



KNOWLEDGE AND PERCEPTIONS OF FINAL-YEAR STUDENTS TOWARDS PHARMACOVIGILANCE AND ADVERSE DRUG REACTION REPORTING AT THE FACULTY OF MEDICAL SCIENCES, AL-RAZI UNIVERSITY - SANA`A - YEMEN

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Background: There is a serious problem with adverse drug reactions (ADRs) everywhere including Yemen. Since it helps with the detection, assessment, reporting and prevention of ADRs, pharmacovigilance (PV) is an essential part of the healthcare system. The unbiased reporting of ADRs remains the foundation of PV. Students majoring in healthcare should acquire the knowledge and skills necessary to conduct PV in a range of clinical settings. The primary objective of this study was to evaluate the understanding and attitudes of final-year Pharmacy, Nursing, and Midwifery students at Al-Razi University in Sana'a, Yemen regarding PV and ADRs reporting. **Methods:** The study followed descriptive cross-sectional approach. A validated, self-administered questionnaire with three parts—demographic information, knowledge, and perceptions of Pharmacovigilance was online distributed to final-year Pharmacy, Nursing, and Midwifery students. The questionnaire was given to 175 students; 122 of them responded with a percentage (69.7%). **Results:** The majority of respondents were male (79.5%). More than the tow-third of the students 68.9% were beyond the age of 23. Although the majority of students 80% heard about the terms of ADRs and PV, but only 50% and 57.4% of the respondents respectively, could define the both terms correctly. However, only 11.48 % of them, nevertheless, took a PV course. More than a half of them (56.6%) had a positive perceptions towards pharmacovigilance and ADR reporting and had a moderate degree of knowledge (68.9%). **Conclusion:** The study demonstrated that the participants lacked sufficient knowledge of pharmacovigilance and ADR reporting. They showed a moderate level of understanding of reporting ADRs as well as a favorable opinion of dealing with and reporting ADRs. Yemen's health care curriculum should include lessons on pharmacovigilance

Keywords: Adverse Drug Reaction Reporting; Pharmacovigilance Knowledge; Healthcare Students, Perception, Yemen

INTRODUCTION

Pharmacovigilance (PV) is a crucial component of the healthcare system since it aids in the identification, evaluation, comprehension and avoidance of negative

medication responses¹. It entails tracking the security of commercially available medications over time and mostly concentrates on adverse drug reactions and patient care². In order for the benefits of pharmacovigilance to be fully realized, it requires strong national and international collaborations. The Uppsala

Monitoring Center (UMC), which falls under the scientific and technical authority of the WHO Programme for International Drug Monitoring, was the first World Health Organization (WHO) collaborating institution to be formed in terms of pharmacovigilance². The Supreme Board of Medicines & Medical Appliances (SBDMA) created the National Yemeni Pharmacovigilance Centre (NYPVC) in Sana'a, Yemen's capital, early in 2011. This was later than other nations in the region. Nonetheless, the time was difficult because the nation was still dealing with ongoing armed engagements and a war of necessity³. Clinical researchers, healthcare professionals (such as doctors, pharmacists, and nurses..., etc.), as well as patients, family members and attorneys are all required to report adverse events, even if they are only suspected. Such reporting aids in deciding whether side effects, given how well the treatment generating the reaction cures the patient's condition, are worth the risk. The success of the pharmacovigilance program is greatly dependent on the spontaneous reporting of adverse medication reactions^{4&5}. ADRs are typically not well covered and reported in poor nations. Both a plan to track adverse drug reactions and associated issues countrywide and an ADR reporting system that covers all of Yemen are absent⁶. The amount of ADRs reported and how they are handled is not mentioned. However, the subject of any official data or reports did not make public by the SBDMA. This may have its roots in the absence of PV-related regulation and guidelines⁶. To extend services to other governorates and cover the entire nation, it has been suggested to set up branches for the national PV center in various parts of Yemen. It has also been suggested to develop a plan to put the Uppsala Monitoring Centre (UMC) guidelines' fundamental steps for establishing a PV program into action. Therefore, the study objective is to assess the knowledge and perception of pharmacovigilance and ADR reporting among final year Pharmacy, Nursing and Midwifery students at Al-Razi University.

