

Evaluation of Knowledge, Attitude, Practice and Barriers of Pharmacovigilance and Adverse Drug Reaction Reporting Among Pharmacy Students

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ABSTRACT

Drug therapy is an essential part of medical treatment. It has a lot of merits, but it also has a lot of demerits, such as adverse drug reaction (ADR). Adverse Drug Reaction are the major cause of drug related morbidity and mortality. Pharmacovigilance is the science that plays essential role in detection, assessment, understanding and prevention of adverse drug reaction. In India, the government launched Pharmacovigilance programme of India in 14th July 2010. The present study aimed to evaluate knowledge, attitude, practice and barriers of Pharmacovigilance and adverse drug reaction reporting. The cross-sectional, questionnaire based survey was conducted among the pharmacy students. The questionnaire consist of five sections: demographic, attitude, practice, barriers towards Pharmacovigilance and ADR reporting. There are 150 responses are collected.

RESULT: In our study, out of 150 respondents 49% were male and 51% were female pharmacy students. Of all pharmacy students answering the questionnaire [B.Pharm (44%), D.Pharm(27%), M.Pharm(21%) and Pharm.D (21%)] . We observed most of the students had a good knowledge level (66.6%), positive attitudes (79.46%) and good practice level (57.7%).

CONCLUSION: This study showed that pharmacy students had more awareness of ADR reporting due to pharmacovigilance courses in their curriculum. Periodic educational interventions can improve these parameter of pharmacovigilance. This study will bring awareness among the students towards pharmacovigilance and ADR reporting.

KEYWORDS: Adverse Drug Reaction, Attitude, Barriers, Knowledge, Practice, Pharmacovigilance, Pharmacy students.

I. INTRODUCTION:

Everyday a large number of drugs are introduced onto the market around the world; nevertheless, due to a lack of understanding, the safety of medicines remains a key worry for many population groups. Adverse Drug Reactions (ADRs) are one of the major problems associated with medicine^[1]. The World Health Organization (WHO) defined ADR as any response to a drug that is noxious and unintended that occurs at doses used in humans for prophylaxis, diagnosis or therapy, excluding failure to accomplish the intended purpose^[2]. ADRs are responsible for a significant number hospital admissions ranging from 0.3% to 11%^[3]. Pharmacovigilance is a part of patient care and patient safety that ensure the best use of medicines for the treatment or prevention of adverse drug reaction^[4]. According to World Health Organization (WHO) Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or other drug related problems^[5,6]. The most extensively utilized and cost effective surveillance strategy for ADRs is spontaneous (yellow card) reporting which is cornerstone of drug safety is monitoring in clinical practice. It detects previously unrecognized adverse reactions and identifies risk factors that pre-dispose to drug toxicity and investigates causality^[7,9]. According to ICH GCP, an adverse event (AE) is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a casual relationship with this treatment^[8]. However, education and training are important in maintaining and increasing ADR reporting by pharmacist's. Intrinsic factors such as knowledge, attitude, practice and barriers can help in understanding the relationship of pharmacist's with patients and other healthcare

professionals and formulating strategy to encourage pharmacist's to report ADRs^[10,11]. The National pharmacovigilance programme was launched by the Ministry of Health and Family Welfare in 14th July 2010, primarily overseen by CDSCO, New Delhi . Indian Pharmacopoeia Commission (IPC) under the MoHFW has been functioning as the NCC for PvPI since April 2011. Currently 179 Medical Council of India approved teaching hospitals and corporate hospitals have been identified as ADR Monitoring Centre across the country.

The National Coordination Centre will conduct causality assessment and upload the reports into pharmacovigilance software. Lastly, the integrated ADR data will be transmitted through vigiflow software interface into the Uppsala Monitoring Centre's ADR database where signal processing will be carried out^[12,13].

II. MATERIALS AND METHODS

The cross-sectional questionnaire based survey was conducted among the pharmacy students. The questionnaire consist five section : demographic, knowledge, attitude, practice and barriers towards Pharmacovigilance and ADR reporting. The questionnaire consisted of questions include in previous studies that examined the knowledge ,attitude ,practice and barriers of pharmacy students. The questionnaire was comprised 42 questions. The questions were distributed as follows: 12 questions were related to knowledge,10 questions related to attitude ,12 questions were related to practice and 8 questions were related to barriers. Four questions were included at the beginning of the survey to collect demographic data like age, gender, course of study (B.pharm, D.pharm, Pharm.D). The pretested questionnaire was made available to the pharmacy students (n=150) at their colleges. The response to the questionnaire were

analyzed by performing descriptive statistics. The study was conducted over a period of 3 months from September 2023 to November 2023. The responses to the questionnaire were analyzed by performing descriptive analysis.

III. RESULTS

In our study, out of 150 respondents 49% were male and 51% were females pharmacy students. Of all pharmacy students answering the questionnaire , 44% were B.Pharm students, 27% were D.Pharm students, 21% were Pharm.D students and 8% were M.Pharm students. The average age of all responding pharmacy students 24.44% years. There are listed in Table-1

There were 12 questions assessing knowledge of the pharmacists about ADR reporting and Pharmacovigilance. Among the 150 respondents , 78.6% (n=118) respondents were aware of the term of Pharmacovigilance. Then, 64.6% (n=97) were aware of the term of ADR, 70.6% (n=106) respondents knew an International Centre for adverse effect reaction monitoring is located. 50.6% (n=76) of respondents knew major risk factors for occurrence of maximum ADRs and 57.3% (n=86) knew that where a serious averse event should be reported in India.

