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# Knowledge, Attitude, and Practice of Healthcare Professionals at Selected Public Hospitals Regarding Adverse Drug Reaction Reporting and Related Factors

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**Abstract**

**Background:** Adverse drug reactions (ADRs) are a significant public health concern, causing morbidity, prolonged hospitalization, and even death. Despite the critical importance of reporting ADRs for patient safety and pharmacovigilance, healthcare professionals (HCPs) often underreport these events due to insufficient knowledge, lack of proper training, and various logistical barriers. This study aimed to assess the knowledge, attitude, and practice (KAP) of HCPs regarding ADR reporting in selected public hospitals.

**Methods:** A hospital-based cross-sectional study was conducted among healthcare professionals, including nurses, doctors, pharmacists, midwives, and health officers, at two public hospitals . A structured self-administered questionnaire was used to gather data on sociodemographic characteristics, knowledge, attitudes, and practices regarding ADR reporting. Descriptive and inferential statistical analyses, including bivariate and multivariate binary logistic regression, were performed using SPSS version 20.

**Results:** Out of 150 distributed questionnaires, (95%) were completed. The majority of respondents (87.7%) acknowledged that ADR reporting was their professional responsibility, and 76.3% supported making ADR reporting mandatory. However, only 29.8% of participants reported encountering at least one ADR in the past year, with just 50% of those documenting and reporting it. Barriers to ADR reporting included a lack of feedback (58.8%), unavailable reporting forms (46.4%), and uncertainty regarding the ADR's causal relationship with the drug (35.9%).

**Conclusion:** Despite positive attitudes toward ADR reporting, healthcare professionals demonstrated insufficient knowledge and practices related to ADR reporting. Key barriers such as lack of training, feedback, and available reporting forms contribute to underreporting. Addressing these barriers through targeted training, improved reporting systems, and regular feedback is essential for enhancing ADR reporting, ultimately improving patient safety and healthcare quality.

## Introduction

Each day, numerous new drugs are introduced to the market globally, yet the safety of these medications continues to raise concerns due to insufficient awareness. The World Health

Organization (WHO) defines an adverse drug reaction (ADR) as any harmful, unintended, and unwanted effect of a drug when used at therapeutic doses for prevention, diagnosis, or treatment, excluding accidental or intentional overdoses or misadministration (1). ADRs can vary, including dose-related, unpredictable non-dose-related, both dose and time-related, delayed reactions, withdrawal effects, and unexpected outcomes resulting from treatment failure (2,3).

Modern pharmaceuticals have significantly improved the management of various diseases, enhancing treatment outcomes in many conditions. Despite this progress, adverse drug reactions remain a prevalent cause of morbidity, hospitalization, prolonged stays, disabilities, and even death (4). They not only have a profound impact on public health but also diminish patients' quality of life and incur substantial costs within healthcare systems (5,6).

The history of ADR monitoring dates back several decades, notably marked by the thalidomide tragedy, which caused birth defects in thousands of children worldwide (5,7). Pharmacovigilance, the field dedicated to detecting, assessing, understanding, and preventing adverse drug effects or related issues, has since emerged as a critical area of focus (3).

Studies have shown that the reporting of ADRs is influenced by the knowledge and attitudes of healthcare professionals (HCPs). It is crucial for all HCPs to report suspected ADRs to the relevant authorities to enable swift and effective actions to prevent further harm and minimize medicine-related injuries for other patients in the future (2,8).

Reporting all ADRs, from mild to severe reactions, is essential, with particular emphasis on reactions to new drugs, severe ADRs, unexpected effects, and clinically significant drug interactions. Additionally, the uncertainty regarding the cause of an ADR should not deter reporting (2,9).

A major challenge in many regions has been the underreporting of ADRs by healthcare professionals to the appropriate authorities. A review of the literature regarding the knowledge, attitudes, and practices (KAP) of HCPs towards ADR reporting revealed a lack of research in this area. Therefore, conducting this study is critical to identify gaps in the KAP of HCPs concerning ADR reporting and to explore factors contributing to inadequate knowledge.

## Methods

This study employed a hospital-based quantitative cross-sectional design targeting healthcare professionals (HCPs), including nurses, doctors, pharmacists, midwives, and health officers. The study took place in two hospitals: a general hospital and a primary hospital.

The study population consisted of all physicians, pharmacy professionals, nurses, health officers, and midwives employed in the selected hospitals during the study period.

