KNOWLEDGE, ATTITUDE AND PRACTICES REGARDING PHARMACOVIGILANCE AMONG MEDICAL STUDENTS IN MEDICAL COLLEGES IN LUCKNOW, UTTAR PRADESH

DISSERTATION

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Of

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In

PUBLIC HEALTH DENTISTRY

By

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Enrollment No.

Under the guidance of

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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled **'KNOWLEDGE, ATTITUDE AND PRACTICES REGARDING PHARMACOVIGILANCE AMONG MEDICAL STUDENTS IN MEDICAL COLLEGES IN LUCKNOW, UTTAR PRADESH'** is a bonafide, & genuine research work carried out by me under the guidance of **Dr. Anuradha P, Professor and Head,** Department of Public Health Dentistry, Babu Banarasi Das College of Dental sciences, Babu Banarasi Das University, Lucknow, Uttar Pradesh.

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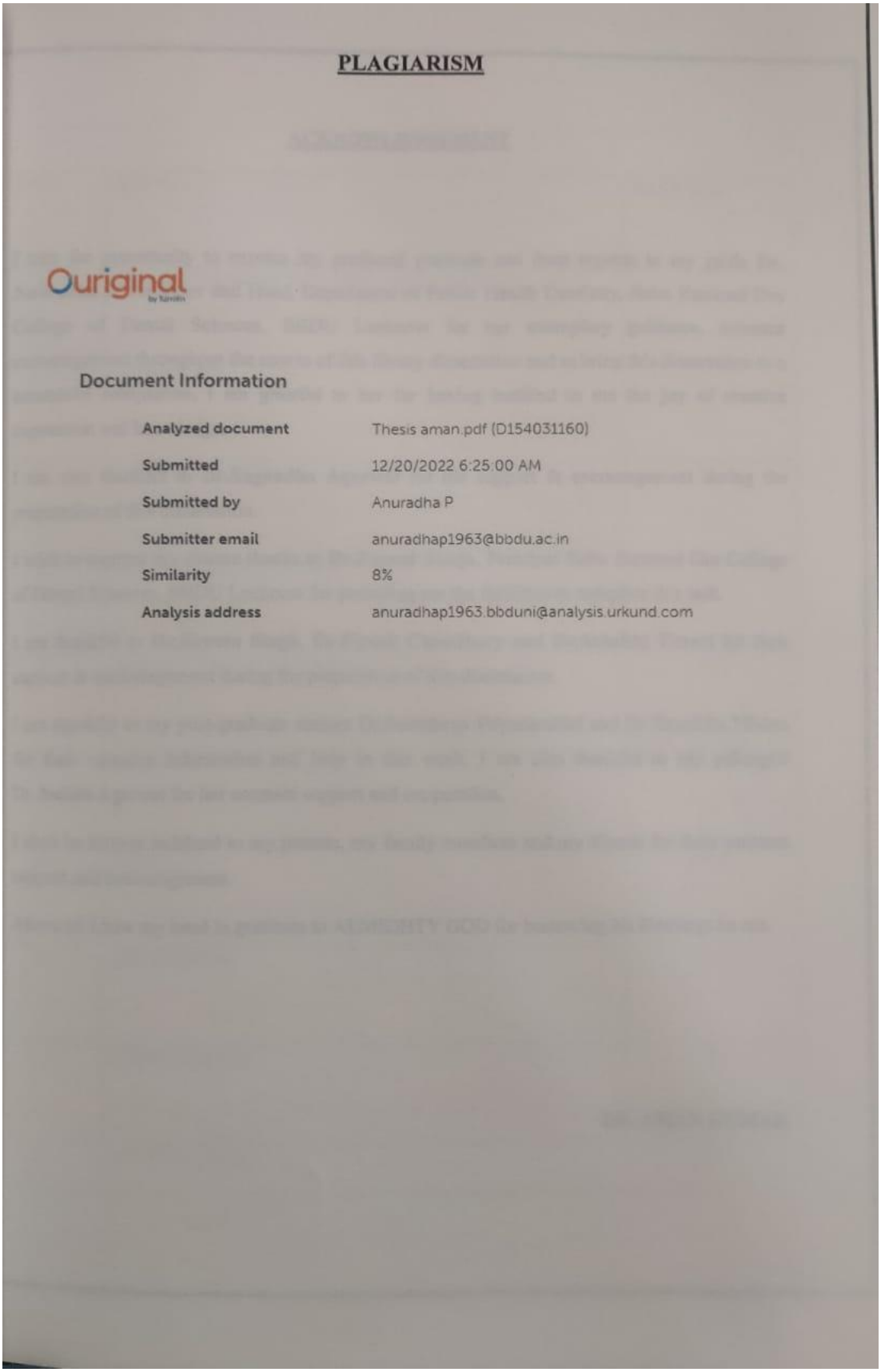

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DR. AMAN KUMAR

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LIST OF ABREVIATION

ADRs	**Adverse Drug Reactions**
WHO	**World Health Organization**
UMC	**Uppsala Monitoring Centre**
PvPI	**Pharmacovigilance Programme of India**
MoHFW	**Ministry of Health and Family Welfare**
AMCs	**ADR monitoring centers**
NCC	**National Coordinating Centre**
KAP	**KNOWLEDGE ATTITUDE AND PRACTICE**
MBBS	**Bachelor of Medicine and Bachelor of Surgery**
SPSS	**Statistical Package of Social Sciences**
CDSCO	**Central Drug Standard Control Organization**

ABSTRACT

Introduction: Adverse drug reaction means a noxious, unintended and undesirable effect that occur as a result of drug treatment at doses normally used in man for diagnosis, prophylaxis and treatment Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems As such, adverse drug reaction (ADR) reporting is the foundation of any Pharmacovigilance system and the timely identification and reporting of ADRs to the regional or national drug-regulating authorities are critical. Hence, this study is planned with an Aim to assess the Knowledge, Attitude and Practices regarding Pharmacovigilance among medical students in medical colleges of Lucknow, Uttar Pradesh.

Materials & Methods: A Cross-Sectional, questionnaire study was conducted to assess Knowledge, Attitude and Practices regarding Pharmacovigilance among medical students in medical colleges of Lucknow, Uttar Pradesh. The questionnaire was arranged in two sections. The first section contained questions on demographic characteristics. The second section assessed the participants' Knowledge, Attitude and Practices regarding Pharmacovigilance among medical students in medical colleges of Lucknow, Uttar Pradesh. The Chi square test was used to compare the gender wise knowledge, Attitude and Practices regarding Pharmacovigilance among medical students.

Results: In the present study, 3040 clinical MBBS students (III year and Final year BDS and interns) participated out of which 1800 (59.22%) of the subjects were males and 1240 (40.78%) were the females. It is observed that 32.05 % knew that doctors, nurses, pharmacists and dentists can report Adverse drug reactions and about 60.5% knew about the existence of a national pharmacovigilance program in India. 86.10% participants think that Pharmacovigilance should be taught in detail to healthcare professionals and 33.80% was confident enough to report an ADR to concern authority.

Conclusion: The present study suggests that the knowledge regarding pharmacovigilance among the medical students of Lucknow city was satisfactory, but their experience of adverse drug

reaction in patient and reporting of adverse drug reaction to the concerned authority during their professional practice was low.

Keywords: Pharmacovigilance, ADR, Knowledge, Attitude, Practice, Medical students

INTRODUCTION

Adverse Drug Reactions (ADRs) are global problems of major concern. Adverse drug reaction means a noxious, unintended and undesirable effect that occur as a result of drug treatment at doses normally used in man for diagnosis, prophylaxis and treatment. [1]

The Joint Commission on the Accreditation of Healthcare Organisations defines an adverse drug reaction as an undesired effect of a medication that either increases toxicity, decreases desired therapeutic effect, or both[2]. ADR are rather a complex issue which requires special attention; they involve patients, Medical professionals, the Pharmaceuticals industries, drug regulatory agencies and academic scientist. [1]

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems [3.] Pharmacovigilance is defined by WHO as "the science and activities relating to the detection, understanding, and prevention of adverse effects or any other drug-related problems" [4]

Pharmacovigilance aims at enhancing patient safety by assessing the risk-benefit profile of medicines. As such, adverse drug reaction (ADR) reporting is the foundation of any Pharmacovigilance system and the timely identification and reporting of ADRs to the regional or national drug-regulating authorities are critical. [4]

ADRs are reported to be the 4-6th leading cause of death in United States of America. The burden of ADRs is even higher in developing countries. The most common contributory factors being the widely prevalent self-medication, availability of adulterated and fake medicines . Adverse drug reactions thus have a major impact on public health. [5]

ADRs are reported to be the 4-6th leading cause of death in United States of America[6].

The ADR reporting rate in India is below 1% compared to the worldwide rate of 5% [7]. The Uppsala Monitoring Centre (UMC) in Sweden has the international database of suspected adverse drug reaction reports from all over the world [5]. However, still, it is estimated that only 6-10% of all ADRs are reported in all over world.

Pharmacovigilance Programme of India (PvPI) was formed in July 2010. A combined initiated by Central Drugs Standard Control Organization, New Delhi, MoHFW, Government of India.

The AIIMS was established as the National Coordinating Centre under which 22 ADR monitoring centers (AMCs) all over India were formed for monitoring ADR's in India. Later the NCC was relocated to Indian Pharmacopoeia Commission, Ghaziabad, (U.P.) [8].

The committees under the National Coordinating Centre (NCC-PvPI) are the Steering committee, working group, Quality review panel, Signal review panel and the Core training panel . At present, there are 202 ADR monitoring centers under Pharmacovigilance Programme of India (PvPI). [8]

In order to improve the reporting rate, it is important to improve the knowledge, attitude and practices of the healthcare professionals regarding ADR reporting and Pharmacovigilance. The best period to improve the KAP regarding ADR and Pharmacovigilance activity is during the under graduate and post graduate education [9,10]

Hence,this study is planned with an Aim to assess the Knowledge, Attitude and Practices regarding Pharmacovigilance among medical students in medical colleges of Lucknow, Uttar Pradesh.

AIM

Assessing the Knowledge, Attitude and Practices regarding Pharmacovigilance among medical students in medical colleges of Lucknow, Uttar Pradesh.

OBJECTIVES

1. Assess knowledge regarding Pharmacovigilance among Medical students of Lucknow, Uttar Pradesh.
2. Assess Attitude regarding Pharmacovigilance among Medical students of Lucknow, Uttar Pradesh.
3. Assess Practice regarding Pharmacovigilance among Medical students of Lucknow, Uttar Pradesh.

REVIEW OF LITERATURE

1. **REHAN HS, VASUDEV K, TRIPATHI CD (2002) [11].** Conducted a study on Adverse drug reaction monitoring: Knowledge, attitude and practices of medical students and prescribers. Adverse drug reactions (ADRs) contribute to excessive health care costs through increased patient morbidity and mortality. The present study was designed to assess the knowledge, attitude and practices of fifth semester undergraduate students and prescribers (interns, junior residents and senior residents) towards the recording and reporting of ADRs. The fifth semester MBBS undergraduate students (n= 107) and prescribers (n= 117) working in different disciplines of Lady Hardlnge Medical College and associated hospitals were given a questionnaire to answer. The responses of the undergraduate students were compared with those of prescribers. Knowledge about definition, classification, objectives and methods of ADR monitoring was found to be comparable in both groups. Spontaneous and intensive methods of ADR monitoring were known to the majority of participants of both groups. Attitude and practices of the prescribers were significantly ($p<0.01$) better with regard to the status of ADR monitoring in the institute. A significantly higher ($p<0.01$) proportion of prescribers (82%) as compared to the undergraduate students (64.5%), felt that ADRs should be reported both when it causes inconvenience to the patient as well as death. ADRs were encountered by both undergraduates (46%) and prescribers (66%) during their clinical project exercises and patient care, respectively. A majority of ADRs were suspected and subsided on their own by either stopping the drug or reducing its dose. The knowledge, attitude and practices of both undergraduates and prescribers were comparable but need further improvement. This suggests the need for suitable changes in the undergraduate teaching curriculum. Further, the prescribers also need periodic reinforcement regarding ADR monitoring.

2. **Dhananjay K, Himasri E (2003) [12]**. Conducted a study on A study of assessing knowledge, attitude and practice of pharmacovigilance among medical students of a South Indian teaching hospital. Pharmacovigilance is the science relating to detection,

assessment, understanding and prevention of adverse drug reaction. The purpose is to improve patient safety in relation to use of medicines. It is estimated that only 6-10% of adverse drug reactions (ADRs) are reported worldwide. The underreporting of ADR is due to lack of adequate knowledge, attitude and practice among healthcare professionals towards ADR reporting. Health care professional like physicians, pharmacist and nurses have immense responsibility in reporting ADR. Therefore, the objective of this study was to evaluate the knowledge, attitude and practices (KAP) of undergraduate medical students towards pharmacovigilance. A cross-sectional KAP based questionnaires study was carried out in 100 undergraduate students of Konaseema Institute of Medical Sciences, Amalapuram. The response of KAP questionnaires were analyzed in percentage and tabular form. Nearly 87% participants heard about pharmacovigilance, but only 65% know its need or purpose. 88% people feel that ADR reporting may improve patient safety. Less than half of the students know about Institutional ADR centre. 81% students have seen ADR but only 31% knew about ADR reporting form and surprisingly only 20% have reported ADR. More than 80% feels reporting ADR will increase patient safety. Participants have good knowledge about Pharmacovigilance but lacks in attitude and practice towards reporting ADR. Greater awareness of pharmacovigilance and incorporation of it in medical curriculum will further strengthen pharmacovigilance activity.