Also 71.3% (n=107) of respondents knew the correct way of ADR classification. 62.6% (n=94) of respondents knew the WHO online database for reporting ADRs and 78% (n=117) of respondents knew that which of the sources do you gather information about ADR. 69.3% (n=104) knew healthcare worker's role and 70% (n=105) of respondents knew that which ADRs must be reported. 66.6% (n=100) of respondents knew who can report an ADR in India. 60.6% (n=91) of respondents knew the helpline for ADR reporting. The responses are listed in Table-2.

Table-1:Demographic profile of sample(n=150)

DEMOGRAPHIC FACTORS	CATEGORIES	TOTAL (n=150) (%)
Age	18-20	65(43.2%)
	21-25	80(53.3%)
	26-30	3(2.0%)
	31-35	1(0.6%)
	36-40	1(0.6%)
Gender	Male	73(48.6%)
	Female	77(51.3%)
Course of study	B.Pharm	66(44.0%)
	D.Pharm	41(27.3%)
	M.Pharm	11(7.3%)
	Pharm.D	32(21.3%)

There were 10 questions related to the attitudes of pharmacy students towards the ADR reporting and Pharmacovigilance. In general, the respondents had a good attitude towards the ADR reporting and Pharmacovigilance. The details regarding the responses of pharmacy students about their attitude towards Pharmacovigilance and ADR reporting are listed in Table -3.

There were 12 Pharmacovigilance and ADR practice related questions. It was found that the respondents (n=67;44.6%) had ever reported any suspected ADR and the respondents (n=61;40.6%) also received training on ADR reporting. The respondents (n=80;53.3%) had adverse reporting form available your practice /training hospitals.

Table-2 : Responses of knowledge related questions

KNOWLEDGE QUERY (n=150)	CORRECT RESPONSE n(%)	INCORRECT RESPONSE n(%)
1. Define Pharmacovigilance?	118(78.6%)	32(21.4%)
2. Define ADR?	97(64.6%)	53(35.4%)
3. Where an International Centre for adverse effect reaction monitoring is located?	106(70.6%)	44(29.4%)
4. Which of the following is a major risk factor for the occurrence of maximum adverse drug reaction ?	76(50.6%)	74(49.4%)
5. In case a serious adverse event in India is observed where it should be reported?	86(57.3%)	64(42.6%)
6. Which is the correct way for ADR classification?	107(71.3%)	43(28.6%)
7. Which one of the following is the WHO online database for reporting ADRs?	94(62.6%)	56(37.4%)
8. From which of the sources do you gather information about ADR?	117(78.0%)	33(22.0%)
9. Health care worker's role?	104(69.3%)	46(30.6%)
10. Which ADRs must be reported?	105(70.0%)	45(30.0%)
11. Who can report an ADR in India?	100(66.6%)	50(33.4%)
12. What is the helpline for ADR reporting?	91(60.6%)	59(39.4%)

It was found that nearly half the respondents (n=72;48.0%) had filled out an ADR reporting form and the respondents (n=78;52.0%) attended the Pharmacovigilance awareness programme. Only 64% (n=96) respondents read an article about how to avoid ADR and 49.3% (n= 74) respondents maintained record of ADR. 76.6% (n=115) respondents advise the patients to read the drug leaflets every time. Then, 72.6% (n=109) respondents

were aware of any formal reporting system available in our country and 76.0% (n=114) of respondents were aware of any banned drugs due to the adverse drug reaction. Out of the 150 respondents, 72.6% (n=109) had shared information about ADR with anyone and 73.3% (n=110) respondents knew the difference between adverse drug reaction and adverse events. The details about the responses of pharmacy students are listed in Table-4.

Table-3 : Responses of attitude related questions

ATTITUDE QUERY(n=150)	STRONGLY AGREE	AGREE	STRONGLY DISAGREE	DISAGREE
1.Side effects like headache, fever, and vomiting should not be reported?	17(11.3%)	75(50.0%)	12(8.0%)	46(30.6%)
2.Is ADR reporting a mandatory process?	34(22.6%)	86(57.3%)	10(6.6%)	20(13.3%)
3.Whether ADR reporting increases patient safety?	51(34.0%)	58(38.6%)	12(8.0%)	29(19.3%)
4.Is ADR reporting time - consuming process?	27(18.0%)	100(66.6%)	11(7.3%)	12(8.0%)
5.I believe that the topic of PV is well covered in curriculum?	22(14.6%)	107(71.3%)	11(7.3%)	10(6.6%)
6.Do you know pharmacy students could help with ADR reporting?	39(26.0%)	92(61.3%)	14(9.3%)	5(3.3%)
7.Do you believe that new drugs should be closely monitored?	49(32.6%)	76(50.6%)	11(7.3%)	14(9.3%)
8.Do you think that ADR can even result in death?	33(22.0%)	67(44.6%)	6(4.0%)	44(29.3%)
9.I believe that I have acquired enough knowledge to enable me to report ADRs ?	22(14.6%)	106(70.6%)	6(4.0%)	16(10.6%)
10.A pharmacist is one of the important health care professional to report ADR?	54(36.0%)	78(52.0%)	10(6.6%)	8(5.3%)