METHODS

A descriptive, cross-sectional study was undertaken on a sample of students enrolled in the faculty of medical sciences at Al-Razi

University in Yemen to determine how they perceived about PV and ADRs reporting and how much they knew about it. Al-Razi University Research Ethics Review Committee's ethical approval was received (Ref: 024/FMHS/2022). Before participation in the study, permission was acquired from each student and they were told of its objectives. The online questionnaire was sent to the study sample. The participants included male and female final-year pharmacy, nursing, and midwifery (PNM) students. Raosoft (<http://www.raosoft.com/samplesize.html>) calculated the sample size to be 122 with a 95% confidence interval using a standard random sampling approach. Each participant was individually invited to participate in the study. The sampling frame consisted of the final-year students of the three professional programs. Based on tools used in earlier, comparable investigations, a self-administered structured pre-validated questionnaire was created^{7&8}. Following that, four specialists from the faculty of medical sciences underwent a face and content validity process on the questionnaire. To ensure that the questionnaire was adequately comprehensive, expert opinions were offered with the aim of making the questionnaire more pertinent and significant. The validity, reliability, and intelligibility of the questionnaire were checked in a pilot study process. The questions were initially in English and then translated to Arabic. On a small sample of final-year PNM students (n=10), a pilot study was also carried out. The final results did not contain the findings of the pilot study. The questionnaire was modified in an effort to make it shorter and easier. Following analysis of the feedback, the double-barreled, imprecise and misleading items were changed, and a finished questionnaire was produced.

Three sections made up the questionnaire. The first section consisted of six items on demographic information, including age, department, and gender, as well as inquiries into the students' familiarity with the terms ADRs and PV and whether they have taken any pharmacovigilance-related courses. The students' knowledge of PV was tested in the second section, which included 15 closed-ended items with multiple-choice answers. The third section of the questionnaire had 15 items that assessed the participants' opinions on

reporting ADRs. The questionnaire items were graded on a 5-point Likert scale (1=strongly disagree, 2=disagree, 3=neutral, 4=agree, and 5=strongly agree) to determine how students perceive about ADR reporting. Knowledge and perception served as the study's dependent variables. The study participants received the questionnaire once it had been transformed into a Google Docs format. Data were gathered between March 30 and May 31, 2022. The authors read the relevant literature before creating the questionnaire in both English and Arabic. The class representative for each program received the link to the online questionnaire, and the representatives shared the link with the students via their WhatsApp groups. The results were downloaded and stored in Microsoft Excel spreadsheets. The data were analyzed using SPSS version 25 statistical software (IBM Inc., Chicago, USA). Descriptive statistics (mean and standard deviation) were processed to describe the

categorical study and outcome variables. A P value of ≤ 0.05 was used to report the statistical significance and precision of the results in the tables.

RESULTS AND DISCUSSION

Results

Socio-demographic characteristics of participants

Among the total 175 final-year students, 122 students (80 Pharmacy, 27 Nursing and 15 Midwifery students) responded (response rate of 69.7 %). Most of the students 84 (68.9%) were in the age of more than 23 years and were males 97 (79.5%) and 25 (20.5%) were females. Eighty percent of the respondents heard about ADRs and PV. However, only (11.48%) of them attended a PV course. The details of the respondents' demographic profile are illustrated in **Table (1)** below.

Table 1: Comparison of the overall knowledge and perceptions based on socio-demographic characteristics of the respondents (n = 122).

Variables	Category	Frequency N (%)	Knowledge		Perception	
			Mean Rank Score	P-value	Mean Rank Score	P-value
Gender*	Male	97 (79.5)	60.52	0.543	62.26	0.641
	Female	25 (20.5)	65.32		58.56	
Age (years)*	< 23	38 (31.1)	65.55	0.392	54.66	0.150
	> 23	84 (68.9)	59.67		64.60	
Department**	Pharmacy	80 (65.6)	59.31	0.580	65.54	0.009+
	Nursing	27 (22.1)	63.89		43.57	
	Midwifery	15 (12.3)	68.87		72.20	
Hearing of the terms ADRs and PV*	Yes	98 (80.3)	61.07	0.786	63.27	0.265
	No	24 (19.7)	63.25		54.29	
Attended PV course*	Yes	14 (11.5)	40.54	0.018+	50.54	0.217
	No	108 (88.5)	64.22		62.90	

Notes: +P value ≤ 0.05 ; * Mann-Whitney U-test; ** Kruskal-Wallis test.

Abbreviations: ADR, Adverse Drug Reaction; PV, Pharmacovigilance.

Table 2: Knowledge and perceptions of final-year PNM students regarding PV and ADRs reporting (n =122).