3. **Dhikav V, Singh S, Anand KS (2004)**[2] conducted a study on Adverse Drug Reaction Monitoring In India. Adverse drugs reactions (ADRs), put simply, are noxious, unintended, and undesirable effects that occur as a result of drug treatment at doses normally used in man for diagnosis, prophylaxis, and treatment. Although there are many terms indicating the harmful and undesirable effects of drug treatment, the term ‘adverse drug reaction’ describes them best. During the course of treatment, drugs prescribed to patients produce certain effects other than the desired or expected effects. These cause concern both to the physician and the patient. They not only add to spiralling costs of medical treatments, but also cause a great deal of morbidity and mortality. These are generally referred to as ‘side effects’. People usually attribute these abnormal effects to either overdose or inappropriate medications prescribed by the doctor or the attending

specialists. The unwanted effects are categorised into many types such as toxic effects, side effects, adverse reactions, and adverse drug events etc., depending upon the taxonomic classification used. Worldwide, studies have shown them to be a major cause of morbidity and mortality. Though Indian studies in this regard are very few, the pattern of reactions seems to be similar. Moreover, we have certain peculiarities of drug use such as: large number of patients, poor doctor-patient ratio, self-medication, drugs of alternative systems of medicine, malnutrition, widespread anaemias, presence of counterfeit drugs, and presence of the highest number of drug combinational products in the world. Therefore, incidence of the adverse drug reactions is likely to be same as that of the West, or more. Unfortunately, inspite of presence of five wellorganised centres for drug monitoring in the country, the number of reports sent annually are dismal. Most of the adverse drug reactions are, fortunately, preventable. This calls for the urgent need to reinforce the monitoring of adverse reactions to drugs; public education against self-medication, inclusion of reaction monitoring, and an introduction to drug-safety in the curriculum of medical undergraduates, and systemic and periodic continuing medical education of health professionals. This multi-pronged strategy can lead to reduction in the incidence of adverse drug reactions.

4. **Vora MKB , Paliwal NP , Doshi VG , Barvaliya MJ and Tripathi CB(2012)[9]** . Conducted a study to analyze the baseline knowledge of awareness regarding the ADRs and Pharmacovigilance activity in the undergraduate medical students of different Medical Colleges in Gujarat, India. Settings and Design: A cross-sectional questionnaire based multicentric study in six Government Medical Colleges of Gujarat (India). Questionnaire was developed to assess the knowledge of the ADRs and Pharmacovigilance activity. A total 18 questions were divided in two groups: Type-A regarding the ADRs and Type-B regarding the Pharmacovigilance. The questions were distributed to all 2nd and 3rd year undergraduate medical students and allowed to write down the answers independently. Each correct answer was given a score of '1' whereas the wrong/not given answer was given a score of '0'. The total score was 18. Statistical analysis: We applied appropriate statistical test and used Epi Info software for analysed the data. Data was expressed in number as well as percentage. The study involved total

880 undergraduate medical students, of them 526 were the 2nd year students whereas 354 were the 3rd year students. Among 2nd year students, 54(10.3%) and 34(6.5%) have given the correct answer of type-A and type-B questions, respectively whereas in 3rd year, 22(6.2%) and 04 (1.1%) have given the correct answer of type-A and type-B questions, respectively. Overall knowledge of ADRs and Pharmacovigilance activity was poor in undergraduate medical students of Gujarat. The undergraduate medical students are a future doctor in society. The deficiencies in knowledge regarding ADRs and Pharmacovigilance need the urgent attention on priority basis, not only for the success of the Pharmacovigilance program, but for the better clinical management of the patients in general.

5. **Ahmad A, Patel I , Balkrishnan R , Mohanta GP, Manna PK (2013) [13]**. Conducted a study on An evaluation of knowledge, attitude and practice of Indian pharmacists towards adverse drug reaction reporting: A pilot study. Pharmacovigilance is a useful to assure the safety of medicines and protect consumers from their harmful effects. Healthcare professionals should consider Adverse Drug Reaction (ADR) reporting as part of their professional obligation and participate in the existent pharmacovigilance programs in their countries. In India, the National PV Program was re-launched in July 2010. This survey was conducted in order to assess the knowledge, attitude and practice of Indian pharmacists with the aim of exploring the pharmacists' participation in ADR reporting system, identifying the reasons of under reporting and determining the steps that could be adopted to increase reporting rates. A cross-sectional survey was carried out among the pharmacists in India using a pretested questionnaire with 33 questions (10 questions on knowledge, 6 on attitude, 7 on practice, 7 on future of ADR reporting in India and 3 on benefits of reporting ADRs.). The study was conducted, over a period of 3 months from May 2012 to July 2012. Out of the 600 participants to whom the survey was administered, a total of 400 were filled. The response rate of the survey was 67%. 95% responders were knowledgeable about ADRs. 90% participants had a positive attitude towards making ADRs reporting mandatory for practicing pharmacists. 87.5% participants were interested in participating in the National Pharmacovigilance program, in India. 47.5% respondents had observed ADRs in their practice, and 37% had reported

it to the national pharmacovigilance center. 92% pharmacists believed reporting ADRs immensely helped in providing quality care to patients. The Indian pharmacists have poor knowledge, attitude, and practice (KAP) towards ADR reporting and pharmacovigilance. Pharmacists with higher qualifications such as the pharmacists with a PharmD have better KAP. With additional training on Pharmacovigilance, the Indian Pharmacists working in different sectors can become part of ADR reporting system.

6. **Vora MKB and Barvaliya M (2014)[1]** conducted a study on Knowledge, Attitude and Practices towards Pharmacovigilance and Adverse Drug Reactions in health care professional of Tertiary Care Hospital, Bhavnagar. It was a cross-sectional questionnaires based study. 22 questionnaires about knowledge, attitude and practices towards ADRs and Pharmacovigilance were developed and peer viewed of all questionnaires by expert faculties from Pharmacology department. The questionnaires were distributed, 30 minutes time given to fill the form. The filled KAP questionnaires were analyzed and their percentage value was calculated by using Microsoft excel spread sheet and online statistical software. In study, postgraduate residents (n=81) and faculties (n=63) from different clinical departments were present throughout study. Of all post graduate students, an average 27.82% and 40.76% faculties were true knowledge about ADRs and Pharmacovigilance. From attitude of students and faculties towards reporting ADRs an average 91.77% and 91.53% were agreed to reporting ADRs is necessary, mandatory and increased patient's safety. In practice based questionnaires, 74.07% students and 71.43% faculties found difficulty like non-availability of ADR form, do not have time, patient co-operation etc. to report ADR. 47.62% in faculties and 43.21% in students said managing patient are more important than reporting ADR. Only 11.11% and 12.35% of faculties and students were found the factors like how to report, where to report etc. discouraging factors for reporting ADRs. It was concluded that post graduate students and faculties of tertiary care hospital have better attitude towards reporting ADRs, but have lack of knowledge and practices of ADRs.

7. **Bharti N ,Khosla PP, Gupta S (2014) [14].** Conducted a study on Assessment of Knowledge, Attitude and Practices (KAP) of Health Professionals Towards Adverse

Drug Reactions (ADRs) and Pharmacovigilance in a Tertiary Hospital of North India . Pharmacovigilance is a method of quick detection and reporting, of adverse drug reactions and adverse drug events after drug is in clinical use, thus preventing major drug events. Ignorance of physicians in developing world, about reporting adverse drug reaction is a big roadblock to pharmacovigilance. This cascades into many problems e.g.; increased lab to clinic interval, increased premarketing expense for newer drugs. In quickly changing genomes scenario it leads to almost fatal therapeutic failures. The huge population of India and lack of appropriate post marketing surveillance contribute towards disasters due to adverse drug reactions. With evolution of pharmaceutical industry, the Indian doctors have gained wide knowledge of drugs but the area of adverse drug reactions still remains neglected. Indian Government launched National Pharmacovigilance Programme in 2004 to inculcate the culture of Adverse Drug Reaction reporting among Indian health professionals. Medical Council of India has also made Pharmacovigilance Programme mandatory in every medical college. Still the picture is disheartening. Motivated to improve Adverse Drug Event reporting in Chattrapati Shivaji Subharti Hospital, the present survey was conducted to find Knowledge, Attitude, Practices (KAP) of physicians, surgeons & nurses regarding Adverse Drug Reaction reporting.

8. **Shalini S and Mohan S (2015)** [15]. Conducted a study on Knowledge and Attitude towards Pharmacovigilance and Adverse Drug Reaction Reporting among Dental Students in a Private University, Malaysia . This study was conducted among the dental students to evaluate the knowledge and attitude towards pharmacovigilance and adverse drug reactions reporting among the dental students in a private university. The survey was carried out among the pre-final and final year dental students using a pre-validated questionnaire that included the demographics details and survey items related to knowledge and perception aspects towards adverse drug reactions and pharmacovigilance. The questionnaire was distributed to the participants (n=100). A total of 61 questionnaires were duly filled out, giving a response rate of 76.25%. The survey data was analyzed using SPSS version 20. The overall mean score on knowledge among the dental students was found to be 15.84. The study also observed that mean score on

attitude in pre-final year and final year dental students were 11.03 and 20.44 respectively. The overall mean score for attitude on ADRs reporting and pharmacovigilance was found to be 22.65. The results show that knowledge of dental students who participated in the study towards pharmacovigilance and adverse drug reaction reporting was low. However, 15.6% of pre-final year students and 27.6% of final year students expressed positive attitude towards pharmacovigilance and ADRs reporting. As part of future health care professionals, they are expected to have sound knowledge and positive attitude towards pharmacovigilance activities.

9. **Upadhyaya HB , Vora Muskesh KB, Nagar JG, Patel PB (2015)[6]** conducted a study on Knowledge, attitude and practices toward pharmacovigilance and adverse drug reactions in postgraduate students of Tertiary Care Hospital in Gujarat. A cross-sectional questionnaires based study was carried out in tertiary care hospital attached with Govt. Medical College, Vadodara, Gujarat (India). A total of 22 questionnaires about KAP toward ADRs and pharmacovigilance were developed and peer viewed of all questionnaires by expert faculties from our institute. We were contacted directly to postgraduate students of respective clinical department; questionnaires were distributed and taken back after 30 min. The filled KAP questionnaires were analyzed and their percentage value was calculated by using Microsoft Excel spreadsheet. Postgraduate residents (n = 101) from different clinical departments were enrolled in the study. Average 34.83% correct and 64.08% incorrect knowledge about ADRs and pharmacovigilance and an average 90.76% students were agreed to reporting ADRs is necessary, mandatory and increased patient's safety. Only 7.92% of postgraduate doctors were reported ADR at institute or ADR reporting center. It was concluded that postgraduate students have a better attitude toward reporting ADRs, but have lack of knowledge and poor practices of ADRs. The majority of postgraduate students were felt ADR reporting and monitoring is very important, but few had ever reported ADRs because of lack of sensitization and knowledge of pharmacovigilance and ADR.

10. **Dharmadhikari PP , Date AP, Patil KS (2015) [16]**. Conducted a study on Knowledge, attitude, and practice among healthcare professionals of adverse drug reactions reporting

in a tertiary care center. There has been a rapid increase in the number of drugs entering the market from last few decades. Preclinical and clinical data are insufficient to conclude the complete safety of drugs. Hence, it is necessary to have a robust pharmacovigilance system in place to generate safety signals. Under reporting of adverse drug reactions (ADRs) exists as an inherent weakness of current voluntary reporting scheme. This study was therefore taken up, to evaluate the knowledge, attitude, and practice about ADR reporting among doctors in a tertiary care center. The present study was a cross-sectional questionnaire-based study, which included prescribers of a tertiary care teaching hospital. We tried to find out the possible ways to improve reporting of ADR and factors responsible for deficient reporting of ADRs. After analyzing the data, we observed that 59% of the responders were aware of the ADRs reporting system. And the most encouraging finding was 94% of the respondents think that this reporting system is necessary. However, the practice was very poor just 14% among the respondents. 74% and 61% of participants felt creating awareness among healthcare professionals, and training to healthcare professionals would lead to improvement in reporting of ADRs respectively. Main factors which discouraged ADR reporting by healthcare professionals were reporting would lead to extra work 70.5%, non-availability of forms 64.5%. The deficiencies in ADR reporting require attention so as to improve spontaneous reporting and enhance safety of patients.

11. **Ganesan S, Vikneswaran G, Reddy KS, Subrahmanyam DK, Adithan C (2016)**[5] conducted A Survey on Knowledge, Attitude and Practice of Pharmacovigilance towards Adverse drug reactions reporting among Doctors and Nurses in a Tertiary Care Hospital in South India. It was a cross-sectional questionnaire-based survey. A pre-designed and structured multiple choice questionnaire containing 19 questions was used to assess knowledge (1-9), attitude (10-14) and practice (15-19). The data obtained were analyzed using appropriate statistical analysis through SPPS version 19.0. A total of 318 healthcare professionals participated in the study. Among them 46.2% were doctors, and 53.8% were nurses. The participants had good knowledge regarding the purpose of monitoring ADRs, type of ADRs to report, who can report, etc. They also felt reporting of ADRs is a professional obligation and all ADRs should be reported. There was no significant

difference in the knowledge and attitude between doctors and nurses. The practice of ADR reporting was significantly higher in doctors compared to nurses. It was concluded that majority of participants have good knowledge about local hospital based ADR monitoring. However, the transition from knowledge to practice was not adequate.

12. **Bhagavathula AS, Elnour AA ,Jamshed sq , Shehab A (2016)** [17] . Conducted a study on Health Professionals' Knowledge, Attitudes and Practices about Pharmacovigilance in India: A Systematic Review and MetaAnalysis Abstract Background Spontaneous or voluntary reporting of suspected adverse drug reactions (ADRs) is one of the vital roles of all health professionals. Reviewing the literature can provide a better understanding of the status of knowledge, attitude and practice (KAP) of Pharmacovigilance (PV) activities by health professionals. A systematic review was performed through Pubmed, Scopus, Embase and Google Scholar scientific databases. Studies pertaining to KAP of PV and ADR reporting by Indian health professionals between January 2011 and July 2015 were included in a meta-analysis. A total of 28 studies were included in the systematic review and 18 of them were selected for meta-analysis. A total of 28 studies were included in the systematic review and 18 of them were selected for meta-analysis. Overall, 55.6% (95% CI 44.4–66.9; $p<0.001$) of the population studied were not aware of the existence of the Pharmacovigilance Programme in India (PvPI), and 31.9% (95% CI 16.3–47.4; $p<0.001$) thought that "all drugs available in the market are safe". Furthermore, 28.7% (95% CI 16.4–40.9; $p<0.001$) thought that "all drugs available in the market are safe". Furthermore, 28.7% (95% CI 16.4–40.9; $p<0.001$) never reported any ADR to PV centers. There was an enormous gap of KAP towards PV and ADR reporting, particularly PV practice in India. There is therefore an urgent need for educational awareness, simplification of the ADR reporting process, and implementation of imperative measures to practice PV among healthcare professionals. In order to understand the PV status, PvPI should procedurally assess the KAP of health professionals PV activities in India.