- General knowledge of HCPs about ADR reporting
- General attitude of HCPs towards ADR reporting
- Age, gender, profession, education level, years of experience, prior training on ADR reporting, and type of hospital (primary or general)

A structured self-administered questionnaire was utilized for data collection. The questionnaire was adapted from similar studies and guidelines from the relevant authority (2, 6, 10–14). It included questions on the sociodemographic characteristics of participants, as well as specific questions designed to assess their knowledge, attitudes, and practices regarding ADR reporting. Before the study began, the questionnaire, along with a written consent form, was distributed to participants. Participation was voluntary.

### 2.6. Data Entry, Management, and Statistical Analysis

Data were entered into Epi Info version 3.5.3, cleaned, and transferred to Statistical Package for the Social Sciences (SPSS) version 20 for analysis. Descriptive and inferential statistical tests were performed. Both bivariate and multivariate binary logistic regression were used to examine the relationship between independent variables and the participants' overall

knowledge and attitudes toward ADR reporting. A p-value < 0.05 was considered statistically significant.

For knowledge assessment, HCPs were asked twelve questions. Each correct answer was scored 1, and each incorrect answer was scored 0, yielding a total score ranging from 0 to 12. The overall knowledge level was classified based on the mean score, with scores equal to or above the mean indicating adequate knowledge, and scores below the mean indicating inadequate knowledge. Attitudes were evaluated using a set of thirteen questions rated on a three-point Likert scale (agree, neutral, disagree). A score of 3 was assigned for "agree," 2 for "neutral," and 1 for "disagree." A score of 75% or more on the total 13 questions indicated a favorable attitude, while scores below 75% indicated an unfavorable attitude. The practice of ADR reporting was assessed by whether participants documented and reported ADRs.

**Table 1. Health care providers' knowledge of ADR in selected public hospitals**

| Questions | Category | Percentage |
|---|---|---|
| Know that all drugs in the market are not safe | Yes | 87.72 |
| | No | 12.28 |
| Know ADR is different from overdose toxicities/side effects | Yes | 66.67 |
| | No | 33.33 |
| Know the term pharmacovigilance | Yes | 20.18 |
| | No | 79.82 |
| Write the definition of pharmacovigilance* | Yes | 8.77 |
| | No | 91.23 |
| Know national ADR reporting system | Yes | 21.05 |
| | No | 78.95 |
| Know availability of ADR reporting forms | Yes | 22.81 |
| | No | 77.19 |
| Know how to report | Yes | 20.18 |
| | No | 79.82 |
| Know the responsible body that monitors ADR in Ethiopia | Yes | 30.70 |
| | No | 69.30 |
| Know ADR reporting is a professional obligation | Yes | 48.25 |
| | No | 51.75 |
| The possibility of an ADR should be the first differential diagnosis at all times | Yes | 21.93 |
| | No | 78.07 |
| Who is the responsible professional to report ADR in hospitals? (yes answers are only indicated) | Medical doctors | 73.68 |
| | Health officers | 67.54 |
| | Midwives | 59.65 |
| | Nurses | 65.79 |
| | Pharmacy personnel | 85.96 |
| | All | 58.77 |
| When should ADRs be reported? (yes answers are only indicated) | Serious and life-threatening | 81.58 |
| | Severe and cause disability | 45.61 |
| | Mild and cause less inconvenience | 21.05 |

| | | |
|---|---|---|
| What kinds of ADRs need to be reported? (yes answers are only indicated) | Suspected reactions | 43.86 |
| | Certain reactions | 48.25 |
| | Serious reaction, e.g., SJS | 61.40 |
| | Slight reaction, e.g., nausea | 9.65 |
| | Reaction to all drugs | 27.19 |
| | Reaction to new drugs | 36.84 |
| | Known reactions | 17.54 |
| | Unexpected reactions | 42.98 |
| | Drug interactions | 28.95 |
| | Teratogenic phenomenon | 42.11 |

*For this item, the correct response was considered when the study participant wrote not only the precise definition but also the general concept of pharmacovigilance. Do not know and unrelated responses were considered as incorrect.

