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# Knowledge and Perceptions of Pharmacy Students about Pharmacovigilance in Oman

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## ABSTRACT

**Background:** In the modern world, patient safety and the safe use of medicines are of a high priority. Huge competition exists among pharmaceutical manufacturers resulting in medicinal products being registered and marketed in many countries simultaneously. Because of this, adverse drug reactions (ADR) may not always be readily identified or monitored systematically. In order to minimize or prevent harm to patients arising from their drugs, pharmacists can play a vital role in both ADR reporting and pharmacovigilance activities. Rates of ADR reporting can be improved by promoting awareness of its importance and the procedures for doing so, and this is best done during undergraduate pharmacy education. Pharmacy students must be trained well on how to recognize, prevent, and report ADRs. Lack of knowledge about ADR reporting process is associated with negative attitudes towards the pharmacovigilance.

Objectives: We aim in this study to assess pharmacy students' knowledge and perception towards pharmacovigilance and adverse drug reaction reporting.

**Methodology:** a Cross-sectional study was conducted between in the period of February 2017 to April 2017 using a self-administered questionnaire to a sample population of 118 pharmacy students from University of Nizwa and Oman Medical College. Univariate analysis was done to the collected data.

Results: The response rate of the survey was 79%. The study revealed that mean knowledge score of the pharmacy students for pharmacovigilance and ADR reporting was 8.65 (±2.91)

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Significant differences in the mean score of the knowledge in domains of study institution and nationality of the pharmacy students were observed. Majority of the respondents answered correctly the definitions of pharmacovigilance (61%) and ADRs (55.9%). About 81.35% of the respondents answered correctly about the question related to the required data that should be collected for the assessment of a suspected ADR. Almost 61 % of the pharmacy students had a correct knowledge about the types of ADRs that should report. Almost 65% of the pharmacy students agreed that they can perform ADR reporting during their clerkship/internship program.

**Conclusion:** Respondents had adequate knowledge on pharmacovigilance and ADR reporting. However, pharmacy students lack an in-depth understanding of concepts about ADR reporting and may require more information on the national pharmacovigilance program and reporting process of ADRs. Educational intervention should be done in order to increase the awareness of pharmacovigilance and ADR reporting process among pharmacy student.

**Keywords:**

*Pharmacovigilance, Adverse drug reactions, Knowledge, Perception, students*

## Introduction

In the modern world, patient safety and the safe use of medicines are of a high priority. Huge competition exists among pharmaceutical manufacturers resulting in medicinal products being registered and marketed in many countries. Because of this, adverse drug reactions (ADR) may not always be readily identified or monitored systematically (V.L.Reddy, Pasha, Rathinavelu & Y.P. Reddy, 2014).

According to World Health Organization (WHO, 2002) adverse drug reaction is defined as "a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function".

Medications, regardless of its therapeutic benefits have caused and will continue to cause harm to the life of humans. Adverse Drug Reactions are considered as one the leading causes of mortality and morbidity (Lazarou et al., 1998; Classen et al., 1997, as cited in Latif & Abdel-Wahab, 2015). ADRs are accountable for about 5% to 20% of hospital admissions (Lazarou et al., 1998; Pirmohamed et al., 2008, as cited in Elkalmi et al., 2011).

In order to minimize or prevent harm to patients arising from their drugs, it is essential to monitor ADRs, to detect ADRs before they are clinically manifested (Sivadasan et al., 2014).

Pharmacists had moved ahead from their traditional role of preparing and dispensing medicines. Now they play vital roles such as preventing ADRs and medication errors, improving patient satisfaction and quality of life and improving economic outcomes. Pharmacists as key drug experts can play a vital role in both ADR reporting and

pharmacovigilance activities. Community pharmacists are contacted first by the patients for information about ADRs, are an important source of ADR reports. While in hospital setting, pharmacists can play key role in ADR reporting because they have access to the information necessary to report ADRs (Changhai et al., 2010; Kaboli et al., 2006; Kane et al., 2003; Sears et al., 2005; Van Grootheest et al., 2005, as cited in Elkalmi et al., 2011) (Birdwell et al., 2003, as cited in Shakeel et al., 2014).

