

ORIGINAL RESEARCH ARTICLE

EDUCATIONAL INTERVENTION TO IMPROVE THE KNOWLEDGE, ATTITUDE, PRACTICES OF HEALTH CARE PROFESSIONALS AND STUDENTS REGARDING THE PHARMACOVIGILANCE IN TERTIARY CARE HOSPITALS

ABSTRACT:

INTRODUCTION: Adverse drug reactions any noxious, unintended, and undesired effect of a drug, which occurs at the doses which are used in humans for prophylaxis, diagnosis, or therapy, which is reported by “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem” known as Pharmacovigilance. Adverse drug reactions are significantly underreported worldwide. A KAP survey usually conducted to collect information on the knowledge, attitudes, and practices about general and/or specific topics of a particular population

AIM AND OBJECTIVES: To evaluate the KAP studies on the educational intervention to improve the knowledge, attitude, practice of health care professionals and students regarding the pharmacovigilance in tertiary care hospitals. To evaluate, assess and evaluate the measures the knowledge, attitude and practice of Pharmacovigilance among students and Health Care Professionals in tertiary care hospital of India.

METHODS: Pharmacists and Health Care Professionals were asked to complete a paper-based 21 item questionnaire.

RESULTS: A total of 250 participants were received the questionnaire and 214 agreed to participate, giving a response rate of 85.6%. In knowledge, component of Adverse drug reactions were known by 71.2% and the term Pharmacovigilance and Adverse drug reaction were answered correctly (97.3%). In practice 55.9% were

attended the **Pharmacovigilance** workshop and 88.8% were willing to implement **Adverse drug reaction** reporting in practice.

CONCLUSION: Most of the participants were relatively better knowledge and practice towards Pharmacovigilance and Adverse drug reactions reporting. Majority of the **health care professional** felt Adverse drug reactions reporting to be important. In our study also shows, after counseling to them we got better response and results than before. The finding of our study suggests that there is scope for improving the ongoing **Pharmacovigilance** activities in India. There is a need for continuing educational initiatives for pharmacist and other **health care professionals**.

Key words: Pharmacovigilance, Adverse drug reactions reporting, KAP, Health Care Professionals.

INTRODUCTION:

WHO defines ADR as any response to a drug which is noxious, unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function.¹ Most cases of morbidity and mortality in people are due to ADRs. In the year 1994, cost of treatment to ADRs was 4billion dollars. In the year 1989 number of deaths was 12000 due to ADRs, it was reported by FDA.² Drugs are taken by patients to treat symptoms of diseases or disorders and to improve healthcare quality of life, but these drugs have some hazards. Pharmacists are mostly involved to prevent these hazards due to drugs by actively involved in ADRs reporting and pharmacovigilance related activities.³ Pharmacovigilance (PV) as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem”.⁴ PV aims at enhancing patient safety by assessing the risk-benefit profile of medicines. In United States of America ADRs is the sixth

leading cause of death. In United Kingdom 6.5% hospital admissions are due to ADRs and in France 3.2%, Sweden 12% hospital admissions occurs. In south India region overall incidence of ADRs was 9.8%.⁵ WHO establish pharmacovigilance throughout the country. National pharmacovigilance centre is established by Saudi food and drug authority in Saudi to report Saudi ADRs internationally by associated with WHO Uppsala monitoring centre, Sweden. Saudi Arabia hospitals developed medication safety units to improve ADR reporting, it is present under division of pharmaceutical care services.⁶

In Nepal, national medicine regulatory authority is Department of Drug Administration. DDA is a national pharmacovigilance centre in Nepal. This was appointed by Nepal government to liaise with the WHO program for International Drug Monitoring. In the past 16 years DDAs submit 547 ADR reports. By conducting educational studies about pharmacovigilance in Nepal, to report that those healthcare professions in Nepal have a lack of knowledge about pharmacovigilance. After educational intervention about PV in healthcare professionals have lead to improve knowledge on pharmacovigilance.⁷ In Nepal, pharmacovigilance programme was started in 2004. Over the period of four and a half year national centre in Nepal receives more than 300 ADR reports. Actually nurse is responsible to observe the patient in hospital and also teach the patient and report sign and symptoms that occur immediately and after next visit.⁸

