

**KNOWLEDGE AND PERCEPTION ABOUT PHARMACOVIGILANCE AMONG 4<sup>TH</sup>  
AND 5<sup>TH</sup> LEVELS PHARMACY STUDENTS IN SOME PUBLIC AND PRIVATE  
UNIVERSITIES, SANA'A YEMEN**Maged Alwan Noman<sup>1</sup>, Mahmoud Mahyoob Alburyhi\*<sup>1</sup> and Abdalwali Ahmed Saif<sup>1</sup><sup>1</sup>Professor Dr of Pharmaceutics and Industrial Pharmacy, Department Pharmaceutics and Industrial Pharmacy, Faculty of Pharmacy, Sana'a University, Sana'a, Yemen.**\*Corresponding Author: Mahmoud Mahyoob Alburyhi**

Professor Dr of Pharmaceutics and Industrial Pharmacy, Department Pharmaceutics and Industrial Pharmacy, Faculty of Pharmacy, Sana'a University, Sana'a, Yemen.

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**ABSTRACT**

Pharmacovigilance is the “science and activities relating to the detection, assessment, understanding and prevention of adverse effects. The Pharmacists in community or hospital setting play a key role in reporting Adverse Drug Reaction (ADRs) during practice. To determine the level of knowledge and perception about pharmacovigilance and ADRs reporting among 4<sup>th</sup> and 5<sup>th</sup> level Pharmacy students in six Public and Private Universities at Sana'a City, Yemen. The study was carried out in two Public and four Private Universities, selected randomly. The questionnaire contained, student demographic data, knowledge, perception about Pharmacovigilance and ADRs. The data were analyzed using SPSS program. The demographic details, included in the study 320 that only 300 were response sheets from study, regarding awareness of knowing the meaning Pharmacovigilance, which was correctly answers by 67 answers, which is in percentage (22.3%) of Pharmacy students. When asked the Pharmacy students if they have written reports for the adverse drug reactions yet: the correct answers were 29 answers which is in percentage (9.7%) and when asked if subjects studying in the third level, the correct answers were 240 answers which is in percentage (80.0%) of Pharmacy students. Poor knowledge among Pharmacy students in in the selected Universities towards Pharmacovigilance and ADRs reporting. This survey strongly suggests that educational programs are needed to increase awareness among Pharmacy student's role and their knowledge about ADRs.

**KEYWORDS:** Pharmacovigilance, Adverse drug reactions, Reporting.**INTRODUCTION**

Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problem.<sup>[1]</sup>

The thalidomide tragedy in the mid twentieth century triggered a chain of activities that were part of a global effort to avert a recurrence. Australia, Canada, several European countries, New Zealand and the United States of America established monitoring schemes based on reporting of suspected adverse drug reactions (ADRs).<sup>[2]</sup>

Adverse drug reactions are defined as a ‘one which is noxious and unintended and which occurs in doses normally used in human for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological functions.<sup>[3]</sup>

Detection of ADRs is a challenging issue. Animal toxicological studies and pre-clinical trials done in

humans before the drug is marketed cannot reflect all the drug related hazards. Previously unidentified ADRs can occur when the drugs are used in the general population.<sup>[4]</sup>

Where fourth leading cause of death and treatment related morbidity is considered to be ADRs.<sup>[5]</sup>

So adverse drug reactions (ADRs) remain one of the most prime reasons of morbidity and mortality worldwide.<sup>[6]</sup>

Doctors, nurses, Pharmacists and pharmacologists play an important role in the identification of such unseen ADRs.<sup>[7]</sup>

In the past few decades, there has been an exponential growth in the global human population. Improved patient care and better medicines to treat diseases have played a pivotal role in extending human lifespan and reducing

morbidity. However, medicines could also be potentially hazardous.