World Health Organization (WHO, 2006) defines pharmacovigilance "as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems". The foundation of any successful pharmacovigilance program is spontaneous monitoring of ADRs (Upadhyaya et al., 2012).

In 1994 functioning under the patronage of Drug Control Department, Directorate General of Pharmaceutical Affairs and Drug Control (DGPA&DC), Oman had launched its own pharmacovigilance program and became a member of the Uppsala Monitoring Centre (UMC, WHO) for International Drug Monitoring in 1995. ADR reporting is mandatory for all healthcare providers. There are two methods related to ADR reporting system: National scenario and international scenario. The national scenario is reporting to national pharmacovigilance center. Ministry of health (Drug Control Department, Directorate General of Pharmacy Affairs and Drug Control) using specified forms. It is coordinated by the department of clinical pharmacy/drug information center of the hospital. The International scenario is that the national center coordinates with an international pharmacovigilance center of World Health Organization-Uppsala Monitoring Centre. Further, United States Food-Drugs Administration has MedWatch-FDA safety information and adverse drug event reporting program. The directorate organizes periodic pharmacovigilance workshops to all healthcare

professionals. In 2011, a survey conducted in Oman revealed that 60% of healthcare professionals reported ADRs as they suspected or detected a problem, while 40% did not report due to varying reasons such as lack of knowledge about the system, unavailability of ADR reporting forms, lack of knowledge in filling ADR forms, lack of time, and lack of confidentiality (Jose et al., 2013; Varughese et al., 2011). According to the Directorate General of Pharmaceutical Affairs and Drug Control (DGPA &DC,2015) annual report on ADRs, 1954 cases had been reported in the year 2015 which evidenced about 55% increase in reporting compared to the year 2010.

Rates of ADR reporting can be improved by promoting awareness of the importance of ADR reporting and the procedures for doing so, and this is best done during undergraduate teaching. As a future pharmacist, pharmacy students must be trained well on how to recognize, prevent and report ADRs (Reddy et al., 2014; Shakeel et al., 2014). It is obligatory to possess a proper assessment and discussion to determine whether the school leaving pharmacy graduates are confident and trained enough to take up this new role or not. It has been reported that lack of knowledge about ADR reporting process is associated with negative attitudes towards the pharmacovigilance (Savage, 2013 as cited in Rajiah et al., 2015).

While a study was conducted to evaluate knowledge and attitudes of community pharmacists about ADR reporting in Oman (Jose et al., 2013), limited studies have been conducted to evaluate pharmacy students' knowledge, perception, and attitudes about pharmacovigilance and ADR reporting (Rajiah et al., 2015; Shakeel et al., 2014;.Elkalmi et al., 2011).To the best of the investigator's knowledge, there is no published study done in Oman to evaluate pharmacy students' knowledge and perception about pharmacovigilance and ADR reporting.

For making any process into regular practice students' perception of their preparedness and ability must be systematically examined before any new implementations in healthcare education (Bojanic´ et al., 2009 as cited in Rajiah et al., 2015). This study, therefore, intended to assess pharmacy students' knowledge and perception about pharmacovigilance and ADR reporting.

**Methodology:**

The study was approved by the School of Pharmacy, and Institutional heads of College of Pharmacy, University of Nizwa and Oman Medical College.

A cross-sectional questionnaire-based survey was conducted at University of Nizwa and Oman medical college campus in the period of February to April 2017. Final year Bachelor of Pharmacy students who had completed the Pharmacy Practice and Pharmacogenetics & Pharmaco-epidemiology courses from School of Pharmacy, UON. Final year Bachelor of Pharmacy students who had completed Pharmacy Practice course at Oman Medical College

The questionnaire was developed on the basis of review and using information from the similar literatures about pharmacovigilance and ADR reporting among healthcare professionals and pharmacy students(Tabassum et al., 2015; Rajiah et al., 2015;Upadhyaya et al., 2014; Shakeel et al., 2014; Reddy et al., 2014; Ahmad et al., 2013; Elkalmi et al., 2011)

A 32-item questionnaire consisted of three (3) sections to obtain pharmacy students' demographic data, knowledge on ADR reporting and pharmacovigilance and perception towards the ADR reporting procedures. The first section consisted of 8 questions to record demographics of the student