Variable	Category	Frequency	Percent
Knowledge	Poor	19	15.6
	Moderate	84	68.9
	Good	19	15.6
Perceptions	Positive	69	56.6
	Moderate	51	41.8
	Negative	2	1.6

Knowledge of participants towards PV and ADRs reporting

In terms of knowledge, the majority (68.9%) of the participants had a moderate level of knowledge as shown in **Table (2)** above. The terms ADR and PV were correctly defined by (50.0%) and (57.4%) of students, respectively. SBMD is the responsible organization for ADRs monitoring in Yemen was known to (54.1%) of respondents. However, only (26.2%) and (22.1%) students correctly identified Vigibase as the "WHO online database" for ADRs reporting and the International Adverse Reaction Center is located in Sweden, respectively. According to (55.7%) of respondents, not all side effects were known before marketing the drug. The majority of participants (67.2%) thought that reporting ADRs is the combined responsibility of pharmacists, nurses and midwives. Respondents of (15.6%) showed very poor knowledge to the question "Do you think there are no guidelines for reporting ADRs in Yemen?". Moreover, only about a quarter (27.0%) of the respondents demonstrated that ADRs differ from adverse drug events (ADEs). On the other hand, (66.4%) of the respondents mentioned that ADRs associated with herbal products should be reported. Further details on PV knowledge of respondents are given in **Table (3)** below.

Perceptions of participants towards PV and ADRs Reporting

More than a half (56.6%) of the respondents had a positive perception towards PV and ADRs reporting as illustrated in **Table (4)**. According to the study, (31.1%) and (22.2%) of students believed they were well prepared to report ADRs and either agreed or strongly agreed that the topic of PV was well-covered in their faculty curriculum, respectively while (64.8%) of the participants demonstrated that they had no understanding on how to submit ADR to Yemen's appropriate authority. A significant percentage of the participated students (84.4%) thought that ADRs that were reported late or not at all could have serious health consequences. (80.3%) of the participants agreed that all healthcare professionals ought to disclose ADRs. During clerkship programs, more than a half (56.6%) of the participated students said they could do ADR reporting. ADRs linked to cosmetics, in the opinion of the majority 109 (89.3%) of the participants, ought to be disclosed. The reporting rate will decrease if ADR reporters' identities are kept hidden, according to 44.2% of the participants while (45.5%) of participants thought it will increase. Further details on PV perception of respondents are given in **Table (4)** below.

Table 3: Knowledge of the final-year students of PNM regarding PV and ADRs reporting (n = 122).

Knowledge Question	Correct answer	
	n	%
What is ADRs?	61	50.0
What is PV?	70	57.4
What is the consequence of a severe ADR?	101	82.8
Who should report ADRs in Yemen?	82	67.2
Which types of ADRs should be documented?	105	86.1
The international ADR center is located at	27	22.1
Which of the following is the "WHO online database" for adverse reaction reporting?	32	26.2
What kind of ADR reporting system do we have in Yemen?	41	33.6
To which organization should the case of adverse reactions in Yemen be reported?	66	54.1
What is the main purpose of PV?	48	39.3
Do you think that all ADRs are known before a drug is marketed?	68	55.7
Do you think that ADRs caused by herbal medicines are not documented reported?	81	66.4
Do you think there are no guidelines on ADR reporting in Yemen?	19	15.6
Do ADRs differ from adverse drug events (ADEs)?	33	27.0
What type of drug is suitable for reporting ADRs?	105	86.1

Table 4: Perception of final-year PNM students towards PV and ADRs reporting (n = 122).

Perception Statement	Strongly agree N (%)	Agree N (%)	Neutrally N (%)	Disagree N (%)	Strongly disagree N (%)
I've learned enough to report ADRs.	7(5.7)	31(25.4)	29(23.8)	31(25.4)	24(19.7)
PV is fully addressed in my curriculum.	8(6.6)	19(15.6)	20(16.4)	42(34.4)	33(27.0)
I have no idea how to report ADR to Yemen's relevant authority.	30(24.6)	49(40.2)	22(18.0)	15(12.3)	6(4.9)
late or non-reporting of ADRs could have serious health consequences.	47(38.5)	56(45.9)	7(5.7)	9(7.4)	3(2.5)
PNM should disclose potential ADRs.	56(45.9)	42(34.4)	12(9.8)	4(3.3)	8(6.6)
Side effects of herbal medicines should be reported.	39(32.0)	64(52.5)	10(8.2)	5(4.1)	4(3.3)
During their clerkship, students can report ADRs.	25(20.5)	44(36.1)	25(20.5)	21(17.2)	7(5.7)
With my current knowledge, I am fully prepared to report all ADR encounters in the future.	34(27.9)	44(36.1)	18(4.8)	17(13.9)	9(7.4)
ADRs reporting is an integral part of health care.	45(36.9)	57(46.7)	10(8.2)	5 (4.1)	5(4.1)
The reporting of ADRs should not be prohibited for PNM in the case in several countries.	34(27.9)	55(45.1)	12(9.8)	10(8.2)	11(9.0)
Easy access to ADRs forms.	9 (7.4)	30(24.6)	25(20.5)	41(33.6)	17(13.9)
When the identities of ADR reporters become known, the reporting rate increases.	18(14.8)	38(31.1)	22(18.0)	27(22.1)	17(13.9)
If the identity of ADR reporters is not disclosed, the reporting rate decreases.	21(17.2)	33(27.0)	20(16.4)	28(23.0)	20(16.4)
PV should only be taught in higher levels of medical schools.	18(14.8)	24(19.7)	20(16.4)	32(26.2)	28(23.0)
Cosmetic-related ADRs should be disclosed.	47(38.5)	62(50.8)	6 (4.9)	1 (0.8)	6 (4.9)

