

# Adverse Drug Reactions and Medication Errors: A Quantitative Insight in Aden, Yemen

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## ABSTRACT

**Objectives:** The study aimed to detect and assess common prescribing and dispensing Medication Errors (MEs); frequency of Adverse Drug Reactions (ADRs); the drugs causing frequent ADRs; and the typical types of ADRs. **Methods:** A cross sectional study was applied at three hospitals in Aden city. ADRs were verified through Micromedex, Martindale and British National Formulary. All patients admitted in different wards with informed consent were included in the study. Critical patients and children under five years of age were excluded. Data for MEs were evaluated to determine the types, frequency and other responsible factors. ADRs reporting form consisted of information relating to a patient with an Adverse Event (AE) suspected to be induced by a medicine, also information about the patient, AE, suspected medicines or other medicine use including self-medication, severity of the AE and name, address and telephone number of the reporter. **Results:** The MEs are estimated in 265 prescriptions, while a total of 225 ADRs were reported. The most common of prescribing error was inappropriate use of decimal point (n=252, 95.1%). The most common of dispensing error was inaccurate directions for the use of medication

(n=253, 95.5%). AEs most commonly happened with oral medications (n=166, 73.7%), highly related to gastrointestinal system (n=72, 32%) and most commonly caused skin rash and allergic reactions (n=32, 14.2%). Antihypertensive (71.0%) and ceftriaxone (8.8%) accounted for the majority of the ADRs. **Conclusion:** Many of the MEs were preventable with pharmacist's intervention. Pharmacovigilance activities and policy need to be strengthened to protect public from harmful effects of medicines.

**Key words:** Adverse drug event, Drug-related problem, Pharmacovigilance, Resource poor setting, Pharmacy intervention.

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## INTRODUCTION

Pharmacovigilance has not received considerable attention in some developing countries due to a lack of resources and technical expertise. Pharmacovigilance is defined by the World Health Organization (WHO) as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems".<sup>1</sup> Pharmacovigilance is an aspect of patient care that seeks to make the best use of drugs and medications for the treatment or prevention of disease without undesired effects. International pharmacovigilance was begun forty years ago to establish an international system of monitoring adverse drug reactions (ADRs), which was a resolution of twentieth WHO assembly.

Medication errors and adverse drug reactions (ADRs) are of major concern because they result in significant morbidity, mortality and health care costs. ADRs represent unwanted, uncomfortable, or dangerous effects from a drug.<sup>2</sup> A commonly quoted meta-analysis performed in the United States indicated that ADRs were between the fourth and sixth most common cause of death in 1997.<sup>3</sup> Over 770,000 patients have been injured or died every year due to adverse drug events,<sup>4</sup> and 3.2-7% of acute hospital admissions are solely due to ADRs.<sup>5,6</sup> Furthermore, ADRs increase morbidity, mortality and the duration of hospital stays, culminating in unwarranted hospital costs.<sup>7,8</sup>

The incidence of ADRs has been reported in many studies. An observational prospective study from Iran identified that 11.75% of patients

had experienced at least one ADR.<sup>9</sup> Another study done in Iran reported that approximately 16.8% of patients had at least one ADR and 2.9% of ADRs were identified as lethal.<sup>10</sup> A study in South India found that the overall incidence of ADRs was 9.8%. This included 3.4% of ADR-related hospital admissions and 3.7% of ADRs that occurred during the hospital stay.<sup>11</sup> In Saudi Arabia, a retrospective study showed 54% of ADRs to be preventable. The prevalence per year ranged from 0.07% in 1993 to 0.003% in 1999.<sup>12</sup> In Nepal, the prevalence of ADRs was 0.86%. In addition, the male-to-female ratio of patients experiencing ADRs was 0.85 and 10.81% of the ADRs were severe.<sup>13</sup>

Safeguards against medication errors are a relevant way to control ADRs. A medication error is defined as "any preventable event that may cause or lead to inappropriate medication use or patient harm during medication to patient and is in the control of the health care professional, patient and consumer".<sup>14</sup>

Medication errors may occur at any stage of the medication-use system, including preparation, prescription transcription, dispensation, storage, administration of drugs and patient and compliance; however, the most common errors take place during prescribing and administration.<sup>15</sup>

According to the American Society of Health-System Pharmacists (ASHP) in 2014, medication errors may include "prescribing errors, omission errors, wrong time errors, unauthorized drug errors, wrong

