a variety of roles by thoroughly analyzing the entire patient history, including the history of drug allergies and drug-drug interactions. Additionally, a pharmacovigilance strategy that can be used to minimize ADRs is reporting ADRs to the responsible office at their hospital or the regulatory authority because doing so can raise HCPs' awareness of reactions, which could lead to the avoidance of specific drugs, reducing the harm associated with reactions to those drugs. If the members of the

group share the mechanism generating the ADRs, reporting ADRs also makes HCPs more aware of the effects of a medicine or a class of drugs. As a result of HCPs reporting ADRs, a number of medications have been taken off the market. ADRs are between the fourth and sixth main causes of death in the US, according to a meta-analysis of research from the years 1966 to 1996. In 1994, fatal ADRs occurred in 6.7% and 0.32% of hospitalized patients, respectively (Lazarou et al., 1998).

Furthermore, in 2000, 7.5% of hospital admissions in Canada were for ADRs; of these ADRs, 36.9% were thought to be preventable, and 20.8% of the patients who were admitted passed away as a result of the ADRs (Baker et al., 2004). Additionally, children's hospital admissions due to ADRs ranged from 0.4% to 10.3%, and 0.6% to 16.8% of children hospitalized due to ADRs (Smyth et al., 2012).

The public, healthcare institutions, and healthcare providers are all becoming much more aware of the problems surrounding medication safety. The word "pharmacovigilance" has developed to reflect the significance of enhancing and monitoring medication safety (Abdel-Latif and Abdel-Wahab, 2015). Pharmacovigilance is "the research and practices connected to the detection, evaluation, understanding, and prevention of adverse responses to medicines or any other medicine-related problems," according to the World Health Organization (WHO, 2002b). The field name for the Collaborating Centre for International Drug Monitoring of the World Health Organization is Uppsala Monitoring Centre (UMC), which is situated in Uppsala, Sweden. The UMC functions by gathering, evaluating, and disseminating data from



member nations' national programs regarding the advantages, drawbacks, efficacy, and hazards of pharmaceuticals.

The Saudi Food and Drug Authority (SFDA) created a national pharmacovigilance center in March 2009, and it is a member of the WHO Collaborating Centre in Uppsala, Sweden. The primary method for gathering data about ADR incidence in both hospital and community settings is through the national pharmacovigilance system. Any pharmacovigilance system's efficacy and performance heavily depend on the involvement of all medical professionals as well as the level of cooperation and communication between the practitioners and pharmacovigilance center (Abdel-Latif and Abdel-Wahab, 2015).

### **1.1 Research Problem**

Studies that examine healthcare workers' knowledge, attitudes, and perceptions of the ADR reporting system and pharmacovigilance system used in this nation are lacking. Practitioners can play a significant role in identifying and reporting adverse drug reactions (ADRs) linked to the use of such products in a nation like Saudi Arabia with multiethnic populations and a high prevalence of use of herbal and alternative medicine. It is crucial to carry out thorough research to investigate and assess the contributions made by healthcare professionals to pharmacovigilance operations. The aim of the present study is to assess the health awareness of adverse drug reactions among patients in Saudi Arabia.

### **1.2 Research Questions**

The problem of the current study can be summarized in the following questions:

1. Is there awareness of pharmacovigilance and ADR reporting systems?
2. What is the position of health care professionals (HCPs) regarding ADRs?
3. What are the criteria that would make it easier for pharmacists to report adverse drug reactions (ADRs) in community and hospital settings?

### **1.3 Objectives of The Study**

The problem of the current study can be summarized in the following objectives:

1. Assess the awareness of pharmacovigilance systems and ADR reporting systems
2. Assess the knowledge and attitude of Healthcare professionals (HCPs) on the ADRs
3. Determine the criteria that would make it easier for pharmacists to report adverse drug reactions (ADRs) in community and hospital settings.

## **2. Methodology**

The study employs qualitative research, a technique designed to first determine the current context of a particular event before attempting to provide an explanation. As a result, it is focused on accurately depicting



the event and is based on the study of reality or the event as it truly occurs (Creswell, 2003).