The second section (questions 9-23) included components designed to assess knowledge about pharmacovigilance and ADR reporting. The respondents were asked to select the correct answer from multiple-choice response options. A score of 1 was given for each correct answer and 0 for each wrong answer. The maximum score obtainable was 15 and the minimum was 0. The mean knowledge score was calculated. The third section (questions 23 to 32) was designed to evaluate the perceptions of pharmacy students towards pharmacovigilance and ADR reporting aspects. The items were assessed using a 5-point Likert rating scale (5 = strongly agree, 4 = agree, 3 = neutral, 2=disagree, and 1= strongly disagree). Both positively and negatively-worded items were included in the section to avoid agreement bias. Face validity was done to the questionnaire by showing the questionnaire to a variety of panels asking for their expert opinions to make sure that the questionnaire is measuring what it is intended to measure, minor editing has been done as per experts' comments and recommendations. This was a crucial step to validate the study instrument before actually starting collecting data.

**Study population:** A total sample population of 118 students comprising of 83 Bachelor of pharmacy students from School of Pharmacy, University of Nizwa and 35 from the Department of Pharmacy, Oman Medical College was enrolled into the study.

**Study procedure:**

Verbally consented students who meet the inclusion criteria were distributed with the questionnaire for self-administration. The students took approximately 20 minutes to complete the questionnaire. The completed questionnaires were sealed in envelopes and confidentiality of the collected data was maintained. The collected data was used only for the purpose of the present study.

**Statistical analysis:**

The data from completed questionnaires were entered into Microsoft Excel data sheet and imported into SPSS program version 15.0. Descriptive statistical analysis such as frequencies and percentages were used to represent the participant's demographic data.

When appropriate independent sample test was used to compare the means of two variables. Kruskal-Wallis test and one way ANOVA were used for multiple comparisons in order to detect the existence between pairwise groups.

## Results:

The survey questionnaire was administered to 190 pharmacy students of the University of Nizwa and Oman Medical College. Among the distributed questionnaire, only 150 duly filled the questionnaire. The average time taken to complete the questionnaires was approximately 20 minutes. The survey had a response rate of 79%. Among the received questionnaires, 118 questionnaires met the inclusion criteria of the study were included. Among the total survey population (118), 70.3% (n=83) of the participants were the pharmacy students of UON and 35 (29.7%) were the pharmacy students of Oman Medical College.

### Demographic characteristics:

Among the total survey population of pharmacy students (n=118), 89% (n=105) were female and 11% (n=13) were male. The survey showed that among the pharmacy students of University of Nizwa 93 %(n=77) were female and 7% (n=6) were male while in Oman Medical College, 80% (n=28) were female and 20%(n=7) were male students.

The majority (97.6%; n=81) of pharmacy students from UON were in age group of 20-25 years, while 2.4% (n=2) were in the age group of 26-30 years and the mean age of the pharmacy students was observed to be 23.8 (□1.09) years. Whilst all the pharmacy students of OMC were in the age group of 20-25 years (100%) and the mean age was observed to be 22.45 (□1.44) years.

The study demonstrated that, out of 83 UON pharmacy students, 89.2% (n=74) were Omani followed by 2.4 %( n=2) for Egypt, Palestine, and Sudan. While there was one participant each from the countries Iraq and Somalia and Jordan. About 54.3 % (n=19) of the participants

from OMC were Omani followed by 20 % (n=7) Egyptian and 11.4 % (n=4) were Iraqi.

The knowledge about pharmacovigilance and ADR reporting among the pharmacy students of the University of Nizwa and Oman medical college was assessed by asking to select the correct answer from multiple-choice response options.

The overall mean knowledge score of the pharmacy students on pharmacovigilance and ADR reporting was found to be 8.65 (±2.910). The mean knowledge score of pharmacovigilance and ADR reporting for the pharmacy students of the University of Nizwa was 7.96(±2.77) whereas for the pharmacy students of Oman medical college it was 10.29(±2.58). The observed results revealed that there was no significant difference in the mean score of the knowledge domain by gender (P=0.392), however, there was a significant difference in the mean score of the knowledge domains of study institution and nationality of the pharmacy students.