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dosage form errors, improper dose error, wrong drug preparation errors, wrong administration or technique errors, monitoring errors, deteriorated drug errors, compliance errors". Errors arise when an action is intended but not performed; errors that arise from poor planning or inadequate knowledge are characterized as mistakes; those that arise from imperfect execution of well-formulated plans are called slips when an erroneous act is committed and are called lapses when a correct act is omitted.<sup>16</sup>

The role of the pharmacist is to provide optimal pharmaceutical care for individual patients and optimal pharmaceutical care is attained when the right drug in the correct dosage and quality reaches the right patients at the right point in time with the right information.<sup>17</sup> In a country at war such as Yemen, relatively less is known about the extent of medication errors and ADRs and in many health systems, it is not routine to detect them. Pharmacists must be more vigilant, especially in a situation of limited resources during the war.

This study is considered crucial in the present state and it was conducted to estimate the epidemiology of ADRs and medication errors in three hospitals in Aden, Yemen. During the civil conflict, the port city of Aden in the coastal area of Yemen was destroyed. Not only was the political stability affected, but the economic aspects, social services and health-care system were disrupted, too. The city ran short of food, water and medical supplies. Such a study in Yemen has not yet been considered; thus, it is beneficial. Specifically, the objectives are as follows:

1. To detect common prescribing and dispensing medication errors.
2. To detect the frequency of adverse drug reactions reporting by healthcare providers (HCP) to the Yemeni Pharmacovigilance Center (YPC) in Aden city.
3. To identify the drugs causing frequent adverse drug reactions.
4. To identify the typical types of adverse drug reactions.

## METHODOLOGY

### Study Design and Site

To achieve the objective of this research, a cross-sectional prospective study design was used at two different phases of the study. The various ADRs and medication errors reported by HCPs were estimated and analyzed by YPC forms. The study was conducted at Al-Gamhouria Teaching-based Hospital, Alsadaqa Hospital and 22-May-Hospital in Aden city for a period of two months from May to June 2017. Prior permission was obtained from the Ethics Research Committee of the Faculty of Medicine and Health Sciences, Aden University to carry out the study. Informed consent was obtained from all individual participants included in the study.

### Ethical Consideration

The Ethics Research Committee of the Faculty of Medicine and Health Sciences, Aden University, had provided ethical clearance for this study. Written informed consent was obtained from all participants who were willing to take part in the study after the objectives, importance and benefits of the research were described to them.

### Study Tools

Two tools were used in this study.

- A. Medication errors data collection form:** A suitably designed questionnaire was used to analyze the types, frequency and factors responsible for medication administration errors. Data were collected from the case reports, treatment charts and medication administration records and by interviewing the in-patients ad-

mitted to various wards. Demographic details of the patients and their diagnosis and treatment recommendations were documented. The causes of error due to prescribing and dispensing and the patient's demographic details such as the patient's name, age, sex, address and patient identification number, occupation, allergic history and social habits were recorded. The prescriber's information included name, date, signature, superscription and registration number. The information related to the drugs included name of the drug, strength, drug type (brand/generic), dosage form, quantity, dose, frequency, route of administration and direction for administration.

- B. Adverse drug reaction reporting form:** The ADR reporting form is a YPC form of the YPC International College used by health-care professionals. It consists of information related to a patient with an adverse event suspected of being induced by a medication; the form also includes information about the patient, adverse event, suspected medicines or other medicine use including self-medication, severity of the adverse event and the name, address and telephone number of the reporter.

## Data Collection Method

### PHASE 1

All the collected data concerning medication errors were collected, analyzed and evaluated to determine the types, frequency and other responsible factors. Analysis parameters were date of prescription, age, weight, sex and address of the patient; superscription, name, registration number and signature of the prescriber; and dosage form, quantity, frequency and route of administration (May to August 2017).

### PHASE 2

A data collection tool for ADRs was designed and reviewed. The face and content validation were done by healthcare experts. All ADR forms were submitted to the YPC unit for further approval. Relevant data were extracted using the data collection tool. ADRs were verified through Micromedex, Martindale and the British National Formulary (September 2017) to establish whether the reported adverse reactions were known and documented in the compendia or not.

### Participants

**Inclusion criteria:** All patients admitted in the different wards of the three participating hospitals were included in the study.

**Exclusion criteria:** Patients treated on an outpatient basis, patients in critical condition requiring a critical care stay and children under the age of five years were excluded from the study.