The most used ADR reporting system worldwide is spontaneous and voluntary reporting. However, significant underreporting of ADRs by healthcare professionals has been identified as a serious drawback of the voluntary reporting system and is prevalent in various countries.<sup>[8]</sup>

There was an increased public awareness pertaining to drug associated ADRs after the USA senates passed a bill which aimed at supplying the ADRs information to common public.<sup>[9]</sup>

Therefore, medical practitioners have been advised by several policy makers and highly publicized reports to dedicate more effort to eliminate the ADRs problem.<sup>[10]</sup>

Drug use is generally associated with injury that may range from mild to fatal ADRs. Many studies were conducted to determine the incidence of ADR responsible for patient admission, about 5% to 20% of admissions were related to such reaction.<sup>[11]</sup>

ADRs are considered one of the major causes of patient related morbidity and mortality, ADRs require special consideration; and they involve academic scientists, Pharmaceutical industries, patients, medical professionals, and drug regulatory agencies.<sup>[12]</sup>

In Yemen health services particularly, hospitals and private health facilities are concentrated in major cities. Primary health units and centers as well as polyclinics are scattered throughout the country. The local Pharmaceutical Industry is growing at a slow rate and most of the country's needs are catered to by imports.<sup>[13]</sup>

In Europe and the United States there is now over two decades of experience regarding consumer ADR reporting. A study done to investigate the relative contribution of patient reporting to signal detection in the UK showed that patient reporting may provide a positive complementary contribution to the reports received from health care practitioners (HCPs).<sup>[14]</sup>

The Ministry of Health and Population, Department of Drug Administration (DDA) was established in Nepal as per the Drug Act 1978. It is responsible for the manufacture, import/export, sales, distribution, and storage of drugs in Nepal.<sup>[15]</sup>

In India there is a strong belief that underreporting of ADRs is because of multiple reasons. Pharmacovigilance program was launched in India to enhance the voluntary reporting.<sup>[16]</sup>

In Malaysia, spontaneous, voluntary ADR reporting is the most used method, and the program is monitored by the National Adverse Drug Monitoring Center.<sup>[17]</sup>

## MATERIALS AND METHODS

### Research Methodology

#### Study Design

Exciting descriptive cross-sectional study was conducted to assess Pharmacy students' knowledge and perception about Pharmacovigilance and adverse drug reaction who were in fourth & fifth Pharmacy level at Sana'a City.

#### Study Setting

This study was conducted Pharmacovigilance among level 4<sup>th</sup> and 5<sup>th</sup> Pharmacy students of some universities in Sana'a city, Yemen. The following Universities were selected, include, Sana'a University, September 21 University, Azal University, AL -Nasser University, AL-Razi University and Yemen Jordanian University.

**Table 1: Demographic Details of Respondent's Dents N=300.**

Demographics	F (300)	Percentage (%)	
Gender	Male	210	70.0
	Female	90	30.0
Age (Years)	<23	103	34.3
	≥23	197	65.7
University	Public	100	33.3
	Private	200	66.7

#### Study Population

The study population consisted of 300 students' all the level fourth and fifth Pharmacy students at Six Universities of Sana'a. Two are public and the others are private's universities. This study was done in the two public university and four private universities that were selected randomly by simple random sampling. The students were recruited according to the proportions of students in each university. Students not willing to participate in the study were excluded from the study.

#### Sample Size Determination

Sample size was calculated by using the equation of one proportion formula; {with P: proportion of Internet addiction from previous study in Malaysia.<sup>[17]</sup> Sample size was calculated as 300 students.

The Pharmacovigilance among level fourth and fifth pharmacy students in six universities of Sana'a Yemen. The sample size were 300 students.

The sample size according to gender (male = 70.0%, female = 30.0%), age in years (<23 = 34.3%, ≥ 23 = 65.7%) and university (Public = 33.3%, Private = 66.7%) As shown in **table (1)**.

#### Study Duration

This study was carried out between August 2022 to September 2022.

**Materials****Inclusion Criteria**

Pharmacy students who agreed to participate in this study they are 300 students.

**Data Collection Tools**

The data was collected using a validated self-administered questionnaire. The questionnaire was designed after a detailed review of relevant literatures.<sup>[18]</sup>

The questionnaire was written in English and Arabic and used to assess final years Pharmacy students' knowledge and perceptions about Pharmacovigilance and ADRs reporting.

The questionnaire comprised of 14 questions and divided into three portions; The first portion concerned with students' demographic data. The 8 questions of second portion were related to the Pharmacy students' knowledge and attitude of Pharmacovigilance and ADR

reporting. The answer to each question consisted of yes and no answers.