Biggest problem in world is underreporting of ADRs. Systematic review involved in analysis of causes of under reporting, which was published in 2006. Pharmacist role in reduce the risk of ADRs include promotion, development, maintenance and educate physicians, nurses and encourage compliance of ADR reporting programme. In the year 2007, Nepal to be a member of international

pharmacovigilance programme. National pharmacovigilance centre is responsible for encouraging of ADR reporting in healthcare professionals. According to DDA statistics at the end of 2013, only 523 ADRs were reported.⁷ Healthcare students are educated in the school of medicine, pharmacy, dentistry or nursing and also promote in clinical practice to take responsibilities of prescribing, administration and monitoring of medication. It is essential to ensure the safe use of medications.⁹

The estimated annual burden due to ADR in USA was 30-130 billion US dollars. The pharmaceutical products safety became most important by improving its efficacy after thalidomide disaster. In 196 for international drug monitoring globalisation of PV studies was initiated by WHO through establishment of WHO programme.¹⁰ Low number of healthcare professionals in Nepal ,those only 731 licensed pharmacists leads to increased burden that cause difficulty in spending time for ADR reporting . It is an important reason for underreporting in healthcare professionals in Nepal.¹¹

AIM:

To evaluate the KAP studies on the educational intervention to improve the knowledge, attitude, practice of health care professionals and students regarding the pharmacovigilance in tertiary care hospitals.

The key objectives of the study include:

- To evaluate the knowledge, attitude and practice of PV among pharmacy students and Health Care Professionals in tertiary care hospital of India.
- To suggest the measures to improve the KAP of pharmacovigilance among health care professionals students.

- To assess knowledge, attitude, perception/practices (KAP) of pharmacy students and Health Care Professionals toward ADR reporting.

MATERIALS AND METHOD

STUDY DESIGN:

It is a prospective, observational study

Study was conducted from December 2020 –May 2021.

SAMPLE SIZE:

A total of 214 samples were collected.

INCLUSION CRITERIA:

1. Students and health care professional willing to give written informed consent
2. Pharmacists who were co-operative and interested to give the consent for the study
3. Study population consisting of healthcare students (medical, pharmacy, and nursing) at any stage of their post graduate training.
4. Study population consisting of health care professional and post graduate student.

Exclusion criteria:

1. Pharmacists who were busy and not interested to participate in the study.
2. Those who returned the questionnaire unanswered.
3. Study population consist of non medical students.

METHOD OF COLLECTION OF DATA:

1. Data collection would be done by using the following documents.
2. Self designed, structured and validated questionnaire forms were prepared to collect data.

ANNEXURE-I (Participants demographic details).

ANNEXURE-II (Questionnaire form).

SCORING AND EVALUATION: Self prepared, structured and validated questionnaire were prepared to assess the knowledge, attitude and practice.

Those members who were low and medium scored participants were separated and sent leaflet to them for updating of knowledge about pharmacovigilance.

KNOWLEDGE AND PRACTICE:

Each domain consists of 7 questions were scoring will be given as below:

- A score will be allotted for knowledge, each correct answer (“yes” for positive & “no” for negative statements) was given 1 point.
- Incorrect answer (“no” for positive and “yes” for negative statements) was given 0 point.
- The level of knowledge and practice was categorised.
 - As “low” (≤ 7 points)
 - “Average” (8-10 points)
 - “High” (>11 points)

ATTITUDE:

In order to evaluate attitude “Likert scale” is used:

The level of concern was categorised as

- “Extremely concerned” (if agreement was marked for all 6 - 7 statements)
- “Quite concerned”(if agreement was shown for 3-5 statements)
- “Little concerned”(if agreement as marked for 1-2 statements)
- “Not concerned”(no agreement).

STATISTICAL ANALYSIS:

1. Microsoft excel was used for recording the data of recruited subjects. All the graphs and tables were created using Microsoft excel.

2. We used descriptive statistics like mean, median, standard deviation was used to assess demographic characteristics features of subjects included in the study.