## Comparison of knowledge between the pharmacy students of University of Nizwa and Oman medical college

Out of the 118 pharmacy students, 61 %( n=72) of respondents answered correctly for the definition of pharmacovigilance, while among the institutions 61.4% (n=51) of the UON pharmacy students and 60.0% (n=21) of OMC pharmacy students answered the definition correctly. About the functions of pharmacovigilance, 46.6% (n=55) of the total surveyed population responded correctly, among UON pharmacy students 38.6% (n=32) answered correctly and 65.7% (n=23) of OMC pharmacy students answered correctly. However, there was a significant difference (p = 0.007) in responses to this question by the pharmacy students of these two institutions.

The study revealed that out of 118 pharmacy students, 42.4% (n=50) answered correctly the components of pharmacovigilance, while among the institutions 62.9% (n=22) of OMC

pharmacy students and 33.7% (n=28) of the UON pharmacy students had the correct answer for the components of pharmacovigilance. There was a significant difference (p=0.004) in answering this question by the student pharmacists of these two institutions.

The survey demonstrated that 78 %( n= 92) of the total surveyed pharmacy students had the correct knowledge about the national center for pharmacovigilance program in Oman. Among the pharmacy students, 77.1% (n=64) of UON pharmacy students answered correctly and 80% (n=28) of OMC pharmacy students answered correctly for this question.

A remarkably low number of the total study population study population (17 %;n=20) answered correctly the question on WHO Program for International Drug Monitoring center (Uppsala Monitoring center).Among the institutions, 8.4% (n=7) of the UON pharmacy students and 37.1% (n=13) of OMC pharmacy students answered correctly to this question. A significant difference (P<0.05) was observed between the two groups of student pharmacist who answered this question.

The study demonstrated that about 55.9 %( n= 66) of the total student pharmacist was able to answer correctly the definition of adverse drug reactions, whereas 59 %( n= 49) of UON pharmacy students and 48.6 %( n=17) of OMC students answered correctly the definition of ADR.

According to the survey analysis, 62.7% (n=74) of respondents answered correctly about the description of type A (augmented) ADRs, while among the institutions 61.4% (n=51) of the UON pharmacy students and 65.7% (n=23) of OMC pharmacy students answered correctly the description of type A ADRs. Whilst regarding the description of type B reactions (Bizarre) approximately about half of the study population (54.2 %; n=64) answered correctly. Nearly 51.8 % (n=43) of the UON pharmacy students and 60% (n=21) of the OMC

pharmacy students were able to describe correctly the type B reactions.

The survey showed that less than half of the population (47.4%; n=56) had a correct knowledge about the healthcare professional responsible for reporting of ADRs. Among the study institutions, 36.1 %( n=30) of UON pharmacy students and74.3 %( n=26) of OMC pharmacy students had a correct knowledge. Significantly higher percentage(74.3%) of the OMC pharmacy students answered correctly about the health care professional responsible for reporting of ADRs (p<0.05).

The survey results showed that 81.35 % (n=96) of the total respondents answered correctly about the question related to the required data that should be collected for the assessment of a suspected ADR. Majority (77.1%; n=64) of the UON pharmacy students and OMC pharmacy students (91.4 %; n=32) answered correctly for this question.

According to the survey results, 61 % (n=72) of the total pharmacy students had a correct knowledge about the types of ADRs that should report. Whilst 50.6% (n=42) of the UON pharmacy students and 85.7 %( n=30) of the OMC pharmacy students answered correctly about the types of ADRs that should report. Significantly higher percentage (85.7%) of the OMC pharmacy students answered correctly about the types of ADRs that should report (p<0.05).

The study revealed that 78.8 %( n=93) of the total student pharmacist had a correct knowledge of the reporting the type products that may cause ADR. Among the institutions, 72.3% (n=60) of the UON pharmacy students and 94.3% (n=33) of OMC pharmacy students answered the question on reporting the types of products that cause ADRs. Significantly higher percentage (94.3%) of the OMC pharmacy students answered correctly about the reporting the types of products that cause ADRs (p=0.008).

The study analysis showed that 71.1 %( n=84) of the pharmacy students had a correct knowledge about the existence of ADR reporting form in Oman. Among the study institutions, 69.9 % (n=58) of the UON pharmacy students and 74.3% (n=26) of the OMC pharmacy students had a correct knowledge about the existence of ADR form.

