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Assessment of The Knowledge and Perceptions of Pharmacy Students Towards Pharmacovigilance and ADR Reporting

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ABSTRACT

AIM: The present cross-sectional questionnaire survey was conducted to assess the knowledge, and perception related to pharmacovigilance and ADR reporting among the B.pharm Final year students. **MATERIALS AND METHODS:** To assess the demographic details of the pharmacy students, their knowledge and perception toward pharmacovigilance and ADR reporting; a validated pre-tested questionnaire was used which comprises 11 knowledge-based closed-ended questions and 14 perceptions based agree/disagree questions. **RESULT:** The questionnaire was distributed to the 150 respondents of B. Pharm final year students who were willing to participate in the study. A response rate of 75% was recorded. The number of female respondents 53.3% was comparatively higher than the male respondents 46.6%. Most of the respondents were between 20 -22 years of age and only 4.7% were of 25 years of age. The average positive response for the knowledge-related statements was found to be 86.5% and the average positive response for the perception-related statements was found to be 70.67%. **CONCLUSION:** The findings showed adequate knowledge among pharmacy students and positive perception towards pharmacovigilance and ADRs reporting. This survey strongly suggests that there is a great need for increasing knowledge in clinical pharmacy courses and practical exposure to cases in the hospitals through internship programs which are meant to provide a unique opportunity for the pharmacy students that they must learn and practice the skills required for quality ADR reporting.

INTRODUCTION

Pharmacovigilance (PV) is an intrinsic part of the drug regulation system. PV plays a key role in the identification, assessment, and publicizing of adverse drug reactions (ADRs) through various methods. ADRs account for the serious effect on the patients and eventually lead to morbidity and mortality. The PV databases help in the promotion of the safe use of drugs and public health. [(1)]

An adverse drug reaction (ADR) as defined by WHO as a "response to a drug that is noxious and unintended and that occurs at doses in humans for prophylaxis, diagnosis, or therapy of disease and modification of physiologic function. [(2)] As per global statistics, the ADR reporting rates are the highest for the high-income countries and lowest for the low-income countries. According to the Centre for Health Policy Research, the number of approved drugs in the U.S. associated with adverse drug reactions that were undetected during trials is about 50%. It has been reported that ADRs can occur in about 10-20% of hospitalized patients, with their overall incidence being around 6.7% and that of fatal ADRs around 0.32%. They are the 4^{th} to 6^{th} largest cause of death in the U. S [(3)]. It has been estimated the incidence of suspected ADRs to be around 2% to 3% among the hospitalized patients in India. [(4)]. According to the center for disease control, about 40% of ambulatory ADRs are preventable and this is a huge concern worldwide. [(5)]

In India, the government had launched a national Pharmacovigilance program, called the Pharmacovigilance Program of India (PvPI) in 2010 to safeguard the health of the people of the country and ensure that the benefits of the medications consumed outweigh the risks. [(6)] India has almost 150 ADR monitoring centers (AMCs) in several medical colleges across the country. Indian Pharmacovigilance program is still in its early stages. The reporting rate of ADR in India is just about 1% compared to 5% worldwide. Despite the establishment of 150 AMC, the AMC functional rate is just around 56%. [(7)]

Adverse events reporting system is crucial for detection, processing, and reporting adverse drug & supplement associated events. The perspective of pharmacy students on adverse drug reaction reporting can have an impact on their attitude toward patient care and patient safety issues. Availability of a pharmacy student to facilitate reporting of ADRs may increase the frequency of ADR reporting and could decrease pharmacist workload, this activity is also a potentially valuable learning experience for students. [(8)]

Thus the present study was designed to assess the knowledge and perception of pharmacy students towards ADR reporting and Pharmacovigilance, as well as to lower the risk of ADRs by detecting and reporting suspected ADRs.This can help identify the present need for pharmacovigilance education and training, as well as the research needed to better understand pharmacy students' knowledge and perceptions of ADR reporting and pharmacovigilance.

MATERIALS AND METHODS

Study Design

The study was designed as a cross-sectional, observational, questionnaire-based survey.

Study Setting

A web-based survey using Google forms as a platform to create questionnaires comprised of 25 questions aimed at gathering information from Pharmacy students about Understanding the concept of Pharmacovigilance and ADR reporting. The survey link was disseminated through email and various Social Media Platforms. The participant's responses were secured using a "Cloud" database where the data was automatically sorted, organized, and analyzed.