Discussion

Knowledge is the fundamental component of any healthcare system activity. Without it, thorough patient care is not feasible. Drug safety concerns are something that all health care professionals (HCPs) should be aware of because if they are ignored, they may have a significant negative impact on patient care and safety⁹. In Yemen, to the best of our knowledge, this is the first study conducted in a private university to investigate the knowledge and perceptions toward PV and ADR reporting among final-year students of pharmacy, nursing and midwifery. Because all healthcare professionals are unable to participate effectively in ADR reporting without adequate knowledge of PV and therefore the reporting process, this issue must be thoroughly researched to identify the necessary interventions so that the spontaneous ADR reporting can be improved. Since there was little exposure to PV until recently during the training of healthcare students, the idea is still relatively new in Yemen. This is not surprising, considering that only about

(11.5%) of the participants indicated that they attended a PV course. By promoting an ADR reporting culture among healthcare students, the problem of underreporting could be reduced¹⁰. The national Yemeni Pharmacovigilance Center wasn't founded until the start of 2011, which is late compared to other countries in the region. However, the period has been challenging as the country was still enduring continuous military conflicts and an emergency war^{6,11&12}. Only two studies were conducted in Yemen that investigated healthcare students' knowledge, attitudes and practices regarding ADRs and their reporting^{7&8}. Few studies were carried out to evaluate the Yemeni healthcare professionals about PV and ADRs reporting^{6,11,13&14}.

The results of the current study showed that the majority of the participated students (68.9%) had a moderate knowledge towards PV and ADR reporting. Similar studies conducted locally and globally gave the inconsistent results¹⁵⁻¹⁷. These findings can be perhaps attributed to the shortage of courses on ADR and PV in their educational curriculum¹⁸. More than three -fourth of the participated students (80.3%) heard about PV. It is

inconsistent with the study conducted among Yemeni pharmacists in five governorates (29.6%)¹⁹. The term PV was also accurately defined by (50.0%) of participants whereas studies from Malaysia and Ethiopia contrast with it^{17,20}. Furthermore, more than a third (39.3%) of the participants correctly identified PV's goal. This is both greater and lower than the studies carried out in Saudi Arabia (65.2%) and Ethiopia (27.7%) respectively^{17&18}. Additionally, (66.4%) of the participants stated that herbal products have ADRs and should be documented and reported. This is consistent with many previous studies conducted.

Despite the moderate knowledge, more than a half (56.6%) of the participants had a positive perception. This result corroborates with the findings of previous studies conducting by Othman et al., and lower than a study done by Alshakka et al., in Yemen. The present study revealed that only (22.2%) participants said that the topic of PV is well covered in their curriculum, which is nearly similar to the findings (21%) of the study done by Limaye et al., among pharmacy students at Mumbai University and lower (55%) than the study conducted by Rajiah et al., among pharmacy students in Kuala Lumpur. Moreover, the present study revealed that more than (64.8%) of the participated students did not have any idea about how to report ADRs. This finding is supported by a study conducted by Othman et al., among pharmacy students in Yemen. More than three-fourth (78.1%) of the participated students agreed that the PV concept should be included as a core topic in their health curriculum. This is supported by many previous studies as well. Around three-fourth (71.6%) of the participants also agreed that information on how to report ADR should be taught to the students. It is supported by the study reports from Malaysia. In this study, however, about less than two-thirds (61.4%) of the participants disagreed that the topic of PV is well-covered in their study curriculum. However, (64.0%) of the participants either agreed or strongly agreed with the statement that "With their current knowledge, they are fully prepared to report all ADRs encounters in their future practice". These findings are consistent with the results of a study in Oman (48.3%). This may greatly affect the students' motivation in reporting ADRs encounter on different occasions which results in underreporting of ADRs. Moreover, more than three-fourth (78.1%) of the participated students agreed that the PV concept