The study results revealed that 66.1 %( n=78) of the student pharmacists had a correctly identified Drug control department of DGPA&DC as the regulatory body to which ADRs should be reported. Among the institutions 67.5 %( n=56) of the UON pharmacy students and 62.9 % (n=22) of the OMC pharmacy students correctly identified the regulatory body in Oman to which ADRs should be reported.

A remarkably a lower percentage (39%; n=46) of the survey population had a correct knowledge about the department that coordinates with the national reporting of ADRs. Significantly higher percentage (65.7%) of the OMC pharmacy students had a correct knowledge of the department that coordinates with the national reporting of ADRs when compared to UON pharmacy students (p<0.05).

**Perception analysis towards pharmacovigilance and adverse drug reaction reporting**

Ten questions were used to explore the perception of pharmacy students towards pharmacovigilance and adverse drug reaction reporting.

The study results showed that the average positive response for the 10 statements was 56.34% for the UON pharmacy students and the mean score was found to be 3.58 (±0.49).Whilst among the among OMC pharmacy students the average positive response was 62.56% and the mean score was found to be 3.52(±0.606).

The study showed that 80.5% total study population agreed that pharmacovigilance should be included as a core topic in pharmacy education. The study observed that 75.9% of the UON and 91.4 % of the OMC pharmacy students were in an agreement that pharmacovigilance should be included as a core topic in pharmacy education.

The study revealed that 71.2% of the total pharmacy students were in an agreement that topic of pharmacovigilance is well covered in their pharmacy school curriculum. About 74.6% of the UON and 62.85% of the OMC pharmacy students agreed or strongly agreed to that the topic of pharmacovigilance is well covered in their pharmacy school curriculum.

Surprisingly 39.8% of the total pharmacy students were in disagreement with the statement that they don't have the idea how to report ADRs to the relevant authorities in Oman. The study also observed that only 38.5% of the UON and 22.8% of the OMC pharmacy students were in disagreement to the statement that they don't have the idea how to report ADRs to the relevant authorities in Oman. However, there was a significant difference (p=0.025) in response to this statement between the students at different institutions.

Overall 65% of the total student pharmacists were in an agreement that pharmacy students can perform adverse drug reactions reporting during their clerkship/internship. About 63.8% and 68.5% of the UON and OMC pharmacy students respectively agreed or strongly agreed to the statement that pharmacy students can perform adverse drug reactions reporting during their clerkship/internship.

The study showed that 61% of the total sample population was in agreement with the statement that ADR reporting should be made compulsory for pharmacists.Approximately 54.2% of the UON and 77.1% of the OMC student pharmacist were in an agreement that ADR reporting should be made compulsory for pharmacists. Whilst 68.6% and 71.4% of the UON and OMC student pharmacist respectively agreed or strongly agreed to the statement that information on how to report ADRs should be

taught to senior pharmacy students. The overall response to this statement was 69.5%.

A lower percentage (27.1%) of the total study population was in disagreement with the statement that reporting of known ADRs makes no significant contribution to the reporting system. The study also observed that approximately one fourth (21.6%) of the UON students and less than half (40%) of the OMC pharmacy students were in disagreement to the statement that reporting of known ADRs makes no significant contribution to the reporting system. There was a significant difference (p=0.013) in the disagreement between the students of two institutions.

Only less than half (48.3%) of the total pharmacy students agreed to the statement that with their present knowledge, they are well prepared to report any ADRs that may be encountered in their future practice. The study analysis also showed that nearly half (51.8%) of the pharmacy students of UON and about less than half (40%) of OMC pharmacy students agreed to the statement that with their present knowledge, they are well prepared to report any ADRs that may be encountered in their future practice. There was a significant difference (p= 0.021) in response to the item between the two groups of pharmacy students. The majority (80%) of the total study population agreed or strongly agreed to the statement that pharmacist is one of the most important healthcare professionals to report adverse drug reactions.

About 86.7% and 62.8% of the UON and OMC pharmacy students respectively agreed or strongly agreed to the statement that pharmacist is one of the most important healthcare professionals to report adverse drug reactions. The study observed significant difference (p= 0.009) in response to the item between the pharmacy students of two institutions.

