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Knowledge, Attitude and Practice on Adverse Drug Reactions and its Reporting Among Nursing Students

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Abstract

Adverse Drug Reaction (ADR) is defined as 'a response to a medicine which is noxious and unintended, and which occurs at doses normally used in man'. ADR reporting does not yet appear to be regarded by healthcare practitioners as an integral element of standard professional practice. This is mainly because there isn't a robust and active ADR monitoring system or a culture of reporting among medical personnel. If given sufficient knowledge and skills during their undergraduate training careers, medical students could play a significant role and shift the paradigm in the successful implementation of a Pharmacovigilance program. At the moment, they don't have any significant roles due to insufficient training they received regarding ADR reporting. Thus it can be reasoned that effective educational intervention regarding ADR reporting improves Spontaneous Reporting. This study improves the Knowledge Attitude and Practice on ADRs among nursing students as they are the next generation of healthcare workers who will be the first point of contact in case a patient develops an adverse drug reaction in hospital settings. The goal of the study is to assess and improve the Knowledge, Attitude and Practice on Adverse Drug Reactions and its reporting among nursing students. The study also aimed to identify the barriers associated with reporting of Adverse Drug Reactions among the study subjects. An educational interventional study was carried out among 150 samples in selected nursing colleges of Bengaluru. The data was collected by using self designed content validated questionnaire and responses were recorded. All data obtained was processed and analyzed by using Microsoft excel. It was found that most of the student's knowledge towards Adverse Drug Reactions and its reporting were found to be improved after suitable intervention. Lack of training, less exposure, absence of professional confidence was identified as barriers associated with reporting of ADR. With the right coaching and guidance provided by means of educational programs, this study was able to further enhance nursing student's knowledge, attitude and practice regarding Adverse Drug Reactions and its reporting.

Keywords: Adverse Drug Reactions, Pharmacovigilance, Adverse Drug Event, PvPi, MNP, Education, Medical curriculum, ADR reporting.

1. Introduction

The Indian population is perhaps the largest consumer of drugs in the world, with an estimated 60,000–80,000 prescription brands that are erroneously prescribed and misused in the Indian market. This negligent practice could be attributed to a lack of pharmaceutical safety practices as well as regulatory failures.[1]

Adverse Drug Reactions and its reporting According to World Health Organization (WHO) , Adverse Drug Reaction (ADR) is defined as "a response to a medicine which is noxious and unintended, and which occurs at doses normally used in man." [2] PvPI (Pharmacovigilance Programme of India) promotes the reporting of all suspected ADRs, regardless of whether there is a proven causal link between the suspected ADR and a drug. This includes reactions that are known, unknown, serious, nonserious, frequent, or infrequent. You can report ADRs associated with the use of allopathic medications, vaccinations, conventional medications, medical equipment, contrast media, etc.[3]ADRs can be reported to NCC (National Coordinating Center) or AMCs (ADR monitoring centers) by all healthcare providers, doctors, dentists, pharmacists, nurses, etc., they can also be reported by patients. Additionally, pharmaceutical firms have the option of sending NCC specific case safety data for their product.[3]

ADR Healthcare professionals and consumers can report suspected ADR using the forms available on the IPC (Indian Pharmacopoeia Commission) website. There is a separate form for consumers which is available in 10 regional languages in order to eliminate linguistic barriers. ADRs can also be reported by calling the PvPI helpline number (18001803024).[4] ADRs may send their completed ADR reporting form to the NCC or the nearby AMC. These reports are entered into Vigiflow and sent to NCC for additional evaluation in the case of AMC after being verified by medical experts. [4] The WHO-UMC (Uppsala Monitoring Center) receives these reports after final evaluation at NCC and then experts study and evaluate the collected data to find new signals before entering it in the medication safety database. There are no legal repercussions for the reporters as a result of the submitted ADR report. [5]ADRs are increasing in frequency, which is a worldwide health issue that needs to be addressed by all parties, regardless of the practice environments.

Adverse medication reactions have been identified as a major source of illness and mortality in people of all ages, as well as a large financial burden on society and healthcare systems. In order to improve drug safety everyone regardless patients, health professionals should be encouraged to report adverse drug events. [6,7].