RESULT:

GENDER WISE DISTRIBUTION:

A total of 214 participants were include in the study, the number of female were more actively involved in research work. Female (135) were majorly occupiees the study when compare to males (79) as represented in table.1

Table .1 Categorization of Percentage distribution based on gender

S.NO.	GENDER	NO.OFSTUDENTS	PERCENTAGE
1.	Male	79	37%
2.	Female	135	63%
3.	Total	214	100%

Designation wise distribution:

Students were actively participated in the study followed by pharmacist. Among Nurses and Physicians, most of the nurses were not aware about Pharmacovigilance, physicians were not responded well due to their busy schedule, lack of time, lack of interest.

Table .2 Categorization Percentage distribution Based on Designation

S.NO.	DESIGNATION	NO.OF PARTICIPANTS	PERCENTAGE
1.	Physicians	25	12%
2.	Pharmacist	64	30%
3.	Nurses	30	14%

4.	Students	95	44%
5.	Total	214	100%

In this research study entire 214 study participants were recruited based on designation i.e., Physicians, Nurses, pharmacists, students as represented in Table.2

Responses of KAP before and after counseling:

Before and after counseling the participants were got the responses (marks) were knowledge, attitude and practice were show in the table.3

Counseling was given to the participants who got less than 10 points. Participants who were involved in the study got the information leaflet to their email ID and we recollect the data from participants who got less than 10 points. Counseling were done through online because of Covid-19 situation.

After the re-collecting of responses most of the participants were improved their knowledge about PV and ADR reporting. When compare to before, after counseling the participants were more aware about the PV.

Table .3 Comparison of Responses of knowledge and practice before and after counseling

	Before counseling		After counseling	
	Knowledge	Practice	knowledge	Practice
Poor	13 samples	9 samples	2 samples	1 sample
Average	67 samples	117samples	9 samples	29 samples
Excellent	134 samples	88 samples	80 samples	61 samples

Response of attitude before counseling (214 samples) and after counseling (91 samples: The participants who got low score less than 10, they only got counsel) as show in Table.4.

Table .4 Comparison of Responses of attitude before and after

S.NO	RANGE	BEFORE COUNSELING	AFTER COUNSELING
1.	Extremely concerned	23	20
2.	Quite concerned	119	14
3.	Little concerned	55	10
4.	Not concerned	17	47
5.	Total	214 samples	91 samples

DISCUSSION:

This study evaluated the effect of an educational intervention and reminders in improving the KAP of HCPs and student in tertiary care hospital towards PV and ARD reporting. Most of the participants were well about knowledge and positive activity towards practice. But few more peoples were not well towards attitude. A study KAP of pharmacovigilance and ADR reporting among pharmacist working in secondary and tertiary governmental hospital in Kuwait which is closely related to our study. In our study, questioner forms were used in three categories such as knowledge, attitude and practice. In each category had 7 questions, totally 21 questions. Most of the participants were not interest in filling forms if it had more than 20 questions, most of them loss their interest towards filling forms. Our study was helps to evaluate, assess, and measure to improve the knowledge, attitude, practice of PV among health care professionals. The major reason of under reporting of ADRs are lack of knowledge about the reporting procedure, unavailability of the

reporting centre mail address, unavailability of ADR form, lack of knowledge of the existences of a national ADR reporting system.

The definition of term PV and ADR most of the participants were answered correctly with 97.3%. Very few members were not known about the term PV and ADR. 89.2 % and 76.3% participants were aware about the PV programme and aware about the national PV center in India respectively. 88.8% were know the difference between the ADR and ADE , 83.7 % were know the causality assessment of ADR .71.2 % were know the components of PV and remaining 28.8% were don't know about the components . Only 78 % participants were knowing where to obtain the ADR forms.

Among that 63.7% were feel that ADR reporting can benefits to public health. Here 31.6% were strongly agreed and 43.1 % agree for barriers for reporting ADR. 27.8% were disagree the only serious ADR that results in life threatening conditions should be reported. 38.3% were agree that hypersensitivity were related to ADR., 48.1% strongly agree the reporting ADR were a pharmacist duty.59.3% strongly agree the ADR reporting is benefit to both patients and doctors .29.2% were disagree that ADR reporting can create additional work load ,only 16.6% were strongly agree.