Questionnaire Development

A validated pre-tested questionnaire was used to assess the knowledge and perception of pharmacy students. The questionnaire consisted of three sections; socio-demography, knowledge, and perception of Pharmacovigilance and ADR reporting. [9,10,11]

The following are the specifics of the questionnaire:

1. Socio-demography questions:

The first section consisted of 3 questions about participant's demographics and general information, such as age, gender, and current year of study.

2. Knowledge-related questions:

A total of eleven questions were designed to evaluate the participant's knowledge of pharmacovigilance and ADR reporting. It was measured using 11 Yes or No responses. Each correct answer received a weighted value of 1 and each incorrect answer received a score of 0. The 11-item survey had a maximum score of 11 points and a minimum score of 0.

3. Perception-related questions

A total of 14 Questions were designed to evaluate the participant's perceptions of Pharmacovigilance and ADR reporting was measured using questions such as the importance of ADR reporting, information needed for reporting, how-to and to whom ADRs, etc.

The questions were asked on a five-point Likert scale. The respondents' perceptions were analyzed using a five-level Likert scale (1=strongly agree, 2=agree, 3=neutral, 4=disagree, and 5=strongly disagree). This indicated whether they agreed or disagreed with statements about ADR monitoring and reporting, as well as pharmacovigilance. [9,10,11]

Study population

The study participants were a convenient sample of students studying final year B. Pharm.

Inclusion and Exclusion Criteria

The questionnaire was disseminated through email and various Social media platforms to pharmacy students. Students were briefed about the objectives of the survey utilizing an explanatory letter and also with a note for their informed consent which was attached to the survey questionnaire. Anonymity and confidentiality were ensured. It was the pharmacy student's decision either to participate or withdraw from the study. Those who were not willing to participate in the study were suggested not to respond to the email sent. Those who had registered their response were deemed to have voluntarily participated in the study.

Sample size

A total of 150 B. Pharm Final year students participated in the study.

Data collection and analysis

The questionnaire was distributed to all the subjects via email and was asked to register their responses in their free time.

The data on demographics, knowledge, and perceptions of pharmacy students' toward ADRs about Pharmacovigilance activities obtained from filled questionnaires were sorted and analyzed with the help of a Microsoft Excel Spreadsheet and appropriate descriptive analysis was done. Data were presented as a percent (%) of the respondents.[9,10,11]

RESULTS

1. Demographic detail of the Participants

The present study involved 150 pharmacy students who participated and responded. Demographic details of the participants involved in the study were categorized based on gender distribution, age, and educational qualification, the results of which were thoroughly analyzed and reported in Table No.1

Table No. 1: Demographic detail of the respondents

CATEGORY	SUBCATEGORY	FREQUENCY	PERCENTAGE
Gender	Male	70	46.6%
	Female	80	53.3%
Age	20-22	119	79.3%
	23-25	24	16%
	>25	7	4.7%
Pharmacy Course	BPharm4thyear	150	100%

2. ADR Reporting and Pharmacovigilance -Evaluation of Knowledge

The results for knowledge on pharmacovigilance and ADRs reporting based on questions are presented in Table No. 2.

Table No.2: Respondent's knowledge on ADR Reporting & Pharmacovigilance

S.NO	KNOWLEDGE RELATED QUESTIONS	PHARMACY STUDENTS	
		YES	NO
1.	Do you know what are adverse drug reactions	145(96.7%)	5(3.3%)
2.	Reporting ADR helps measure the incidence of ADR	136(90.7%)	14(9.3%)
3.	In India is there any Pharmacovigilance center	145(96.7%)	5(3.3%)
4.	Do you think Pharmacovigilance is also known as drug safety	142(94.7%)	8(5.3%)
5.	Do you know the different classifications of ADRs	136(90.7%)	14(9.3%)
6.	Type AADRs augmented and also predictable	131(87.3%)	19(12.7%)
7.	Do you think hypersensitivity reactions are related to ADRs	125(83.3%)	25(16.7%)
8.	Do you know the different types of hypersensitivity reactions	134(89.3%)	16(10.7%)
9.	Is there a difference between ADRs and the adverse event	124(82.7%)	26(17.3%)
10.	Have you ever seen an official standardized form for reporting adverse drug reaction	71(47.3%)	79(52. 7%)
11.	Do you know what is post-marketing surveillance	131(87.3%)	19(12.7%)