should be included as a core topic in their health curriculum. This is supported by many previous studies as well. Around three-fourth (71.6%) of the participants also agreed that information on how to report ADR should be taught to the students. It is supported by the study reports from Malaysia. In this study, however, about two-thirds (66.6%) of the participants disagreed that the topic of PV is well-covered in their study curriculum. About (45%) of the participants also disagreed with the statement that "With their current knowledge, they are well prepared to report any ADRs noticed in their future practice". These findings are consistent with the results of a study in Oman (48.3%). This may greatly affect the students' motivation in reporting ADRs encounter on different occasions which results in underreporting of ADRs.

Limitations

The main drawback of this study is that the number of participants was very small compared to the total number of students enrolled at the faculty of medical sciences, Al-Razi University when conducting the study. The omission of final-year students from other programs may be another drawback for the study. Because the study was self-reported, recollection bias cannot be completely eliminated. In addition, the findings of this study could not apply to all Yemeni students attending healthcare institutions.

Conclusion

The study's results indicate that a sizable percentage of Al-Razi University students are insufficiently knowledgeable about pharmacovigilance. Students in their last year showed some awareness of reporting ADRs as well as a favorable perception toward dealing and reporting ADRs. The study outlines the necessity of including pharmacovigilance education in Yemeni healthcare schools' curricula in order to prepare students for real-world practices and workplaces. In addition, to educational and awareness-raising initiatives.

Acknowledgement

The three professional programs of the Faculty of Medical Sciences at Al-Razi University's personnel and final-year students are acknowledged by the authors for their invaluable assistance in the effective completion of this study.

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نشرة العلوم الصيدلانية جامعة أسيوط



معارف ومواقف طلاب السنة النهائية تجاه التيقظ الدوائي والإبلاغ عن التأثيرات الجانبية للأدوية في كلية العلوم الطبية، جامعة الرازي - صنعاء - اليمن

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هناك مشكلة خطيرة في الأعراض الجانبية للأدوية في كل مكان بما في ذلك اليمن. نظراً لأنه يساعد في الكشف عن التفاعلات الدوائية الضارة وتقييمها والإبلاغ عنها والوقاية منها، فإن التيقظ الدوائي هو جزء أساسي من نظام الرعاية الصحية. لا يزال الإبلاغ غير المتحيز عن التفاعلات الدوائية الضارة هو أساس التيقظ الدوائي. يجب على طلاب التخصصات الطبية اكتساب المعارف والمهارات اللازمة بذلك. كان الهدف الأساسي من هذه الدراسة هو تقييم معارف ومواقف طلاب السنة النهائية الصيدلة والتمريض والقبالة في جامعة الرازي في صنعاء، اليمن اتجاه التيقظ الدوائي. تم إجراء مسح مقطعي قائم على الاستبيان المكون من ثلاثة أجزاء - المعلومات الديموغرافية والمعارف والمواقف من التيقظ الدوائي عبر الإنترنت على طلاب السنة النهائية في الصيدلة والتمريض والقبالة. تم إرسال الاستبيان إلى ١٧٥ طالباً وطالبة. أجاب ١٢٢ منهم بنسبة (٦٩.٧٪). غالبية المستجيبين كانوا من الذكور (٧٩.٥٪). أكثر من ثلثي الطلاب ٦٨.٩٪ تجاوزوا سن ٢٣ عاماً. على الرغم من أن غالبية الطلاب سمع ٨٠٪ عن المصطلحين ADRs و PV، إلا أن ٥٠٪ و ٥٧.٤٪ فقط منهم على التوالي، يمكنهم تعريفهما بشكل صحيح. لأن ١١.٤٨٪ فقط منهم، أخذوا دورة عن التيقظ الدوائي. أكثر من نصفهم (٥٦.٦٪) لديهم موقف إيجابي تجاه التيقظ الدوائي والإبلاغ عن التفاعلات الدوائية الضارة وكان (٦٨.٩٪) لديهم درجة معتدلة من المعرفة.

أظهرت الدراسة أن المشاركين يفتقرون إلى المعرفة الكافية بالتيقظ الدوائي وتقارير ADR. أظهروا مستوى معتدلاً من الفهم للإبلاغ عن التفاعلات الدوائية الضارة بالإضافة إلى رأي إيجابي في التعامل مع هذه التفاعلات والإبلاغ عنها. يجب أن يتضمن منهج الرعاية الصحية اليمني دروساً في التيقظ الدوائي.