### Statistical Analysis

SPSS (Statistical Package for the Social Sciences) version 19 was the statistical software used to examine, analyze and evaluate data obtained from study tools. Descriptive statistics were applied to calculate frequency and percentage.

## RESULTS

### Phase 1: Detection of Prescribing and Dispensing Medication Errors

The medication errors were estimated in a total of 265 prescriptions. The results of the study revealed that in all the prescriptions evaluated during this study period, minor and serious medication errors were found.

In the study, the number of the male patients was 187 (70.6%) and the number of females was 77 (29.1%). A higher incidence of 174 (65.7%)

**Table 1: Medication errors due to prescribing (n=265).**

S.No.	Parameters	Yes (%)	No (%)
1	Direction mention	38 (14.3)	227 (85.7)
2	Strength mention	56 (21.1)	209 (78.9)
3	Signature mentioned	Nil	265 (100)
4	Reaction with allergy but without allergic speciation	21 (7.9)	244 (92.1)
5	Prescribed two drug at the same time	52 (19.6)	213 (92.1)
6	Poor hand writing	106 (40)	159 (60)
7	Date absent	57 (21.5)	208 (78.5)
8	Wrong indication	27 (10.2)	238 (89.8)
9	Weight mention	Nil	265 (100)
10	Direction not complete / not legible	4 (1.5)	261 (98.5)
11	Use of abbreviation	30 (11.3)	235 (88.7)
12	Inappropriate use of decimal	252 (95.1)	13 (4.9)
13	Age /Name/Weight	92 (34.7)	173 (65.3)
14	Complete instructions to the patients	17 (6.4)	248 (93.6)
15	Wrong route of administration	15 (5.7)	250 (94.3)
16	Prescribing a drug without informing patients its use and side effect	48 (18.1)	217 (81.9)

Note: The total percentage is not equal to 100% due to missing value.

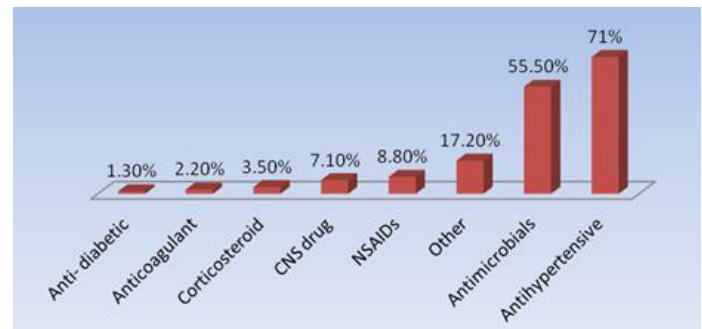
**Table 2: Causes of errors due to dispensing.**

S. No.	Parameters	Yes (%)	No (%)
1	Dispensing the wrong drug	12 (4.5)	253 (95.5)
2	Dispensing the wrong dose	7 (2.6)	258 (97.4)
3	Inaccurate directions for the use of medication	253 (95.5)	12 (4.5)
4	Failure to educate patient regarding the use of medication	251 (94.7)	14 (5.3)
5	Dispensing an expired medication	3 (1.1)	263 (98.9)
6	Failure to assess, review the patient medication profile	245 (92.5)	20 (7.5%)
7	Dispensing without knowing patient allergic history	86 (32.5)	179 (67.5)
8	Dispensing without knowing patient conditions, and medical history (such as why the drug is prescribed)	8 (3)	257 (97)
9	Have a current drug reference available	84 (31.7)	181 (68.3)
10	More than one month supply given	15 (5.7)	250 (94.3)
11	Substitution/Dispensing product not available	10 (3.8)	255 (96.7)
12	Short supply of medicine	33 (12.5)	232 (87.5)
13	Staff knowledge about medication	13 (4.9)	252 (95.1)
14	Incorrect Label	6 (2.3)	259 (97.7)
15	Short/Expired drug dispensed	15 (5.7)	250 (94.3)
16	Wrong concentration dispensed	7 (2.6)	258 (97.4)

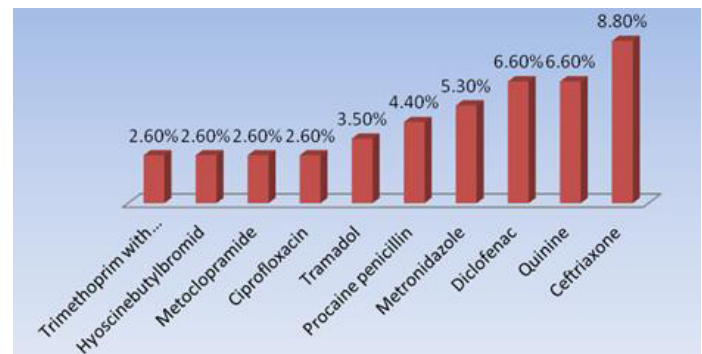
Note: The total percentage is not equal to 100% due to missing value.