The qualitative method is important in research since it is viewed as a core tenet of scientific inquiry and is usually regarded as the only way capable of researching many human fields. The qualitative method is concerned with precisely characterizing and communicating the phenomenon both qualitatively and numerically, and it involves treating the phenomenon as it actually is, in accordance with its definition (Williams, 2007).

The study followed the qualitative approach to assess the health awareness of adverse drug reactions among patients in Saudi Arabia through the literature review.

### **3. The Awareness of Pharmacovigilance Systems and ADR Reporting Systems**

The study by Abdel-Latif and Abdel-Wahab (2015) highlighted the under awareness of healthcare personnel regarding hospital pharmacovigilance systems and ADR reporting systems. ADR reporting and enhancing pharmacovigilance procedures is primarily under the purview of physicians, pharmacists, and nurses. Additionally, the findings offer baseline information to healthcare policymakers, health authorities, and educational efforts aimed at enhancing pharmacovigilance policies and ADR reporting in hospitals.

According to Sales et al., (2017) with a response rate of 68%, 204 questionnaires in total were gathered. Only 23% of people could define

ADRs correctly. Just 13 respondents, or 15.7%, knew what "pharmacovigilance" meant, and only 78.6% knew of the Saudi Pharmacovigilance Center. Sixty-seven percent of respondents said that neither their doctors nor pharmacists actively urge them to report any adverse drug reactions (ADRs) that may occur while taking their drugs. The majority of respondents (73.2%) thought that the medical staff should report adverse drug reactions rather than patients. When asked why patients don't report ADRs, 19.1 (48.5%) said it's because they don't know if the ADR is related to their medication or not, 18.1 (46.1%) said it's because they don't know about the Pharmacovigilance Center, 16.7 (40.7%) said it's because they don't know how important it is to report ADRs, and 14.3 (36.3%) said it's because they don't know.

Islam et al., (2020) clarified that while the public had a high level of medication knowledge and a propensity to report adverse drug reactions (ADRs), its level of medication safety awareness was subpar. The findings indicated that more education about the Saudi NPC and the ADRs reporting system has to be provided to the Saudi populace. The general public has a good outlook on getting medical information and disclosing adverse drug reactions (ADRs).

The study conducted by Al Doughan et al., (2019) aimed to compare the knowledge and awareness of community and hospital pharmacists towards reporting ADRs in various Saudi Arabian regions. According to the study's findings, community pharmacists who worked at neighborhood pharmacies were less knowledgeable about the



pharmacovigilance system than pharmacists who worked at hospitals in various parts of Saudi Arabia.

Torwane et al., (2015) distributed a total of 392 questionnaires among healthcare professionals. The study found that only 38.01% of healthcare professionals comprising 54.43% medical, 38.01% nursing, and 19.01% dental professionals were aware of the existence of a pharmacovigilance program in India. Only 40.56% of healthcare professionals felt that ADR monitoring centers should be established in every hospital. Similarly, very few healthcare professionals, that is, 6.12% have ever reported ADR to a pharmacovigilance center. The results of the study indicated that the majority of the healthcare professionals had poor knowledge and attitude about pharmacovigilance. There was a huge gap between the ADR experienced, and ADR reported by the healthcare professionals, especially among dentists and nursing staff. It has been advised that healthcare professionals; especially dental and nursing, should be trained properly on ADR reporting to improve the current scenario in the pharmacovigilance program of the country.

According to Adisa and Omitogun, (2019) ADR reporting was viewed with a moderately positive attitude by health workers in the chosen PHCs, although they had limited knowledge of ADRs and the ideas behind pharmacovigilance. Contrarily, patients showed little understanding of pharmacovigilance and ADR reporting, with less than a fifth reporting prior ADR experiences. This may highlight the necessity of ongoing public education and awareness campaigns on spontaneous reporting of ADRs in order to increase reporting rates, as well as frequent mandated

education and training on ADRs/pharmacovigilance concepts for PHC health workers.