13. **Jadhav A ,Chandrikapure A ,Tarte P (2017)**[18]. Conducted a study on Pharmacovigilance in dental practice: A study to evaluate knowledge, attitude and

practices (KAP) of reporting of adverse drug reactions (ADR) among dental practitioner in a city of central region of Maharashtra, India Abstract Background: Adverse drug reaction (ADR) is defined as a response of a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of a disease or for the modification of physiological function. These adverse drug reactions are an imperative public health crisis striking a substantial fiscal burden on the society and healthcare system. ADR leads to the number of medical and economic consequences like prolonged hospital stay, increased cost of treatment and risk of death also increases. Hence detection, recording and reporting of adverse drug reactions become vital. For this purpose the concept of pharmacovigilance has been formed. As a large number of dentist are using various drugs during treatment of dental problems. But various KAP studies performed on dentist shows that there is negligible role of dentist in pharmacovigilance programme. This was a cross sectional questionnaire-based study in which 106 private dental practitioners were involved who answered predesigned questionnaire prepared based on previous studies on knowledge, attitude and practices of pharmacovigilance. The results were calculated by using MS-Excel spreadsheet and expressed in terms of percentage of observations. Conclusion: We conclude that 106 dentists in our study have poor knowledge about pharmacovigilance. They have good attitude towards practice of reporting ADR. But unable to report ADR due to lack of knowledge, lack of training of ADR reporting, non-remuneration of reporting, difficult to decide whether ADR has occurred or not.

14. **Alsaleh Fatemah M, Alzaid Sherifah W, Abahussain Eman A, Bayoud Tania, Lemay Jacinthe (2017)[4]** conducted a study on Knowledge, attitude and practices of pharmacovigilance and adverse drug reaction reporting among pharmacists working in secondary and tertiary governmental hospitals in Kuwait. Pharmacists working at governmental hospitals were asked to complete a paper-based 25-item questionnaire. A total of 414 pharmacists received the questionnaire and 342 agreed to participate, giving a response rate of 82.6%. Most pharmacists were knowledgeable about the concepts of PV(61.5%) and ADRs (72.6%) and the majority (88.6%) was willing to implement ADR reporting in their clinical practice. Despite this positive attitude, only 26.8% of

participants had previously reported an ADR and the main reason for underreporting was stated as not knowing how to report (68.9%). Barriers that hinder the implementation of a PV center included lack of cooperation and communication by healthcare professionals and patients (n = 62), lack of time and proper management (n = 57), lack of awareness of staff and patients (n = 48) and no qualified person to report ADRs (n = 35). It was concluded that hospital pharmacists in Kuwait had good knowledge and positive attitude toward PV and ADRs reporting. However, the majority of them have never reported ADRs.

15. **SRINIVASAN V, SHEELA D and MRIDULA D (2017)[8]** conducted a study on Knowledge, Attitude and Practice of Pharmacovigilance among the Healthcare Professionals in a Tertiary Care Hospital – A Questionnaire Study. The Pharmacovigilance Programme of India (PvPI) aims at sensitizing the healthcare professionals towards strengthening the Spontaneous reporting system in order to protect the lives of millions of people living in a vast country like India. Currently India's contribution to global drug safety database is about 3%, which is meagre in comparison with the huge population.).This present study was done to identify the possible factors responsible for underreporting (UR) of adverse drug reactions (ADRs) and encourage the healthcare professionals to substantiate the Pharmacovigilance Programme of India (PvPI). The present study was a cross-sectional questionnaire-based study to assess the knowledge, attitude, and practice (KAP) of pharmacovigilance among practicing healthcare professionals working in the Saveetha Medical College & Hospital, Thandalam, Chennai. The statistical analysis was done using Statistical Package for Social Sciences (SPSS) version 23 software. The result shows difference in explicit knowledge and tacit knowledge among healthcare professionals. Attitude questions have identified the affective behaviour of the respondents and practice questions shows evidence of a paradigm shift towards an organized pharmacovigilance constructivism. KAP of the healthcare professionals highlights the under-reporting of ADR, Multimodality interventions are needed to improve spontaneous ADR reporting.

16. **Katekhaye1 VM, Kadhe NG , John J , Pawar SR (2017) [19]** . Conducted a study on Knowledge, attitude and practice of pharmacovigilance among medical professionals at a tertiary care hospital in Mumbai, Maharashtra, India. Many adverse drug reactions (ADRs), interactions and specific toxicities are known once drug is exposed to a larger population. Spontaneous reporting adverse events (AEs) are fundamental to a robust pharmacovigilance (PhV). Increasing physician awareness about the pharmacovigilance and ADR reporting can significantly contribute the safety of medicines. Objective of the study was to assess the knowledge, attitude and practices related to PhV among medical professionals at a tertiary care teaching hospital. Postgraduate students (PGs) and medical teachers at a Medical College and tertiary care hospital were evaluated for their knowledge, attitude and practice of pharmacovigilance with the help of a structured questionnaire. Suggestions for improving the effectiveness of the pharmacovigilance practices were also sought. One-hundred and fifty doctors [91 (60.7%) PGs and 59 (39.3%) medical teachers] participated. Overall, 48.7% were males. 96% believed that PhV is important in medical practice but only 79.3% knew the definition of pharmacovigilance. Only 24.7% were aware of the existing nationwide pharmacovigilance program whereas the international collaborating center was known to 26% of the participants. 96% believed that it is the duty of a treating physician to report an ADR while 36.7% felt that ADR reporting should be the responsibility of a separate team. Surprisingly, 54% felt that financial aid should be provided for ADR reporting. 42.7% have not reported any ADR whilst only 16% have reported more than 10 ADRs in their career. To create an ADR database (79.3%) was the common expectation from the PhV center. 98.7% suggested continued medical education (CME) and trainings to improve the effectiveness of PhV in Indian setting. Regardless of a fair attitude towards PhV, the practice of ADR reporting is poor probably because of lack of sufficient knowledge about PhV. Motivating the physicians through CMEs and trainings so as to improve and strengthen the pharmacovigilance practices is the current need in India.

17. **R Subramaniam, Kuruvilla Suneesh, Latti Pooja, M Noushida N, Pius Liyas (2019)[7]** conducted a study on knowledge, attitude and practices regarding pharmacovigilance among students, house surgeons and teaching faculty in a dental

college in kerala. The study was a cross-sectional questionnaire based survey. A prefabricated validity tested questionnaire was devised for use based on previous studies. The questionnaire consisted of questions on professional data designation, grade; and18 questions assessing the knowledge, attitude and practices on Pharmacovigilance. Results were expressed as a number and percentage of respondents for each. Chi-square test was performed to compare the response in relation to year of study and designation. The total sample size was 162. 28% knew that doctors, nurses, pharmacists and dentists can report Adverse drug reactions. About 25% knew about the existence of a pharmacovigilance program in India. 65% knew the regulatory body responsible for monitoring ADR's in India. About 96% felt that ADR reporting should be mandatory. 93.8% opined that pharmacovigilance should be taught in detail to health care professionals. About 35% reported to experiencing ADR's during their practice, yet none of the 162 respondents have reported an ADR to the pharmacovigilance centre. Only 2.5% had seen a reporting form and only 1.2% had received a prior training on reporting of the same. It was concluded that although the respondents had a positive attitude towards pharmacovigilance, their knowledge and practice was poor.

18. **Gidey K , Seifu M, Hailu BY, Asgedom SW, Niriayo YL (2020) [20] .** Conducted a study on Healthcare professionals knowledge, attitude and practice of adverse drug reactions reporting in Ethiopia: a crosssectional study. This study aimed to assess the knowledge, attitude and practice of adverse drug reactions (ADRs) reporting and identify factors associated with ADRs reporting among healthcare professionals (HCPs) working in Tigray region, Ethiopia. A cross-sectional study was conducted between January and March of 2019 in a tertiary care hospital in Tigray region, Ethiopia. A selfadministered, pretested questionnaire was administered to HCPs. Data were summarised using descriptive statistics. Logistic regression analysis was used to identify factors associated with poor ADRs reporting practices. In total, 362 questionnaires were distributed, and the response rate was 84.8% (n=307). Of all respondents, 190 (61.9%) were nurses, 63 (20.5%) were pharmacist and 54 (17.6%) were physicians. About 58.3% of HCPs had poor knowledge of ADRs reporting. The majority of the respondents had a positive attitude (59.9%), and only a few (32.1%) respondents have good ADRs reporting

practices. Poor knowledge (adjusted OR (AOR)=2.63, 95% CI: 1.26 to 5.45) and lack of training on ADRs reporting (AOR=7.31, 95%CI: 3.42 to 15.62) were both negatively associated with ADRs reporting practice, whereas higher work experience (≥10 years) (AOR=0.36, 95%CI: 0.13 to 0.97) was positively associated with ADRs reporting practice. The majority of HCPs had poor knowledge and practice, but a positive attitude towards ADRs reporting. Poor knowledge, less work experience and lack of training were associated with poor ADRs reporting practice. Hence, strategies to improve the knowledge and practice of ADRs reporting should be implemented, particularly for untrained and less experienced HCPs.

19. **Meher BR, Joshua1 N, Asha B, Mukherji D (2021)** [21] . conducted a study on A questionnaire based study to assess knowledge, attitude and practice of pharmacovigilance undergraduate medical students in a Tertiary Care Teaching Hospital of South India. Spontaneous reporting of adverse drug reaction (ADR) is the backbone of pharmacovigilance program. Under reporting by prescribers is still exist. This study was done to assess the knowledge, attitude, and practice (KAP) of undergraduate students about pharmacovigilance. It was a questionnaire-based cross-sectional study. Study tool was a validated questionnaire containing 21 questions to evaluate KAP of pharmacovigilance among undergraduate medical students in a Tertiary Care Teaching Hospital of South India. All data were analyzed by using Microsoft Excel sheet, Chi-square, and ANOVA. The mean score of final, prefinal, and 2nd year students is respectively (4.76, 5.63, and 4.73) for knowledge, (4.26, 4.95, and 4.53) for attitude and (1.66, 1.55, and 1.28) for the practice. There is a significant difference in mean score between three groups for knowledge and attitude, but not for practice. They have a better attitude, but poor in knowledge and practice regarding pharmacovigilance. Students lack adequate knowledge and skill of reporting ADR, but they have a positive attitude toward pharmacovigilance program. The integration of pharmacovigilance with undergraduate curriculum may help in improving ADR monitoring and reporting.

20. **Acharya R , Naik R , Rang S , Jani CA , Galib R (2022)** [22] . Conducted a study on Knowledge, attitude and practice towards pharmacovigilance among ayurveda physicians

and teachers of Gujarat State: A cross sectional study. this study was to assess the knowledge, attitude, and practice towards pharmacovigilance for Ayurveda among the teachers and practitioners working in Ayurveda colleges of Gujarat State. A survey questionnaire with 29 questions covering points like participants' knowledge, attitude and practice towards pharmacovigilance, adverse drug reaction reporting, and misleading advertisements related Ayurveda drugs was developed in Google form format. The study was carried out during December 2020 and January 2021. Question-wise analysis was made and their percentage value was calculated with the help of a Microsoft Excel spreadsheet in MS Office 2010. The result was presented using simple frequencies with percentages in appropriate tables. Results from this study show that majority of the respondents were having a good knowledge regarding the concept of pharmacovigilance and ADRs in terms of their definitions and purposes. An encouraging attitude towards reporting of adverse drug reaction of ASU&H drugs and teaching of Pharmacovigilance for all the healthcare professionals by majority of the participants was observed A major part of respondents (78.03%) opine that poor quality of drug, medication errors, prescription errors, dispensing errors are part of Pharmacovigilance under drug-related problems. One-third of the participants reported their experience about adverse drug reactions during their professional practice, out of which very few have reported ADRs. A large number of respondents were also not familiar with reporting misleading advertisements. Findings of this study reflects a good knowledge of the participants about the concept of Pharmacovigilance but unfamiliarity about the programme. The positive attitude towards practice of Pharmacovigilance and ADR reporting can be converted to foster pharmacovigilance practice through series of awareness programs.

MATERIALS AND METHODS

STUDY DESIGN:

A Cross-Sectional, questionnaire study was conducted to assess Knowledge, Attitude and Practices regarding Pharmacovigilance among medical students in medical colleges of Lucknow, Uttar Pradesh.

STUDY AREA:

- A questionnaire survey was conducted among the medical students of Lucknow city.
- Lucknow is the capital of Uttar Pradesh.
- The city remains at an elevation of roughly 123 meters (404 ft) above the sea level. Lucknow region covers a total area of 2,528 square kilometers (976 sq mi)
- It is bounded by Barabanki on the east, by Unnao on the west, by Raebareli in the south and by Sitapur and Hardoi in the north, Lucknow lies on the northwestern bank of the Gomti River.
- According to the provisional report of Census of India in 2011, the population of Lucknow city was 2,815,601, out of which 1,470,133 were men and 1,345,468 women.
- The city has a total literacy level in 2011 of 84.72% in Lucknow city, the total literate population totalled 2,147,564 people of which 1,161,250 were male and 986,314 were female.
- Relevant Demographic Details along with questions on knowledge, perceptions and interest in supplements and alternative medicine were included in the study.

STUDY SETTING:

- Lucknow city was divided into 5 geographical regions: East, West, North, South and Central zone.
- There are 7 medical colleges and around 2800 students in Lucknow city.

- Students from both the government and private medical colleges of Lucknow city who met the eligibility criteria were selected.

STUDY POPULATION:.

- The study population consisted of 3rd year, 4th year medical students and interns of various medical colleges of Lucknow , Uttar Pradesh

ETHICAL CLEARANCE:

- Ethical clearance was obtained from Institutional Ethical Committee of Babu Banarasi Das College of Dental Sciences, BBDU, Lucknow.

CONSENT:

- Verbal consent was obtained from all the subjects participating in the study.
  and permission was taken from the college authorities.