**Table 3: Adverse drug reaction and organ system involved.**

Organ system involved	N. of ADRs
Gastrointestinal disorder	72 (32%)
Skin mucous membrane	38 (16.8%)
Respiratory disorder	10 (4.4%)
CNS and neurological disorder	16 (7.1%)
Cardiac disorder	20 (8.9%)
Urinary and Reproductive disorder	12 (5.3%)
Hepato-billiary disorder	6 (2.7%)
Other	51 (22.7%)
Total	225



**Figure 1:** Pharmacological classes of drug implicated to cause adverse drug reaction.



**Figure 2:** Drug name and No. of ADRs report.

medication errors was found in patients aged less than 35 years, while in patients aged 35 years or more, there were 91 medication errors found (34.3%).

On evaluating the prescribing errors from the collected data on the approved data sheet, it was found that complete instructions to the patients regarding the use and side effects of the drugs were not mentioned in most of the prescriptions (n=248 (95%)). The highest number of prescribing errors regarded the absence of the weight of the patients (100%) and the registration number of the prescribers (100%). This indicated that while prescribing drugs, the weight of the patient was not considered; the lack of a registration number indicated ambiguity regarding the registered prescriber for prescribing the drugs. Other prescribing errors were inappropriate use of decimals (n=252 (95.1%)), which might lead to severe health hazards. Errors concerning the allergic specification on

the prescriptions were found in 21 instances (7.9%), which may result in a severe hypersensitivity reaction in the patients if they are allergic to a particular drug. Following this were errors in the use of abbreviations in all the prescriptions studied; this often results in an incorrect interpretation of an abbreviation by the pharmacists or nurses. Abbreviations or acronyms can stand for more than one word and therefore can be misinterpreted. Illegible handwriting in 106 (40%) cases was found to be another important reason for the occurrence of medication errors that may lead to dispensing the wrong drug to wrong patient (Table 1).

Among various serious errors related to dispensing, the maximum number of errors concerned inaccurate directions ( $n=253$  (95.5%)) for the use of a medication and failure to educate patients ( $n=251$  (94.7%)) regarding the use of a medication (Table 2).

## Phase 2: Analysis of the ADRs Reported by the Healthcare Professionals

The healthcare professionals reported the ADRs by filling the ADR reporting form. The various ADRs reported by the healthcare professionals and patients were analyzed.

The healthcare professionals reported a total of 225 ADRs. The total number of adverse drug reaction reports over the audit period was 225. ADRs caused by oral route of administration were the highest, occurring in 166 (73.7%) patients, while ADRs caused by oral route of administration only occurring in 2 (0.9%) patients out of 225 patients

More than half of the ADRs reported occurred in male patients (57%) and nearly half (44.24%) of the patients were in the age group of 21-40 years. Among the organ systems affected, gastrointestinal ADRs constituted a major component followed by skin reactions, as mentioned in Table 3.

There was a spectrum of ADRs reported among the 225 patients. The highest proportion involved skin rashes and allergic reactions and the second highest was nausea and vomiting; other common ADRs were also reported from various drugs used, including gastritis and gastric pain, diarrhea, hypotension and renal impairment, etc.

The largest number of reports were associated with antihypertensive drugs. Most of the drug categories suspected to cause ADRs were related to antihypertensive drugs, antibiotics and antibacterial drugs NSAIDs, etc. The anti-diabetic, anticoagulant, corticosteroid and CNS medications also have roles in ADRs. The drugs other than those in these studied categories play a substantial role in producing ADRs, as mentioned in Figure 1.

Results for the specific drugs related to ADRs showed that ceftriaxone (8.8%) made the highest contribution to ADRs, followed by quinine (6.6%) and diclofenac (6.6%). Generic drugs such as trimethoprim-sulfamethoxazole combination, hyoscinebutylbromide, metoclopramide and ciprofloxacin were found to produce the fewest ADRs (2.6%) as following Figure 2.