A majority of healthcare students will work in clinical settings where they must regularly administer, prescribe, distribute, and/or monitor medications. In order to guarantee the safe use of drugs, healthcare students (particularly those enrolled in the curricula for Medicine, Pharmacy, Dentistry, and Nursing, and also other allied health science majors) should have a minimal set of Pharmacovigilance (PV) abilities before they graduate and start clinical practice. [18,9]According to numerous prospective cross-sectional studies, ADRs place a significant financial burden on the healthcare system by increasing the risk of patient injury, hospitalization, readmission, prolonged hospital stays, high healthcare costs, morbidity and mortality. These are preventable or somewhat controllable with proper monitoring and intervention, making PV an essential clinical profession for ensuring proper medication use and patient safety. [10] Healthcare personnel are primarily obligated to identifying and report serious ADRs because the PV program in India heavily relies on spontaneous reporting of ADRs.[11] Numerous studies have shown that the healthcare students in India lack

sufficient knowledge of PV and adverse event reporting. Lack of correct knowledge, attitude, and practice (KAP) among healthcare personnel is one of the major reasons ADRs are underreported.[12, 13,14] As a result, all healthcare students should have an education in PV and ADR reporting, and it is essential that PV is included in their curricula.[14]

In order to decrease under-reporting of ADR, lower the incidence of ADR, and ensure that patients receive high-quality care, it is also crucial to ensure that they are properly taught and knowledgeable on PV and ADR reporting. [15] The insufficient response to ADRs and reporting is believed to be caused by inadequate of ADR-reporting skills, lack of knowledge negative attitudes like fear of legal liability, and lack of importance.[16,17] With an ageing population, increased prescription drug use and polypharmacy will likely cause a sharp increase in ADRs. This could soon result in a higher burden on patients and healthcare systems, along with underreporting of ADRs and a lack of knowledge and comprehension of ADRs [16,18].

A KAP survey (Knowledge, Attitudes, and Practices) is a quantitative instrument for collecting quantitative and qualitative data (predefined questions formatted in structured questionnaires). Misconceptions revealed by KAP surveys can present impediments to the exercises we like to execute, as well as possible barriers to behavior change. A KAP survey records an "opinion" and is based on "declarative" data (i.e; statements). KAP measures the scope of a known situation in order to confirm or reject a hypothesis, provide new perspectives on the facts and improve basic awareness, attitudes, and practices; determine what is understood and what is being done regarding different health-related topics. Create a benchmark for potential comparisons and aid in determining the efficacy of health education program, KAP will establish a benchmark for future comparisons, which will aid in determining theefficacy of health education program in changing health-related behaviors and propose an intervention approach that takes into account particular local conditions as well as the cultural factors that affect them; devise activities that are appropriate for the target population.[19]

A substantial part of the Pharmacovigilance program is played by healthcare professionals. ADR reporting does not yet appear to be regarded by healthcare practitioners as an integral element of standard professional practice. This is mainly because there isn't a robust and active ADR monitoring system or a culture of reporting among medical personnel. If given sufficient knowledge and skills during their undergraduate training careers, medical students could play a significant role and shift the paradigm in the successful implementation of a Pharmacovigilance program. At the moment, they don't have any significant roles due to insufficient training they received regarding ADR reporting.

Previous studies conducted among nursing students found that the majority of them had a poor Knowledge, Practice, and moderate Attitude towards PV and ADRs which is due to the lack of knowledge/training. Thus it can be reasoned that effective educational intervention regarding ADR reporting improves Spontaneous Reporting. This study improves the KAP on ADRs among nursing students as they are the next generation of healthcare workers who will be the first point of contact in case a patient develops an Adverse Drug Reaction in hospital settings.

2. Methodology

This was a Cross Sectional study carried out over a period of 6 months at selected nursing colleges in North Bengaluru. The study was approved by the ethics commitee of the institute in which it was conducted and all the participants were recruited after obtaining written informed consent. A total of 200 subjects were collected out of which 150 subjects were selected for the study.Subjects were selected

based on the inclusion and exclusion criteria.The different source of data were one to one interview with the study subject and questionaire.A self – designed validated questionnaire was given to the study subjects to fill and all the obtained data was entered in Microsoft Excel Sheet and statistical analysis was performed using paired t-test and data interpretation was carried out.

Inclusion criteria:

a. Final year student enrolled in recognized nursing colleges.
b. Post graduate nursing students
c. Subjects of both genders.

Exclusion criteria:

Subjects who are not willing to give the consent.

3. Results:

The study was conducted in selected nursing colleges in North Bengaluru, which was carried out for a period of 6 months. A total of 211 participants were included in the beginning out of which 61 samples were dropped out due to insufficient data and the final sample size was 150.

DISTRIBUTION OF RESPONSES RECEIVED TO KAP QUESTIONNAIRE

Respondents were interviewed using a self-designed questionnaire about their knowledge, attitude and practice on adverse drug reactions and its reporting. The KAP questionnaire consisted of 23 questions divided into three domains – Knowledge, Attitude and Practice. The knowledge domain consisted of 12 questions, Attitude domain consisted of 6 questions and practice domain had 5 questions.

There were 12 multiple choice questions in knowledge domain. The respondent's knowledge about adverse drug reaction and its reporting was assessed and improved based on their responses.