INCLUSION CRITERIA:

- Both genders and 18 years and above.
- Clinical MBBS students with ward posting and interns.

Exclusion Criteria

- Those who were not able to understood the questions and not willing to participate.

PILOT STUDY:

- A pilot study was conducted on 50 participants to pre-test the questionnaire to check for feasibility, reliability of the study.
- The reliability was calculated using test retest and Cronbach's alpha.

SAMPLE SIZE ESTIMATION:

- Total Enumerates

SCHEDULE OF THE SURVEY:

- The collection of data was carried for 4 months between July 2022 to October 2022.
- Daily and weekly schedules were prepared.
- The schedule was made available to the college authorities.
- The schedules took into account some adaptability, so that the unexpected delays don't cause significant upsets in the survey schedule.
- The plan for scheduling the time survey included: Introducing the examiner to the college director and teachers concerned; Distributing the questionnaire, Providing a short oral report to the incharge; Traveling to the next college.
- Questionnaire was distributed to the students and they were given 5-7 min to fill the questionnaire.
- Completed questionnaire was obtained back by the investigator.

CALIBRATION AND TRAINING

- The calibration of the principal investigator was done by the research head who had conducted various epidemiological study and has thorough knowledge of the subject.

EXAMINATION AREA

- The study was carried in the class room or field of the college.

INSTRUMENTS AND SUPPLIES

- The following instruments and supplies were used

1. Questionnaire

2. Pencil/pen
3. Eraser

- An adequate supply of assessment forms, hardboard bases and clips, sharpened pencils, erasers and pens was readily available.

DAILY REVIEW OF ASSESSMENT FORMS

- It is vital that the investigator surveys every day's assessment forms around the same time, for completeness and accuracy of recordings.

QUESTIONNAIRE:

- A pre-validated questionnaire was used for the study.
- The final questionnaire consisted of 16 variable, self-administered, close ended questions.
- The questionnaire was arranged in two sections. The first section contained questions on demographic characteristics. The second section assessed the participants' Knowledge, Attitude and Practices regarding Pharmacovigilance among medical students in medical colleges of Lucknow, Uttar Pradesh.
- There were 4 questions on knowledge , 8 questions on attitude and 4 questions on practice.

DATA COLLECTION:

- The questionnaire was distributed personally by the investigator himself and collected back the same day.

STATISTICAL ANALYSIS:

- The data collected were entered in IBM SPSS 20.0 version (Chicago, Inc, USA).
- The results are presented in frequency and percentage through graphs and tables.

- The Chi square test was used to compare the gender wise knowledge, Attitude and Practices regarding Pharmacovigilance among medical students.
- P value less than 0.05 was considered statistically significant. All the data were reported with exact p-values and 95% confidence intervals (CI) and 5% margin of error (z).

RESULTS

In the present study, 3040 clinical MBBS students (III year and Final year BDS and interns) participated out of which 1800 (59.22%) of the subjects were males and 1240 (40.78%) were the females (Table -1 and Graph- 1). 33.20% were the III rd year, 33.20% were the fourth year students and 33.60% were the interns (Table -2 and Graph -2)

Table -1 Gender Distribution of Study Subjects

	N	Percentage
Male	1800	59.22%
Female	1240	40.78%

Graph – 1 Gender Distribution of Study Subjects

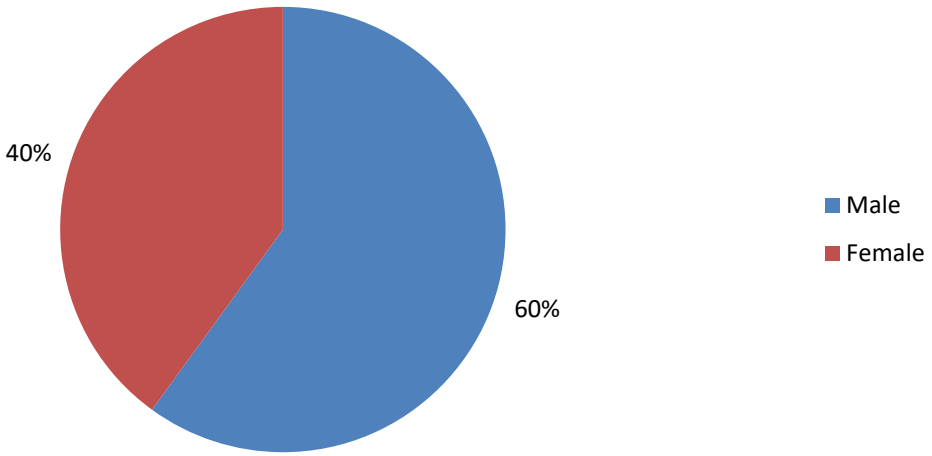

Table -2 Distribution of Study Subjects Based on Year of study

	N	Percentage
IIIrd Year	1010	33.20%
IVth year	1010	33.20%
Interns	1020	33.60%

Graph -2 Distribution of Study Subjects Based on Year of study

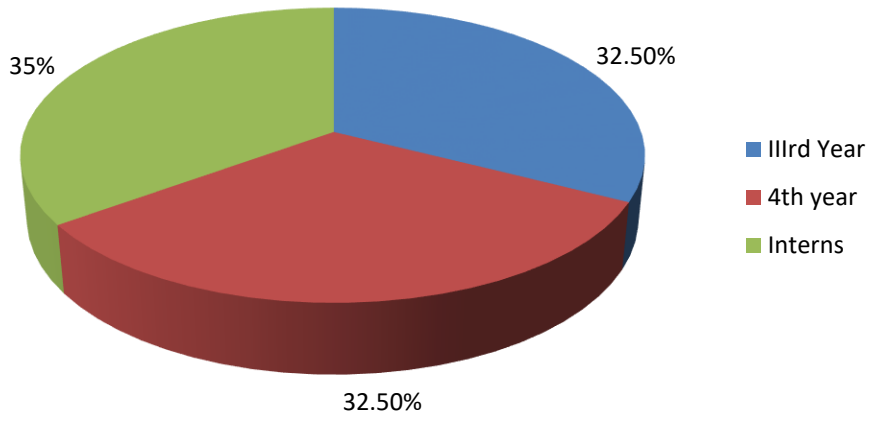

Table no. 3, 4 and graph no. 3,4 shows the response to the questions assessing the Knowledge, regarding Pharmacovigilance. It is observed that 32.05 % knew that doctors, nurses, pharmacists and dentists can report Adverse drug reactions. About 60.5% knew about the existence of a national pharmacovigilance program in India. 67.5% percent of the respondents knew the regulatory body responsible for monitoring ADR's in India. About 32.35% have experience adverse drug reaction in their patient during their professional practice.

Table -3 Response to the questions assessing the Knowledge, regarding Pharmacovigilance

	Doctors	Nurses	Pharmacist	Dentist	All the above
The healthcare professionals responsible for reporting ADR's in a hospital is/are (can tick multiple options) ?	1251	732	267	654	974
	41.15	24.1	8.8	21.5	32.05

Graph -3 Response to the questions assessing the Knowledge, regarding Pharmacovigilance

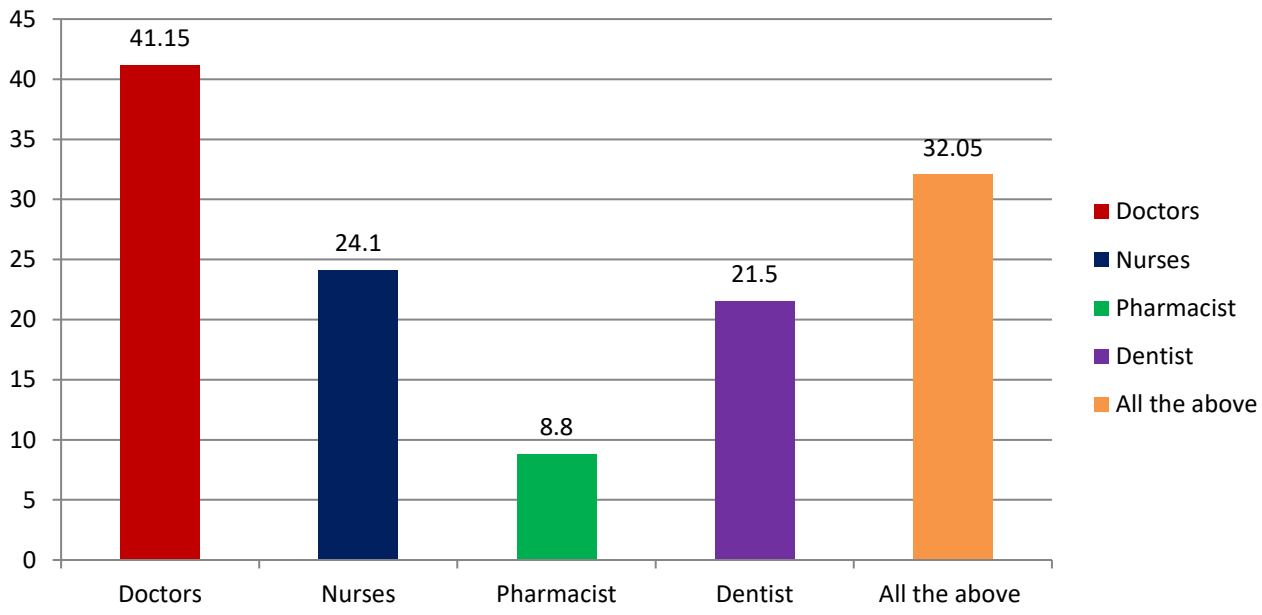

Table -4 Response to the questions assessing the Knowledge, regarding Pharmacovigilance.

	Yes	No	P value	Significance
Do you know regarding the existence of a national Pharmacovigilance	1840 (60.5%)	1200 (39.5%)	0.001	Significant
Do you know In India Central Drug Standard Control Organization (CDSCO is the regulatory body responsible for monitoring ADRs?	2040 (67.10%)	1000 (32.90%)	0.001	Significant
Have you ever experienced adverse drug reaction in your patient during your professional practice	983 (32.35%)	2057 (67.65%)	0.001	Significant

Chi Square test

Graph -4 Response to the questions assessing the Knowledge, regarding Pharmacovigilance.

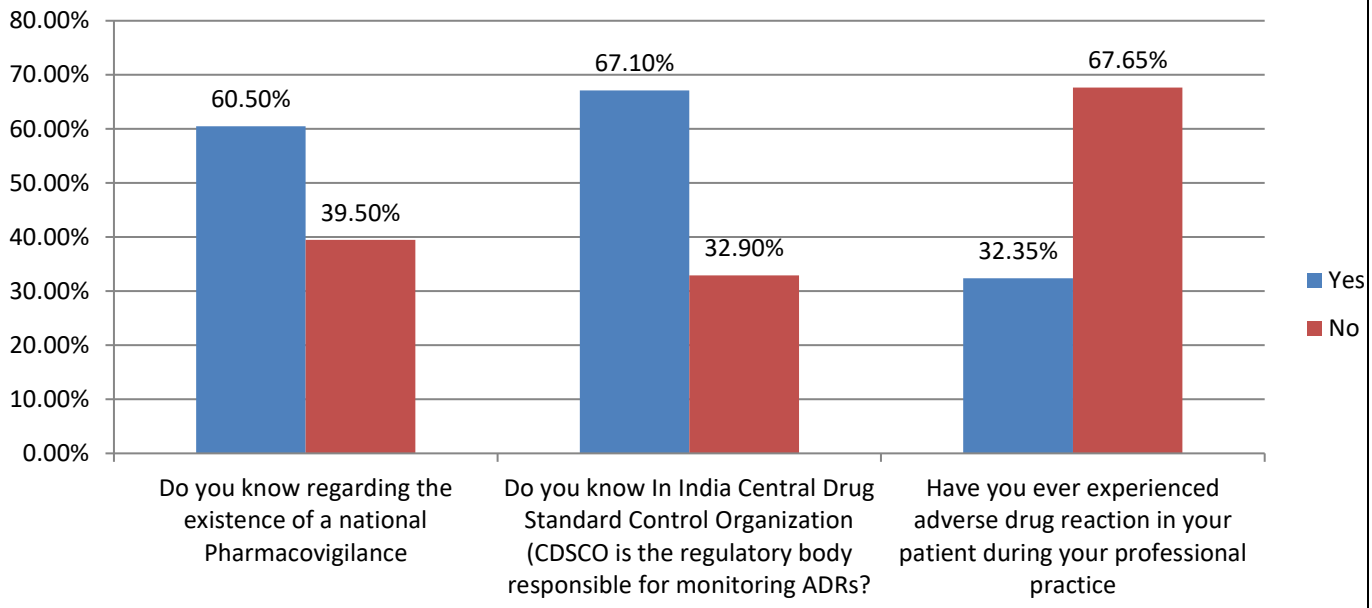

Table – 5 and Graph – 5 shows gender based knowledge response assessing the knowledge regarding pharmacovigilance . It was observed that 57.45% of males and 65% of females knows about the existence of a national pharmacovigilance while 42.55% of male and 35% of female were unaware about the existence of national pramacovigilance . 64.27% male and 71.21% females knows that in india Central Drug Standard Control Organization (CDSCO) is the regulatory body responsible for monitoring ADRs, which was found to be statistically signifinact. 30.33% males and 35.24% female have experienced adverse drug reaction in their patient during your professional practice while 69.67% of male and 64.76% of female have never experienced adverse drug reaction in your patient during your professional practice, which was found to be statistically significant.