A low percentage (45%) of the total sample population was in disagreement with the statement that serious and unexpected reactions that are not fatal or life-threatening during clinical trials must not be reported. The study also revealed that 38.5% of the UoN pharmacy students and 60% of the OMC pharmacy students were in disagreement to the statement that serious and unexpected reactions that are not fatal or life-threatening during clinical trials must not be reported. There was a significant difference (p= 0.01) in disagreement to the item between the two groups of pharmacy students.

The study showed that among the 10 statements that assessed the perception toward pharmacovigilance and adverse drug reaction, both pharmacy students of UON and OMC showed a positive perception towards 7 statements.

## Discussion

To the best of investigator's knowledge, this is the first study in Oman which evaluates and compares the knowledge and perception of final year pharmacy students towards pharmacovigilance and ADRs reporting. The response rate of the present study was 79% which was high when compared to the other studies (Sivadasan et al., 2014; Shakeel et al., 2014). In order maximize response rate and minimize response bias, the survey questionnaire was administered personally to the students by the investigator in presence of the course co-coordinators of the two institutions (Lydeard 1999; Hartge 1999).

The mean knowledge score of pharmacy students on pharmacovigilance and ADR reporting obtained from both institutions were (8.65±2.90). The results were higher than the mean knowledge score for pharmacy students obtained in a Malaysian study (Elkalmi et al., 2011) and similar to the study done by Sivadasan et al. (2014).This may be because the pharmacy students are exposed to all basic concepts of pharmacovigilance in their syllabus. It was noted in the present study that there was a significant difference (p<0.05) in mean

knowledge score of pharmacy students between the two institutions.

It was also observed in the present study that less than half of the student pharmacist (42.4%) answered correctly the components of pharmacovigilance and the findings were lesser than when compared to the study done by Reddy et al. (2014).It is the reflection of the fact that pharmacy students were taught about the detection, assessment, understanding, and prevention of ADRs and the components of their syllabus. The study also witnessed significant difference (p=0.004) in the correct knowledge on components of pharmacovigilance between the student pharmacists of UON and OMC.

The findings of the study revealed that 78 % the pharmacy students had a correct knowledge of the national center for pharmacovigilance in Oman. The results were much higher than observed in the Malaysian study (Sivadasan et al., 2014) where only 39.4% of pharmacy students of Malaysian university had correct knowledge about the national center for pharmacovigilance in Malaysia.

Unfortunately, a low percentage of the student pharmacist (17 %) answered correctly the question on WHO Program for International Drug Monitoring center (Uppsala Monitoring Centre).The findings were similar to the study done by Reddy et al. (2014). The study also witnessed significant difference (p=0.004) in the correct knowledge on WHO Program for International Drug Monitoring center between the student pharmacists of UON and OMC.

The study findings showed that more than half (55.9%) of the of the student pharmacist had a correct knowledge on the definition of ADRs and the results were similar to the study done by Sivadasan et al., (2014).While an Indian study (Sharma et al., 2012) showed that only 44.4% of the pharmacy students had correct knowledge of the definition of ADRs.

In the present study, about 62.7% and 54.2% of the student pharmacists answered correctly the definition of type A ADRs and type B ADRs respectively. The results were marginally lower than when compared to the Malaysian study (Elkalmi et al., 2011) where 76.5% of the pharmacy students answered correctly the definition of type A ADRs and 59.7% of the pharmacy students answered correctly the definition of type B ADRs.

The present study revealed that less than half (47.4%) of the student pharmacist had the knowledge on health care professional responsible for reporting ADRs. This was higher in comparison to the Malaysian study (Sivadasan et al., 2014) where only 29.2 % of the pharmacy students demonstrated good knowledge about the healthcare professional responsible for reporting ADRs. Significantly higher percentage of the OMC pharmacy students answered correctly than UON pharmacy students about the healthcare professional responsible for reporting of ADRs (p<0.05).

The present study revealed that higher percentage (78.8%) of the student pharmacists had correct knowledge about reporting the type of products that cause the ADR when compared to the Malaysian study (Elkalmi et al., 2011).There was a significant difference(P<0.05) between the student pharmacists of OMC and UON.