## DISCUSSION

Pharmacovigilance plays an indispensable role in inhibiting and overcoming ADR-related problems. Nevertheless, ADR-related monitoring and pharmacovigilance activities are still very minimal in a country such as Yemen, where instances undermining patient drug safety are rampant, as strongly shown in this study. This is a pioneer study in Yemen that evaluates ADR events reported by HCPs. Our objectives were to evaluate data on the issues of pharmacovigilance and ADRs, reporting that can further support the pharmacovigilance system in better ADR reporting and, henceforth, enhance health outcomes as well.

A thorough review of 265 prescriptions indicated serious prescription errors in providing the prescriber signature and the patient's weight

measurement; other significant errors were inappropriate use of decimal points, poor hand writing, as well as inconsistencies in writing the age/name of the patient. These prescription errors may result in relevant health hazards to the patient in various manners.

Pharmacist-augmented errors in dispensing further accentuate the contribution to poor outcomes of therapy or the creation of health hazards. Inaccurate directions for use of the medication, failure to educate patients regarding the use of medication, failure to assess and review the patient medication profile, dispensing without knowing the patient's history of allergies and dispensing without having a current drug reference available are major contributory factors. The dispensing errors estimated in this study need to be addressed as soon as possible without any further delay. Benkirane *et al.* reported that preventable ADEs occurred in the prescribing (71.1%), administration (21.2%), transcription (5.7%) and dispensing stages.<sup>18</sup> According to Gandhi *et al.* computerized monitoring represents an efficacious approach for identifying ADEs.<sup>19</sup>

The ADRs reported by the healthcare professionals are also found to be lacking. Out of 225 ADRs, most of them were related to oral administration of medications and caused gastrointestinal disorders. These major ADRs in patients result in suspicions about the rationality of the medication used. A study conducted in an ICU by Benkirane *et al.* in 2009 indicated that out of 696 patients studied, approximately 70% of the AEs were considered ADRs.<sup>18</sup> They also mentioned that 53.8% led to potential ADEs and 46.2% led to actual preventable ADEs.

On evaluating the errors by drug class, antihypertensive drugs were found to be the largest contributor of ADRs followed by antibiotics and antibacterial drugs and NSAIDs. This is a serious concern for drug regulatory authorities to address regarding the control of ADRs. On evaluating the ADRs involving generic-name drugs, the study also found that ceftriaxone was the main drug producing ADRs, followed by quinine and diclofenac. Sakuma *et al.* reported that antibiotics were the most frequent cause of ADEs in patients younger than 65 years old.<sup>20</sup> They also mentioned that antihypertensives were most often associated with fatal or life-threatening ADEs (25%) in younger patients. As we have already estimated that the greatest number of ADRs involved gastrointestinal disorders, the contribution of diclofenac to ADRs is verified. Antibiotics are the most common class of drugs causing ADRs. The irrational use of antibiotics/antibacterials has already been demonstrated by researchers in Yemen.<sup>21</sup> Moreover, in Yemen, community pharmacists dispense antimicrobials without a prescription. Studies from the hospital settings in Yemen have already raised concerns regarding irrational antimicrobial use. Additionally, it is a common problem in both the hospital and community setting that analgesics and NSAIDs are the second most common class of drugs implicated for causing ADRs. NSAID drugs have caused several ADRs, including gastric problems. Many times, they are used OTC by the public. The pharmacist can play an important role in minimizing these ADRs by providing simple information to patients regarding the precautions to be followed while taking these medicines, such as taking them accordingly either before or after food and drinking additional water with the medicine.

A majority of the ADRs were associated with oral administration of medications, followed by the parenteral route. Most of the ADRs with injectable medications were severe. Gastrointestinal-related ADRs were most commonly observed with oral medications. In our study, we found gastrointestinal side effects (e.g., gastritis, dysphagia, etc.) at the top of the list of ADRs followed by skin and subcutaneous disorders. Next, the main groups of side effects noted were related to metabolic, nutritional, CNS and neurological disorders. Neurological ADRs were at the top of the list of ADRs in previous studies and gastrointestinal ADRs were reported among the top three groups of ADRs.<sup>22,23</sup>

The incidence of adverse drug events is directly proportional to the number of drugs being taken and increases remarkably as the number of drugs rises. Many epidemiological studies of risk factors for adverse drug reactions have shown that the number of concurrently used drugs is the most important predictor of these complications.<sup>22-24</sup> Polypharmacy needs to be discouraged, as a good number of ADRs result from drug-drug interactions.<sup>25</sup> This can be a risk factor in the development of undesirable adverse drug events.