Table -4 : Responses of practice related questions

PRACTICE QUERY (n=150)	YES	NO
1.Have you ever reported any suspected ADR?	67(44.6%)	83(55.3%)
2.Have you received training on ADR reporting?	61(40.6%)	89(59.3%)
3.Do you have the adverse reporting form available in your practicing /training hospital?	80(53.3%)	70(46.6%)
4.Have you filled out an ADR reporting form?	72(48.0%)	78(52.0%)
5.Have you attended any Pharmacovigilance awareness programme ?	78(52.0%)	72(48.0%)
6.Have you ever read an article about how to avoid ADR?	96(64.0%)	54(36.0%)
7.Do you maintain record of ADR?	74(49.3%)	76(50.6%)
8.Advise the patients to read the drug leaflets every time?	115(76.6%)	35(23.3%)
9.Are you aware of any formal reporting system available in our country?	109(72.6%)	41(27.3%)
10.Are you aware of any banned drugs due to adverse drug reaction ?	114(76.0%)	36(24.0%)
11.Have you ever shared information about ADR with anyone?	109(72.6%)	41(27.3%)
12.Do you know the difference between adverse drug reaction and adverse drug events?	110(73.3%)	40(26.6%)

There were 8 Pharmacovigilance and ADR reporting questions related to the barriers. Only 32.0% (n=48) respondents stated that unavailability of ADR reporting forms in health care setting and 57.3% (n=86) reported that lack of training and educational support. The 68%(n=102) respondents stated that inadequate knowledge of pharmacotherapy in detecting ADR and 52% (n=78) respondents mentioned that more time consuming . 54% (n=81)

of respondents stated that no idea to how to report ADR and only 24.6% (n=37) or respondents thinking that ADR reporting is not a duty.

Then 42.6% (n=64) of respondents stated that other coworkers are not reporting ADR cases and 48% (n=72) mentioned that forgetfulness is a barrier. The details about the responses of pharmacy students are listed in Table-5.

Table-5 : Responses of barriers related questions

BARRIERS QUERY (n=150)	YES	NO	DON'T KNOW
1.Unavailability of ADR reporting forms in health care setting.	48(32.0%)	59(39.3%)	43(28.6%)
2.Lack of training/educational support.	86(57.3%)	34(22.6%)	30(20.0%)
3.Inadequate knowledge of pharmacotherapy in detecting ADR.	102(68.0%)	34(22.6%)	14(9.3%)
4.More time consuming.	78(52.0%)	37(24.6%)	35(23.3%)
5.No idea how to report ADR.	81(54.0%)	46(30.6%)	23(15.3%)
Thinking that ADR reporting is not a duty.	37(24.6%)	84(56.0%)	29(19.3%)
7.Other coworkers are not reporting ADR cases.	64(42.6%)	49(32.6%)	37(24.6%)
8.Forgetfulness is a barrier.	72(48.0%)	47(31.3%)	31(20.6%)

IV. DISCUSSION

The present study was a questionnaire based study which included the pharmacy students about Pharmacovigilance and Adverse drug reaction. Pharmacovigilance deals with detection, assessment, understanding and prevention of adverse effects or any other drug related problems. The ultimate aim of Pharmacovigilance is to ensure patient safety and rational use of medicines once a new medicine is released for general use in the society. The most notable outcome of Pharmacovigilance is the prevention of patients being affected unnecessarily due to the negative consequences of pharmacotherapy. ADRs are a serious public health issue that result in higher mortality , morbidity and expenses as well as more hospital admissions and duration of stay. Spontaneous reporting program operate on the basis that all ADRs should be reported despite uncertainty about a casual relationship^[14]. This study shows that undergraduate pharmacy students as B.Pharm(44%), D.Pharm(27%) and post graduate students as M.Pharm(8%) and Pharm.D(21%). Increasing the ADR reporting is through the promotion of patient

self reporting. From our study, we observed most of the respondents had a good knowledge level (66.6%) and a considerable proportion had a poor knowledge level(33.3%). In the terms of attitudes and practices, only 79.46% and 57.7% had positive attitudes and practice respectively, while 20.6% and 42.2% had negative attitudes and practices.

V. CONCLUSION

This study showed that pharmacy students had more awareness of ADR reporting due to Pharmacovigilance courses in their curriculum. Hence, it is necessary to include Pharmacovigilance and ADR reporting in other healthcare curriculum to reduce ADR under reporting in the future. Periodic educational interventions can improve these parameter of Pharmacovigilance. In our study most of the students have correct answer of knowledge related questions. The study will bring awareness among the students towards Pharmacovigilance and ADR reporting.

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Conflict of interest:

There were no conflicts of interest to declare.

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