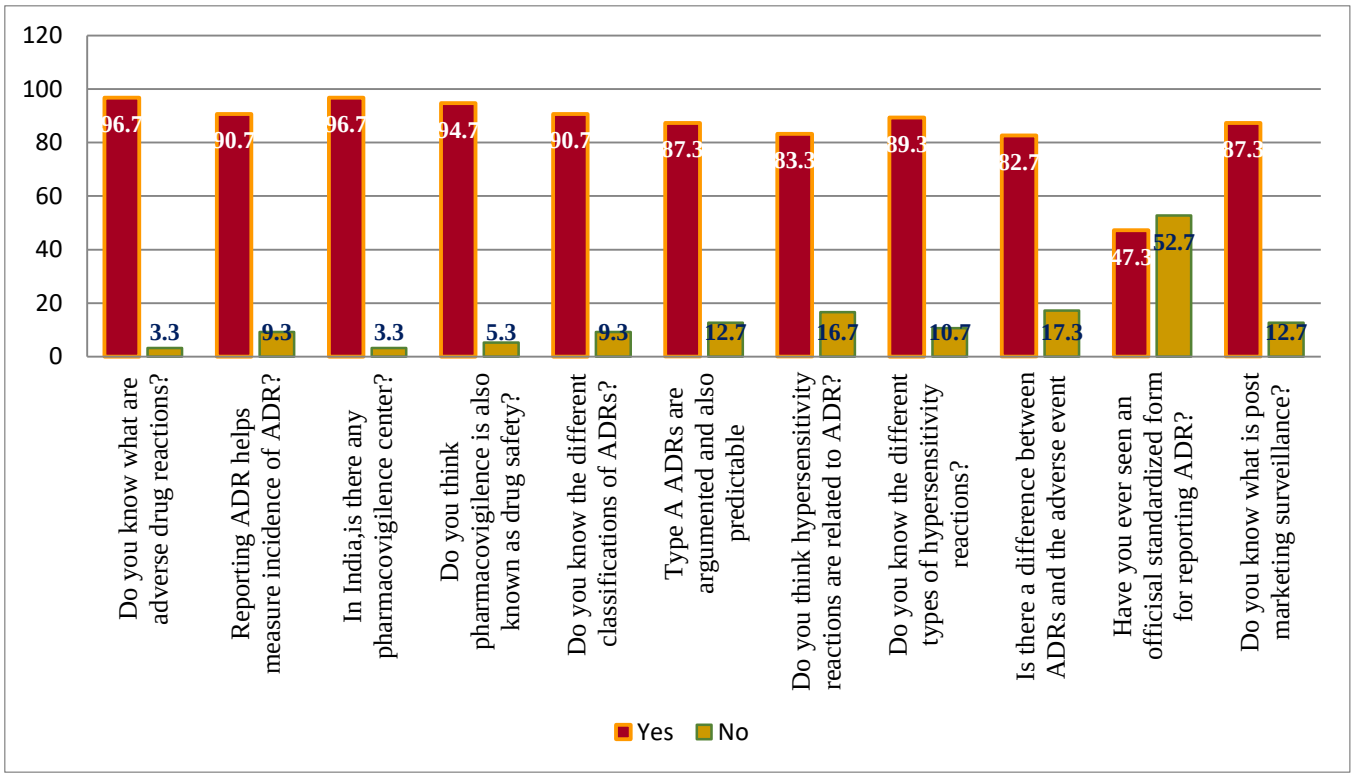

Figure No: 1 ADR Reporting and Pharmacovigilance -Evaluation of Knowledge

3. ADR reporting and Pharmacovigilance-Evaluation of Perception

All the values and percentages of positive and negative responses for the perception-based questionnaire, comprising of 14 questions were evaluated and tabulated in Table No.3. The data about perception revealed that there was a positive perception of respondents towards pharmacovigilance and ADRs reporting.