#### **4. The Knowledge and Attitude of Healthcare Professionals (HCPs) on the ADRs**

AlShammari and Almoslem, (2018) investigated HCPs' knowledge, attitudes, and practices surrounding the ADRs reporting system. A total of 480 questionnaires were given out, and 336 people responded, or 70% of the total. The National Pharmacovigilance Centre was only known to 33% of participants (NPC). The majority (50%) of HCPs who were aware of the NPC and their obligation to report ADRs were pharmacists, followed by doctors (24%) and nurses (16%), and these distinctions were statistically significant ( $p < 0.01$ ). 27 percent of the participants reported ADRs; of these HCPs, 62% were pharmacists, 26% were nurses, and 6% were doctors. 95% of participants preferred reporting ADRs brought on by antibiotics and new/old medications. Fear that the report might be inaccurate (46%) and a lack of time (44%) were the main barriers to ADR reporting. Hospital HCPs were found to have a serious lack of understanding, supportive behaviors, and practices surrounding ADRs and reporting. To advance drug safety and pharmacovigilance in this area, immediate action is required in light of this finding, which raises concerns on a global scale.

Moreover, Ali et al., (2018) noted that the majority of healthcare professionals have limited knowledge of ADR and pharmacovigilance and were ignorant of the ADR reporting system. Healthcare professionals were keen to participate in ADR reporting despite their lack of

understanding of they would be given good training for the ADR reporting systems and procedures. Therefore, it is advised that healthcare professionals working in KSA receive quality instruction on the idea of ADR reporting and its process.

Mahmoud et al., (2014) designed a questionnaire which was distributed to 147 pharmacists in Saudi Arabia to evaluate their knowledge, attitudes, and experiences with reporting adverse drug reactions (ADRs). Only 21 (20.2%) people understood that pharmacists can file ADR reports online, and only 23 (22.1%) people claimed to be familiar with the ADR reporting process. N = 90, or 86.5% of the subjects, had never reported an ADR. Lack of knowledge about the reporting process (n = 22, 45.9%), the misconception that reporting ADRs is the responsibility of the doctor and hospital pharmacist (n = 8, 16.6%), and the idea that ADRs in community pharmacies are straightforward and shouldn't be reported (n = 8, 16.6%) were the main reasons for not reporting ADRs. Referring patients with ADRs to a doctor was considered to be the most prevalent strategy by community pharmacists (n = 80, 76.9%).

The study of Khan, (2013) aimed to examine community pharmacists' existing knowledge of and perceptions of barriers to adverse drug reaction (ADR) reporting systems in the Eastern region of Alahsa, Saudi Arabia. 71.43% of those surveyed responded. Few pharmacists (four, or 8.0%) lacked the ability to distinguish between the proper and incorrect definitions of ADRs. The majority of pharmacists—42 (84.0%)—mentioned that patients frequently report unfavorable events. However, 45 people (90.0%) did not know that Saudi Arabia has an ADR reporting

system. The ADR reporting process was primarily hampered by a poor professional environment. Other major obstacles to the reporting process included the lack of reporting forms and a lack of awareness of the reporting procedure. The vast majority of neighborhood pharmacists were not familiar with Saudi Arabia's ADR reporting system. The main challenges to the ADR reporting process were logistical ones.

In Najran, Saudi Arabia, the study of Alshabi et al., (2022) sought to determine hospital pharmacists' knowledge, attitudes, and practices regarding PV and the reporting of adverse drug reactions (ADRs), as well as the reasons that deter them from doing so. Overall, the pharmacists had a good to excellent understanding of, attitudes toward, and practices for reporting PV and ADRs. There is a tremendous opportunity for further strengthening the idea of PV and ADR reporting.

Moinuddin et al., (2018) distributed a total of 399 questionnaires among healthcare professionals. Only 14.8% were familiar with the term "ADR," and 55.1% of the respondents said that they had encountered ADRs while practicing. ADR reporting should be made mandatory for healthcare personnel, according to 93.8% of respondents, who also concurred that it increases patient safety by 94.5%. The results showed that healthcare workers in tertiary care settings are not familiar with the term "ADR." The main causes of underreporting are a lack of pharmacovigilance training, a heavy workload, and legal liabilities. More than half of the respondents concurred that patient safety is ultimately improved by ADR reporting.