The attitude domain consisted of 6 multiple choice questions. There were three general questions to assess the attitude of the respondent regarding ADR and its reporting, while remaining questions assess the barriers associated with reporting of ADRs.

There were 5 multiple choice questions in practice domain. One question to assess practice on how well they are trained on reporting an ADR, and another questions to assess their ability to report ADR. One question to assess the if they have received PV education from any other sources and remaining two questions to assess the willingness to participate and need for education on PV and ADR reporting system.

ASSESSMENT OF KNOWLEDGE ON ADVERSE DRUG REACTIONS AND ITS REPORTING:

Questions	Pre-test		Post-test	
	n	%	n	%
K1	51	34%	99	66%
K2	53	35.33%	71	47.3%
K3	32	21.33%	109	72.66%

K4	43	28.66%	103	68.66%
K5	38	25.33%	102	68%
K6	100	66.66%	112	74.66%
K7	71	47.33%	111	74%
K8	51	34%	104	69.33%
K9	45	30%	116	77.33%
K10	62	41.33%	100	66.66%
K11	64	42.66%	97	64.66%

Table 1: *Distribution of response to knowledge questions*

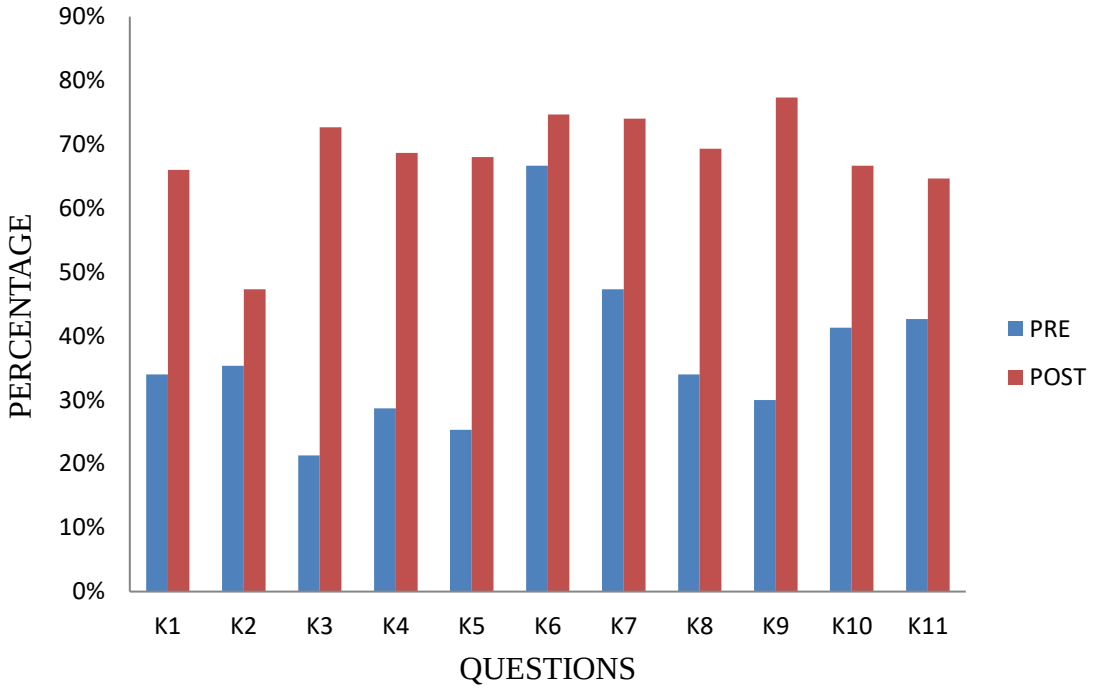

Figure 1: *Distribution of responses to knowledge questions*

Test	Right responses	Total number of respondents	Mean
PRE	610	150	4.06
POST	1124	150	7.49