The findings of the present study revealed that 66.1% of the student pharmacists had a correct knowledge about the regulatory body DGPA& DC to which ADRs has to be reported. This finding is higher when compared Malaysian study (Sivadasan et al., 2014) where only 39.4% of the pharmacy students had a correct knowledge about the regulatory body MADRAC to which ADRs has to be reported. Interestingly another Malaysian study (Elkalmi et al., 2011) showed that a higher percentage (94%) of pharmacy students had a correct knowledge about the regulatory body MADRAC.

Pharmacy student's perception of pharmacovigilance and ADR reporting activities were explored by asking pharmacy students to

respond to 10 statements using a 5-point Likert scale

About 80.5% of the pharmacy students were in an agreement with the statement that pharmacovigilance should be included as a core topic in pharmacy education which designates their positive perception of the importance of pharmacovigilance. This finding is similar to the studies conducted by Elkalmi et al. (2011) and Sivadasan et al. (2014).

The study findings indicated that 71.2% of the pharmacy students believed that the topic of pharmacovigilance is well covered their pharmacy school curriculum. The finding is higher than when compared to the two Malaysian studies (Elkalmi et al., 2011; Sivadasan et al., 2014).This is the refection of the fact that comprehensive teaching of pharmacovigilance in the pharmacy curriculums.

About one third (39.8%) of the pharmacy students were in an agreement that they had knowledge on way of reporting ADRs to the regulatory authorities. The statement was significantly associated with the institution attended (p=0.025). This is the refection of the fact that pharmacy students were under taught on how to report ADRs to the relevant authorities even though the pharmacovigilance is taught to a certain extent in their pharmacy curricula. Findings of this study were consistent with the previous study reports (Elkalmi et al., 2011; Sivadasan et al., 2014; Sharma et al., 2012).Deficiency in knowledge and perception about pharmacovigilance and ADR reporting would lead to underreporting of ADRs (Lopez-Gonzalez et al., 2009)

Almost 65% of the pharmacy students agreed that they can perform ADR reporting during their clerkship/internship program. This shows the positive attitude of pharmacy students towards reporting of ADRs and was similar to the results reported in earlier studies (Elkalmi et al., 2011; Sharma et al., 2012).

The study findings indicated that less than half (48.3%) of the pharmacy students were in an agreement with their current knowledge they are very well prepared to report any ADRs that may be encountered in their future practice. The statement was significantly associated with the institution attended (p=0.021).The findings were inconsistent with results of the Malaysian study (Sivadasan et al., 2014). Pharmacists who receive more training and education on ADR reporting are more likely to report ADRs (Su et al.,2010).

About 80% of the pharmacy students agreed that pharmacist is one of the most important healthcare professionals to report adverse drug reactions. The statement was significantly associated with the institution attended (p=0.009).These findings are similar to the results of other previous studies (Elkalmi et al., 2011; Sivadasan et al., 2014).

About less than half (45%) of the pharmacy students agreed that serious and unexpected reactions that are not fatal or life-threatening during clinical trials must be reported. The statement was significantly associated with the institution attended (p=0.01).

**Limitations of the study:**

This study analyzed information only from pharmacy students of two colleges in Oman, hence results may not be generalizable to pharmacists across Oman. Further studies should be done across the nation to enhance the generalizability of the research

**Conclusion**

The observed results of the study revealed that knowledge of pharmacovigilance and ADR reporting for the pharmacy students of the University of Nizwa was less than for the pharmacy students of Oman medical college. A significant difference in the mean score of the knowledge in domains of study institution and nationality of the pharmacy students was observed. Pharmacy students lack in-depth understanding of concepts about ADR reporting and may require more information on the national pharmacovigilance program and reporting process of ADRs. The study indicated

a positive perception of pharmacy students towards pharmacovigilance and ADR reporting. The student's perception can be amplified by providing more workshops and hands-on training during their clinical placements or clerkship/internship programs. This will prepare them to play a vital role in ADR reporting in future practices and reduce the incidence of ADRs related to hospital admissions in Oman. Educational intervention should be done in order to increase the awareness of pharmacovigilance and ADR reporting process among pharmacy students. Moreover, there is a need for regular conduction of pharmacovigilance and ADR reporting workshops/ hands-on training during pharmacy students clinical placements or clerkship/internship programs.

## Conflict of interest

None to be declared

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