The study by Alsaleh et al., (2017) demonstrated that hospital pharmacists in Kuwait had positive attitudes and a good awareness of PV and ADR reporting. Most of them, though, have never reported ADRs. These findings imply that focused training initiatives and a clear reporting policy for ADRs may boost ADR reporting and promote the establishment of an independent PV center in Kuwait that is fully operational.

Bakhsh et al., (2016), the study's preliminary findings indicate that while the majority of doctors had favorable attitudes and a good awareness of adverse drug reactions (ADRs) and their reporting, only a portion of their knowledge of ADRs and their reporting method was accurate. Since the majority of doctors were not exposed to ADR training programs, they undoubtedly need to be made mandatory in order to improve their knowledge of ADRs and how to report them.

Demographic analysis showed that 59% of patients were men, 56% were from rural areas, and 45% were graduates. Regarding knowledge about ADR, 78.6% of patients were aware that medicines can cause ADRs and 33% had experienced side effects in past. None of the respondents were aware of the ADR reporting center. Regarding perceptions toward ADR, 86.7% agreed to report ADR in the future and 56% of respondents believed ADR reporting may strengthen patient safety. According to 70% of patients, an awareness campaign is the best way to educate them regarding ADR (Joshi et al., 1970).

## **5. Criteria of Reporting of Adverse Drug Reactions (ADRs)**

The purpose of Aldryhim et al., (2019) study was to discover potential criteria that would make it easier for pharmacists to report adverse drug reactions (ADRs) in community and hospital settings. This study included 1,717 community pharmacists and 153 hospital pharmacists. Only 10.2% and 26.8%, respectively, of community pharmacists and hospital pharmacists acknowledged ever reporting an ADR. The most frequently mentioned elements that may encourage the reporting of ADRs include ongoing advancements in therapeutic understanding of ADRs, participation in educational programs offering credits for continuing medical education, the gravity of the experienced ADRs, and accessibility to patient medical profiles. The least significant factors that pharmacists identified were the impact of peers on colleagues reporting ADRs and ADRs resulting from herbal or conventional drugs.

According to Kassem et al., (2021); eleven participants were aware of the term "ADR" as per the WHO recommendations. All of the participants denied having any prior training in ADRs, attending any related events, and being aware of Saudi Arabia's FDA-ADR reporting mechanisms. The use of technologies like SPAs has been broadly accepted, but there is still a lot of concern about data privacy and confidentiality.

The findings of Nisa et al., 2018 showed that physicians and pharmacists in both public and commercial institutions have low knowledge of and poor ADR reporting practices. However, ADR reporting is seen favorably by doctors and pharmacists alike. Lack of awareness about where and how to report ADR is the main barrier preventing individuals from doing

so. Furthermore, most doctors and pharmacists are encouraged to report ADR because of how deadly the response can be.

Priyadharsini et al., (2011) reported a total of 30 ADRs were reported during the middle of 2009. 60% of ADRs included children under the age of one. The majority of medicines generating ADRs (67%) were antibiotics. The most frequent ADR (37%) was rashes and urticaria, which was followed by fever, anaphylactic shock, vomiting, chills, and rigors. During the research period, there had been one documented death. ADRs occurred more frequently with multi-drug therapy than with single-drug therapy. 87% of the ADRs had a possible preventable component, and almost 80% had a probable causal component. There were no mild reactions; instead, 77% of the reactions were moderate, and 23% of the reactions were severe. Infants are more likely to experience ADRs, and antibiotics are more frequently blamed. Most of the responses were mild to moderate in intensity. This shows that in order to guarantee the security of pharmacological therapy, pediatric patients must be subject to stringent ADR surveillance.