Table 2: *Mean response to knowledge questions*

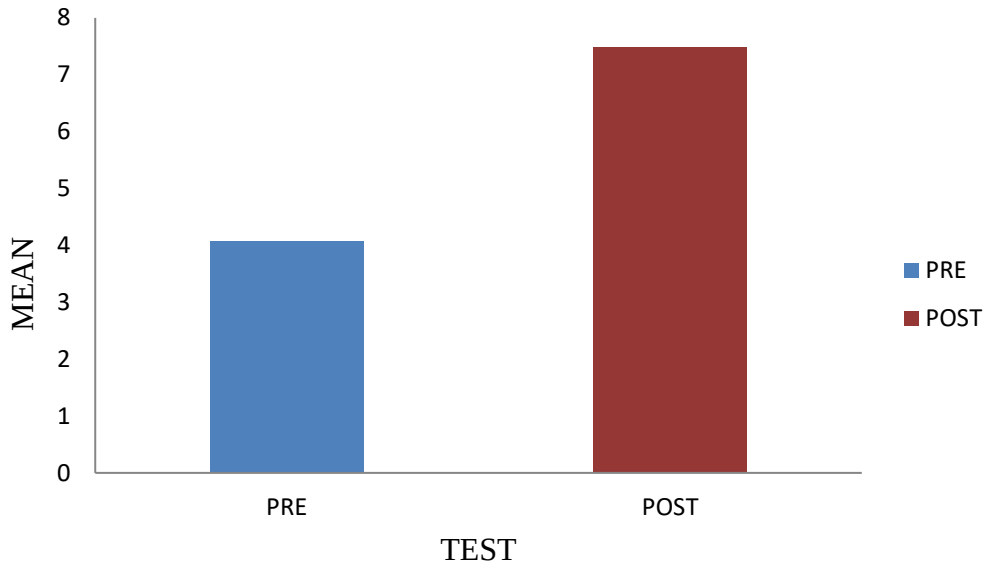

Figure 2: Mean response to knowledge questions

The mean value of the pre-test responses was 4.06 and the mean value of the post-test responses was 7.49. It is evident from the figure that the mean value of the post-test is increased compare to pre-test.

	Pre-test	**Post-test**
Mean	55.45454545	102.1818182
Variance	350.6727273	142.9636364
Pearson Correlation	0.128219964	
t Stat	9.880307089	
P(T<=t) two-tail	2.26162E-05	
t Critical two-tail	2.228138852	

Table 3: Paired samples t-test of knowledge

A t-test was conducted with the pre and post scores for the area of Knowledge. A paired-samples t-test was conducted to test the difference of pre and post test scores on a sample of 150 individuals for the area of knowledge. A statistical difference in pre and post test scores, t (150) = 9.880. It was found at α = 0.05 and critical value is 2.22 and upon comparison with the t value we can see that it is much larger compared to the critical value. This re-emphasizes how both the sets of pre and post scores are greatly different from each other.

The significance value (p value less than .05) shows that the differences between the groups are significant. t Stat greater than t critical, we reject our null hypothesis and accept our alternative hypothesis

ASSESSMENT OF ATTITUDE TOWARD ADVERSE DRUG REACTIONS AND ITS REPORTING:

The attitude of the respondents towards adverse drug reactions and its reporting was assessed by using self-designed questionnaire.

	PRE TEST	POST TEST
Mean	74	95.33333333
Variance	172.8	601.0666667
Pearson Correlation	0.923420977	
t Stat	3.909422219	
P(T<=t) two-tail	0.011301556	
t Critical two-tail	2.570581836	

Table 4: Paired samples t-test of attitude

A t-test was conducted with the pre and post scores for the area of Attitude. A paired-samples t-test was conducted to test the difference of pre and post test scores on a sample of 150 individuals for the area of knowledge. A statistical difference in pre and post test scores, t (150) = 3.909. It was found at α = 0.05 and critical value is 2.57 and upon comparison with the t value we can see that it is much larger compared to the critical value. This re-emphasizes how both the sets of pre and post scores are greatly different from each other.

The significance value (p value less than .05) shows that the differences between the groups are significant. t Stat greater than t critical, we reject our null hypothesis and accept our alternative hypothesis.

ASSESSMENT OF PRACTICE ON ADVERSE DRUG REACTIONS AND ITS REPORTING:

The practice of the subjects towards adverse drug reaction and its reporting was assessed by using self-designed questionnaire.

Question P1: Are you well trained on how to report ADR?

Practice	Yes	Percentage	No	Percentage
PRE	47	31.33%	103	68.66%
POST	52	34.66%	98	65.33%