Table No.3: Respondent's perception on ADR Reporting & Pharmacovigilance

S.NO	PERCEPTION RELATED QUESTIONS	PHARMACY STUDENTS				
		STRONGLY AGREE	AGREE	NEUTRAL	DISAGREE	STRONGLY DISAGREE
1.	Do you think adverse drug reaction reporting is necessary	66(44%)	63(42%)	12(8%)	4(2.7%)	5(3.3%)
2.	Do you think reporting adverse drug reactions is a professional obligation	24(16%)	68(45.3%)	20(13.3%)	29(19.3%)	9(6%)
3.	Do you think ADR reporting should be made compulsory for health care professionals	72(48%)	57(38%)	14(9.3%)	3(2%)	4(2.7%)
4.	Does the topic of Pharmacovigilance is well covered in your curriculum	25(16.7%)	60(40%)	50(33.3%)	8(5.3%)	7(4.7%)
5.	Information on how to report ADRs should be taught to Pharmacy students	75(50%)	55(36.7%)	13(8.7%)	4(2.7%)	3(2%)
6.	With your present knowledge do you think you are very well prepared to report any ADRs Noticeable in your future practices	27(18%)	58(38.7%)	54(36%)	8(5.3%)	3(2%)
7.	Do you believe a pharmacist is one of the most important health care providers to Report adverse drug reactions	70(46.7%)	60(40%)	14(9.3%)	3(2%)	3(2%)
8.	Serious and unexpected reactions that are not fatal or life-threatening during clinical trials must not be reported	20(13.3%)	34(22.7%)	22(14.7%)	47(31.3%)	27(18%)
9.	Any ADR (Serious/NonSerious) should be reported spontaneously	57(38%)	71(47.35)	11(7.3%)	8(5.3%)	3(2%)
10.	Do you believe that adverse reactions caused by cosmetics should be reported	51(34%)	74(49.3%)	16(10.7%)	7(4.7%)	2(1.3%)
11.	Patients should be counseled about ADR every time their medications are dispensed	57(38%)	67(44.7%)	18(12%)	6(4%)	2(1.3%)
12.	Disclosure of identities of ADR reporters would increase reporting	25(16.7%)	60(40%)	39(26%)	19(12.7%)	7(4.7%)
13.	Do you believe that if the identities of ADR reporters are not disclosed reporting rate will decrease	18(12%)	50(33.3%)	52(34.7%)	20(13.3%)	10(6.7%)
14.	Will practice Pharmacovigilance if trained	52(34.7%)	68(45.3%)	18(12%)	8(5.3%)	4(2.7%)

DISCUSSION

This study evaluates the knowledge and perception of B. Pharm final year students towards pharmacovigilance and ADR reporting. In the present study, an overall response rate of 75%was recorded. From the results, it was observed that the knowledge and perception were better among pharmacy students and this is not surprising as pharmacy students are exposed to all basic aspects of PV in their syllabus.

The finding of this study revealed that the majority of the students had complete knowledge about what are adverse drug reactions (96.7%), reporting ADR helps measure the incidence of ADR (90.7%), Pharmacovigilance centers in India (93%), Pharmacovigilance is also known as drug safety(94.7%),different classifications of ADRs(90.7%), hypersensitivity reactions related to ADRs (89.3%), the difference between ADRs and adverse event (82.7%) and also aware of post-marketing surveillance (87.3%). On the other hand, about 52.7 % of students have not seen the official standardized form for reporting ADRs; this shows that there are no sufficient practical knowledge of ADRs reporting among pharmacy students.

The perception of pharmacy students towards Pharmacovigilance and ADR reporting for the 14 statements was 70.67%. Almost all the students (86%) believed all types of ADR should be reported. Nearly 58.6% of these students agreed that ADR reporting is a professional obligation for them. About 56.7% of students specified that the topic of pharmacovigilance is well covered in their curriculum and also they are very well prepared to report any noticeable ADR and it shows that they are well educated about ADR reporting.

The study showed that 86% of the total sample population was in agreement with the statements that ADR reporting should be made compulsory for health care professionals, information on how to report ADRs should be taught to the pharmacy students and they also agreed that pharmacist is one of the most important healthcare providers to report adverse drug reactions. About 56.6% 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. On the other hand, 49.3% 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 the majority of the students agreed to the statement that any ADR should be reported spontaneously (85.3%), adverse reactions caused by cosmetics should be reported (83.3%) and also patients should be counseled about ADR every time

their medications are dispensed (82.7%). About 56.7% of the students believed that disclosure of identities of ADR reporters would increase reporting.

The interesting finding of this study is that80% of the students are willing to practice pharmacovigilance if trained.

The findings of this study showed adequate knowledge among pharmacy students in the Telangana state and positive perception towards pharmacovigilance and ADRs reporting. This survey strongly suggests that there is a great need for increasing knowledge in clinical pharmacy courses and practical exposure to cases in the hospitals through internship program which is meant to offer a unique opportunity for the pharmacy students that they must utilize to understand and acquire the skills required for quality ADR reporting.

CONCLUSION

The results showed that respondents had adequate knowledge of pharmacovigilance and ADR reporting. However, pharmacy students may require more information on the national pharmacovigilance program and the ADR reporting process since they lack a complete understanding of concepts related to ADR reporting. The student's perception of ADR reporting can be increased by providing more workshops and hands-on training during their clinical placements. Educational interference should be done to increase the awareness of pharmacovigilance and the ADR reporting process among pharmacy students. It will allow the m to play an important role in ADR reporting in future practices.

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