During ward rounds 82.4 % were seen the patient suffered with ADR after taking drug. 59 % were prevented the ADR from occurring , 65.8 % and 76.3 % were keep the records of ADR and had the idea of improving ADR reporting respectively . 88.8% were willing to implement ADR in practice, 88.8% were reported that ADR reporting was mandatory in practice. Nearly 44.1% were not attended any workshop on PV.

Physicians were less involved in our study when compare to other other HCPs. Some barriers were a raised during our study, those were lack of time, lack of interest, busy schedule, don't know how to fill the form, lack of motivations. Measure to improve knowledge about KAP were Attending workshops, continue education on PV and ADR reporting, Awareness program on PV. The current study showed female was higher in participation than males. These finding were similar to the study conducted by Sunil Shrestha et al.,⁷ in 2020 in Nepal. Majority of participants were felt that the ADR reporting should be compulsory which is matched with the study of Hardeep et al., in 2013 in northern India.² Eighty three percent participants did not know about how causality assessment of ADRs is done. This finding is similar to the study conducted by Gamil qasem Othman et al., in 2017 in Sana'a Yemen.⁴

The study reveals that male participants were low knowledge of ADR reporting and PV than their female, the finding is similar to the study of Kanayo P. Osemene et al., in 2017¹³. About 36% of the respondents were not aware of the existence of the national reporting system which is similar to Palaian Set al., in 2011 in Nepal. Most participants were correctly identified definitions of PV and ADRs which is similar in the study of F.M. Alsaleh et al., 2017 in Kuwait¹⁴. In this study, 63% of the study participants were females and 37% were males which are similar in the study of kumar G Chhabra et al., 2017 in India.¹⁵ The least knowledge of pharmacovigilance and ADRs was found in nurses which is similar to the study of Tadvi, et al. In 2018. ¹⁶

LIMITATIONS:

The main limitation of our study was the relatively small number of responders, especially physicians.

CONCLUSION:

Most of the participants were relatively better knowledge and practice towards PV and ADR reporting. Knowledge and practice scores were higher among physicians and pharmacist followed by students. Majority of the health care professional felt ADR reporting to be important. Most of them were interested in ADR reporting. In our study also shows, after counseling to them we got better response and results than before. The finding of our study suggests that there is scope for improving the ongoing Pharmacovigilance activities in India. There is a need for continuing educational initiatives, workshops, awareness programme for pharmacist and other health care professionals.

This study was aimed to assess the level of knowledge, Attitude and practice of the health care professionals and pharmacy students about pharmacovigilance activities and ADRs reporting in tertiary health care hospital.

Table of content:

S.No	Abbreviation	Full form
1	ADR	Adverse Drug Reactions
2	DDA	Department of Drug Administration
3	PV	Pharmacovigilance
4	FDA	Food and Drug Administration
5	KAP	Knowledge, Attitude And Practice
6	HCP	Health Care Professionals
7	WHO	World Health Organisation
8	ADE	Adverse Drug Events

REFERENCE:

1. The World Health Organisation. International drug monitoring: the role of national centres. Report of a WHO Meeting. Geneva:1972.[Pubmed]
2. Hardeep, Jagminder Kaur Bajaj, Rakesh Kumar , A Survey on the Knowledge, Attitude and the Practice of Pharmacovigilance Among the Health Care Professionals in a Teaching Hospital in Northern India, Journal of Clinical and Diagnostic Research. 2013 January, Vol-7(1): 97-99
3. The World Health Organisation. Pharmacovigilance. [Accessed February 15,2017]. Available from https://www.who.int/medicines/areas/quality_safety/safety_efficacy/S.AfricaDraftGuidelines.pdf.
4. Gamil Qasem Othman, Mohamed Izham Mohamed Ibrahim, Mohammed Alshakka, Mukhtar Ansari, Farouk Al-Qadasi, Abdulsalam M. Halboup, Knowledge and Perception about Pharmacovigilance among Pharmacy Students of Universities in Sana'a Yemen: journal of Clinical and Diagnostic Research. 2017 Jun, Vol-11(6): FC09-FC13
5. Fatemah M. Alsaleh , Sherifah W. Alzaid , Eman A. Abahussain , Tania Bayoud , Jacinthe Lemay, Knowledge, attitude and practices of pharmacovigilance and adverse drug reaction reporting among pharmacists working in secondary and tertiary governmental hospitals in Kuwait: Saudi Pharmaceutical Journal 25 (2017) 830–837
6. Asmatanzeem Bepari, Rasha Assad Assiri , Maya Abdullah AlYahya , Shaden Jamaan AlGhamdi, Amal Mohammed AlGhamdi, Afrah Asaad AlOnazi, The comparative assessment of awareness, perspective, and basic practice skills about the Saudi pharmacovigilance system among students of different