***Table 5:** Distribution of response to question P1*

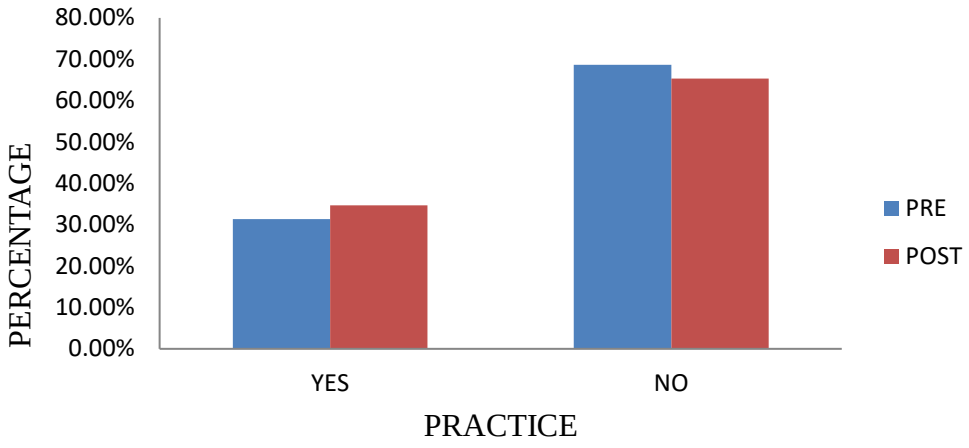

Figure 3: Distribution of response to question P1

Out of 150 subjects, only 47(31.33%) subjects knew how to report ADR and 103(68.66%) did not know how to report ADR in pre-test however, in post-test about 52(34.66%) subjects responded yes and 98(65.33%) responded no to the same. The graphical representation from above figure indicates that majority of the study population are not well trained on how to report ADR.

Question P2: Will you be able to perform ADR reporting during your academics?

Practice	Yes	Percentage	No	Percentage
PRE	81	54%	69	46%
POST	88	58.66%	62	41.33%

Table 6: Distribution of response to question P2

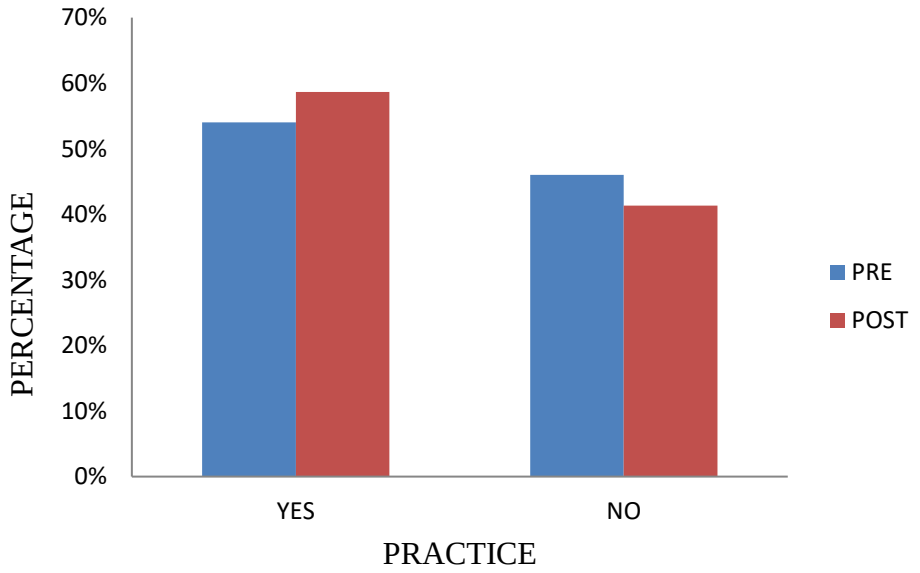

Figure 4: Distribution of response to question P2

Out of 150 subjects, only 81(54%) subjects will be able to perform ADR reporting during their academics and 69(46%) will not be able to perform ADR reporting during their academics in pre-test while in post-test 88(58.66%) subjects responded yes and 62(41.33%) responded no to the same. The graphical representation from above figure indicates that majority of the study population will be able to perform ADR reporting during their academics.

Question P3: Have you received some form of Pharmacovigilance education previously through any extra sources?

Practice	Yes	Percentage	No	Percentage
PRE	46	30.66%	104	69.33%
POST	30	20%	120	80%

Table 7: Distribution of response to question P3

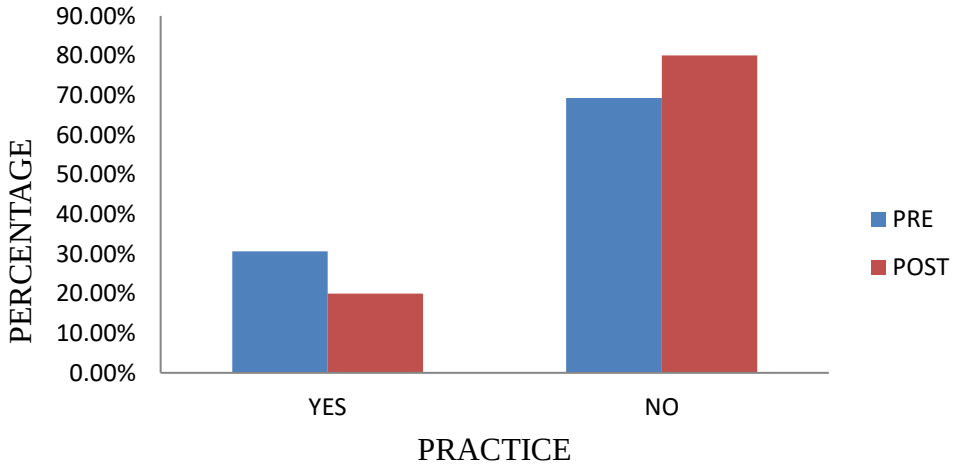

Figure 5: Distribution of response to question P3

Out of 150 subjects, only 46(30.66%) subjects responded yes and 104(69.33%) responded no to having received some form of Pharmacovigilance education previously through any extra sources in pre-test while in post-test 30(20%) subjects responded yes and 120(80%) responded no to the same. The graphical representation from above figure indicates that after the post-test it was found that majority of the study population did not received any form of Pharmacovigilance education from other extra sources.