Medication errors can occur anywhere in the healthcare system, from prescriber to dispenser to administrator and finally to patient use. Thus, the reporting and prevention of medication errors has become an important consideration; the therapeutic outcomes of drug therapy increase with the reduction in the incidence of medication error, which will ultimately improve the quality of the patient's life.

The major controversy arising from this study is pointing toward the role of both parties, patient and physician; usually, the patients are unaware of the ADRs. In our hospital and in other health care facilities, documentation of ADRs is unintentionally missed. This could be because of technical issues, a shortage of staff or a lack of proper sensitization; many times, the mortality and morbidity associated with the ADR are taken as an outcome of disease processes itself.

Medication errors may be caused by the high number of prescriptions and the limited number of pharmacists. Providing incomplete or simply no drug information to the patient can cause discrepancies between the doctor's prescription and what the patient takes in actual practice. The impact of medication misuse because of these discrepancies can lead to morbidity and mortality. To avoid such medication misuse, pharmacists should provide information and education to the patients until they understand the role of medications in their health.

Our study has its own limitations. Underreporting, a well-known limitation of spontaneous reporting programs, needs to be taken into consideration while interpreting the data. Since the study data were obtained from only three hospitals, the results may not be generalizable to the entire population. However, our study data should give insight into the pattern of ADRs that occur in tertiary care hospitals with a comparable pattern of patient demographics and drug usage. In addition, another of our study limitations was the relatively small number of respondents. The target group was chosen conveniently rather than with random sampling. The study findings could not be applied to the whole country because this study was done among the HCP only working in Aden city. It is also worth noting that some of the HCP were not cooperative.

It is worth providing some recommendations to improve the pharmacovigilance activities in countries with poor resources:

1. A course in pharmacovigilance should be incorporated in the pharmacy and medicine curriculum, creating a culture of safety among students in the health care professions.
2. Pharmacovigilance workshops and seminars should be conducted to provide guidance to healthcare providers for recognizing and reporting ADRs. Additionally, pharmacovigilance studies should be supported.
3. ADR reporting by healthcare professionals and manufacturing companies as well as by patients and the public should be encouraged.
4. Incentives should be provided to healthcare professionals reporting ADRs not associated with human errors.
5. ADR forms should be collected periodically from health facilities by sending representatives and/or be facilitated by E-mail, fax and phone.
6. There should be assurance of non-involvement in legal matters, if they arise.

## CONCLUSION

In summary, the study has assessed the common prescribing and dispensing Medication Errors (MEs), frequency of Adverse Drug Reactions (ADRs), the drugs causing frequent ADRs and the typical types of ADRs. It has provided baseline information about the prevalence of ADRs and their distribution regarding different age groups, sexes, affected organ systems and therapeutic classes of medicines. This study calls for the institution of a 'pharmacovigilance program' and the establishment of pharmacovigilance centers in association with regulatory bodies such as SBDMA (Supreme Board for Drugs and Medical Appliances). The data presented here will be useful in the development of future, long-term and more extensive ADR monitoring programs in the hospitals and will be useful in framing policies regarding the rational use of drugs.

## Limitation

Our study has its own limitations. Underreporting, a well-known limitation of spontaneous reporting program needs to be taken into consideration while interpreting the data. Since the study data were obtained from only three hospitals, the results may not be generalizable to the entire population. But, our study data would give an insight into the pattern of ADRs which do occur in tertiary care hospitals with a comparable pattern of patient demographics and drug usage. The main limitation of our study was the relatively small number of respondents. The target group was chosen conveniently rather than random sampling. Another major limitation of our study is that the findings could not be applied to the whole country because this study was done on the HCP working in Aden city only. It is also worth noting that, some of the HCP was not cooperative.

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## CONFLICT OF INTEREST

The authors declare no conflict of interest.

## ABBREVIATIONS

**HCP:** Healthcare providers; **YPC:** Yemeni Pharmacovigilance Center; **ADRs:** Adverse Drug Reactions; **MI:** Medication Errors; **CNS:** Central nervous system; **NSAIDs:** Non-steroidal anti-inflammatory drugs.

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