Table – 5 Gender Based Knowledge Response To The Questions Assessing The Knowledge, Regarding Pharmacovigilance

		Yes	No	P value	Significance
Do you know regarding the existence of a national Pharmacovigilance	Male	1034	766	0.001	Significant
		57.45%	42.55%		
	Female	806	434		
		65%	35%		
Do you know In India Central Drug Standard Control Organization (CDSCO is the regulatory body responsible for monitoring ADRs?	Male	1157	643	0.001	Significant
		64.27%	35.72%		
	Female	883	357		
		71.21%	28.79%		

Have you ever experienced adverse drug reaction in your patient during your professional practice Total Score	Male	546	1254	0.001	Significant
		30.33%	69.67%		
	Female	437	803		
		35.24%	64.76%		

Graph – 5 Gender Based Knowledge Response To The Questions Assessing The Knowledge, Regarding Pharmacovigilance

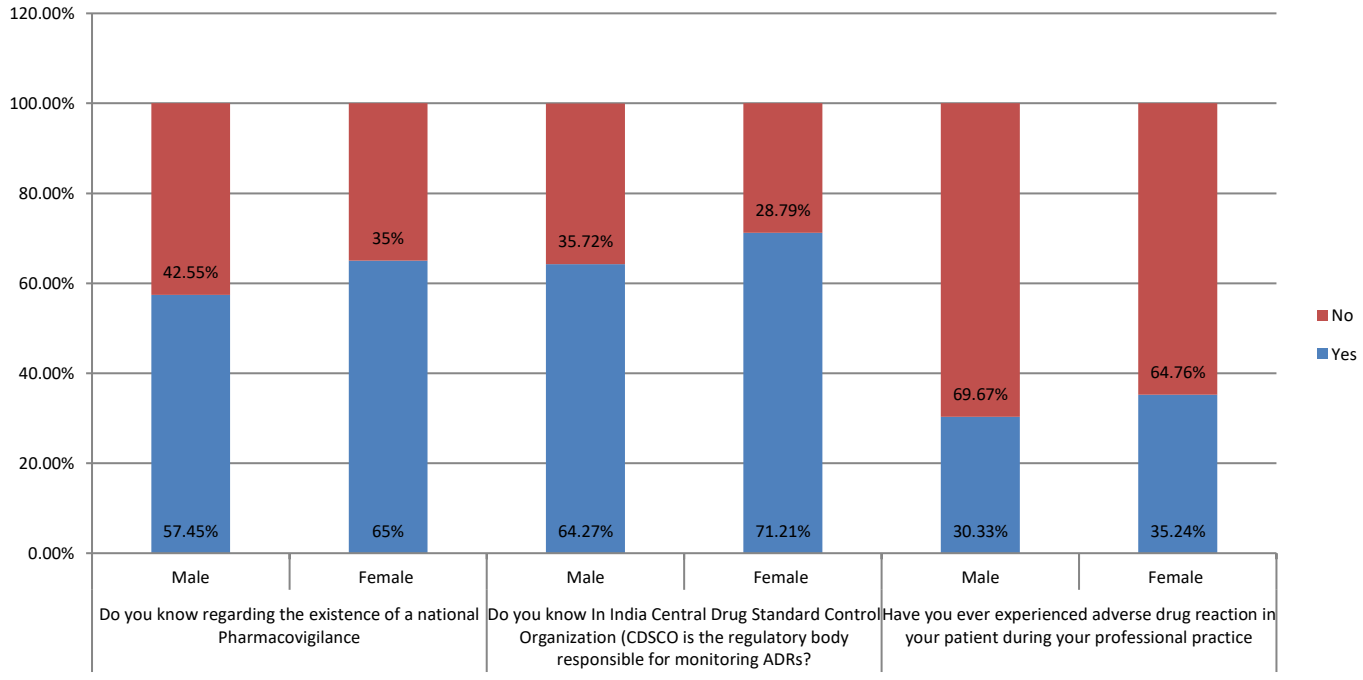

Table - 6 and Graph - 6 shows year wise response to the questions assessing the knowledge, regarding pharmacovigilance. It was observed that 51.78% of third year MBBS student, 54.95% of MBBS final year and 75.45% of MBBS internship students knows about the existence of a national pharmacovigilance , while 48.22% of MBBS third year, 45.05% of MBBS final year, 25.55% of MBBS internship student were unaware about the existence of national pramacovigilance. 55.34% of MBBS third year , 59.00% of MBBS final year, and 86.76% of MBBS internship students knows that in india Central Drug Standard Control Organization (CDSCO) is the regulatory body responsible for monitoring ADRs, which was found to be statistically signifinact. About 24.95% of MBBS third year , 29.01% of MBBS final year, and 42.94% of MBBS internship students have experienced adverse drug reaction in their patient during their professional practice while About 75.05% of MBBS third year , 70.99% of MBBS final year, and 57.06% of MBBS internship students have never experienced adverse drug reaction in their patient during their professional practice, which was found to be statistically significant.

Table – 6 Year Wise Response To The Questions Assessing The Knowledge, Regarding Pharmacovigilance

		Yes	No	P value	Significance
Do you know regarding the existence of a national Pharmacovigilance	IIIrd Year	523	487	0.001	Significant
		51.78%	48.22%		
	IVth year	555	455		
		54.95%	45.05%		
	Interns	762	258		
		75.45%	25.55%		
Do you know In India Central Drug Standard Control Organization (CDSCO is the regulatory body responsible for monitoring ADRs?	IIIrd Year	559	451	0.001	Significant
		55.34%	44.66%		
	IVth year	596	414		
		59.00%	41.00%		
	Interns	885	135		
		86.76%	13.24%		
Have you ever experienced adverse drug reaction in your patient during your professional practice Total Score	IIIrd Year	252	758	0.001	Significant
		24.95%	75.05%		
	IVth year	253	717		
		29.01%	70.99%		
	Interns	438	582		
		42.94%	57.06%		

Graph – 6 Year Wise Response To The Questions Assessing The Knowledge, Regarding Pharmacovigilance

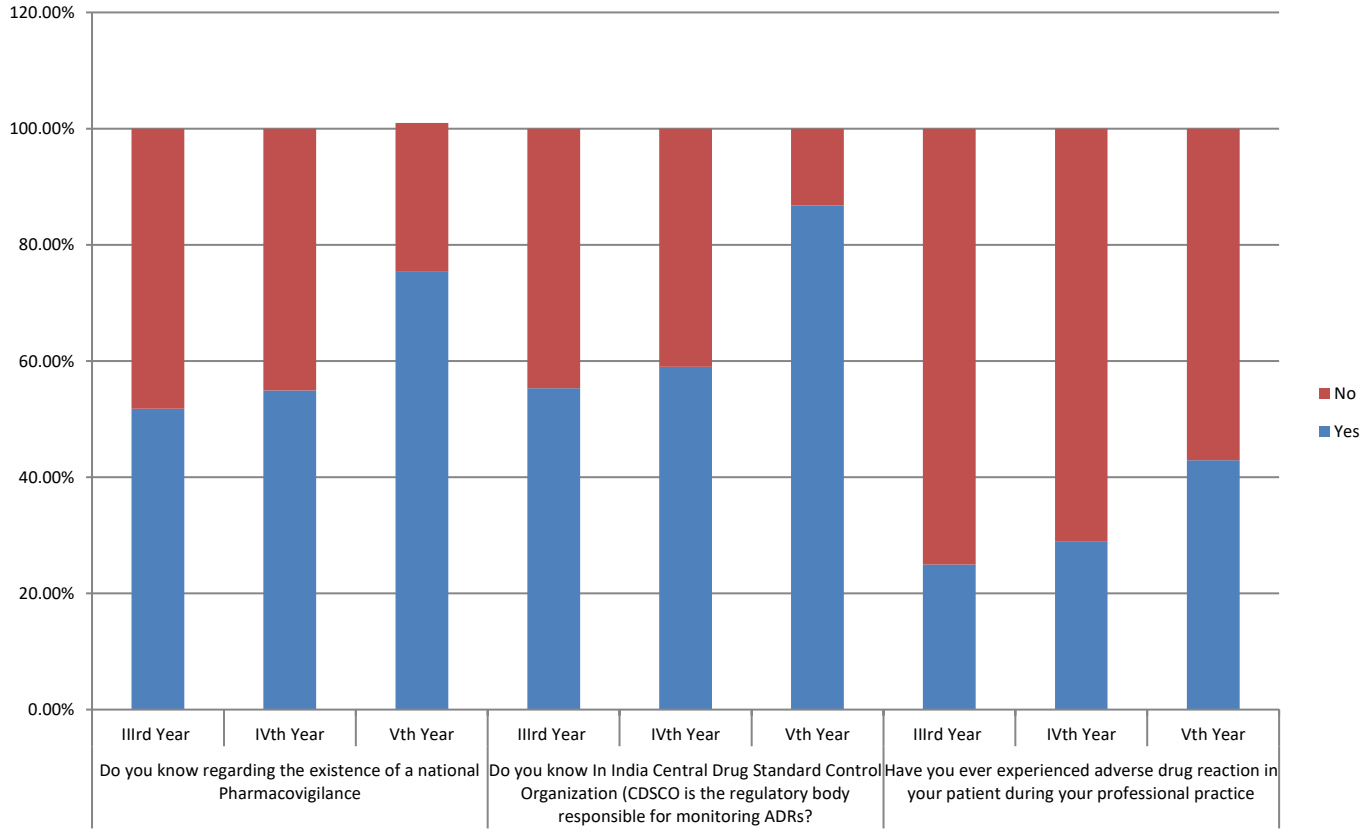

Table – 7 and Graph – 7 shows response to the questions assessing the Attitude regarding Pharmacovigilance. It was observed that 49% think they need to worry about legal problem while thinking about ADR reporting. 93.65% think ADR reporting should be made mandatory, 86.10% you think Pharmacovigilance should be taught in detail to healthcare professionals, 33.80% was confident enough to report an ADR to concern authority while 66.20% was not confident enough to report ADR to concern authority, 32.35% have reported ADR to the pharmacovigilance Centre, 67.10% have seen the ADR reporting form, and 60.50% where trained on how to report ADR, which was found to be statistically significant.

Table – 7 Response to the questions assessing the Attitude regarding Pharmacovigilance

	Yes	No	P value	Significance
Do you think we need to worry about legal problem while thinking about ADR reporting?	1490 (49%)	1550 (51%)	0.001	Significant
At present ADR reporting is voluntary do you feel that it should made mandatory?	2847 (93.65%)	193 (6.35%)	0.001	Significant
Do you think Pharmacovigilance should be taught in detail to healthcare professionals?	2617 (86.10%)	423 (13.90%)	0.001	Significant
Are you confident enough to report an ADR to concern authority?	1028 (33.80%)	2012 (66.20%)	0.001	Significant
Have you ever reported ADR to the Pharmaco-vigilance centre?	983 (32.35%)	2057 (67.65%)	0.001	Significant
Have you ever seen the ADR reporting form?	2040 (67.10%)	1000 (32.90%)	0.001	Significant
Have you ever been trained on how to report Adverse Drug Reaction (ADR)?	1840 (60.5%)	1200 (39.5%)	0.001	Significant

Graph – 7 Response to the questions assessing the Attitude regarding Pharmacovigilance

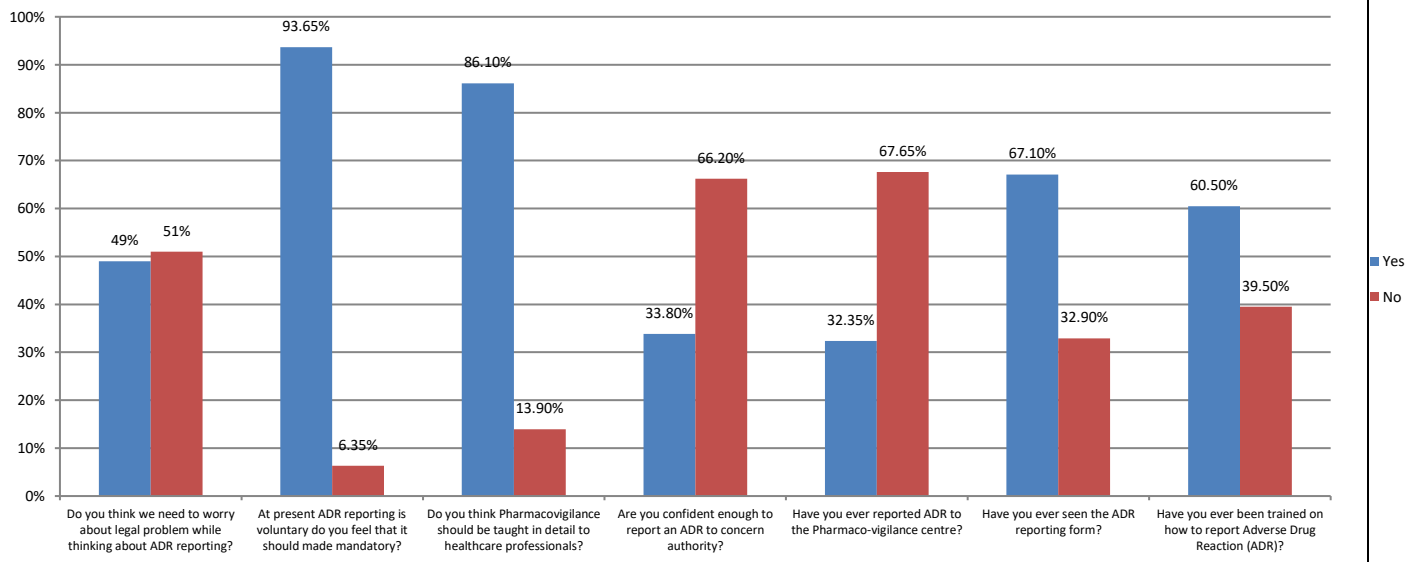

Table – 8 and Graph – 8 shows gender Wise Response to the questions assessing the Attitude regarding Pharmacovigilance. It was observed that 46.28% male and 52.98% female think they need to worry about legal problem while 53.72% male and 47.02% female think they need not to worry about legal problem while thinking about ADR reporting. 92.06% male and 95.97% female think ADR reporting should be made mandatory, 84.11% male and 88.95% female think Pharmacovigilance should be taught in detail to healthcare professionals which was found to be statistically significant. 32.33% male and 35.97% female was confident enough to report an ADR to concern authority while 67.67% male and 64.03% female was not confident enough to report ADR to concern authority, 32.33% male and 35.24% female have reported ADR to the pharmacovigilance Centre. 64.27% male and 71.21% female have seen the ADR reporting form. and 57.45% male and 65% female where trained on how to report ADR, which was found to be statistically significant.