health-care professionals of a Saudi Female University: Saudi Pharmaceutical Journal 28 (2020) 828–836

7. Sunil Shrestha, Sabina Sharma, Ramesh Bhasima, Puskar Kunwor, Baburam Adhikari and Binaya Sapkota, Impact of an educational intervention on pharmacovigilance knowledge and attitudes among health professionals in a Nepal cancer hospital: BMC Medical Education (2020) 20:179
8. Palaian S, Ibrahim MI, Mishra P. Health professionals' knowledge, attitude and practices towards pharmacovigilance in Nepal. Pharmacy Practice (Internet) 2011 Oct-Dec;9(4):228-235.
9. Nisha Jha, Devendra Singh Rathore, P Ravi Shankar, Sudesh Gyawali, Mohamed Alshakka, Shital Bhandary ,An educational intervention's effect on healthcare professionals' attitudes towards pharmacovigilance : AMJ 2014;7(12):478–489
10. Monira AlwhaibiID, Noha A. Al Alooda ,Healthcare students' knowledge, attitude and perception of pharmacovigilance: A systematic review : may 20 2020
11. Muberra Devrim Guner, and Perihan Elif Ekmekci, Healthcare professionals' pharmacovigilance knowledge and adverse drug reaction reporting behavior and factors determining the reporting rates : JOURNAL OF DRUG ASSESSMENT 2019, VOL. 8, NO. 1, 13–20
12. Nisha Jha, Devendra Singh Rathore, Pathiyil Ravi Shankar, Shital Bhandary , Rabi Bushan Pandit , Sudesh Gyawali and Mohamed Alshakka ,Effect of an educational intervention on knowledge and attitude regarding pharmacovigilance and consumer pharmacovigilance

among community pharmacists in Lalitpur district, Nepal :BMC Res Notes (2017) 10:4

13. Kanayo P. Osemene and Margaret. O. Afolabi ,An evaluation of the knowledge and perceptions of pharmacy students on pharmacovigilance activities in Nigeria : Osemene and Afolabi BMC Res Notes (2017) 10:273
14. F.M. Alsaleh , J. Lemay , R.R. Al Dhafeeri , S. AlAjmi , E.A. Abahussain , T. Bayoud ,Adverse drug reaction reporting among physicians working in private and government hospitals in Kuwait: Saudi Pharmaceutical Journal 25 (2017) 1184–1193.
15. Kumar G Chhabra, Ashish Sharma, Chaya Chhabra, J Jyothirmai Reddy, Shravani G Deolia, Yogesh Mittal, Knowledge, Attitude, and Practices regarding Pharmacovigilance and Adverse Drug Reaction reporting among Dental Students in a Teaching Hospital, Jodhpur, India: A Cross-sectional Study: The Journal of Contemporary Dental Practice, October 2017;18(10):964-969.
16. Naser Ashraf Tadv, Ali Ahmed Alromaih , et al. Knowledge, Attitude, and Practices Pharmacovigilance in health care professional and Medical Student in Majmaah, Saudi Arabia Care Centre: Inj J Med Res Health Sci 2018, 7(4): 101-107.

https://www.who.int/medicines/technical_briefing/tbs/04-PG_Dug-Safety_final-08.pdf?ua=1