**Data Processing and Statistical**

Data analyses were carried using the statistical package for the social sciences (SPSS) version 23.0 (SPSS Inc., Chicago, IL, USA). Descriptive statistics such as percentages and frequencies for categorical data and means for numerical data also determined.

**Limitation**

Limitations of the study are the number of students who participated in this study was relatively small considering the number of students currently enrolled in various universities in Yemen. Additionally, this study was conducted in universities located in Sana'a city only. Knowledge and perception may vary based on the other localities. Hence, this study may not generalize the perception for all Pharmacy students in Yemen.

**RESULTS AND DISCUSSION****Table 2: Knowledge Among Medical Interns About ADR Reporting and Pharmacovigilance.**

Q No.	Questions were asked for assessing knowledge	Correct Response N (%)		Incorrect Response N (%)		Total	
		N	(%)	N	(%)	N	(%)
1.	Do you know the meaning of the Pharmacovigilance?	67	22.3	223	77.7	300	100.0
2.	Have you heard of the Pharmacovigilance?	65	21.7	235	78.3	300	100.0
3.	Have you studied pharmacovigilance?	10	3.3	290	96.7	300	100.0
4.	Are the topics of Pharmacovigilance fully covered?	16	5.3	284	94.7	300	100.0
5.	Do you know the meaning of the adverse drug reactions?	182	60.7	118	39.3	300	100.0
6.	Do you know the difference between adverse drug reactions and side effects?	170	56.7	130	43.3	300	100.0

**Table 3: Attitude Among Medical Interns About ADR Reporting and Pharmacovigilance.**

Q No.	Questions were asked for assessing attitude	Correct Response N (%)		Incorrect Response N (%)		Total	
		N	(%)	N	(%)	N	(%)
7.	Have you heard about reports adverse drug reactions?	88	29.3	212	70.7	300	100.0
8.	Have you seen reports of adverse drug reactions?	47	15.7	253	84.3	300	100.0
9.	Can you write adverse drug reactions reports?	58	19.3	242	80.7	300	100.0
10.	Have you written an adverse drug reaction report yet?	29	9.7	271	90.3	300	100.0
11.	Do you know where to reports of adverse drug reactions?	33	11.0	267	89.0	300	100.0
12.	Have you heard about the Pharmacovigilance center in Yemen?	40	13.3	260	86.7	300	100.0
13.	Do you think Pharmacovigilance will improve the morbidity and mortality of patients in clinical practices?	226	75.3	74	24.7	300	100.0
14.	Should you study the practice of side effects from among the subjects in the third level?	240	80.0	60	20.0	300	100.0

The demographic details of the Pharmacists student included in the study were 320 where 300 is response sheets from study of level fourth and fifth pharmacy students of the 6 Universities in Sana'a were analyzed after removing incomplete respondents and those who did not return the response sheets even after multiple reminders are shown in table (1).

All the answers are mentioned in terms of numbers, percentages for questionnaire. In this study number of male participants 210 (70.0%) and females 90 (30.0%).

In this study, 100 (33.3%), of the Pharmacy students of public universities, while 200 (66.7%) of private universities.

In this study a number of age < 23 years 103 (34.3%) and age  $\geq$  23 years 197 (65.7%) of the Pharmacy students.

### **Knowledge**

#### **As shown in table (2)**

Question 1 was regarding awareness of knowing the meaning pharmacovigilance which was correctly answers were 67 answers (22.3%) of pharmacy students.

Question 2 regarding the hearing of the Pharmacovigilance which was correctly answers by 65 answers (21.7%) of pharmacy students.

Question 3 about the studying of Pharmacovigilance as a subject; only 10 answers as (3.3%) of pharmacy students.

Question 4 about the awareness of Pharmacovigilance topics as fully covered were 16 answers as (5.3%) of Pharmacy students.

Question 5 was about the meaning of adverse drug reactions; the answers were correctly 182 answers, (60.7%) of Pharmacy students.

Question 6 was about awareness of knowing the difference between adverse drug reactions and side effects, it was correctly answers by 170 (56.7%) of Pharmacy students.

### **Attitude**

#### **As shown in table (3)**

Question 7 was regarding to the awareness of hearing about the reports of adverse drug reactions, the correctly answers were 88 answers which is in percentage (29.3%) of Pharmacy students.