Question P4: Do you believe that you need education about Pharmacovigilance and ADR reporting system?

Practice	Yes	Percentage	No	Percentage
PRE	106	70.66%	44	29.33%
POST	108	72%	42	28%

Table 8: Distribution of response to question P4

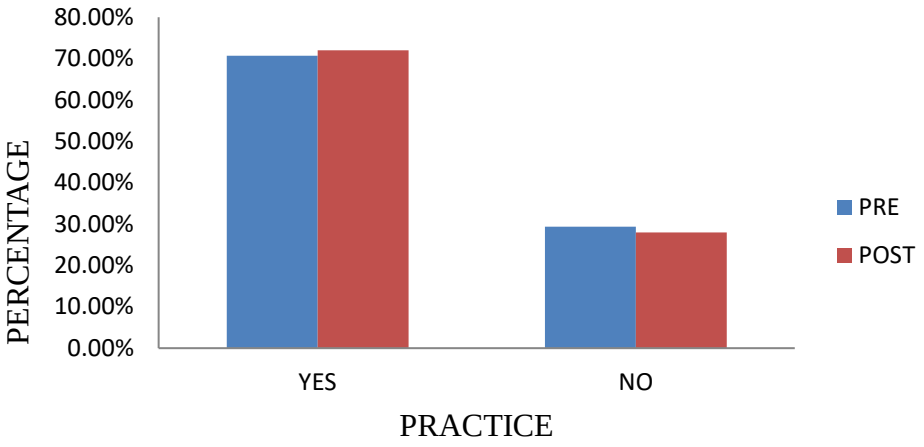

Figure 6: Distribution of response to question P4

Out of 150 subjects, only 106(70.66%) subjects believed in the need of education about Pharmacovigilance and ADR reporting system and 44(29.33%) subjects did not believed in the need about Pharmacovigilance and ADR reporting system in pre-test while in post-test about 108(72%) subjects responded yes and 42(28%) responded no to the same. The graphical representation from above figure indicates that majority of the study population believed in the need of education about Pharmacovigilance and ADR reporting system.

Question P5: Are you willing to participate if you are offered with an opportunity to undertake education in Pharmacovigilance and ADR reporting system?

Practice	Yes	Percentage	No	Percentage
PRE	102	68%	48	32%
POST	104	69.33%	46	30.66%

Table 9: Distribution of response to question P5

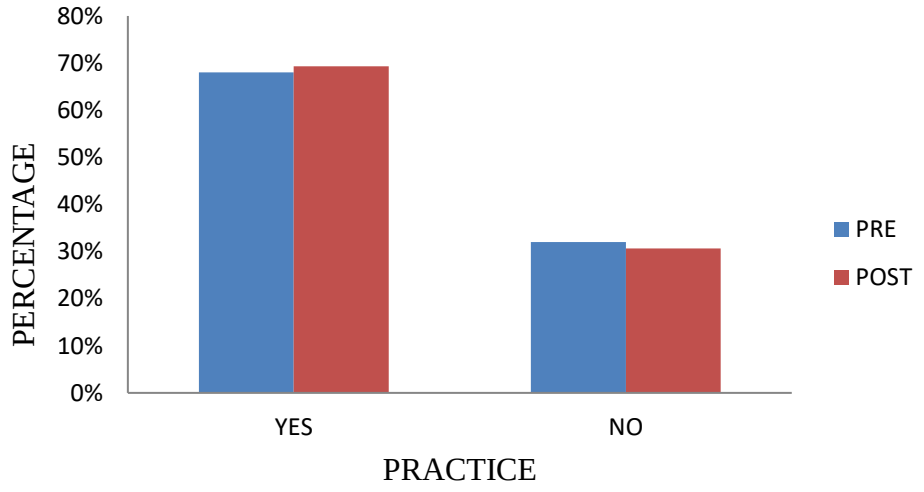

Figure 7: Distribution of response to question P5

Out of 150 subjects, only 102(68%) subjects responded yes, and 48(32%) subjects responded with no when asked about their willingness to participate, if they are offered with an opportunity to undertake education in PV and ADR reporting system in pre-test .However in post-test 104(69.33%) subjects responded yes, and 46(30.66%) subjects responded no to the same. The graphical representation of above figure indicates that majority of the study population had a positive attitude after the pre-test.