Graph 8 - Gender Wise Response to the questions assessing the Attitude regarding Pharmacovigilance

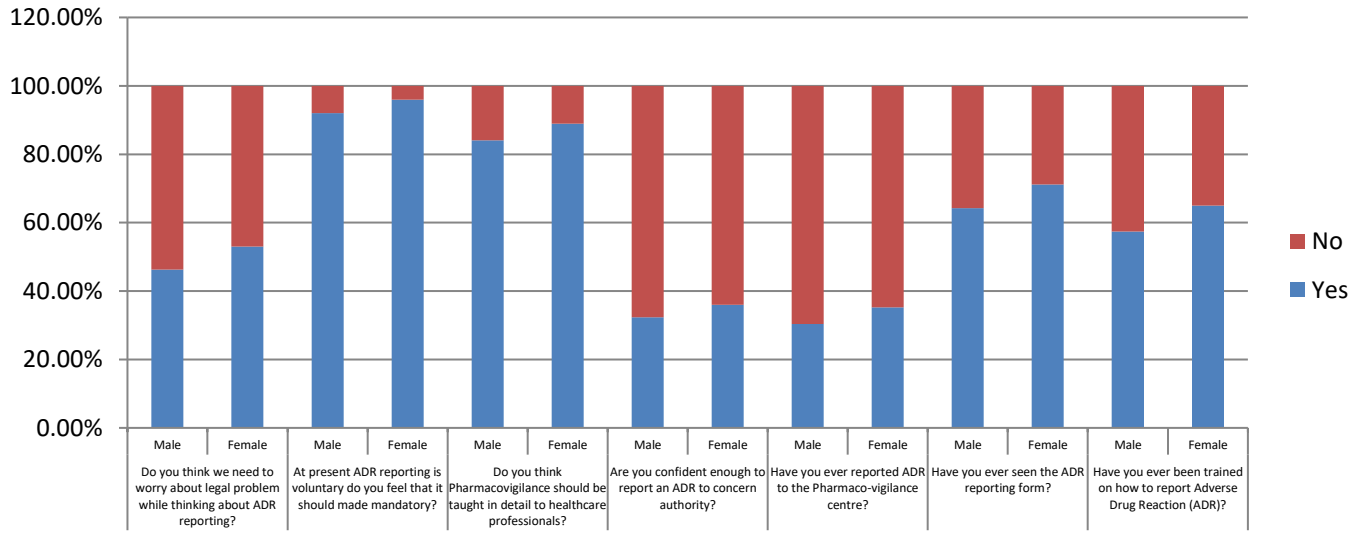

Table 8 - Gender Wise Response to the questions assessing the Attitude regarding Pharmacovigilance

		Yes	No	P value	Significance
Do you think we need to worry about legal problem while thinking about ADR reporting?	Male	833	967	0.001	Sig
		46.28%	53.72%		
	Female	657	583		
		52.98%	47.02%		
At present ADR reporting is voluntary do you feel that it should made mandatory?	Male	1657	143	0.001	Sig
		92.06%	7.94%		
	Female	1190	50		
		95.97%	4.03%		
Do you think Pharmacovigilance should be taught in detail to healthcare professionals?	Male	1514	286	0.001	Sig
		84.11%	15.89%		
	Female	1103	137		
		88.95%	11.05%		
Are you confident enough to report an ADR to concern authority?	Male	582	1218	0.037	Sig
		32.33%	67.67%		
	Female	446	794		
		35.97%	64.03%		
Have you ever reported ADR to the Pharmaco-vigilance centre?	Male	546	1254	0.001	Sig
		30.33%	69.67%		

	Female	437	803		
		35.24%	64.76%		
Have you ever seen the ADR reporting form?	Male	1157	643	0.001	Sig
		64.27%	35.72%		
	Female	883	357		
		71.21%	28.79%		
Have you ever been trained on how to report Adverse Drug Reaction (ADR)?	Male	1034	766	0.001	Sig
		57.45%	42.55%		
	Female	806	434		
		65%	35%		

Table - 9 and Graph - 9 shows year wise response to the questions assessing the Attitude regarding Pharmacovigilance. It was observed that 40.99% of third year MBBS student, 44.95% of MBBS final year and 60.98% of MBBS internship students think they need to worry about legal problem.88.51% of third year MBBS student, 94.36% of MBBS final year and 98.04% of MBBS internship students think ADR reporting should be made mandatory which was found to be statistically significant. 79.50% of third year MBBS student, 86.14% of MBBS final year and 92.55% of MBBS internship students think Pharmacovigilance should be taught in detail to healthcare professionals which was found to be statistically significant. 23.96% of third year MBBS student, 26.93% of MBBS final year and 50.39% of MBBS internship students was confident enough to report an ADR to concern authority while 76.03% of third year MBBS student, 73.06% of MBBS final year and 49.60% of MBBS internship students was not confident enough to report an ADR to concern authority. 24.95% of third year MBBS student, 29.01% of MBBS final year and 42.94% of MBBS internship students have reported ADR to the pharmacovigilance Centre. 55.34% of third year MBBS student, 59.00% of MBBS final year and 86.76% of MBBS internship students have seen the ADR reporting form. 51.78% of third year MBBS student, 54.95% of MBBS final year and 75.45% of MBBS internship students where trained on how to report ADR, which was found to be statistically significant.

Graph- 9 Year wise response to the questions assessing the Attitude regarding Pharmacovigilance

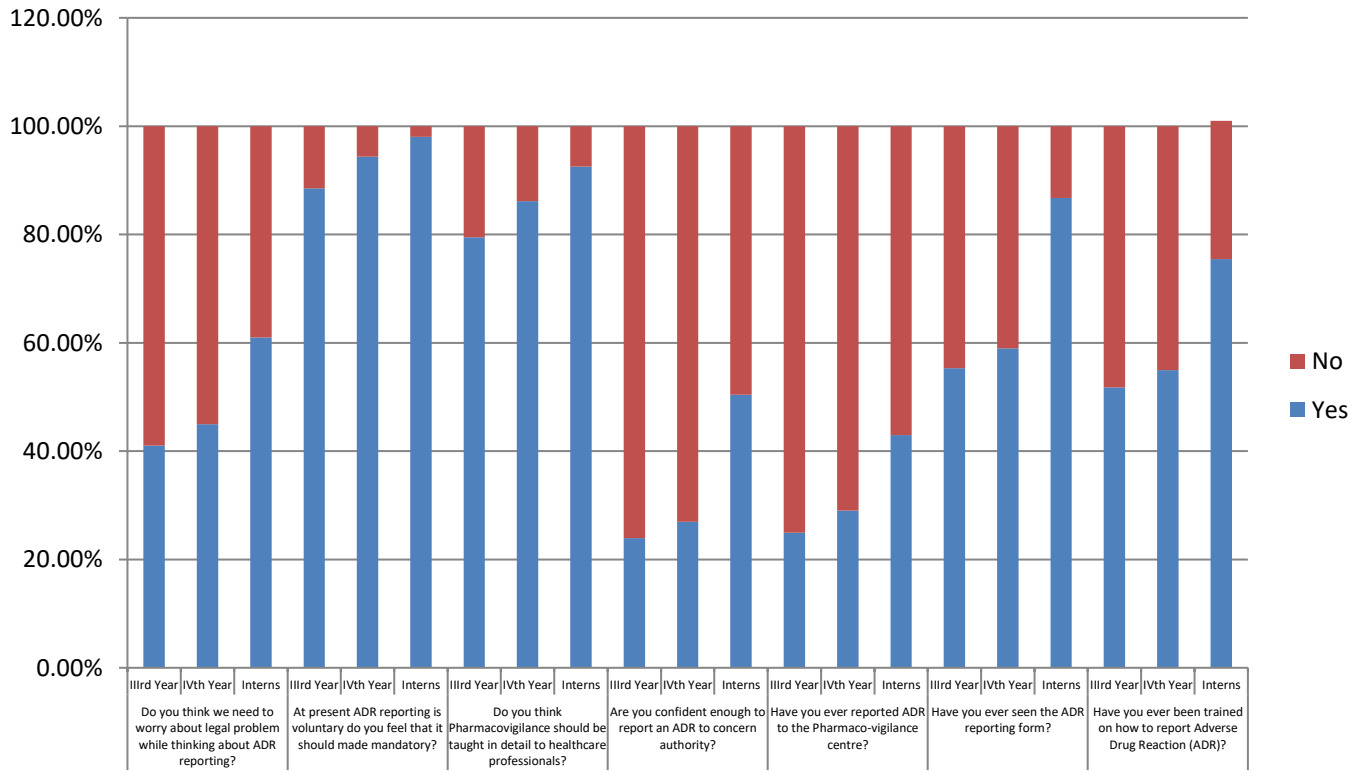

Table- 9 Year wise response to the questions assessing the Attitude regarding Pharmacovigilance

		Yes	No	P value	Significance
Do you think we need to worry about legal problem while thinking about ADR reporting?	IIIrd Year	414	596	0.001	Significant
		40.99%	59.01%		
	IVth year	454	556		
		44.95%	55.05%		
	Interns	622	398		
		60.98%	39.02%		
At present ADR reporting is voluntary do you feel that it should made mandatory?	IIIrd Year	894	116	0.001	Significant
		88.51%	11.49%		
	IVth year	953	57		
		94.36%	5.64%		
	Interns	1000	20		
		98.04%	1.96%		
Do you think Pharmacovigilance should be taught in detail to healthcare professionals?	IIIrd Year	803	207	0.001	Significant
		79.50%	20.50%		
	IVth year	870	140		
		86.14%	13.86%		
	Interns	944	76		
		92.55%	7.45%		
Are you confident enough to report an ADR to concern authority?	IIIrd Year	242	768	0.001	Significant
		23.9604	76.0396		
	IVth	272	738		

	year				
		26.93069	73.06931		
	Interns	514	506		
		50.39216	49.60784		
Have you ever reported ADR to the Pharmaco-vigilance centre?	IIIrd Year	252	758	0.001	Significant
		24.95%	75.05%		
	IVth year	253	717		
		29.01%	70.99%		
	Interns	438	582		
		42.94%	57.06%		
Have you ever seen the ADR reporting form?	IIIrd Year	559	451	0.001	Significant
		55.34%	44.66%		
	IVth year	596	414		
		59.00%	41.00%		
	Interns	885	135		
		86.76%	13.24%		
Have you ever been trained on how to report Adverse Drug Reaction (ADR)?	IIIrd Year	523	487	0.001	Significant
		51.78%	48.22%		
	IVth year	555	455		
		54.95%	45.05%		
	Interns	762	258		
		75.45%	25.55%		

Table – 10 and Graph – 10 shows response to the questions assessing the Practice regarding Pharmacovigilance. . It was observed that 76.48% think there should be establishment of ADR monitoring centre in every hospital. 96.1% think that proper ADR reporting and monitoring will benefit the patient while 3.9% think proper ADR reporting and monitoring will not benefit the patient. 82% think patient confidentiality should be maintained while reporting ADR. 8.20% think ADR reporting is a time consuming activity with no outcome.

Table -10 Response to the questions assessing the Practice regarding Pharmacovigilance

	Yes	No	P value	Significance
What is your opinion regarding establishing ADR monitoring centre in every hospital	2325 (76.48%)	715 (23.52%)	0.001	Significant
Do you think proper ADR reporting and monitoring will benefit the patient?	2921 (96.1%)	119 (3.9%)	0.001	Significant
Do you feel that patient confidentiality should be maintained while reporting ADR?	2492 (82%)	547 (18%)	0.001	Significant
Do you feel that ADR reporting is a time consuming activity with no outcome?	249 (8.20%)	2791 (91.80%)	0.001	Significant

Graph -10 Response to the questions assessing the Practice regarding Pharmacovigilance

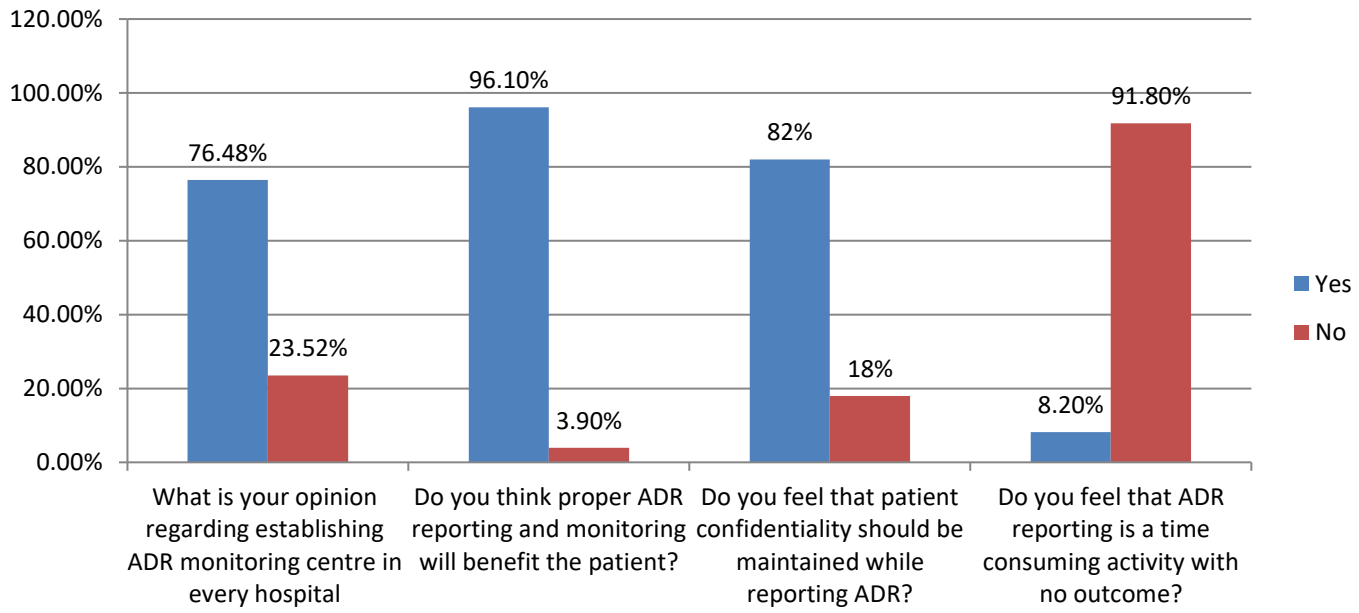

Table – 11 and Graph – 11 shows gender Wise Response to the questions assessing the Practice regarding Pharmacovigilance. . It was observed that 74.72% male and 79.03% female think there should be establishment of ADR monitoring centre in every hospital. 94.78% male and 97.98% female think that proper ADR reporting and monitoring will benefit the patient while 5.22% male and 2.02% female think proper ADR reporting and monitoring will not benefit the patient. 80.67% male and 83.87% female think patient confidentiality should be maintained while reporting ADR. 7.67% male and 8.95% female think ADR reporting is a time consuming activity with no outcome.