Question 8 was regarding awareness of seeing the reports of adverse drug reactions, the correctly answers was 47 answers which is in percentage (15.7%) of Pharmacy students.

Question 9 was, if the students know how to write reports about adverse drug reaction, the correctly answered with 58 answers (19.3%).

Question 10 about, if they have written reports for the adverse drug reactions yet, the correct answers are 29 answers, which is in percentage of (9.7%).

Question 11 about knowing where to raise the reports of adverse drug reactions and the correct answers were 33 answers, which is in percentage of (11.0%).

Question 12 about hearing of the Pharmacovigilance center in Yemen and the correct answers were 40 answers, which is in percentage of (13.3%) of Pharmacy students.

Question 13 about, if they think that Pharmacovigilance will improve the morbidity and mortality of patients in clinical practices and the corrected answers were 226 answers, which is in percentage of (75.3%) of Pharmacy students.

Question 14, regarding to that, if the practice of adverse drug reactions should be included with other subjects in studying at the third level and the correct answers were 240 answers, which is in percentage of (80.0%) of Pharmacy students.

This is the study reporting Knowledge and Attitude of ADR and Pharmacovigilance of the fourth and five-year Pharmacy students of Six Universities in Sana'a city, Yemen. The response rate was high (93.75%), high response rate in our study attributed to the help of course coordinators during data collection. This result was similar to two different studies conducted in Malaysia and Yemen which showed response rate as (84%) and (92.1%), respectively.<sup>[18,19]</sup>

After analysis each demographic factor separately, the study found that majority of student were the male 210 (70.0%). The present study revealed that more than (77.5%) of the students did not have any know about meaning of the Pharmacovigilance. This finding is unlike the report of previous studies conducted that present (72.6%) is correct from among medical interns in Sangli, by Shetti SA, et al.<sup>[20]</sup> The present study revealed that also more than (94.5%) of the students reported that the topic of Pharmacovigilance not covered in curriculum.

In the present study (78.3%) of the students did not hear about Pharmacovigilance. More than sixty present of the students did know about the meaning of the adverse drug reactions.

This finding unlike the report of previous studies conducted, that present (100%) is known meaning of the adverse drug reactions, from among medical interns in Sangli by Shetti SA, et al.<sup>[20]</sup>

In this study, more than eighty students were not fully prepared to write adverse drug reactions reports, which may in a nearby to the study conducted that present (77.4%) from among the medical interns in Sangli by Shetti SA, et al.<sup>[20]</sup>

In the present study (75.3%) of the students did think Pharmacovigilance will improve the morbidity and mortality of patients in clinical practices and this may in a nearby to the study conducted that present (96.8%) from among the medical interns in Sangli by Shetti SA, et al.<sup>[20]</sup>

In the present study (80.0%) of the students answer that Pharmacovigilance should be taught to undergraduate medical, nursing, pharmacy and other healthcare professionals, to ensure a well-prepared graduate in future practice and these may in a nearby to the study conducted that present (93.5%) from among the medical interns in Sangli by Shetti SA, et al.<sup>[20]</sup>

Educational training programs can clarify and enhance the knowledge of ADR reporting and how causality assessment of ADRs is done.<sup>[21,22]</sup> There is no significant difference in knowledge among the students belonging to different universities. Understanding the procedure of reporting an ADR reflects the knowledge and attitudes towards the ADR reporting. The results revealed that the students were less knowledgeable regarding ADRs reporting, and this result same with the results of the previous study in Sangli by Shetti SA, et al.<sup>[20]</sup>

The finding of this study showed that fourth and five-year Pharmacy students were not willing to write report ADR. In addition, majority of the students reported that ADRs reporting should be made necessarily for healthcare professions.

The previous findings are in the same line with a study conducted in a private university in Sangli.<sup>[20]</sup> The finding of current study revealed that the majority of the students strongly agreed that topic of Pharmacovigilance should be taught to them as they were not sure about their preparedness to report an ADR in the future.

## CONCLUSION

These results of data show poor knowledge among Pharmacy students in Six Universities in Sana'a city, towards Pharmacovigilance and ADRs reporting. This survey strongly suggests that there is a great educational program are needed to increase creating awareness among Pharmacy student's role, their knowledge about the type of ADRs and ADRs reporting processes, thus to have a positive impact on patient caring process.

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