BARRIERS ASSOCIATED WITH REPORTING OF ADVERSE DRUG REACTIONS

Based on the questionnaire, the key barriers associated with reporting of Adverse Drug Reactions were identified.

Question	Number of responses	Percentage
Don't have easy access to ADR reporting forms.	40	26.66%
Topic of PV is not well covered in the curriculum	29	19.33%
Lack of training on how to report ADR	103	68.66%
Absence of professional confidence	69	46%
Less exposure to Pharmacovigilance education	104	69.33%

Table 10: Distribution of subject's by barrier

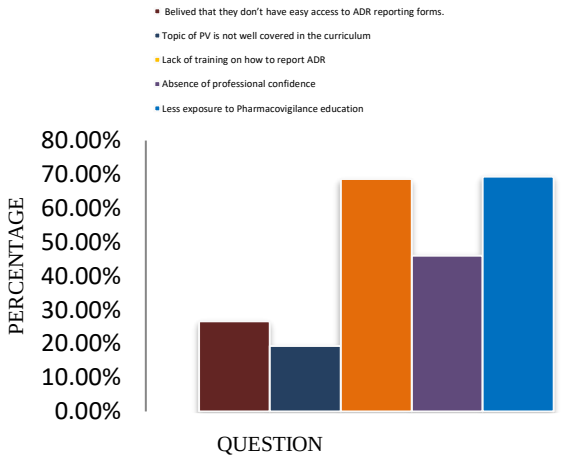

Figure 8: Distribution of subject's by barrier

The *figure 8* depicts that, the most prominent barrier is less exposure to PV education followed by lack of training on how to report ADR.

Out of 150 subjects, during pre-test it was found that,the most frequently cited barriers where, the students believed that they don't have easy access to ADR reporting forms, 21(14%) disagreed and 19(12.66%) strongly disagreed that they have easy access to ADRs reporting forms. The second barrier identified was, the topic of PV is not well covered in their curriculum where, 21(14%) disagreed and

8(5.33%) strongly disagreed that they believe that the topic of PV is well covered in my curriculum in pre-test they believe that the topic of PV is well covered in my curriculum. The third barrier was lack of training on how to report ADR, where about 103(68.66%) subjects did not know how to report ADR.The fourth one is the absence of professional confidence among nursing students, 69(46%) responded that, they will not be able to perform ADR reporting during their academics.The final barrier identified was less exposure to PV education, where 104(69.33%) subjects responded no to having received some form of PV education previously through any extra sources.

4. Discussion:

An educational interventional study was performed in the selected colleges in in North Bengaluru by enrolling 150 study subjects conducted for a period of 6 months.

In the current study final year and post graduate nursing students were included as study subjects whereas, study conducted by **Adegbuyi TA et al.,**[34] **Jnaneswar A et al., Adisa R et al.,**[35] were among healthcare professionals.

Out of 150 subjects, only 28.66% knew about the difference between ADRs and ADEs before the intervention was made and was further improved post intervention whereas in the study conducted by **Chopra D et at.,** which found that one tenth of the doctors knew what should be reported and that only one third knew whom to report to: less than half had actually ever reported an ADR.

From our study it was evident that 47.3% of subjects were aware about the most important purpose of Pharmacovigilance while only 34% were aware of PvPI which is in contrary to the study conducted by **Bhagavathula AS et al.,** where 55.6% of the population studied was not aware of the existence of the PvPI.

It was found that 31.33% subjects knew how to report ADR and 68.66% did not know how to report ADR in pre-test whereas in a study conducted by **Chopra D et al.,** in a teaching hospital 30% knew whom to report to and less than half (30%) had actually ever reported an ADR.

In this study it was found that the most prominent barrier is less exposure to PV education followed by lack of training on how to report ADR. This finding can be correlated with previous studies by **Chhabra KG et al.,** and **Li Q et al.,**[36] which studied the barriers contributing to underreporting with emphasis on- difficulty in deciding whether or not an ADR has occurred, concerns that the report may be wrong, lack of confidence to discuss ADR with colleagues. This is also comparable with the study conducted by **Danekhu K et al.,** where it was found that The main reasons for not reporting were that: ADR reporting was not widely promoted by relevant authorities (47%), followed by not knowing where and how to report ADR (34.9%).

In this study majority of the students reported that they did not have adequate PV education. This result is in agreement with a prior study conducted by **Alwhaibi M et al.,**[37] which found that only 39% of healthcare students revealed that they have received any form of PV education and 49% of them indicated that PV is well covered in their curriculum. In general this study showed that the attitude and knowledge of students towards ADR reporting improved after the educational intervention. The same results were observed in a previous study **Shrestha S et al.,**[38] which showed that knowledge and attitude scores were increased following the educational intervention and training on PV and ADR tends to have a positive impact on knowledge and attitude among nurses and pharmacists working at an oncology based hospital in Nepal.