Table -11 Gender Wise Response to the questions assessing the Practice regarding Pharmacovigilance

		Yes	No	P value	Significance
What is your opinion regarding establishing ADR monitoring centre in every hospital	Male	1345	455	0.001	Significant
		74.72%	25.28%		
	Female	980	260		
		79.03%	20.97%		
Do you think proper ADR reporting and monitoring will benefit the patient?	Male	1706	94	0.001	Significant
		94.78%	5.22%		
	Female	1215	25		
		97.98%	2.02%		
Do you feel that patient confidentiality should be maintained while reporting ADR?	Male	1452	348	0.023	Significant
		80.67%	19.33%		
	Female	1040	200		
		83.87%	16.13%		
Do you feel that ADR reporting is a time consuming activity with no outcome?	Male	138	1662	0.204	Non-Sig
		7.67%	92.33%		
	Female	111	1129		
		8.95%	91.05%		

Graph -11 Gender Wise Response to the questions assessing the Practice regarding Pharmacovigilance

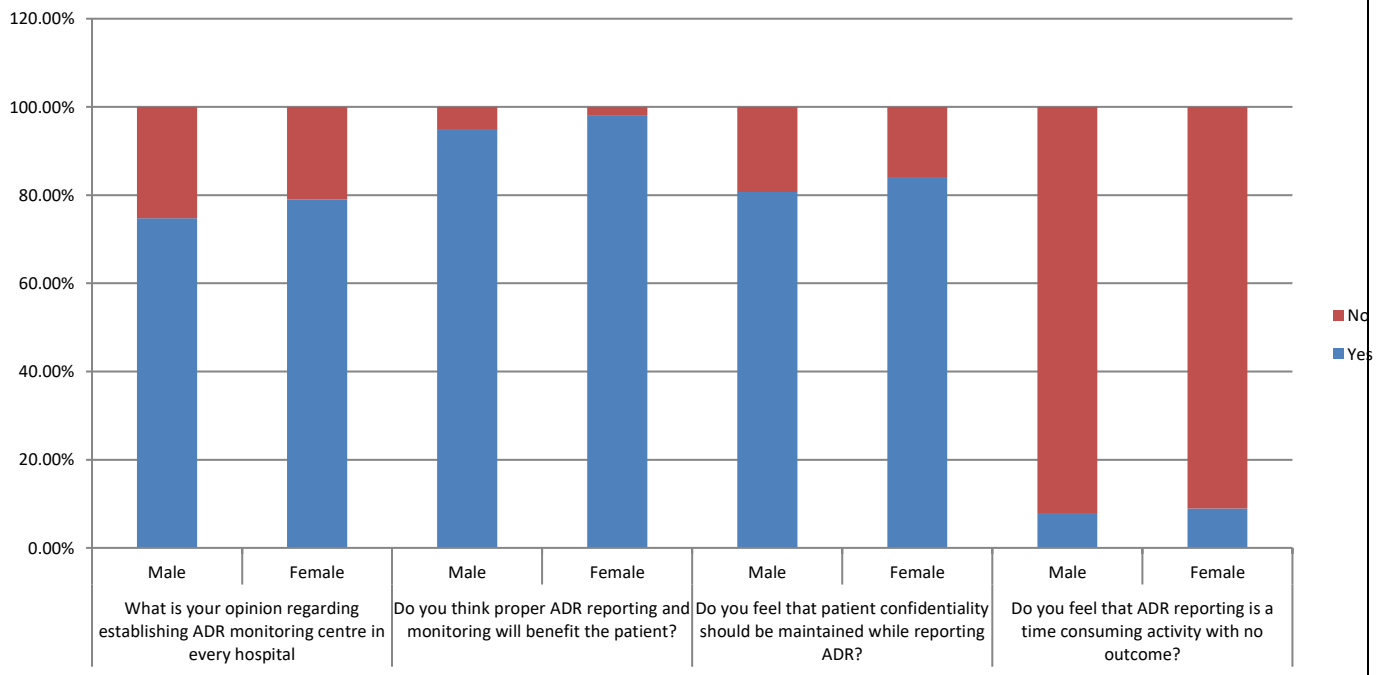

Table - 12 and Graph - 12 shows year wise response to the questions assessing the Practice regarding Pharmacovigilance. It was observed that 68.22% of third year MBBS student, 71.98% of MBBS final year and 89.12% of MBBS internship students think there should be establishment of ADR monitoring centre in every hospital. 88.22% of third year MBBS student, 91.19% of MBBS final year and 99.90% of MBBS internship students think proper ADR reporting and monitoring will not benefit the patient. 73.96% of third year MBBS student, 77.92% of MBBS final year and 93.92% of MBBS internship students think patient confidentiality should be maintained while reporting ADR. 5.94% of third year MBBS student, 7.03% of MBBS final year and 11.57% of MBBS internship students think ADR reporting is a time consuming activity with no outcome.

Graph – 12 Year Wise Response to the questions assessing the Practice regarding Pharmacovigilance

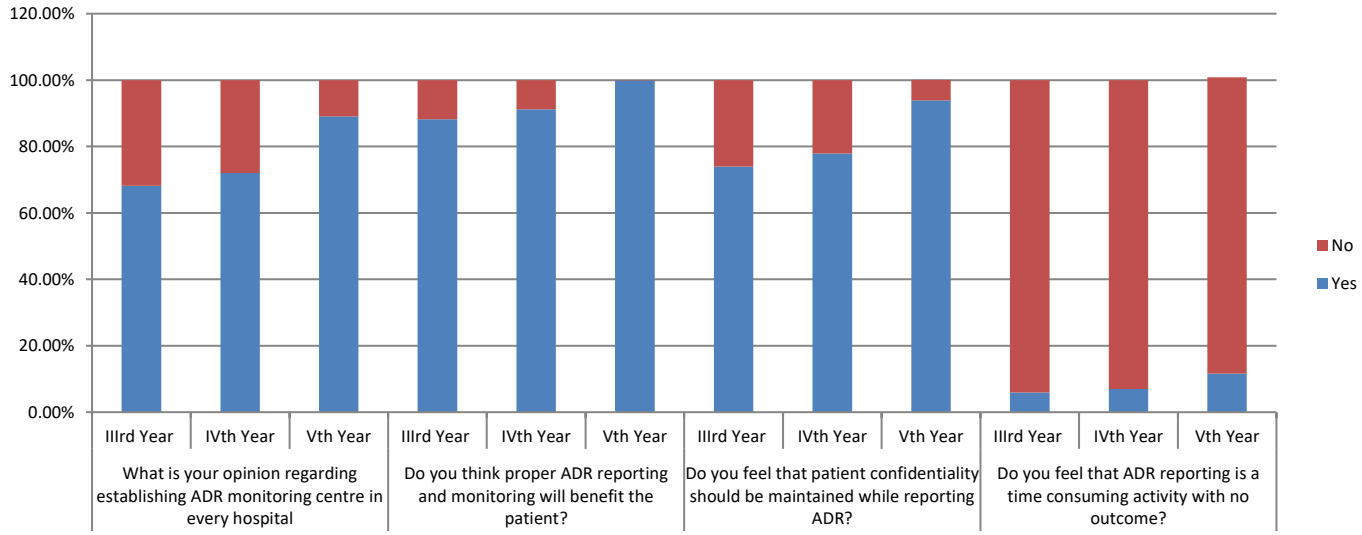

Table – 12 Year Wise Response to the questions assessing the Practice regarding Pharmacovigilance

		Yes	No	P value	Significance
What is your opinion regarding establishing ADR monitoring centre in every hospital	IIIrd Year	689	321	0.001	Significant
		68.22%	31.78%		
	IVth year	727	283		
		71.98%	28.02%		
	Interns	909	111		
		89.12%	10.88%		
Do you think proper ADR reporting and monitoring will benefit the patient?	IIIrd Year	891	119	0.001	Significant
		88.22%	11.78%		
	IVth year	921	89		
		91.19%	8.81%		
	Interns	1019	1		
		99.90%	0.10%		
Do you feel that patient confidentiality should be maintained while reporting ADR?	IIIrd Year	747	263	0.001	Significant
		73.96%	26.04%		
	IVth year	787	223		
		77.92%	22.08%		
	Interns	958	62		
		93.92%	6.14%		
Do you feel that ADR reporting is a time consuming activity with no outcome?	IIIrd Year	60	950	0.001	Significant
		5.94%	94.06%		
	IVth	71	939		

	year	7.03%	92.97%
	Interns	118	902
		11.57%	89.31%

DISCUSSION

Reporting ADRs is an essential component of Pharmacovigilance programme[1] . A spontaneous reporting system of ADR is fundamental to drug safety surveillance but under-reporting is a well recognized issue[12]. Thus the detection of probable harmful consequences arising from the usage of pharmaceutical products requires a decisive, continuous and close monitoring by medical staff who should have knowledge of adverse drug reactions and they should also have to report any suspected instances, when any kind of adverse drug reactions have been observed[23]. Knowledge is a very important factor that influences attitude and practice[24]. ADR have medical as well as economic consequences, leading to increased patient morbidity and mortality[25]. In India, spontaneous monitoring has resulted in lower rates of reporting, and so the Indian contribution to the World Health Organization (WHO) Uppsala Monitoring Centre database is meager. One reason for this is lack of awareness about the detection, communication, and reporting of ADRs, and there is no intensive teaching about ADR reporting in the undergraduate curriculum and no periodic reinforcement of ADR monitoring in internship and postgraduate studies[26] . Thus Pharmacovigilance is an integral part of holistic health care and spontaneous reporting of ADR is vital for the success of pharmacovigialnce program. There are innumerable studies to evaluate the KAP of health care providers toward pharmacovigilance program, but very few study have been conducted among the budding doctors to capture their knowledge about same. [27,28,29]

Hence,this study is planned with an Aim to assess the Knowledge, Attitude and Practices regarding Pharmacovigilance among medical students in medical colleges of Lucknow, Uttar Pradesh.

In the present study, 3040 clinical MBBS students (III year and Final year BDS and interns) participated out of which 1800 (59.22%) of the subjects were males and 1240 (40.78%) were the females, 1010 (33.20%) were the third year, 1010(33.20%) were the fourth year students and 1020 (33.60%) were the interns.

In this study it is observed that 32.05 % knew that doctors, nurses, pharmacists and dentists can report Adverse drug reactions. On gender basis it was observed that 57.45% of males and 65% of females knows about the existence of a national pharmacovigilance while 42.55% of males and 35% of females were unaware about the existence of national pramacovigilance . And on year basis distribution it was observed that 51.78% of third year MBBS students, 54.95% of MBBS

final year and 75.45% of MBBS internship students knows about the existence of a national pharmacovigilance.

Which is similar to study conducted by Dr. Subramaniam R et al [5] in which it was observed that 28% knew that doctors, nurses, pharmacists and dentists can report Adverse drug reactions. And also similar to study conducted by Bikash Ranjan Mehra et al [30] in which it was observed that 38% , 44% and 40% of final, pre-final and 2nd year students respectively knew who can report ADR. And also similar to study done by Manoj Kumar Saurabh et al[31] in which it was observed that 27.94% knew who can report ADR. Another study conducted by Subramaniyan Ganesan et al[6] in which it was observed that 84% doctors knew that Who can report ADRs.

In the present study it is observed that About 60.5% knew about the existence of a national pharmacovigilance program in India out of which 57.45% of males and 65% of females knows about the existence of a national pharmacovigilance and on the basis of students in different years it was observed that 51.78% of this year MBBS students, 54.95% of MBBS final year and 75.45% of MBBS internship students knows about the existence of a national pharmacovigilance.

Which is similar to study conducted by Akram Ahmad et al[13] in which it was observed that 57.5% were aware about the national pharmacovigilance program in India. And also a similar to study conducted by Bikash Ranjan Mehra et at [30] in which it was observed that 41.67% of final year, 55% of pre-final year students were aware about National Pharmacovililance center. And is also similar to study conducted by Shashi Marko [32] in which it was observed that among all the participants 46% second year students, 53.5% pre-final year students and 56.5% interns knew about the existence of pharmacovigilance programme of India.

In this study it is observed that 67.5% of the respondents knew the regulatory body responsible for monitoring ADR's in India out of which 64.27% males and 71.21% females knows that in india Central Drug Standard Control Organization (CDSCO) is the regulatory body responsible for monitoring ADRs, and on the basis of students in different years it was observed that 55.34% of MBBS third year , 59.00% of MBBS final year, and 86.76% of MBBS internship students knows that in india Central Drug Standard Control Organization (CDSCO) is the regulatory body responsible for monitoring ADRs.

Which is in contrast to study conducted by Suresh Chenchu et al [33] in which it was observed that 53.33% doctors knew about the regulatory body responsible for monitoring ADRs in India. And similar to study conducted by Mohit Kulmi et al [34] in which it was observed that 67.5% of MBBS 2nd year students, 77.2% of MBBS 3rd year students and 64.2% of postgraduates were aware that the CDSCO is the regulatory body for ADR monitoring in our country. And also similar to study conducted by Shashi Marko [32] in which it was observed that 61% second year students, 58.75% pre-final year students and 52% interns knew about regulatory body responsible for monitoring ADRs.

In the present study it is observed that About 32.35% have experience adverse drug reaction in their patient during their professional practice among them 30.33% males and 35.24% females have experienced adverse drug reaction in their patient during your professional practice, and about 24.95% of MBBS third year , 29.01% of MBBS final year, and 42.94% of MBBS internship students have experienced adverse drug reaction in their patient during their professional practice.