**Results**

**Sociodemographic Profile**

A total of 150 healthcare professionals (HCPs) participated in the study, which aimed to evaluate their knowledge, attitudes, and practices (KAP) regarding adverse drug reaction (ADR) reporting. a response rate of 95%. Among the participants, 63.2% were male and 36.8% were female. The average age of the respondents was 27.54 years (±3.88), with the majority (71.05%) falling within the 25-34 age range. In terms of professional roles, most respondents were nurses (43%), followed by physicians (22.8%), pharmacy professionals (14.9%), health officers (10.5%), and midwives (8.8%). A significant proportion (83.3%) had not received training on ADR reporting (Table 2)

Participants' knowledge of ADR reporting was assessed using twelve specific questions. A large majority (87.7%) of respondents recognized that not all drugs on the market are safe, while 66.7% could distinguish ADRs from overdose-related toxicities. However, only 20.2% were familiar with the term "pharmacovigilance" and its purpose. Furthermore, only a small number of respondents knew about the national ADR reporting system or the form used for reporting (21.1% and 22.8%, respectively). Only 30.7% were aware of the body responsible for monitoring ADRs, and just under half (48.2%) recognized ADR reporting as a professional obligation. When asked about the necessity of considering ADRs as a differential diagnosis for patients on medication, 21.9% agreed. Additionally, a majority of respondents (81.6% and 45.6%) believed ADRs should only be reported if they are serious or life-threatening, or if they cause significant disability (Table 1).

Regarding general awareness, over half of the respondents (56.1%) cited the National Drug Formulary and Standard Treatment Guidelines as primary sources of information on ADRs, with 46.5% referencing standard textbooks. When asked where ADRs should be reported, 32.5% mentioned the Ethiopian Food and Drug Authority (EFDA), and 28.1% suggested the Drug and Therapeutic Committee at their respective facilities. Several factors, including prescribing errors (80.7%), dispensing errors (76.5%), patient lifestyle (75.4%), overdose (69.3%), and nonadherence (48.2%), were recognized as contributors to ADRs by the participants

A positive attitude toward ADR reporting was observed, with 87.7% of respondents agreeing that reporting ADRs should be a part of their duties. Additionally, 76.3% supported the idea of making ADR reporting compulsory, and 73.7% believed that a single ADR report could make a significant difference. The majority (94.7%) agreed that ADR reporting is important for public health, and 88.6% felt it enhances the quality of patient care. Furthermore, 77.2% of HCPs believed ADRs should be reported regularly, while 76.3% emphasized the importance of confirming a causal link between the drug and the ADR before reporting. About half (52.6%) of respondents expressed concerns about potential legal issues related to ADR reporting

In terms of practical application, only 29.8% of respondents reported encountering at least one ADR case in the past 12 months. Of these, 70.6% documented the ADR, and 50% went on to report it. Among those who reported ADRs, 47.1% submitted reports to the hospital and pharmacy departments, while 29.4% reported to the EFDA. While 51.8% of participants preferred using the yellow card for ADR reporting, many did not use it regularly due to the form's unavailability. Furthermore, 38.6% of respondents did not regularly advise patients about potential ADRs associated with prescribed medications

In a Likert scale evaluation of reasons for not reporting ADRs, the most frequently cited barriers were lack of feedback (58.8%), unavailability of reporting forms (46.4%), uncertainty about where to report (46.4%), and lack of knowledge on how to complete the report forms (41.2%). Additionally, some respondents noted that they were discouraged by the lack of reporting from colleagues (37.7%) and uncertainty about the causal relationship between the drug and the ADR (35.9%)

To improve ADR reporting, respondents suggested several strategies, including the availability of ADR information sheets in outpatient departments (80.7%), encouraging all healthcare professionals to report ADRs (75.4%), providing training on ADR reporting (72.8%), and promoting patient involvement in reporting (66.7%). They also recommended establishing a drug information center and ensuring easy access to ADR reporting forms (59.6%).

**Table 2. Sociodemographic characteristics of HCPs in selected public hospitals**

| Variables | Category | Percentage |
|---|---|---|
| Age | <25 | 21.93 |
| | 25–34 | 71.05 |
| | ≥35 | 7.02 |
| Sex | Male | 63.16 |
| | Female | 36.84 |
| Profession | Physician | 22.81 |
| | Pharmacy personnel | 14.91 |
| | Nurse | 42.98 |
| | Health officer | 10.53 |
| | Midwifery | 8.77 |
| Level of education | Diploma | 17.54 |
| | BSC degree | 77.19 |
| | MSc/MPH | 5.26 |
| Years of clinical experience | <3 | 49.12 |
| | ≥3 | 51.75 |
| Trained on ADR reporting | Yes | 16.67 |
| | No | 83.33 |

**Discussion**

Adverse drug reactions (ADRs) contribute significantly to morbidity, mortality, and increased healthcare costs, making it essential for healthcare professionals (HCPs) to be vigilant in identifying and managing unexpected or suspected ADRs. Prompt reporting of these events is crucial as part of pharmaceutical care processes (2, 8, 15).