According to Tumwikirize et al., (2011); 33 patients (4.5%) were admitted with suspected ADRs, and 1.5% of hospitalizations were due to an ADR. The majority of ADRs were brought on by antiparasitic drugs, primarily quinine (61%). Hospitalization was delayed by community-acquired ADRs, 5.6 days as opposed to 4.0 days (p-value 0.001). In 49.5% of the patients, ADRs happened while they were hospitalized. Quinine-based antiparasitic medicines were the most often prescribed drug class (85.9%) associated with adverse drug reactions. Hospital



duration, 4.2 days vs 3.9 days, was unaffected by hospital-acquired ADRs (p-value 0.129). In conclusion, ADRs constitute a significant contributor to morbidity in patients, both outside of hospitals and in the community, and the majority of them are linked to widely used medications.

According to Vora et al., (2011), 830 of the 860 patients that were admitted were examined because they met the inclusion criteria. 45 patients in total (5.42%) experienced 47 ADRs. Among them, 18 (2.17%) (95% CI, 1.17%-3.17%) patients had ADR while already hospitalized in the medical ward, and 27 (3.25%) (95% CI, 2.03%, 4.47%) patients were obliged to be admitted to the hospital owing to ADR (ADR Ad) (ADR In). The majority of fatal and life-threatening responses were brought on by chemotherapy drugs. Most patients stopped taking the suspected medication and recovered from ADR. The importance of such research and the necessity of raising awareness among health professionals about looking for and reporting such reactions are highlighted by fatal and life-threatening adverse reactions that have been described in the current study as well as other investigations.

## **6. Conclusion and Recommendations**

There is a lack of research on the ADR reporting system and pharmacovigilance system employed in this country, as well as on the knowledge, attitudes, and perspectives of healthcare personnel. In a country like Saudi Arabia with multiethnic populations and a high incidence of using herbal and alternative medicine, practitioners can play a big part in finding and reporting adverse drug reactions (ADRs) associated with the use of such items. To examine and evaluate the



contributions made by healthcare professionals to pharmacovigilance operations, it is critical to conduct an in-depth study. The objective of the current study is to assess the health awareness of adverse drug reactions among patients in Saudi Arabia.

The study uses a qualitative method and is grounded in the examination of reality to assess the health awareness of adverse drug reactions among patients in Saudi Arabia. The qualitative technique involves treating the phenomenon as it actually is, in accordance with its definition, and focuses on precisely characterizing and expressing the phenomenon both qualitatively and statistically.

The findings indicate that while most healthcare professionals were aware of ADRs, they were unable to define the word "pharmacovigilance" appropriately. ADR reporting is more well-known among healthcare professionals, although hospitals do not really use it. The majority of hospitals lack ADR reporting in their systems of follow-up paperwork. The majority of neighborhood pharmacists are not aware that Saudi Arabia has a pharmacovigilance center. Additionally, hospital pharmacists are aware of where to obtain an ADR reporting form, whereas community pharmacists are not. Pharmacists and medical personnel are unaware of the national pharmacovigilance facilities in Saudi Arabia. The severity of the experienced ADRs, accessibility to patients' medical records, attendance at educational programs with continuing medical education credits, and continual advancements in therapeutic knowledge concerning ADRs have all been identified as potential facilitators of ADRs reporting.

Based on the conclusions reached by the study, the study came out with the following recommendations:

- Hospitals and other healthcare facilities could start campaigns to encourage medication safety, pharmacovigilance, and ADR reporting.
- There should be practical instruction and workshops on how to handle ADRs and evaluate the side effects of drugs.
- It should be encouraged for people to attend conferences and seminars about pharmacovigilance and ADR reporting.
- ADR reporting and pharmacovigilance should be included a part of the curriculum for health colleges at universities.
- To apply pharmacovigilance and ADR reporting rules, regulatory agencies and pharmaceutical companies should collaborate more.
- All hospitals should have medication safety officers in charge of all drug safety-related tasks, such as ADR reporting.
- The utilization of technology to involve patients in ADR reporting should be the future objective.
- There should be created an official website where ADRs can be voluntarily reported.

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