Which is in contrast to study conducted by Subish PALAIAN et al [10] in which it was observed that 70.80% doctors came across any patient experiencing ADRs. Another study was conducted by Subramaniyan Ganesan et at [6] which is in contrast to present study and it was observed that 93% of doctors seen patient experiencing ADR. And another study was conducted by Mohit Kulmi et al [34] which is in contrast to present study and it was observed that 16.5% of MBBS 3rd year students and 58.2% of postgraduate residents claimed to have witnessed an ADR.

In the present study it is observed that 49% think they need to worry about legal problems while thinking about ADR reporting out of which 46.28% males and 52.98% females think they need to worry about legal problem and about 40.99% of third year MBBS students, 44.95% of MBBS final year and 60.98% of MBBS internship students think they need to worry about legal problem.

Which is in contrast to study conducted by Pranita P. Dharmadhikari et al [16] in which it was observed that 64.5% of health care professionals fear of legal liability during ADRs reporting. And was also in contrast to study conducted by Dr. Subramaniam R et al [5] in which it was observed that 76% of BDS third year , final year, interns, and faculty think they need to worry about legal problem while thinking about ADR reporting.

In this study it is observed that 93.65% think ADR reporting should be made mandatory out of them 92.06% males and 95.97% females think ADR reporting should be made mandatory, and about 88.51% of third year MBBS students, 94.36% of MBBS final year and 98.04% of MBBS internship students think ADR reporting should be made mandatory.

Which is in contrast to study conducted by Pankaj Gupta et al [35] in which it was observed that 13.7% have responded to make ADRs reporting compulsory. And was also in contrast to study conducted by Suresh Chenchu et al [33] in which it was observed that 60% doctors think that ADRs reporting should be compulsory.

In this study it is observed that 86.10% you think Pharmacovigilance should be taught in detail to healthcare professionals among them 84.11% males and 88.95% females think Pharmacovigilance should be taught in detail to healthcare professionals and 79.50% of third year MBBS students, 86.14% of MBBS final year and 92.55% of MBBS internship students think Pharmacovigilance should be taught in detail to healthcare professionals.

Which is similar to study conducted by V. Srinivasan et al [8] in which it was observed that 91.3% of health care professional think Pharmacovigilance be taught in deatail to healthcare professional. And another similar study was conducted by Shashi Marko [32] in which it was observed that majority 91.66% students thought that pharmacovigilance should be taught to all health-care professional. Another study conducted by Nikhil Era et al[36] is in contrast to present study in which it was observed that 60.97% MBBS third year students and 65% final year students think think Pharmacovigilance should be taught in detail to healthcare professionals.

In the present study it is observed that 33.80% was confident enough to report an ADR to concern authority out of which 32.33% males and 35.97% females was confident enough to report an ADR to concern authority and 23.96% of third year MBBS students, 26.93% of MBBS final year and 50.39% of MBBS internship students was confident enough to report an ADR to concern authority.

Which is in contrast to study conducted by Mohit Kulmi et al [34]] in which it was observed that none of the MBBS third year students was confident enough to fill an ADR form correctly. There is an another study in contrast to the present study conducted by Dr. Subramaniam R et al

[5] in which it was observed that 74% of BDS third year, final year students , interns and faculty are confident enough to report an ADR to concern authourity.

In this study it is observed that 32.35% students have reported ADR to the pharmacovigilance Centre among them 32.33% males and 35.24% females have reported ADR to the pharmacovigilance Centre and 24.95% of third year MBBS students, 29.01% of MBBS final year and 42.94% of MBBS internship students have reported ADR to the pharmacovigilance Centre.

Which is in contrast to study conducted by Nikhil Era et al [36] in which it was observed that only around 20% of students have reported ADR to pharmacovigilance centre, out of which 14.63% of third year MBBS students, and 17.5% of MBBS final year have reported ADR to the pharmacovigilance Centre. Another study was conducted by Dr.Mukeshkumar B Vora [1] which is similar to present study in which it was observed that 24.79% of PG students and 26.98% of faculty have reported an ADR or have filled an ADR reporting form. Similar study was conducted by Suresh Chenchu et al [33] in which it was observed that 33.30% doctors came across with an ADR and reported it.

In this study it is observed that 67.10% have seen the ADR reporting form out of which 64.27% males and 71.21% females have seen the ADR reporting form and 55.34% of third year MBBS students, 59.00% of MBBS final year students and 86.76% of MBBS internship students have seen the ADR reporting form.

Which is similar to study conducted by Bikash Ranjan Mehra et al [30] in which it was observed that 63.33% of third year MBBS students, 61.67% of MBBS final year students have seen the ADR reporting form. And another study done by Kulkarni Dhananjay et al [12] which is in contrast to present study in which it was observed that 31% of undergraduate medical students have seen the ADR reporting form.

In the present study it is observed that 60.50% were trained on how to report ADR among them 57.45% males and 65% females were trained on how to report ADR and 51.78% of third year MBBS students, 54.95% of MBBS final year and 75.45% of MBBS internship students were trained on how to report ADR.

Which is in contrast to study conducted by Pranita P. Dharmadhikari et al [16] in which it was observed that 11.5% doctors were trained on how to report ADR. Another study conducted by Shashi Marko [32] which is similar to the present study in which it was observed that 79.16% interns and 97.5% pre-final year MBBS students were trained to report ADR.

In the present study it is observed that 76.48% think there should be an establishment of ADR monitoring centre in every hospital from which 74.72% males and 79.03% females think there should be an establishment of ADR monitoring centre in every hospital and 68.22% of third year MBBS students, 71.98% of MBBS final year and 89.12% of MBBS internship students think there should be establishment of ADR monitoring centre in every hospital.

Which is similar to study conducted by V. Srinivasan et al [8] in which it was observed that 72.1% of healthcare professionals think that it should be mandatory to have pharmacovigilance unit in the medical colleges. Another study was conducted by Nikhil Era et al [36] which is in contrast to present study in which it was observed that 48.78% of per-final year MBBS students and 62.5% of final year MBBS students think there should be establishment of ADR monitoring centre in every hospital.

In this study it is observed that 96.1% think that proper ADR reporting and monitoring will benefit the patient, among them 94.78% males and 97.98% females think that proper ADR reporting and monitoring will benefit the patient and 88.22% of third year MBBS students, 91.19% of MBBS final year students and 99.90% of MBBS internship students think proper ADR reporting and monitoring will not benefit the patient.

Which is similar to study conducted by Manoj Kumar Saurabh et al[31] in which it was observed that 100% of MBBS interns think that proper ADR reporting and monitoring would improve patient care and their safety. While another study conducted by Chetna K. Desai [37] which is in contrast to the present study in which it was observed that 28.8% prescriber report ADR to improve patient safety.

In the present study it is observed that 8.20% think ADR reporting is a time consuming activity with no outcome of which 7.67% males and 8.95% females think ADR reporting is a time consuming activity with no outcome and 5.94% of third year MBBS students, 7.03% of MBBS final year and 11.57% of MBBS internship students think ADR reporting is a time consuming activity with no outcome.

Which is in contrast to study conducted by Dr. Subramaniam R et al [5] in which it was observed that 30% of doctors, nurses, pharmacists and dentists think ADR reporting is a time consuming activity with no outcome.

LIMITATION

Not much research has been done in India regarding the response of knowledge, attitude and practice of medical students towards pharmacovigilance, so literature available in insufficient.

Since the examining body is a doctor and participants are doctors as well , which can lead to bias by interpreting the result in favor of the participants regarding their knowledge, attitude and practice towards paharmacovigilance.

For Social desirability that being medical students they have to answer appropriately on general awareness topics that is pharmacovigilance, it can lead to variation in their response leading to bias in result.

CONCLUSION

The present study suggests that the knowledge regarding pharmacovigilance among the medical students of Lucknow city was satisfactory, but their experience of adverse drug reaction in patient and reporting of adverse drug reaction to the concerned authority during their professional practice was low. The students are also not confident enough to report the adverse drug reaction to the concern authority. But the students had positive attitude towards pharmacovigilance and most of them agreed that it should be taught in detail to the healthcare professionals. Majority of the students think proper ADR reporting and monitoring will benefit the patient and it should be made mandatory. Most of the students were in favour of establishing ADR monitoring centre in every hospital.

In India, not much of the studies are conducted and hence we do not have sufficient data regarding the knowledge, attitude and practice of medical students towards pharmacovigilance.

Underreporting of ADRs is one of the prime hurdles in the pathway of national PV program. Thus the findings of the study suggest that there is need for continuous educational and training programs regarding pharmacovigilance and ADR reporting system among the students who will be the future health-care givers. This will help to increase awareness towards pharmacovigilance among students and ultimately may translate into increase in the adverse drug reaction (ADR) reporting in future.

RECOMMENDATION

Pharmacovigilance related activities should be included in the medical teaching curriculum in pharmacology as a part of study for the medical students.

Educational interventions like continuous medical education (CME) and workshop on pharmacovigilance should be done to increase the awareness among the students.

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ANNEXURE

BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES
(FACULTY OF BBD UNIVERSITY), LUCKNOW
INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled "**Knowledge, Attitude and Practices Regarding Pharmacovigilance among Medical Students in Medical Colleges in Lucknow, Uttar Pradesh**" submitted by **Dr Aman Kumar** Post graduate student from the **Department of Public Health Dentistry** as part of MDS Curriculum for the academic year 2020-2023 with the accompanying proforma was reviewed by the Institutional Research Committee present on **12th October 2021** at BBDCODS.

The Committee has granted approval on the scientific content of the project. The proposal may now be reviewed by the Institutional Ethics Committee for granting ethical approval.

Prof. Vandana A Pant
Co-Chairperson

Prof. B. Rajkumar
Chairperson

Babu Banarasi Das University
Babu Banarasi Das College of Dental Sciences,
BBD City, Faizabad Road, Lucknow – 226028 (INDIA)

Dr. Lakshmi Bala
Professor and Head Biochemistry and
Member-Secretary, Institutional Ethics Committee

Communication of the Decision of the IXth Institutional Ethics Sub-Committee

IEC Code: 07

BBDCODS/04/2022

Title of the Project: Knowledge, Attitude and Practices Regarding Pharmacovigilance among Medical Students in Medical Colleges in Lucknow, Uttar Pradesh.

Principal Investigator: Dr Aman Kumar

Department: Public Health Dentistry

Name and Address of the Institution: BBD College of Dental Sciences Lucknow.

Type of Submission: New, MDS Project Protocol

Dear Dr Aman Kumar,

The Institutional Ethics Sub-Committee meeting comprising following four members was held on 07th April, 2022.

1.	Dr. Lakshmi Bala Member Secretary	Prof. and Head, Department of Biochemistry, BBDCODS, Lucknow
2.	Dr. Amrit Tandan Member	Prof. & Head, Department of Prosthodontics and Crown & Bridge, BBDCODS, Lucknow
3.	Dr. Rana Pratap Maurya Member	Reader, Department of Orthodontics, BBDCODS, Lucknow
4.	Dr. Akanksha Bhatt Member	Reader, Department of Conservative Dentistry & Endodontics, BBDCODS, Lucknow

The committee reviewed and discussed your submitted documents of the current MDS Project Protocol in the meeting.
The comments were communicated to PI thereafter it was revised.

Decisions: The committee approved the above protocol from ethics point of view.

Forwarded by:

Lakshmi Bala

(Dr. Lakshmi Bala)
Member-Secretary
IEC

Member-Secretary
Institutional Ethic Committee
BBD College of Dental Sciences
BBD University
Faizabad Road, Lucknow-226028

(Dr. Puneet Ahuja)
Principal
BBDCODS

PRINCIPAL
Babu Banarasi Das College of Dental Sciences
(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow-226028

QUESTIONNAIRE ON KNOWLEDGE, ATTITUDE AND PRACTICES REGARDING PHARMACOVIGILANCE AMONG MEDICAL STUDENTS IN MEDICAL COLLEGES IN LUCKNOW, UTTAR PRADESH.

1. Age ____ , 2. Gender: Male/Female.
3. Year of study (for MBBS students) : 3rd __, 4th __, Interns__

1. The healthcare professionals responsible for reporting ADR's in a hospital is/are (can tick multiple options) ?	☐ Doctors ☐ Nurses ☐ Pharmacist ☐ Dentist ☐ All of the above
2. Do you know regarding the existence of a national Pharmacovigilance ?	☐ Yes ☐ No
3. In India which regulatory body is responsible for monitoring ADRs ?	☐ Central Drug Standard Control Organization (CDSCO) ☐ Indian Council of Medical Research (ICMR) ☐ Indian Clinical Research Institute (ICRI) ☐ Medical Council of India (MCI)
4. Do you think we need to worry about legal problem while thinking about ADR reporting ?	☐ Yes ☐ No
5. At present ADR reporting is voluntary, do you feel that it should made mandatory ?	☐ Yes ☐ No
6. Do you think Pharmacovigilance should be taught in detail to healthcare professionals ?	☐ Yes ☐ No

7. What is your opinion about establishing ADR monitoring centre in every hospital ?	☐ Should be in every hospital ☐ Not necessary in every hospital ☐ One in a city is sufficient ☐ Depends on the number of bed size in the hospitals

NOTE : ADR = Adverse Drug Reaction

8. Do you think proper ADR reporting and monitoring will benefit the patient ?	☐ Yes ☐ No
9. Do you feel that patient confidentiality should be maintained while reporting ADR ?	☐ Yes ☐ No
10. Do you feel that ADR reporting is a time consuming activity with no outcome ?	☐ Yes ☐ No
11. Which of the following factor discourage you from reporting ADRs ? (You may tick multiple reasons)	☐ Did not know how to report ☐ Not knowing where to report ☐ Lack of access to ADR reporting forms ☐ Patient confidentiality issues ☐ Legal liability issues ☐ Concerns about professional liability
12. Are you confident enough to report an ADR to concern authority ?	☐ Yes ☐ No
13. Have you ever experienced adverse drug reaction in your patient during your professional practice ?	☐ Yes ☐ No

14. Have you ever reported ADR to the Pharmacovigilance centre ?	☐ Yes ☐ No ☐ Don't know where to submit the ADR reporting form ☐ Don't know how to fill up the ADR reporting form
15. Have you ever seen the ADR reporting form ?	☐ Yes ☐ No
16. Have you ever been trained on how to report Adverse Drug Reaction (ADR) ?	☐ Yes ☐ No

NOTE : ADR = Adverse Drug Reaction