In this study, a relatively small proportion (24.56%) of HCPs demonstrated sufficient knowledge about ADR reporting. This result aligns with findings from similar research, where the percentage of respondents with adequate knowledge ranged from 21.1% to 34.2% in various locations (14, 16, 17, 12). However, the figure in this study is lower than reports from other studies, where 39.4% to 77% of HCPs showed adequate knowledge (18, 19, 6, 10, 20).

Regarding the understanding of ADRs, 66.67% of participants in this study correctly identified ADRs as distinct from overdose toxicities or side effects, which is higher than studies conducted in some regions (10, 14) but lower than others (21). According to the World Health Organization (WHO), side effects refer to minor effects that result from the pharmacological properties of a drug (7, 22). Additionally, only 20.18% of the respondents were familiar with the concept of pharmacovigilance, a figure similar to studies in other regions (16). The awareness of national ADR reporting systems was notably low, with only 22.81% of respondents being aware of their existence, which is lower than findings from several studies (23, 10, 14).

Moreover, while 58.77% of participants acknowledged the collective responsibility of all HCPs in reporting ADRs, this figure was lower than in some other studies (12). The understanding that ADRs should always be considered in differential diagnosis was also limited, with only 21.93% of respondents recognizing the importance of considering ADRs first in such cases. One factor contributing to the inadequate knowledge of HCPs could be the lack of formal training, as only 16.67% of respondents had received ADR training. Therefore, ongoing education and awareness campaigns are critical to improving HCPs' understanding of ADRs and their importance (2).

A significant portion of the respondents (81.58%) believed that ADRs should only be reported when they are severe or life-threatening, contrasting with the views of other healthcare professionals, who consider reporting a wider range of ADRs, including those that are mild to moderate (25, 12). This highlights the need for broader awareness that even non-life-threatening ADRs can be important for monitoring drug safety.

Despite the knowledge gaps, 73.68% of the respondents expressed a positive attitude toward ADR reporting, which is more favorable than results from other studies (6, 14, 18). In line with these findings, 87.7% of the participants agreed that ADR reporting is part of their professional responsibility, consistent with attitudes observed in other studies (14, 10). However, the perception that ADR reporting is time-consuming and creates additional workload was shared by a substantial proportion of respondents (73.7% and 52.6%, respectively). These concerns may diminish the motivation for ADR reporting in clinical practice.

In terms of practical ADR reporting, only 29.82% of HCPs had encountered patients with ADRs in the past year, a finding consistent with similar studies (14, 10, 29, 25). Among those who did report ADRs, 50% claimed they reported the event, but only 29.41% submitted reports to the appropriate regulatory body. This underreporting remains a challenge, and both HCPs and regulatory agencies must collaborate more effectively to ensure comprehensive drug safety monitoring.

The barriers to ADR reporting identified in the study include lack of feedback, unavailability of reporting forms, uncertainty about where or how to report ADRs, and insufficient clinical knowledge. To address these issues, the study participants suggested solutions such as regular training, provision of ADR information sheets, timely availability of reporting forms, and effective communication with regulatory bodies like EFDA. These strategies are consistent

with previous research, which has demonstrated that education and feedback can significantly improve ADR knowledge, attitudes, and reporting practices (30–32).

Finally, factors influencing knowledge about ADR reporting included professional roles. Compared to pharmacy professionals, nurses, health officers, and physicians were significantly less likely to have adequate knowledge, aligning with findings from other studies (10). Conversely, a study from the Philippines reported better knowledge among nurses and physicians than among pharmacy professionals (20).

Although the study was limited by a small sample size and the exclusion of some HCPs, its findings provide valuable insights into the current state of ADR knowledge and reporting practices. These results highlight the importance of addressing the knowledge gaps through targeted interventions, thereby improving ADR reporting and ultimately enhancing patient care.

In conclusion, the study revealed that HCPs had insufficient knowledge of ADR reporting, which contributed to underreporting. Although most HCPs had a positive attitude toward ADR reporting, practical barriers such as time constraints and workload must be addressed. Enhanced education, timely feedback, and improved reporting systems are essential to fostering a culture of ADR reporting, which is crucial for patient safety and quality healthcare.

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