5. Conclusion

ADR reporting is not highly regarded by healthcare practitioners as an integral element of standard professional practice. This is mainly because there isn't a culture of robust and active ADR monitoring system or a reporting among medical personnel. The participants had a comparatively favorable attitude toward ADR, but their knowledge, and skill of reporting ADR needs considerable improvements. There is an urgent need for educational awareness, simplification of the ADR reporting process, and implementation of imperative measures to practice PV among nursing students. The key barriers associated with reporting of ADRs were identified using a self validated questionnaire, which found that students don't have easy access to ADR reporting forms, topic of PV is not well covered in the curriculum, lack of training on how to report ADR, absence of professional confidence, less exposure to PV education. Among which the most prominent barrier is their minimal exposure to PV education followed by lack of training on how to report ADR.

The study concluded the following; there is a necessity of regular training and reinforcement for the ADR reporting among the health care personnel. The integration of PV with undergraduate curriculum could potentially help in improving ADR monitoring and reporting. The improvement and expansion of the existing system is imperative for the success of the PV program and for the better clinical management of the patients in general.

In a nutshell, in today's busy clinical practice, drug-related problems such as the prevention, recognition and management of ADRs do not always get the attention they need. When students are competent at preventing, recognizing and managing ADRs, they can and will improve the safe use of drugs. Since PV is important for all HCPs in clinical and public health disciplines, key PV aspects should be integrated into existing programs and courses for medical, pharmacy, dentistry and nursing education.

6. Acknowledgement

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Questionnaire

Dear respondents please choose the appropriate options

1. What is Pharmacovigilance?
   - Effects of drugs and mechanism of action
   - Biochemical and physiological effect of drug
   - Analyze the risk, safety of medicine
   - Role of the drug of Genome Response
   - Don't know
2. Do you think there are no guidelines for reporting ADRs in India?
   - Yes
   - No
   - May be
   - Don't know
3. What is the consequence of serious ADR?
   - Death
   - Hospital admission
   - Increased health care cost
   - All of the above
4. Who can report an ADR in India?
   - Doctors and Nursing
   - Pharmacists
   - Parents
   - All of the above
5. Do you think all ADRs are known before a drug is marketed?
   - Yes
   - No
   - May be
   - Don't know
6. Which type of ADRs should be reported?
   - All ADRs should be reported regardless its severity
   - Only serious adverse drug reaction should be reported
   - Don't know
7. Before reporting ADR, conformation that ADR is related to a particular drug is
   - Necessary
   - Not necessary
   - Don't know
8. Do you think ADRs caused by herbal medicines are neither documented nor reported?

- Yes
- No
- May be
- Don't know

9. Do you think ADRs are the same as adverse drug events (ADEs)?
   - Yes
   - No
   - May be
   - Don't know
10. Which types of ADRs should be documented?
   - Suspected ADRs for a new drug
   - Suspected ADRs for an old drug
   - Suspected ADRs for a vaccine
   - All of the above
11. Which of the following is the most important purpose of Pharmacovigilance?
   - To identify safe drugs
   - Detect the incidence of ADRs
   - Detect the incidence of side effects
   - To identify predisposing factors to ADRs
   - Don't know
12. Which type of medication is a candidate for ADR reporting?
   - ADRs to traditional medicines
   - ADRs to medicated cosmetics
   - ADRs to vaccines
   - ADRs to all drugs
13. Are you well trained on how to report ADR
   - Yes
   - No
14. Will you be able to perform ADR reporting during your academics
   - Yes
   - No
15. Have you received some form of Pharmacovigilance education previously through any extra sources?
   - Yes
   - No
16. Do you believe that you need education about Pharmacovigilance and ADR reporting system?
   - Yes
   - No
17. Are you willing to participate if you are offered with an opportunity to undertake education in Pharmacovigilance and ADR reporting system
   - Yes
   - No

For questions below, please tick in the column as you wish to select.

Questions	**Strongly agree**	**Agree**	**Neutral**	**Disagree**	**Strongly disagree**
Reporting ADR make a significant contribution to reporting system	☐	☐	☐	☐	☐
Reporting ADR is my responsibility	☐	☐	☐	☐	☐
PV should be included as a core topic in curriculum	☐	☐	☐	☐	☐
I believe that the topic of PV is well covered in my curriculum	☐	☐	☐	☐	☐
Believe I have easy access to ADRs reporting forms	☐	☐	☐	☐	☐
Information on how to report ADR should be taught to students	☐	☐	☐	☐	☐